PacificSource Community Solutions

2025 Prior Authorization Criteria
Last Modified: 11/15/2025

PacificSource Community Solutions

2025 Medicaid Preapproval Criteria

POLICY NAME:
ABATACEPT
Affected Medications: ORENCIA CLICKJET AUTO-INJECTOR, ORENCIA PREFILLED SYRINGE, ORENCIA INTRAVENOUS (IV) SOLUTION

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis (RA)
	  ○ Polyarticular Juvenile Idiopathic Arthritis (JIA)
	  ○ Psoriatic Arthritis (PsA)
	  ○ Acute Graft Versus Host Disease (GVHD) Prophylaxis

Required Medical Information:	**Rheumatoid Arthritis**
	• Documentation of current disease activity with one of the following (or equivalent objective scale):
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted Routine Assessment of Patient Index Data 3 (RAPID3) of at least 2.3
	
	Psoriatic Arthritis
	• Documentation of Classification for Psoriatic Arthritis (CASPAR) criteria score of 3 or greater based on chart notes:
	  ○ Skin psoriasis: present – two points, OR previously present by history – one point, OR a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxta-articular bone formation on radiographs (distinct from osteophytes): one point
	
	Psoriatic Arthritis in pediatrics 2 years and older
	• Diagnosis of PsA confirmed by presence of:
	  ○ Arthritis and psoriasis OR
	  ○ Arthritis and at least 2 of the following:
	  ▪ Dactylitis
	  ▪ Nail pitting or onycholysis
	  ▪ Psoriasis in a first-degree relative
	
	Juvenile Idiopathic Arthritis
	• Documentation of current level of disease activity with physician global assessment (MD global score) or active joint count
	
	Acute GVHD Prophylaxis
	• Documentation of a planned hematopoietic stem cell transplant (HSCT) including procedure date, patient weight, and planned dose

Appropriate Treatment Regimen & Other Criteria:	**Rheumatoid Arthritis** • Documented failure with at least 12 weeks of treatment with methotrexate ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide) • One of the following: Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis), tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV) AND

	• Two of the following: Olumiant, Kevzara, Simponi Aria, Actemra SQ, Kineret, rituximab (preferred biosimilar products Truxima, Riabni, and Ruxience), Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz)
	• Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with intravenous formulation
	
	Psoriatic Arthritis
	• Documented failure with at least 12 weeks of treatment with methotrexate
	  ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide)
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products Inflectra, Avsola)
	• Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with intravenous formulation
	
	Psoriatic Arthritis in pediatrics 2 years and older
	• Documented treatment failure with a nonsteroidal anti-inflammatory drug (ibuprofen, naproxen, celecoxib, meloxicam, etc.) with a minimum trial of 1 month
	• Documented treatment failure with at least one of the following disease-modifying antirheumatic drugs (DMARDs) with a minimum trial of 12 weeks: methotrexate, sulfasalazine, leflunomide
	
	Juvenile Idiopathic Arthritis
	• Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide
	• Documented failure with glucocorticoid joint injections or oral corticosteroids
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of two of the following therapies:
	  ○ tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV), Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), and Simponi Aria
	• Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with intravenous formulation
	
	Acute GVHD Prophylaxis
	• Documentation that the drug will be used in combination with a calcineurin inhibitor (tacrolimus, cyclosporine) AND methotrexate
	
	QL
	Intravenous:
	• RA/PsA: initial IV infusion at weeks 0, 2, and 4, followed by every 4 weeks thereafter per below:
	  ○ <60 kg: 500 mg
	  ○ 60-100 kg: 750 mg
	  ○ >100 kg: 1000 mg
	• JIA: initial IV infusion at weeks 0, 2, and 4, followed by every 4 weeks thereafter per below:
	  ○ <75 kg: 10 mg/kg
	  ○ 75-100 kg: 750 mg
	  ○ >100 kg: 1000 mg (max dose)
	• Acute GVHD Prophylaxis:
	  ○ 2 to <6 years: 15 mg/kg on day -1 (day before transplantation) followed by 12

	mg/kg on days 5, 14, and 28 post-transplant ○ 6 years and older: 10 mg/kg on day -1 (day before transplantation) followed by 10 mg/kg on days 5, 14, and 28 post-transplant (maximum: 1,000 mg/dose) • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced Subcutaneous: • RA: with or without IV loading dose, followed by 125 mg once weekly • PsA: (no IV loading dose) 125 mg once weekly • JIA and PsA (pediatrics): (no IV loading dose) 10-25 kg: 50 mg once weekly, 25-50 kg: 87.5 mg once weekly, 50 kg or more: 125 mg once weekly **Reauthorization:** requires documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit • For Acute GVHD Prophylaxis: prior allogeneic HSCT, HIV infection or any uncontrolled active infection (viral, bacterial, fungal, or protozoal)
Age Restriction:	
Prescriber Restrictions:	• **RA, JIA, PsA**: prescribed by, or in consultation with, a rheumatologist or dermatologist as appropriate for diagnosis • **Acute GVHD Prophylaxis**: prescribed by, or in consultation with, a hematologist or oncologist
Coverage Duration:	• **RA, JIA, PsA:** ○ Initial Authorization: 6 months, unless otherwise specified ○ Reauthorization: 24 months, unless otherwise specified • **Acute GVHD Prophylaxis:** ○ Authorization: 1 month (4 days of treatment maximum) with no reauthorization, unless otherwise specified

POLICY NAME:
ACNE AGENTS
Affected Medications: Adapalene gel 0.1%, adapalene gel 0.3%, adapalene-benzoyl peroxide gel 0.1-2.5%, benzoyl peroxide-erythromycin gel 5-3%, clindamycin phosphate gel 1%, clindamycin phosphate lotion 1%, clindamycin phosphate swab 1%, dapsone gel 5%, dapsone gel 7.5%, erythromycin solution 2%, tretinoin cream 0.025%, tretinoin cream 0.05%, tretinoin cream 0.1%, tretinoin gel 0.01%, tretinoin gel 0.025%, tretinoin gel 0.05%

<table>
<tr><td>Covered Uses:</td><td>

All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Acne vulgaris
Severe acne

Compendia-supported uses

Hidradenitis suppurativa (HS) (clindamycin only)

</td></tr>
<tr><td>Required Medical Information:</td><td>
<u>Severe Acne</u>
For age 21 years and older:

Documentation of severe acne confirmed by ONE of the following:

Persistent or recurrent inflammatory nodules and cysts AND ongoing scarring
Diagnosis of acne conglobata involving recurrent abscesses or communicating sinuses
Diagnosis of acne fulminans

<u>Hidradenitis Suppurativa</u>
For age 21 years and older:

Documentation of baseline count of abscesses and inflammatory nodules

</td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>
<u>Acne:</u>
Step 2 agents:

Approval requires documented trial and failure with ONE Step 1 agent

<table>
<tr><th>Step 1 Agents</th></tr>
<tr><td>• Clindamycin phosphate 1% (solution, gel, lotion, swab)
• Erythromycin 2% (solution, gel)
• Sulfacetamide lotion 10%
• Oral antibiotics for treatment of acne (e.g., doxycycline, minocycline)</td></tr>
<tr><th>Step 2 Agents</th></tr>
<tr><td>• Adapalene gel (0.1%, 0.3%)
• Adapalene-benzoyl peroxide gel 0.1-2.5%
• Benzoyl peroxide-erythromycin gel 5-3%
• Dapsone gel (5%, 7.5%)
• Tretinoin cream (0.025%, 0.05%, 0.1%)
• Tretinoin gel (0.01%, 0.025%, 0.05%)</td></tr>
</table>
<u>Hidradenitis Suppurativa</u>
</td></tr>
</table>

	• Topical clindamycin (clindamycin phosphate solution 1%, clindamycin phosphate gel 1%, clindamycin phosphate lotion 1%, clindamycin phosphate swab 1%) **Reauthorization** requires documentation of treatment success
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• HS: Prescribed by, or in consultation with, a dermatologist
Coverage Duration:	• Approval: 5 years, unless otherwise specified

POLICY NAME:
ACTIMMUNE
Affected Medications: ACTIMMUNE (Interferon Gamma - b)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
	  ○ Chronic Granulomatous Disease (CGD)
	  ○ Severe, malignant osteopetrosis (SMO)
	• NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or higher

Required Medical Information:	• Patient's body surface area (BSA) must be documented along with the prescribed dose.
	• Pediatrics with BSA less than 0.5 m^2: weight must be documented along with prescribed dose.
	
	Chronic granulomatous disease
	• Diagnosis established by a molecular genetic test identifying a gene-related mutation associated with CGD
	
	Severe, malignant osteopetrosis
	• Diagnosis of severe **infantile** osteopetrosis established by **ONE** of the following:
	  ○ Radiographic imaging consistent with osteopetrosis
	  OR
	  ○ Molecular genetic test identifying a gene-related mutation associated with SMO
	
	Oncology indications
	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course

Appropriate Treatment Regimen & Other Criteria:	**Chronic Granulomatous Disease** • Patient is on a prophylactic regimen with an antibacterial and antifungal **All indications** • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization:** documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber Restrictions:	• **CGD:** prescribed by, or in consultation with, an immunologist • **SMO:** prescribed by, or in consultation with, an endocrinologist • **Oncology indications:** prescribed by, or in consultation with, an oncologist

Coverage Duration:	**CGD and SMO** Approval: 12 months, unless otherwise specified **Oncology indications:** Initial Authorization: 4 months, unless otherwise specified Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
ADALIMUMAB
Affected Medications: Adalimumab-fkjp (unbranded Hulio), Hadlima (HC, LC), Adalimumab-adaz (unbranded Hyrimoz)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis (PP)
	  ○ Rheumatoid Arthritis (RA)
	  ○ Psoriatic Arthritis (PsA)
	  ○ Ankylosing Spondylitis (SpA)
	  ○ Non-radiographic axial spondyloarthritis (nr-axSpA)
	  ○ Crohn's Disease (CD)
	  ○ Uveitis
	  ○ Juvenile Idiopathic Arthritis (JIA)
	  ○ Ulcerative Colitis (UC)
	  ○ Hidradenitis Suppurativa (HS)

Required Medical Information:	**<u>Rheumatoid Arthritis</u>**
	• Documentation of current disease activity with one of the following (or equivalent objective scale)
	  ○ The Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ The Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted RAPID3 of at least 2.3
	
	<u>Plaque Psoriasis</u>
	• Documentation that the skin disease is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DQLI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	AND
	• Documentation of one or more of the following:
	  ○ At least 10% body surface area involvement despite current treatment
	OR
	  ○ Hand, foot or mucous membrane involvement
	
	<u>Psoriatic Arthritis</u>
	• Documentation of CASPAR criteria score of 3 or greater based on chart notes:
	  ○ Skin psoriasis: present – two points, OR previously present by history – one point, OR a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxtaarticular bone formation on radiographs (distinct from osteophytes): one point
	
	<u>Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (nr-axSpA)</u>

	• Diagnosis of axial spondyloarthritis (SpA) confirmed by Sacroiliitis on imaging AND at least 1 Spondyloarthritis (SpA) feature:
	  ○ Inflammatory back pain (4 of 5 features met):
	  ▪ Onset of back discomfort before the age of 40 years
	  ▪ Insidious onset
	  ▪ Improvement with exercise
	  ▪ No improvement with rest
	  ▪ Pain at night (with improvement upon arising)
	  ○ Arthritis
	  ○ Enthesitis
	  ○ Uveitis
	  ○ Dactylitis (inflammation of entire digit)
	  ○ Psoriasis
	  ○ Crohn's disease/ulcerative colitis
	  ○ Good response to NSAIDs
	  ○ Family history of SpA
	  ○ Elevated CRP
	OR
	  ○ HLA-B27 genetic test positive AND at least TWO SpA features
	
	• Documentation of active disease defined by Bath ankylosing spondylitis disease activity index (BASDAI) at least 4 or equivalent objective scale
	
	<u>Ulcerative Colitis</u>
	• Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy
	
	<u>Crohn's disease</u>
	• Documentation of moderate to severely active disease despite current treatment
	
	<u>Juvenile Idiopathic Arthritis (JIA)</u>
	• Documentation of current level of disease activity with physician global assessment (MD global score) or active joint count
	
	<u>Uveitis</u>
	• Documented diagnosis of noninfectious intermediate, posterior, or panuveitis uveitis
	
	<u>Hidradenitis Suppurativa (HS)</u>
	• Diagnosis of moderate to severe HS as defined by Hurley stage II or stage III disease
	• Documentation of baseline count of abscesses and inflammatory nodules

Appropriate Treatment Regimen & Other Criteria:	• Dosing is in accordance with FDA-approved labeling and PacificSource quantity limitations
	
	<u>Rheumatoid Arthritis</u>
	• Documented failure with at least 12 weeks of treatment with methotrexate
	  ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide)
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ One of following: Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis), tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV)

PacificSource Community Solutions

- **Maintenance:** 40 mg every other week
- **Dose escalation:** 40 mg every week **OR** 80 mg every other week
    - Approval will require documentation of lost or inadequate response after a minimum of 16 weeks with standard maintenance dosing

Plaque Psoriasis

- Documented treatment failure with 12 weeks of at least TWO systemic therapies: Methotrexate, Cyclosporine, Acitretin, Phototherapy [UVB, PUVA]
- Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola)
- **Initial:** 80 mg as a single dose, followed by 40 mg every other week beginning 1 week after initial dose (160 mg total in first 28 days)
- **Maintenance:** 40 mg every other week
- **Dose escalation:** 40 mg every week **OR** 80 mg every other week
    - Approval will require documentation of lost or inadequate response after a minimum of 16 weeks with standard maintenance dosing

Psoriatic Arthritis

- Documented failure with at least 12 weeks of treatment with methotrexate
    - If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide)
- Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola)
- **Maintenance:** 40 mg every other week

Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (nr-axSpA)

- Documentation of **ONE** of the following:
    - Documented failure with two daily prescription strength nonsteroidal anti-inflammatory drugs (ibuprofen, naproxen, diclofenac, meloxicam, etc.) with minimum 1 month trial each
    - For peripheral arthritis: documented treatment failure with locally administered parenteral glucocorticoid
- Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola)
- **Maintenance:** 40 mg every other week

Crohn's Disease (CD)

- Documentation of **ONE** of the following:
    - Documented treatment failure with at least one oral treatment for a minimum 12 week trial: azathioprine, 6-mercaptopurine, methotrexate, sulfasalazine, balsalazide
      OR
    - Documentation of previous surgical intervention for Crohn's disease
      OR
    - Documentation of severe, high-risk disease on colonoscopy defined by one of the following:
        - Fistulizing disease
        - Stricture
        - Presence of abscess/phlegmon
        - Deep ulcerations

	▪ Large burden of disease including ileal, ileocolonic, or proximal gastrointestinal involvement • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola) • **Initial:** 160 mg on day 1, followed by 80 mg on day 15, then maintenance dosing beginning day 29 • **Maintenance:** 40 mg every other week • **Dose escalation:** 40 mg every week **OR** 80 mg every other week o Approval will require documentation of lost or inadequate response after a minimum of 16 weeks with standard maintenance dosing (e.g., CDAI 220 or greater, CRP 10 mg/mL or greater, serum adalimumab concentrations less than 5 mcg/mL with breakthrough symptoms of disease) **Juvenile Idiopathic Arthritis (JIA)** • Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide • Documented failure with glucocorticoid joint injections or oral corticosteroids • **Maintenance:** Weight-based in accordance with FDA label **Uveitis** • Documented failure with at least 12 weeks of TWO of the following: an immunosuppressive agent such as: methotrexate, azathioprine, mycophenolate or a calcineurin inhibitor such as cyclosporine, tacrolimus • Documented failure with (or documented intolerable adverse event) with 12 weeks of infliximab (preferred biosimilar products Inflectra, and Avsola) • **Initial:** 80 mg as a single dose, followed by 40 mg every other week beginning 1 week after initial dose (160 mg total in first 28 days) • **Maintenance:** Weight-based in accordance with FDA label **Hidradenitis Suppurativa (HS)** • Documented failure with at least 12 weeks trial of oral antibiotics for treatment of HS o Doxycycline, Tetracycline, Minocycline, or clindamycin plus rifampin • Documented failure with 8 weeks on a systemic retinoid (e.g., isotretinoin or acitretin) • Documented failure with (or documented intolerable adverse event) with 12 weeks of infliximab (preferred biosimilar products Inflectra and Avsola) • **Initial:** 160 mg on day 1, followed by 80 mg on day 15, then maintenance dosing beginning day 29 • **Maintenance:** 40 mg every week **OR** 80 mg every other week **Ulcerative Colitis (UC)** • Documentation of **ONE** of the following: o Documented failure with at least two oral treatments for a minimum of 12 weeks: corticosteroids, sulfasalazine, mesalamine, balsalazide, cyclosporine, azathioprine, 6-mercaptopurine o Documentation of severely active disease despite current treatment defined by greater than or equal to 6 bloody, loose stools per day with severe cramps and evidence of systemic toxicity (fever, tachycardia, anemia, and/or elevated CRP/ESR), or recent hospitalization for ulcerative colitis

	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola) • **Initial:** 160 mg on day 1, followed by 80 mg on day 15, then maintenance dosing beginning day 29 • **Maintenance:** 40 mg every other week • **Dose escalation:** 40 mg every week **OR** 80 mg every other week ○ Approval will require documentation of lost or inadequate response after a minimum of 16 weeks with standard maintenance dosing (e.g., baseline low albumin, CRP 10 mg/mL or greater, serum adalimumab concentrations less than 5 mcg/mL with breakthrough symptoms of disease) **<u>Reauthorization</u>** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other biologic therapy or Otezla is considered experimental and is not a covered benefit • Anterior Uveitis
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/ dermatologist/ophthalmologist/gastroenterologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

POLICY NAME:
ADENOSINE DEAMINASE (ADA) REPLACEMENT
Affected Medications: REVCOVI (elapegademase-lvlr)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients

Required Medical Information:	• Diagnosis of ADA-SCID confirmed by genetic testing showing biallelic pathogenic variants in the *ADA* gene
	• Laboratory findings show at least **ONE** of the following:
	  ○ Absent ADA levels in lysed erythrocytes
	  ○ A marked increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates
	  ○ A significant decrease in ATP concentration in red blood cells
	  ○ Absent or extremely low levels of N adenosylhomocysteine hydrolase in red blood cells
	  ○ Increase in 2'-deoxyadenosine in urine and plasma

Appropriate Treatment Regimen & Other Criteria:	• Documentation showing that neither gene therapy nor a matched sibling or family donor for HCT (hematopoietic cell transplantation) is available, or that gene therapy or HCT was unsuccessful • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** requires documentation of treatment success defined as disease stability and/or improvement as indicated by one or more of the following: • Increase in plasma ADA activity • Decrease in red blood cell dATP/dAXP level • Improvement in immune function with diminished frequency/complications of infections
Exclusion Criteria:	• Other forms of autosomal recessive SCIDs • All uses not listed under covered uses are considered experimental
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an immunologist or specialist experienced in the treatment of severe combined immune deficiency (SCID)
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ADZYNMA
Affected Medications: ADZYNMA (apadamtase alfa)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Congenital thrombotic thrombocytopenic purpura (cTTP)

Required Medical Information:	• Diagnosis of severe cTTP confirmed by BOTH of the following:
	  ○ Molecular genetic testing confirming presence of homozygous or compound heterozygous variants in the ADAMTS13 gene
	  ○ ADAMTS13 activity testing showing less than 10% of normal activity
	• **For on-demand treatment:** Documentation of current or past acute event with the following:
	  ○ Reduction in platelet count by 50% or greater **OR** platelet count less than 100,000/microliter
	  ○ Elevation in lactate dehydrogenase (LDH) level to more than 2x baseline or the upper limit of normal (ULN)
	• **For prophylactic use:**
	  ○ Must have history of at least one documented thrombotic thrombocytopenic purpura (TTP) event (past acute event or subacute event such as thrombocytopenia event or a microangiopathic hemolytic anemia event)

Appropriate Treatment Regimen & Other Criteria:	• **Dosing:**
	  ○ Prophylactic: 40 IU/kg once every other week
	  ▪ May be dosed weekly with documentation of appropriate prior dosing regimen or clinical response
	  ○ On-demand therapy: 40 IU/kg on day 1, 20 IU/kg on day 2, and 15 IU/kg on day 3 and beyond until 2 days after the acute event is resolved
	
	<u>Reauthorization</u>:
	• For prophylactic use: documentation of treatment success defined as an improvement in the number or severity of TTP events, platelet counts, or clinical symptoms
	• For on-demand use: documentation of treatment success, defined as an increase in platelet counts to at least 150,000/microliter, or counts returned to within 25% of baseline

Exclusion Criteria:	• Diagnosis of other TTP-like disorder, such as acquired or immune-mediated TTP
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hematologist, oncologist, intensive care specialist, or specialist in rare genetic hematologic diseases
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
AFAMELANOTIDE
Affected Medications: SCENESSE (afamelanotide injection)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of patients with erythropoietic protoporphyria (EPP) with phototoxic reactions (including X-linked protoporphyria [XLP])
Required Medical Information:	**Erythropoietic Protoporphyria (EPP)** • Documented diagnosis of EPP confirmed by biallelic loss-of-function mutation in the ferrochelatase (FECH) gene • Documented increase in total erythrocyte protoporphyrin, with at least 85% metal-free protoporphyrin • Documented symptoms of phototoxic reactions, resulting in dysfunction and significant impact on activities of daily living
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization:** • Documentation of treatment success and clinically significant response to therapy (e.g., decreased severity and number of phototoxic reactions, increased duration of sun exposure, increased quality of life, etc.) AND • Continued implementation of sun and light protection measures during treatment to prevent phototoxic reactions
Exclusion Criteria:	• Cosmetic indications
Age Restriction:	• 18 years of age or older
Prescriber/Site of Care Restrictions:	• Prescribed and managed by a specialist at a recognized Porphyria Center
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
AFINITOR
Affected Medications: AFINITOR DISPERZ (everolimus), everolimus soluble tablet

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher

Required Medical Information:	**Oncology Indications**
	• Documentation of performance status, all prior therapies used, and prescribed treatment regimen
	
	Tuberous Sclerosis Complex (TSC) Indications
	• Documentation of treatment resistant epilepsy, defined as lack of seizure control with 2 different antiepileptic regimens and meeting following criteria:
	  ○ Documentation of treatment failure with Epidiolex (cannabadiol solution) adjunct therapy
	  ○ Documentation that **Afinitor Disperz** (only form approved for TSC-seizures) is being used as adjunct therapy for seizures
	OR
	• Documentation of symptomatic subependymal giant cell tumors (SGCTs) or Tuberous sclerosis complex–associated subependymal giant cell astrocytoma (SEGA) in a patient who is not a good candidate for surgical resection

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of disease responsiveness to therapy
Exclusion Criteria:	**Oncology Indications** • Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber Restrictions:	• **Oncology Indication:** Prescribed by, or in consultation with, an oncologist • **TSC Indication**: Prescribed by, or in consultation with, a neurologist or specialist in the treatment of TSC
Coverage Duration:	• Initial approval: 4 months (2-week initial partial fill), unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
ALEMTUZUMAB
Affected Medications: LEMTRADA (alemtuzumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following:
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)

Required Medical Information:	MS • Diagnosis confirmed with magnetic resonance imaging (MRI) (per revised McDonald diagnostic criteria for MS) ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS

Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure with (or intolerance to) ONE of the following:
	  ○ Rituximab (preferred biosimilar products: Truxima, Riabni, Ruxience)
	  ○ Ocrelizumab (Ocrevus), if previously established on treatment (excluding via samples or manufacturer's patient assistance programs)
	
	Reauthorization requires provider attestation of treatment success
	• Eligible for renewal 12 months after administration of last dose

Exclusion Criteria:	• Human immunodeficiency virus (HIV) infection • Active infection • Concurrent use of other disease-modifying medications indicated for the treatment of MS
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Initial Authorization: 5 doses for 5 days, unless otherwise specified • Reauthorization: 3 doses for 3 days, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ALGLUCOSIDASE ALFA
Affected Medications: LUMIZYME (alglucosidase alfa)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Pompe Disease
Required Medical Information:	• Diagnosis of Pompe disease confirmed by an enzyme assay demonstrating a deficiency of acid α-glucosidase (GAA) enzyme activity or by DNA testing that identifies mutations in the GAA gene. • Patient weight and planned treatment regimen.

Appropriate Treatment Regimen & Other Criteria:	• One or more clinical signs or symptoms of Pompe disease, including but not limited to:
	  ○ Readily observed evidence of glycogen storage (macroglossia, hepatomegaly, normal or increased muscle bulk)
	  ○ Involvement of respiratory muscles manifesting as respiratory distress (e.g., tachypnea)
	  ○ Profound diffuse hypotonia
	  ○ Proximal muscle weakness
	  ○ Reduced forced vital capacity (FVC) in upright or supine position
	• Appropriate medical support is readily available when medication is administered in the event of anaphylaxis, severe allergic reaction, or acute cardiorespiratory failure.
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization will require documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Concurrent use of other enzyme replacement therapies such as Nexviazyme or Pombiliti and Opfolda
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a metabolic specialist, endocrinologist, biochemical geneticist, or physician experienced in the management of Pompe disease.
Coverage Duration:	• Approval: 12 months, unless otherwise specified.

PacificSource Community Solutions

POLICY NAME:
ALPHA-1 PROTEINASE INHIBITORS
Affected Medications: ARALAST NP, GLASSIA, PROLASTIN-C, ZEMAIRA

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe congenital alpha-1 antitrypsin (AAT) deficiency

Required Medical Information:	• Documented diagnosis of severe congenital AAT deficiency, confirmed by **BOTH** the following (a and b):
	  a. Baseline AAT serum concentration of less than or equal to 11 micromol/L (equivalent to 57 mg/dL or less via nephelometry, 80 mg/dL or less via radial immunodiffusion)
	  b. One of the following high-risk phenotypic variants: PiZZ, PiSZ, Pi(null)(null), or other rare allelic mutation
	• Documentation of clinically evident emphysema or chronic pulmonary obstructive disease (COPD), confirmed by **ONE** of the following (a or b):
	  a. Evidence of severe airflow obstruction, defined as forced expiratory volume in one second (FEV1) of 30-65% predicted
	  b. Evidence of mild-moderate airflow obstruction, defined as an FEV1 between 66-80% of predicted, but has demonstrated a rapid decline by at least 100 mL/year

Appropriate Treatment Regimen & Other Criteria:	• Documentation of non-smoker status ○ Has not smoked for a minimum of 6 consecutive months leading up to therapy initiation and will continue to abstain from smoking during therapy • **Glassia:** Documentation of intolerable adverse event to Aralast NP, Prolastin-C, or Zemaira • Dosing: 60 mg/kg intravenously once weekly • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Use in the management of lung disease in which severe AAT deficiency has not been established • Patients with IgA deficiency or with the presence of IgA antibodies • Prior liver transplant
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pulmonologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
AMIFAMPRIDINE
Affected Medications: FIRDAPSE (amifampridine phosphate)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Lambert-Eaton myasthenic syndrome (LEMS)

Required Medical Information:	• Documented diagnosis of LEMS confirmed by **ONE** of the following:
	  ○ Positive anti-P/Q-type voltage-gated calcium channel (VGCC) antibody test
	  ○ Repetitive nerve stimulation (RNS) abnormalities, such as an increase in compound muscle action potential (CMAP) amplitude at least 60 percent after maximum voluntary contraction (i.e., post-exercise stimulation) or at high frequency (50 Hz)
	  ○ Documentation of clinical signs and symptoms consistent with LEMS, as follows: proximal muscle weakness (without atrophy), with or without autonomic features and areflexia

Appropriate Treatment Regimen & Other Criteria:	• Documentation of inadequate clinical response or intolerance to **ONE** of the following (except in active small cell lung carcinoma [SCLC]-LEMS):
	  ○ Combination oral prednisone and azathioprine therapy
	  ○ Combination intravenous immunoglobulin therapy with one of the following: oral prednisone or azathioprine
	
	Reauthorization requires documentation of treatment success, confirmed by improved or sustained muscle strength on clinical assessments

Exclusion Criteria:	• Seizure disorder • Active brain metastases • Clinically significant long QTc interval on ECG in previous year OR history of additional risk factors for torsade de pointes
Age Restriction:	• 6 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
ANAKINRA
Affected Medications: KINERET PREFILLED SYRINGE

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis (RA)
	  ○ Neonatal-onset multisystem inflammatory disease (NOMID), also known as chronic infantile neurological cutaneous and articular (CINCA) syndrome
	  ○ Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
	• Compendia-supported uses that will be covered
	  ○ Juvenile Idiopathic Arthritis (JIA)
	  ○ Still's Disease (SD)
	  ○ Hemophagocytic lymphohistiocytosis (HLH) or Macrophage activation syndrome (MAS) in known or suspected Still's disease or systemic Juvenile Idiopathic Arthritis (sJIA) in patients (newborn and older) with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS

Required Medical Information:	**<u>Rheumatoid Arthritis</u>**
	• Documentation of current disease activity with one of the following (or equivalent objective scale):
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted Routine Assessment of Patient Index Data 3 (RAPID3) of at least 2.3
	
	<u>Juvenile Idiopathic Arthritis</u>
	• Documentation of current level of disease activity with physician global assessment (MD global score) or active joint count
	
	<u>Deficiency of Interleukin-1 Receptor Antagonist</u>
	• Documentation of genetically confirmed DIRA
	
	<u>HLH with MAS</u>
	• Documentation confirming status as a hematopoietic stem cell transplant (HSCT) candidate
	• Diagnosis of HLH and documentation of active MAS in the setting of Adult Onset Still's disease or sJIA with ferritin levels greater than 684 ng/mL
	• Documentation showing at least 2 of the following are present:
	  ○ Decreased platelet count
	  ○ Decreased white blood cell count
	  ○ Decreased erythrocyte sedimentation rate (ESR)
	  ○ Decreased fibrinogen
	  ○ Elevated transaminases (AST, ALT)
	  ○ Elevated triglycerides

Appropriate Treatment Regimen & Other Criteria:	**<u>Rheumatoid Arthritis</u>** • Documented failure with at least 12 weeks of treatment with methotrexate ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:

	○ One of following: Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis), tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV) **Juvenile Idiopathic Arthritis** • Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide • Documented failure with glucocorticoid joint injections or oral corticosteroids • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of two of the following therapies: ○ tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV), Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), and Simponi Aria **QL** • RA/JIA: 100 mg once daily, 18.76 mL per 28 days • DIRA: maximum dose of 8 mg/kg/day **Reauthorization** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit • Sepsis syndrome or graft versus host disease • Use in the management of symptomatic osteoarthritis, lupus arthritis, or type 2 diabetes mellitus
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

POLICY NAME:
ANIFROLUMAB
Affected Medications: SAPHNELO (anifrolumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Systemic Lupus Erythematosus (SLE)
Required Medical Information:	• Documentation of SLE with moderate classification (significant but non-organ threatening disease including constitutional, cutaneous, musculoskeletal, or hematologic involvement) • Autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody
Appropriate Treatment Regimen & Other Criteria:	• Failure with at least 12 weeks of combination therapy including hydroxychloroquine OR chloroquine with one of the following: ○ Cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil **AND** • Documented failure with at least 12 weeks of Benlysta **Reauthorization**: • Documentation of treatment success or a clinically significant improvement such as a decrease in flares or corticosteroid use
Exclusion Criteria:	• Use in combination with other biologic therapies • Use in severe active central nervous system lupus
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist or a specialist with experience in the treatment of systemic lupus erythematosus
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

POLICY NAME:
ANTIEMETICS
Affected Medications: AKYNZEO (fosnetupitant and palonosetron injection), SUSTOL (granisetron extended-release injection)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	• Akynzeo (fosnetupitant and palonosetron)
	  ○ Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy
	• Sustol (granisetron)
	  ○ Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens

Required Medical Information:	**<u>Chemotherapy Induced Nausea and Vomiting Prophylaxis</u>**
	• Documentation of planned chemotherapy regimen
	• Akynzeo
	  ○ Documentation of a highly emetogenic chemotherapy regimen
	• Sustol
	  ○ Documentation of a moderately emetogenic chemotherapy regimen OR anthracycline and cyclophosphamide (AC) combination chemotherapy regimen

Appropriate Treatment Regimen & Other Criteria:	**<u>Chemotherapy Induced Nausea and Vomiting Prophylaxis</u>**
	• Akynzeo
	  ○ Documented treatment failure with both of the following while receiving the current chemotherapy regimen:
	  ▪ 5-HT3 receptor antagonist (e.g., ondansetron, granisetron or palonosetron)
	  ▪ NK1 receptor antagonist (e.g., aprepitant, fosaprepitant or rolapitant)
	• Sustol
	  ○ Documented treatment failure with both of the following while receiving the current chemotherapy regimen:
	  ▪ Granisetron oral tablet
	  ▪ Granisetron intravenous solution
	<u>QL:</u>
	• Akynzeo: 1 dose per 7 days
	• Sustol: 1 dose per 7 days
	
	<u>Reauthorization</u> requires documentation of treatment success and initial criteria to be met

Exclusion Criteria:	• Treatment of acute or breakthrough nausea and vomiting • Used in anthracycline plus cyclophosphamide (AC) chemotherapy (Akynzeo only)
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Authorization: 6 months, unless otherwise specified

POLICY NAME:
ANTIHEMOPHILIC FACTORS
Affected Medications: Advate, Adynovate, Afstyla, Alphanate, AlphaNine SD, Alprolix, Altuviiio, Benefix, Corifact, Eloctate, Esperoct, Feiba NF, Helixate FS, Hemofil M, Humate-P, Idelvion, Ixinity, Jivi, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P, Mononine, NovoEight, Novoseven RT, Nuwiq, Obizur, Rebinyn, Recombinate, Riastap, Rixubis, Sevenfact, Tretten, Vonvendi, Wilate, Xyntha

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information:	• Documentation of dose based on reasonable projections, current dose utilization, product labeling, diagnosis, baseline factor level, circulating factor activity (% of normal or units/dL) and rationale for use
	• Patient weight
	• Documentation of Bethesda Titer level and number of bleeds in past 3 months with severity and cause of bleed
	
	<u>Documentation of one of the following diagnostic categories:</u>
	• Hemophilia A or Hemophilia B:
	  ○ Mild: factor levels greater than 5 and less than 30%
	  ○ Moderate: factor levels of 1% to 5%
	  ○ Severe: factor levels of less than 1%
	• von Willebrand disease (VWD), which must be confirmed with plasma von Willebrand factor (VWF) antigen, plasma VWF activity, and factor VIII activity
	
	<u>Documentation of one of the following indications:</u>
	• Acute treatment of moderate to severe bleeding in patients with:
	  ○ Mild, moderate, or severe hemophilia A or B
	  ○ Severe VWD
	  ○ Mild to moderate VWD in clinical situations with increased risk of bleeding
	• Perioperative management (prophylaxis and/or treatment) of moderate to severe bleeding in patients with hemophilia A, hemophilia B, or VWD
	• Routine prophylaxis in patients with severe hemophilia A, severe hemophilia B, or severe VWD
	  ○ For Wilate and Vonvendi for routine prophylaxis; documentation of severe Type 3 VWD

Appropriate Treatment Regimen & Other Criteria:	• Approval based on necessity and laboratory titer levels **<u>Hemophilia A (factor VIII deficiency)</u>** • Documentation indicates requested medication is to achieve or maintain but not to exceed maximum functional capacity in performing daily activities • For mild disease: treatment failure or contraindication to Stimate (demopressin) • For NovoEight, Afstyla, and Nuwiq: Must have documentation of failure or contraindication to Advate or Hemofil M. • For Eloctate and Altuviiio: documentation of severe hemophilia or moderate hemophilia with a severe bleeding phenotype defined by frequent non-traumatic bleeds requiring prophylaxis **<u>Hemophilia B (factor IX deficiency)</u>** • For Benefix, Idelvion and Rebinyn: documentation of failure or contraindication to

	Rixubis
	• For Alprolix: documentation of contraindication to Rixubis in perioperative management
	
	<u>Von Willebrand disease (VWD)</u>
	• For Vonvendi:
	  ○ Documentation of failure or contraindication to Humate P AND Alphanate for perioperative prophylaxis and/or treatment of acute, moderate to severe bleeding
	  ○ Documentation of treatment failure or contraindication to Wilate for routine prophylaxis
	
	<u>Reauthorization</u>: requires documentation of planned treatment dose, number of acute bleeds since last approval (with severity and cause of bleed), past treatment history, and titer inhibitor level to factor VIII, and IX as appropriate

Exclusion Criteria:	• Acute thrombosis, embolism or symptoms of disseminated intravascular coagulation • Obizur for congenital hemophilia A or VWD • Tretten for congenital factor XIII B-subunit deficiency • Jivi and Adynovate for VWD • Idelvion for immune tolerance induction in patients with Hemophilia B • Vonvendi for congenital hemophilia A or hemophilia B • Afstyla and Nuwiq for VWD
Age Restriction:	• Subject to review of FDA label for each product • Jivi: 7 years of age and older • Adynovate: 12 years of age and older • Vonvendi: 18 years and older • Wilate for routine prophylaxis with von Willebrand disease: 6 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Authorization: 24 months, unless otherwise specified • Perioperative management: 1 month, unless otherwise specified

POLICY NAME:
ANTITHROMBIN III
Affected Medications: ANTITHROMBIN III (THROMBATE III)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Indicated in patients with hereditary antithrombin deficiency (hATd) for:
	  ▪ Prevention of perioperative and peripartum thromboembolism
	  ▪ Prevention and treatment of thromboembolism

Required Medical Information:	**All Indications** • Documented diagnosis of hATd, confirmed by antithrombin (AT) activity levels below 70% on functional assay (not taken during acute illness, surgery, or thromboembolic event that could give falsely low antithrombin levels)

Appropriate Treatment Regimen & Other Criteria:	**Prevention of Perioperative Thromboembolism**
	• Approved first-line for perioperative thromboprophylaxis in combination with heparin, with or without intent to use as bridge to warfarin therapy
	
	Prevention of Peripartum Thromboembolism
	• Documentation of **one** of the following:
	  ○ Personal or family history of thrombosis
	  ○ Insufficient response to heparin **AND** intolerance to direct oral anticoagulants (DOACs)
	
	Prevention of Thromboembolism
	• Documentation of inadequate clinical response, intolerance, or contraindication to **both** of the following:
	  ○ Warfarin
	  ○ At least one DOAC
	
	Treatment of Thromboembolism
	• Approved first-line for treatment of thromboembolism as adjunct to anticoagulant therapy, unless coagulation is temporarily contraindicated

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist, geneticist, or obstetrician
Coverage Duration:	• **Perioperative/peripartum prevention; thromboembolism treatment:** 1 month, unless otherwise specified • **Thromboembolism prevention:** 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ANTITHYMOCYTE GLOBULINS
Affected Medications: ATGAM (antithymocyte globulin – equine), THYMOGLOBULIN (antithymocyte globulin – rabbit)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of allograft rejection in renal transplant recipients **(Atgam, Thymoglobulin)**
	  ○ Treatment of moderate to severe aplastic anemia in patients unsuitable for bone marrow transplantation **(Atgam)**
	  ○ Prophylaxis of acute rejection in renal transplant recipients **(Thymoglobulin)**
	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better
	• Compendia-supported uses that will be covered **(Thymoglobulin)**
	  ○ Prophylaxis and treatment of acute rejection in:
	  ▪ Heart transplant recipients
	  ▪ Liver transplant recipients
	  ▪ Lung transplant recipients
	  ▪ Pancreas transplant recipients
	  ▪ Intestinal transplant recipients
	  ○ Prophylaxis of acute rejection in multivisceral transplant recipients
	  ○ Prophylaxis of graft-versus-host disease in unrelated donor hematopoietic stem cell transplant recipients

Required Medical Information:	• Oncology uses: Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course
	
	<u>All Indications</u>
	• Documentation of a complete treatment plan with planned dose, frequency and duration of therapy
	• Current patient weight
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	<u>Prophylaxis of acute transplant rejection</u>
	• Patient must be considered high risk for acute rejection or delayed graft function based on one or more of either the following donor/recipient risk factors:
	<u>Donor risk factors:</u>
	  ○ Donor cold ischemia for more than 24 hours
	  ○ Donor age older than 50 years old
	  ○ Donor without a heartbeat
	  ○ Donor with ATN
	  ○ Donor requiring high-dose inotropic support
	<u>Recipient risk factors:</u>
	  ○ Repeated transplantation
	  ○ Panel-reactive antibody value exceeding 20% before transplant
	  ○ Black race
	  ○ One or more HLA antigen mismatches with the donor

Appropriate Treatment Regimen & Other Criteria:	**<u>Prophylaxis of acute transplant rejection</u>** • Documented treatment failure, intolerable adverse event, or contraindication to the use of basiliximab **<u>Treatment of allograft rejection in renal transplant recipients</u>** • Requests for Atgam require documented treatment failure or rationale for avoidance of Thymoglobulin
Exclusion Criteria:	• Oncology uses: Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Active acute or chronic infections which contraindicate additional immunosuppression • Use in patients with aplastic anemia who are suitable candidates for bone marrow transplantation or in patients with aplastic anemia secondary to neoplastic disease, storage disease, myelofibrosis, Fanconi's syndrome, or in patients known to have been exposed to myelotoxic agents or radiation **(Atgam)**
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a specialist in oncology, hematology, nephrology or transplant medicine as appropriate for diagnosis
Coverage Duration:	• Authorization: 1 month, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
APOMORPHINE
Affected Medications: APOKYN (apomorphine), APOMORPHINE SOLUTION

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Acute, intermittent treatment of hypomobility, "off" episodes in patients with advanced Parkinson's disease (PD)
Required Medical Information:	• Diagnosis of advanced PD • Documentation of acute, intermittent hypomobility, "off" episodes occurring for at least 2 hours per day while awake despite an optimized treatment regimen

Appropriate Treatment Regimen & Other Criteria:	• Established on a stable dose of carbidopa-levodopa with intent to continue
	• Documented treatment failure with concurrent use of levodopa-carbidopa and a second agent from one of the following classes:
	  ○ Catechol-O-methyltransferase (COMT) inhibitors (e.g., entacapone)
	  ○ Dopamine agonists (e.g., pramipexole, ropinirole)
	  ○ Monoamine oxidase-B (MAO-B) inhibitors (e.g., selegiline, rasagiline)
	
	Reauthorization will require documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Use as monotherapy or first line agent
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
APREMILAST
Affected Medications: OTEZLA, OTEZLA THERAPY PACK

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Psoriatic Arthritis (PsA)
	  ○ Psoriasis (PP)
	  ○ Oral Ulcers associated with Behcet's Disease

Required Medical Information:	**Plaque Psoriasis**
	• Documentation that the skin disease is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	AND
	• Documentation of one or more of the following:
	  ○ At least 10% body surface area involvement despite current treatment
	OR
	  ○ Hand, foot, or mucous membrane involvement
	
	Psoriatic Arthritis
	• Documentation of Classification for Psoriatic Arthritis (CASPAR) criteria score of 3 or greater based on chart notes:
	  ○ Skin psoriasis: present – two points, OR previously present by history – one point, OR a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxta-articular bone formation on radiographs (distinct from osteophytes): one point
	
	Oral Ulcers Associated with Behcet's Disease
	• Diagnosis of Behcet's with documentation of recurrent oral aphthae (ulcer, sore) at least 3 times in a year
	AND
	• Two of the following:
	  ○ Recurrent genital aphthae
	  ○ Eye lesions
	  ○ Skin lesions
	  ○ Positive pathergy test defined by a papule 2 mm or greater

Appropriate Treatment Regimen & Other Criteria:	**Plaque Psoriasis** • Documented treatment failure with 12 weeks of at least TWO systemic therapies: methotrexate, cyclosporine, acitretin, phototherapy [UVB, PUVA] • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis) **AND**

	○ One of the following: Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **Psoriatic Arthritis** • Documented failure with at least 12 weeks of treatment with methotrexate ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Simponi Aria, Orencia IV, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **Oral Ulcers Associated with Behcet's Disease** • Documented clinical failure of at least 1 oral medication for Behcet's disease after at least 12 weeks (colchicine, prednisone, azathioprine) **QL** • Induction (All indications): Titration pack • Maintenance (All indications): 60 tablets per 30 days **Reauthorization** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/dermatologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

POLICY NAME:
ARIPIPRAZOLE LONG ACTING INTRAMUSCULAR INJECTIONS
Affected Medications: ABILIFY MAINTENA (aripiprazole suspension, reconstituted), ABILIFY ASIMTUFII (aripiprazole suspension, prefilled syringe) (**Medical benefit only)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Schizophrenia in adults
	  ○ Bipolar I disorder in adults

Required Medical Information:	• Diagnosis of schizophrenia and on maintenance treatment OR • Diagnosis of bipolar I disorder and on maintenance treatment **AND** • Documentation of established tolerability to oral aripiprazole
Appropriate Treatment Regimen & Other Criteria:	• Documented failure or contraindication to Risperdal Consta **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a psychiatrist or receiving input from a psychiatry practice as appropriate for diagnosis
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
ARISTADA
Affected Medications: ARISTADA (aripiprazole lauroxil), ARISTADA INITIO

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	• Diagnosis of schizophrenia • Documentation of established tolerability with oral aripiprazole for a minimum of 14 days prior to initiating treatment with Aristada. • Documentation of comprehensive antipsychotic treatment regimen (including dosing and frequency of all formulations) • Documentation of Food and Drug Administration (FDA)-approved dose and frequency for the requested formulation **For initial authorization only:** • Documented plan for ensuring oral adherence during first 21 days of initial Aristada **For Aristada Initio:** • Documentation of clinical rationale to avoid 21-day oral aripiprazole loading dose due to history of patient non-compliance or risk for hospitalization
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization:** Documentation of clinically significant response to therapy.

Exclusion Criteria:	• Repeated dosing (greater than 1 dose) of Aristada Initio
	• Women who are pregnant, lactating, or breastfeeding.
	• Patients with dementia-related psychosis
	• Prior inadequate response to oral aripiprazole (unless poor adherence was a contributing factor)
	• No current, or within the last 2 years, diagnosis of:
	  ○ Major Depressive Disorder
	  ○ Comorbid schizoaffective disorder
	  ○ Amnestic or other cognitive disorder
	  ○ Bipolar disorder
	  ○ Dementia
	  ○ Delirium

Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a psychiatrist or behavioral health specialist
Coverage Duration:	Aristada (aripiprazole lauroxil) • Initial approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified Aristada Initio • Approval: 1 month, unless otherwise specified

POLICY NAME:
ARIKAYCE
Affected Medications: ARIKAYCE (Amikacin inhalation suspension)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in adults who have limited or no alternative treatment options, and who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy

Required Medical Information:	• Diagnosis of MAC lung disease confirmed by BOTH the following:
	  ○ A MAC-positive sputum culture obtained within the last 3 months
	  ○ Evidence of underlying nodular bronchiectasis and/or fibrocavity disease on a chest radiograph or chest computed tomography
	• The MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than or equal to 64 mcg/mL
	• Documentation of failure to obtain a negative sputum culture after a minimum of 6 consecutive months of a multidrug background regimen therapy for MAC lung disease such as clarithromycin (or azithromycin), rifampin and ethambutol

Appropriate Treatment Regimen & Other Criteria:	• Document of BOTH the following:
	  ○ This drug has been prescribed as part of a combination antibacterial drug regimen
	  ○ This drug will be used with the Lamira® Nebulizer System
	
	Reauthorization requires documentation of negative sputum culture obtained within the last 30 days.
	
	• The American Thoracic Society/Infectious Diseases Society of America (ATS/IDSA) guidelines state that patients should continue to be treated until they have negative cultures for 1 year. Treatment beyond the first reauthorization (after 18 months) will require documentation of a positive sputum culture to demonstrate the need for continued treatment. Patients that have had negative cultures for 1 year will not be approved for continued treatment.

Exclusion Criteria:	• Diagnosis of non-refractory MAC lung disease
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist
Coverage Duration:	• Initial Approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ASCIMINIB
Affected Medications: SCEMBLIX TABLET (asciminib)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Documentation of Philadelphia chromosome positive (Ph+) or BCR::ABL1- positive chronic myeloid leukemia (CML) in chronic phase
Appropriate Treatment Regimen & Other Criteria:	**Philadelphia chromosome or BCR::ABL1- positive chronic myeloid leukemia (CML) in chronic phase (CP) meeting one of the following:** **Low Risk Score** • Documented treatment failure with imatinib (if used as initial tyrosine kinase inhibitor [TKI]) AND one or more additional tyrosine kinase inhibitor (TKI) bosutinib, dasatinib, or nilotinib. **Intermediate or high-risk score** • Documented treatment failure with a second-generation tyrosine kinase inhibitor (TKI), bosutinib, dasatinib, or nilotinib. **OR** • Documented T315I positive mutation AND • Documented treatment failure with ponatinib **Reauthorization** requires documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Presence of either A337T, P465S, M244V, or F359V/I/C BCR::ABL1 kinase domain mutation
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ATIDARSAGENE AUTOTEMCEL
Affected Medications: LENMELDY (atidarsagene autotemcel)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of children with pre-symptomatic late-infantile (PSLI), pre-symptomatic early-juvenile (PSEJ), or early symptomatic early-juvenile (ESEJ) metachromatic leukodystrophy (MLD)

Required Medical Information:	• Diagnosis of metachromatic leukodystrophy (MLD) confirmed by the following:
	  ○ Arylsulfatase (ARSA) activity below the normal range in peripheral blood mononuclear cells or fibroblasts
	  ○ Presence of two disease-causing mutations of either known or novel alleles
	  ○ Presence of sulfatides in a 24-hour urine collection (to exclude MLD carriers and patients with ARSA pseudodeficiency)
	AND
	• Diagnosis of the late-infantile subtype of MLD confirmed by two out of three of the following:
	  ○ Age at onset of symptoms in the older sibling(s) less than or equal to 30 months
	  ○ Two null (0) mutant ARSA alleles
	  ○ Peripheral neuropathy as determined by electroneurographic study
	OR
	• Diagnosis of the early-juvenile subtype of MLD confirmed by two out of three of the following:
	  ○ Age at onset of symptoms (in the patient or in the older sibling) between 30 months and 6 years (has not celebrated their seventh birthday)
	  ○ One null (0) and one residual (R) mutant ARSA allele(s)
	  ○ Peripheral neuropathy as determined by electroneurographic study

Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Allogeneic hematopoietic stem cell transplantation in the previous six months • Previous gene therapy • Documented HIV infection • Documented history of a hereditary cancer
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by or in consultation with a neurologist or hematologist/oncologist
Coverage Duration:	• Authorization: 2 months (for one time infusion) • No reauthorization

PacificSource Community Solutions

POLICY NAME:
AVACOPAN
Affected Medications: TAVNEOS 10mg Capsule

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ As an adjunctive treatment of adult patients with severe, active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV), including granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), in combination with standard therapy including glucocorticoids

Required Medical Information:	• Diagnosis supported by at least one of the following:
	  ○ Tissue biopsy of kidney or other affected organs
	  ○ Positive ANCA, clinical presentation compatible with AAV, and low suspicion for secondary vasculitis
	  ○ Clinical presentation compatible with AAV, low suspicion for secondary vasculitis, and concern for rapidly progressive disease
	• Documented severe, active disease (including major relapse), defined as: vasculitis with life- or organ-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, subglottic stenosis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia)
	• Documentation of all prior therapies used and anticipated treatment course
	• Baseline liver test panel: serum alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, and total bilirubin
	• Current hepatitis B virus (HBV) status

Appropriate Treatment Regimen & Other Criteria:	• Will be used with a standard immunosuppressive regimen including glucocorticoids
	• Will be used during induction therapy only
	• Will be used in any of the following populations/scenarios:
	  ○ In patients unable to use glucocorticoids at appropriate doses
	  ○ In patients with an estimated glomerular filtration rate less than 30 mL/min/1.73 m^2
	  ○ In patients who have experienced relapse following treatment with two or more different induction regimens, including both rituximab- and cyclophosphamide-containing regimens (unless contraindicated)
	  ○ During subsequent induction therapy in patients with refractory disease (failure to achieve remission with initial induction therapy regimen)
	• Dosing: 30 mg (three 10 mg capsules) twice daily (once daily when used concomitantly with strong CYP3A4 inhibitors)
	
	Reauthorization: must meet criteria above (will not be used for maintenance treatment)

Exclusion Criteria:	• Treatment of eosinophilic-GPA (EGPA) • Active, untreated and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C virus infection, uncontrolled autoimmune hepatitis) and cirrhosis • Active, serious infections, including localized infections • History of angioedema while receiving Tavneos, unless another cause has been established • History of HBV reactivation while receiving Tavneos, unless medically necessary
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist, nephrologist, or pulmonologist
Coverage Duration:	• Authorization: 6 months with no reauthorization, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
AVALGLUCOSIDASE ALFA-NGPT
Affected Medications: NEXVIAZYME (avalglucosidase alfa-ngpt)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Late-Onset Pompe Disease
Required Medical Information:	• Diagnosis of Pompe Disease confirmed by an enzyme assay demonstrating a deficiency of acid α-glucosidase (GAA) enzyme activity or by DNA testing that identifies mutations in the GAA gene • Patient weight and planned treatment regimen

Appropriate Treatment Regimen & Other Criteria:	• One or more clinical signs or symptoms of Late-Onset Pompe Disease:
	  ○ Progressive proximal weakness in a limb-girdle distribution
	  ○ Delayed gross-motor development in childhood
	  ○ Involvement of respiratory muscles causing respiratory difficulty (such as reduced forced vital capacity [FVC] or sleep disordered breathing)
	  ○ Skeletal abnormalities (such as scoliosis or scapula alata)
	  ○ Low/absent reflexes
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization will require documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Diagnosis of infantile-onset Pompe Disease • Concurrent use of other enzyme replacement therapies such as Lumizyme or Pombiliti and Opfolda
Age Restriction:	• 1 year of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a metabolic specialist, endocrinologist, biochemical geneticist, or physician experienced in the management of Pompe disease
Coverage Duration:	• Approval: 12 months, unless otherwise specified.

PacificSource Community Solutions

POLICY NAME:
AVATROMBOPAG
Affected Medications: DOPTELET (avatrombopag), DOPTELET Sprinkle

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure
	  ○ Thrombocytopenia in patients at least 1 year of age with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment

Required Medical Information:	**<u>Thrombocytopenia in patients with CLD undergoing a procedure:</u>**
	• Documentation of planned procedure including date
	• Documentation of baseline platelet count of less than 50,000/microliter
	
	<u>Thrombocytopenia in patients with chronic ITP</u>
	• Documentation of **ONE** of the following:
	  ○ Platelet count less than 20,000/microliter
	  ○ Platelet count less than 30,000/microliter AND symptomatic bleeding
	  ○ Platelet count less than 50,000/microliter AND increased risk for bleeding (such as peptic ulcer disease, use of antiplatelets or anticoagulants, history of bleeding at higher platelet count, need for surgery or invasive procedure)

Appropriate Treatment Regimen & Other Criteria:	**<u>Thrombocytopenia in patients with chronic ITP</u>**
	• Documentation of inadequate response, defined as platelets did not increase to at least 50,000/microliter, to the following therapies:
	  ○ **ONE** of the following:
	  ▪ Inadequate response with at least 2 therapies for immune thrombocytopenia, including corticosteroids, rituximab, or immunoglobulin
	  ▪ Splenectomy
	  ○ eltrombopag olamine
	
	<u>Reauthorization (chronic ITP only):</u>
	• Response to treatment with platelet count of at least 50,000/microliter or above (not to exceed 400,000/microliter) OR
	• The platelet counts have not increased to a platelet count of at least 50,000/microliter and the patient has NOT been on the maximum dose for at least 4 weeks

Exclusion Criteria:	• Use in combination with another thrombopoietin receptor agonist, spleen tyrosine kinase inhibitor, or similar treatments (eltrombopag olamine, Nplate, Tavalisse)
Age Restriction:	• Doptelet tablets: 18 years and older • Doptelet sprinkle: 1 year of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist or gastroenterologist/liver specialist

Coverage Duration:	• **Thrombocytopenia in patients with CLD undergoing a procedure**: 1 month (for a one time 5-day regimen), unless otherwise specified
	• **Thrombocytopenia in patients with chronic ITP**:
	  ○ Initial Authorization: 4 months, unless otherwise specified
	  ○ Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
AXATILIMAB-CSFR
Affected Medications: NIKTIMVO (axatilimab-csfr)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Chronic graft-versus-host disease (cGVHD)
	  ○ NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better

Required Medical Information:	• Diagnosis of cGVHD following hematopoietic stem cell transplantation (HSCT) • Documentation of refractory or recurrent active cGVHD • Patient weight and planned treatment regimen

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with one from each category at maximally indicated doses:
	  ○ Prednisone or methylprednisolone
	  ○ Jakafi (ruxolitinib)
	  ○ Imbruvica (ibrutinib), or Rezurock (belumosudil)
	
	Dosing is in accordance with FDA labeling and does not exceed 0.3 mg/kg (maximum of 35 mg) every 2 weeks

Exclusion Criteria:	• Concurrent use with Jakafi, Imbruvica, or Rezurock • Patient weight of less than 40 kg • Platelet count of less than 50 x 10^9/L • Absolute neutrophil count of less than 1 × 10^9/L • ALT and AST greater than 2.5 times the upper limit of normal • Total bilirubin greater than 1.5 times the upper limit of normal • Creatinine clearance less than 30 mL/minute
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hematologist or oncologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BARICITINIB
Affected Medications: OLUMIANT

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded design ○ Rheumatoid Arthritis (RA)

Required Medical Information:	• Documentation of current disease activity with one of the following (or equivalent objective scale)
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted Routine Assessment of Patient Index Data 3 (RAPID3) of at least 2.3

Appropriate Treatment Regimen & Other Criteria:	• Documented failure with at least 12 weeks of treatment with methotrexate ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide) • Documentation of treatment failure (or documented intolerable adverse event) for 12 weeks or greater with Infliximab (preferred products Inflectra, Avsola) or tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV) **QL** • RA: 30 tablets per 30 days **Reauthorization** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit • Treatment of alopecia areata
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BCR-ABL TYROSINE KINASE INHIBITORS- SECOND GENERATION
Affected Medications: nilotinib capsules, DANZITEN (nilotinib tablets), DASATINIB, BOSULIF (bosutinib)

Covered Uses:	• NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or higher
Required Medical Information:	• Documentation of performance status, all prior therapies used, and prescribed treatment regimen • Documentation Philadelphia chromosome or BCR::ABL1-positive mutation status
Appropriate Treatment Regimen & Other Criteria:	• For patients with chronic phase Chronic Myeloid Leukemia (CP-CML) and low-risk score: o Documented clinical failure with Imatinib **Bosulif, Danziten** • Coverage requires the following: o Documented treatment failure or intolerable adverse event with *both* dasatinib *and* nilotinib **Reauthorization** requires documentation of disease responsiveness to therapy (as applicable, BCR-ABL1 transcript levels, cytogenetic response)
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BELIMUMAB
Affected Medications: BENLYSTA (Belimumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Systemic Lupus Erythematosus (SLE)
	  ○ Lupus Nephritis

Required Medical Information:	• Documentation of patient's current weight (intravenous requests only)
	
	<u>Systemic Lupus Erythematosus</u>:
	• Documentation of active SLE with moderate classification (significant but non-organ threatening disease including constitutional, cutaneous, musculoskeletal, or hematologic involvement)
	• Autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody
	• Baseline measurement of one or more of the following:
	  ○ SLE Responder Index-4 (SRI-4), SLE Activity Index (SLEDAI) variant, or other validated scale
	  ○ Frequency of flares requiring corticosteroid use
	
	<u>Lupus Nephritis:</u>
	• Documentation of biopsy-proven active Class III, IV, and/or V disease
	• Baseline measurement of one or more of the following: urine protein-creatinine ratio (uPCR), urine protein, estimated glomerular filtration rate (eGFR), or frequency of flares requiring corticosteroid use

Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced (intravenous requests only)
	
	<u>Systemic Lupus Erythematosus:</u>
	• Failure with at least 12 weeks of standard combination therapy including hydroxychloroquine OR chloroquine with one of the following:
	  ○ Cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil
	  ○ **Reauthorization:** Documentation of treatment success defined as **ONE** of the following:
	  ▪ Clinically significant improvement in SRI-4, SLEDAI variant, or other validated scale for measurement of disease
	  ▪ Decrease in frequency of flares or corticosteroid use
	
	<u>Lupus Nephritis:</u>
	• Failure of at least 12 weeks of standard therapy with mycophenolate mofetil AND cyclophosphamide
	• **Reauthorization**: Documentation of treatment success defined as **ONE** of the following:
	  ○ Improvement in eGFR
	  ○ Reduction in urine protein-creatinine ratio or urine protein
	  ○ Decrease in flares or corticosteroid use

Exclusion Criteria:	• Use in combination with other biologic therapies for LN or SLE • Use in severe active central nervous system lupus
Age Restriction:	• 5 years of age and older

Prescriber Restrictions:	• Prescribed by, or in consultation with, a nephrologist, rheumatologist, or specialist with experience in the treatment of systemic lupus erythematosus or lupus nephritis
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BELZUTIFAN
Affected Medications: WELIREG (belzutifan)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better

Required Medical Information:	**<u>Von Hippel-Lindau (VHL) disease</u>**
	• Diagnosis documented by the following:
	  ○ Pathogenic VHL germline mutation diagnostic for VHL disease AND at least one of the following:
	  ▪ Presence of solid, locoregional tumor in kidney showing accelerated tumor growth (growth of 5mm or more per year)
	  ▪ Presence of symptomatic and/or progressively enlarging central nervous system (CNS) hemangioblastomas not amenable to surgery
	  ▪ Presence of pancreatic solid lesion or pancreatic neuroendocrine tumor (pNET) with rapid tumor growth
	
	<u>Treatment-refractory advanced or metastatic clear cell renal carcinoma</u>
	• Advanced disease after use of the following treatments: (Per NCCN guidelines)
	  ○ A Programmed death receptor-1 (PD-1) OR programmed death-ligand 1 (PD-L1) AND
	  ○ A vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)
	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course

Appropriate Treatment Regimen & Other Criteria:	**<u>Reauthorization</u>**: documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Metastatic pNET disease • Not to be used in combination with other oncologic agents for the treatment of VHL disease
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
BENRALIZUMAB
Affected Medications: FASENRA (benralizumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Add-on maintenance treatment of patients with severe asthma aged 6 years and older with an eosinophilic phenotype
	  ○ Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Required Medical Information:	**<u>Eosinophilic asthma</u>**
	• Diagnosis of severe asthma with an eosinophilic phenotype, defined by both of the following:
	  ○ Baseline eosinophil count of at least 150 cells/µL **OR** dependent on daily oral corticosteroids
	  AND
	  ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal
	
	<u>EGPA</u>
	• Documented diagnosis of EGPA confirmed by:
	  ○ Eosinophilia at baseline (blood eosinophil level over 10% or absolute count over 1,000 cells/mcL)
	  ○ At least **two** of the following:
	  ▪ Asthma
	  ▪ Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
	  ▪ Peripheral neuropathy (not due to radiculopathy)
	  ▪ Pulmonary infiltrates
	  ▪ Sinonasal abnormality/obstruction
	  ▪ Cardiomyopathy (confirmed on imaging)
	  ▪ Glomerulonephritis
	  ▪ Alveolar hemorrhage
	  ▪ Palpable purpura
	  ▪ Antineutrophil cytoplasmic antibody (ANCA) positive (anti-MPO-ANCA or anti-PR3-ANCA)
	• Documentation that manifestations of EGPA are active and nonsevere (respiratory/sinonasal disease, uncomplicated skin manifestations, arthralgias, mild systemic symptoms, etc.)
	• Documentation of **one** of the following:
	  ○ Refractory disease, defined as inability to achieve remission within the prior 6 months, following induction treatment with a standard regimen
	  ○ Relapsing disease, defined as needing an increased glucocorticoid dose, initiation/increased dose of immunosuppressant, or hospitalization while on oral glucocorticoid therapy

Appropriate Treatment	**<u>Eosinophilic asthma</u>** • Documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms

Regimen & Other Criteria:	AND
	• Documentation of one of the following:
	  ○ Documented history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months while on combination inhaler treatment and at least 80% adherence
	  ○ Documentation that chronic daily oral corticosteroids are required
	
	EGPA
	• Documented treatment failure or contraindication to at least two oral immunosuppressant drugs (azathioprine, methotrexate, mycophenolate) for at least 12 weeks each
	
	Reauthorization requires documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Use in combination with another monoclonal antibody (e.g., Dupixent, Nucala, Xolair, Cinqair, Tezspire)
Age Restriction:	• **Eosinophilic asthma:** 6 years of age and older • **EGPA:** 18 years of age and older
Prescriber/Site of Care Restrictions:	• **Eosinophilic asthma:** Prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist • **EGPA:** Prescribed by, or in consultation with, a specialist in the treatment of EGPA (such as a rheumatologist, nephrologist, pulmonologist, or immunologist)
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BEREMAGENE GEPERPAVEC-SVDT
Affected Medications: VYJUVEK (beremagene geperpavec-svdt)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Dystrophic Epidermolysis Bullosa (DEB)

Required Medical Information:	• Diagnosis of recessive DEB confirmed by both of the following:
	  ○ Skin biopsy of an induced blister with immunofluorescence mapping (IFM) and/or transmission electron microscopy (TEM)
	  ○ Genetic test results documenting mutations in the COL7A1 gene
	• Clinical signs and symptoms of DEB such as skin fragility, blistering, scarring, nail changes, and milia formation in the areas of healed blistering

Appropriate Treatment Regimen & Other Criteria:	• Documentation of receiving standard of care preventative or treatment therapies for wound care, control of infection, nutritional support
	• Documented trial and failure of Filsuvez
	• Dosing is in accordance with FDA labeling and does not exceed the following:
	  ○ Maximum weekly volume of 2.5 mL (1.6mL usable dose)
	  ○ Maximum of 12-week course per wound
	  ○ Maximum of 4 tubes per 28 days
	
	Reauthorization will require documentation of treatment success defined as complete wound healing on a previous site and need for treatment on a new site

Exclusion Criteria:	• Evidence or history of squamous cell carcinoma in the area that will undergo treatment • Concurrent use with Filsuvez (birch triterpenes topical gel) • Dominant DEB (DDEB)
Age Restriction:	• 6 months of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a dermatologist or a specialist experienced in the treatment of Epidermolysis Bullosa
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 3 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BESREMI
Affected Medications: BESREMI (ropeginterferon alfa-2b)

Covered Uses:	• All Food and Drug Administration (FDA)-approved or compendia supported indications not otherwise excluded by plan design
	  ○ Polycythemia vera
	  ○ Essential thrombocythemia
	• NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or higher

Required Medical Information:	**<u>Polycythemia vera</u>**
	• Diagnosis of polycythemia vera confirmed by all major criteria (1-3) OR the first 2 major criteria (1-2) plus the minor criterion:
	  ○ **Major criteria:**
	  (1). Elevated hemoglobin concentration (greater than 16 g/dL), elevated hematocrit (greater than 48 percent), or increased red blood cell mass (greater than 25 percent above mean normal predicted value)
	  (2). Presence of *JAK2* V617F **or** *JAK2* exon 12 mutation
	  (3). Bone marrow biopsy showing age-adjusted hypercellularity with trilineage proliferation (panmyelosis), including prominent erythroid, granulocytic, and increase in pleomorphic, mature megakaryocytes without atypia. May not be required in patients with sustained absolute erythrocytosis (hemoglobin over 18.5 g/dL and hematocrit over 55.5 percent in men; hemoglobin over 16.5 g/dL and hematocrit over 49.5 percent in women) with presence of a *JAK2* V617F or *JAK2* exon 12 mutation.
	  ○ **Minor criterion:** Subnormal serum erythropoietin level.
	
	<u>Essential Thrombocythemia</u>
	• Diagnosis of essential thrombocythemia, confirmed by all major criteria (1-4) **OR** the first 3 major criteria (1-3) plus the minor criterion:
	  ○ **Major criteria:**
	  (1). Platelet count greater than or equal to 450,000 cells/mcL.
	  (2). Bone marrow biopsy showing proliferation mainly of the megakaryocytic lineage, with hyperlobulated staghorn-like nuclei, infrequently dense clusters; no significant increase or left shift in neutrophil granulopoiesis or erythropoiesis; no relevant bone marrow fibrosis.
	  (3). Diagnostic criteria for BCR::ABL1-positive chronic myeloid leukemia, polycythemia vera, primary myelofibrosis, or other neoplasms are not met.
	  (4). Presence of *JAK2*, *CALR*, or *MPL* mutation.
	  ○ **Minor criterion:** Presence of another clonal marker (e.g., *ASXL1*, *EZH2*, *TET2*, *IDH1/IDH2*, *SRSF2*, or *SRF3B1* mutation) **OR** no identifiable cause for thrombocytosis (such as iron deficiency, chronic infection, chronic inflammatory disease, prior splenectomy).

	<u>Oncology Indications</u> • Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course
Appropriate Treatment Regimen & Other Criteria:	**<u>Polycythemia Vera</u>** • Documentation of treatment failure, intolerance, or contraindication to hydroxyurea **<u>Essential Thrombocythemia</u>** • Documented treatment failure, intolerance, or contraindication to both of the following: hydroxyurea and peginterferon alfa-2a (Pegasys) **<u>Reauthorization</u>**: documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist or hematologist
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BETAINE
Affected Medications: Betaine

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Homocystinuria

Required Medical Information:	• Diagnosis of homocystinuria associated with one of the following:
	  ○ Cystathionine beta-synthase (CBS) deficiency
	  ○ 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency
	  ○ Cobalamin cofactor metabolism (cbl) defect
	• Baseline plasma homocysteine levels

Appropriate Treatment Regimen & Other Criteria:	• Documented trial and failure of **ONE** of the following forms of supplementation:
	  ○ Vitamin B6 (pyridoxine)
	  ○ Vitamin B9 (folate)
	  ○ Vitamin B12 (cobalamin)
	
	Reauthorization will require documentation of treatment success and a clinically significant response to therapy shown by lowering of plasma homocysteine levels

Exclusion Criteria:	• Uncorrected vitamin B12 or folic acid levels
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a metabolic or genetic disease specialist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BETIBEGLOGENE AUTOTEMCEL
Affected Medications: ZYNTEGLO (betibeglogene autotemcel)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of beta thalassemia in adult and pediatric patients who require regular red blood cell (RBC) transfusions

Required Medical Information:	• Documented diagnosis of transfusion dependent beta thalassemia (TDT), defined as:
	  ○ Requiring at least 100 mL/kg per year of packed red blood cells (pRBCs) or at least 8 transfusions per year of pRBCs in the 2 years preceding therapy
	  ○ Confirmed genetic testing based on the presence of biallelic mutations at the beta-globin gene (*HBB* gene)
	• Clinically stable and eligible to undergo hematopoietic stem cell transplant (HSCT)
	• Used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture)
	• Females of reproductive potential must have negative pregnancy test prior to start of mobilization, reconfirmed prior to conditioning procedures, and again before administration of Zynteglo

Appropriate Treatment Regimen & Other Criteria:	• Patients must weigh a minimum of 6 kilograms and be able to provide a minimum number of cells (5,000,000 CD34+ cells/kilogram)
Exclusion Criteria:	• Prior HSCT or other gene therapy • Severe iron overload warranting exclusion from therapy, as determined by the treating physician • Uncorrected bleeding disorder • Cardiac T2* less than 10 milliseconds by magnetic resonance imaging (MRI) • White blood cell count less than $3x10^9$/L and/or platelet count less than $100x10^9$/L that is unrelated to hypersplenism • Positive for human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), hepatitis B virus, or hepatitis C virus, advanced liver disease, or current or prior malignancy
Age Restriction:	• Ages 4 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 4 months (one-time infusion), unless otherwise specified

BEVACIZUMAB
Affected Medications: AVASTIN (bevacizumab), MVASI (bevacizumab-awwb), ZIRABEV (bevacizumab-bvzr), ALYMSYS (bevacizumab-maly), VEGZELMA (bevacizumab-adcd), JOBEVNE (bevacizumab-nwgd)

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher
	• For the Treatment of Ophthalmic disorders:
	  ○ Neovascular (Wet) Age-Related Macular Degeneration (AMD)
	  ○ Macular Edema Following Retinal Vein Occlusion (RVO)
	  ○ Diabetic Macular Edema (DME)
	  ○ Diabetic Retinopathy (DR) in patients with Diabetes Mellitus

Required Medical Information:	• Documentation of disease staging, all prior therapies used, and anticipated treatment course

Appropriate Treatment Regimen & Other Criteria:	**Stage III or IV Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer following initial surgical resection**
	• Approval will be limited for up to 22 cycles of therapy
	
	All Indications
	• Coverage for a non-preferred product (Avastin, Alymsys, Vegzelma, Jobevne) requires documentation of one of the following:
	  ○ Use for ophthalmic condition (Avastin only)
	  ○ A documented intolerable adverse event to the preferred products, Mvasi and Zirabev, and the adverse event was not an expected adverse event attributed to the active ingredient
	
	Reauthorization: documentation of disease responsiveness to therapy

Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist or ophthalmologist (depending on indication)
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
BIRCH TRITERPENES
Affected Medications: FILSUVEZ (birch triterpenes topical gel)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Dystrophic Epidermolysis Bullosa (DEB)
	  ○ Junctional Epidermolysis Bullosa (JEB)

Required Medical Information:	• Diagnosis of recessive DEB or JEB confirmed by skin biopsy of an induced blister with immunofluorescence mapping (IFM) and/or transmission electron microscopy (TEM) • Genetic test results documenting mutations in one of the following genes: COL7A1, COL17A1, ITGB4, LAMA3, LAMB3, or LAMC2 • Clinical signs and symptoms of EB such as skin fragility, blistering, scarring, nail changes, and milia formation in the areas of healed blistering • Presence of open partial-thickness wounds that have been present for at least 21 days

Appropriate Treatment Regimen & Other Criteria:	• Documentation of receiving standard of care preventative or treatment therapies for wound care, control of infection, nutritional support
	• **Dosing** does not exceed the following:
	  ○ Maximum of 1 mm layer to affected area(s)
	  ○ Maximum of 28 tubes per 28 days
	
	Reauthorization will require documentation of treatment success defined as complete wound healing on a previous site and need for continued treatment on a new site

Exclusion Criteria:	• Concurrent use with Vyjuvek (beremagene geperpavec-svdt) • Dominant DEB (DDEB)
Age Restriction:	• 6 months of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a dermatologist or a specialist experienced in the treatment of Epidermolysis Bullosa
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 3 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BOTOX
Affected Medications: BOTOX (*onabotulinumtoxinA*)

Covered Uses:	• All Food and Drug Administration (FDA)-approved and compendia-supported indications not otherwise excluded by plan design
	  ○ Spasticity
	  ○ Chronic migraine
	  ○ Overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency
	  ○ Neurogenic detrusor overactivity (NDO)
	  ○ Focal dystonia
	  ▪ Cervical dystonia
	  ▪ Blepharospasm
	  ▪ Laryngeal dystonia
	  ▪ Oromandibular dystonia
	  ▪ Severe brachial dystonia (writer's cramp)
	  ○ Strabismus
	  ○ Achalasia
	  ○ Anal fissure

Required Medical Information:	• Pertinent medical records and diagnostic testing • Complete description of the site(s) of injection • Strength and dosage of botulinum toxin used

Appropriate Treatment Regimen & Other Criteria:	• Approved first-line for: focal dystonia, hemifacial spasm, drug-induced orofacial dyskinesia, upper and lower limb spasticity, or other conditions of focal spasticity wherein botulinum toxin is the preferred mode of therapy
	• For use in all other FDA-approved indications not otherwise excluded by benefit design, failure of first-line recommended and conventional therapies is required
	
	Overactive bladder (OAB)/Neurogenic detrusor overactivity (NDO):
	• Documentation of inadequate response or intolerance to at least **two** urinary incontinence antimuscarinic or beta-3 adrenergic therapies (e.g., oxybutynin, solifenacin, tolterodine, mirabegron, vibegron)
	
	Chronic migraine:
	• Documentation of chronic migraine defined as headaches on at least 15 days per month, of which at least 8 days are with migraine
	• Documented failure with an adequate trial (at least 8 weeks) of a migraine preventive therapy, as follows:
	  ○ Candesartan 16 mg daily
	  ○ Antiepileptics (divalproex sodium 500 mg daily, valproic acid 500 mg daily, topiramate 50 mg daily)
	  ○ Beta-blockers (metoprolol 100 mg daily, propranolol 40 mg daily, timolol 20 mg daily, nadolol 80 mg daily)
	  ○ Antidepressants (amitriptyline 25 mg daily, nortriptyline 25 mg daily, venlafaxine 75 mg daily, duloxetine 60 mg daily)
	
	Achalasia (Cardiospasm):
	• Must meet 1 of the following:
	  ○ Type I or II achalasia: Treatment failure with peroral endoscopic myotomy (POEM), laparoscopic Heller myotomy (LHM), and pneumatic dilation (PD)

	○ Type III achalasia: Treatment failure with tailored POEM and LHM ○ Not a candidate for POEM, surgical myotomy, or pneumatic dilation due to high risk of complications **Anal fissure:** • Documentation of anal fissures that have persisted or progress after 6 weeks of conservative treatment with one of the following: ○ Lifestyle changes (such as increased fiber intake, increase fluid intake, etc.) ○ Bulking agents (such as Psyllium) ○ Stool softeners (such as docusate) **Number of treatments must not exceed the following:** • OAB/NDO: 4 treatments per 12 months • Chronic migraine: initial treatment limited to two injections given 3 months apart, subsequent treatment approvals limited to 4 treatments per 12 months • All other indications maximum of 4 treatments per 12 months unless otherwise specified **Reauthorization:** • **Chronic migraine continuation of treatment:** Additional treatment requires that the member has achieved or maintained a 50% reduction in monthly headache frequency since starting therapy with Botox. • **All other indications:** Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Cosmetic procedures • For intradetrusor injections: current urinary tract infection; urinary retention or post-void residual urine volume over 200 mL if not routinely performing intermittent self-catheterization • Possible medication overuse headache: headaches occurring 15 or more days each month in a patient with pre-existing headache-causing condition possibly due to ○ Use of ergotamines, triptans, opioids, or combination analgesics greater than or equal to 10 days per month for greater than or equal to three months ○ Use of simple analgesics (acetaminophen, aspirin, or an NSAID) greater than or equal to 15 days per month for greater than or equal to 3 months ○ Combined use of any of the previously mentioned products without overuse of any one agent if no causative pattern can be established • Combined use with an anti-calcitonin gene-related peptide (CGRP) monoclonal antibody or an oral CGRP antagonist when used for migraine prevention
Age Restriction:	
Prescriber Restrictions:	• Blepharospasm, strabismus: ophthalmologist, optometrist, or neurologist • Chronic migraine: treatment is administered in consultation with a neurologist or headache specialist • OAB/NDO: urologist or neurologist • Documentation of consultation with any of the above specialists mentioned
Coverage Duration:	**Chronic migraine:** • Initial approval: 12 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified **OAB/NDO:** • Initial approval: 12 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

	Spasticity: • Approval: 24 months, unless otherwise specified **Anal fissure:** • Approval: 3 months (one treatment), unless otherwise specified **All other indications:** • Approval 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
BREXANOLONE
Affected Medications: ZULRESSO (brexanolone)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Treatment of postpartum depression (PPD)

Required Medical Information:	• Documented major depressive episode with peripartum onset as defined by the *Diagnostic and Statistical Manual of Mental Health Disorders*, Five Edition (DSM-5) criteria:
	  ○ At least **five** of the following symptoms have been present during the same 2-week period and represent a change from previous functioning (must include either (1) depressed mood or (2) lack of interest or pleasure):
	  (1). Depressed mood most of the day, nearly every day, as indicated by either subjective report or observation made by others (in adolescents, may present as irritable mood)
	  (2). Markedly diminished interest or pleasure in all (or almost all) activities most of the day, nearly every day, as indicated by either subjective account or observation
	  (3). Significant weight loss when not dieting, weight gain, or decrease or increase in appetite nearly every day (in adolescents, consider failure to make expected weight gain)
	  (4). Insomnia or hypersomnia nearly every day
	  (5). Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
	  (6). Fatigue or loss of energy nearly every day
	  (7). Feelings of worthlessness, or excessive or inappropriate guilt nearly everyday
	  (8). Diminished ability to think or concentrate, or indecisiveness, nearly every day (subjective account or observed by others)
	  (9). Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide
	  ○ Symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning
	  ○ Episode is not attributable to the direct physiological effects of a substance or to another condition
	• Major depressive episode began no earlier than the third trimester and no later than the first 4 weeks following delivery
	• Moderate to severe postpartum depression documented by one of the following rating scales:
	  ○ Hamilton Rating Scale for Depression (HAM-D) score of greater than 17
	  ○ Patient Health Questionnaire-9 (PHQ-9) score of greater than 10
	  ○ Montgomery-Åsberg Depression Rating Scale (MADRS) greater than 20 points
	  ○ Edinburgh Postnatal Depression Scale (EPDS) score of greater than 13

Appropriate Treatment Regimen & Other Criteria:	• Documented trial with an oral antidepressant for at least 8 weeks unless contraindicated or documentation shows that the severity of the depression would place the health of the mother or infant at significant risk

Exclusion Criteria:	• Greater than 6 months postpartum
Age Restriction:	• 15 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a psychiatrist
Coverage Duration:	• One month, one time approval per pregnancy

PacificSource Community Solutions

POLICY NAME:
BUROSUMAB
Affected Medications: CRYSVITA (burosumab-twza)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
	  ○ X-linked hypophosphatemia (XLH)
	  ○ FGF23-related hypophosphatemia in tumor induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors

Required Medical Information:	**<u>All Indications:</u>**
	• Documentation of diagnosis by:
	  ○ A blood test demonstrating **ALL** the following (in relation to laboratory reference ranges):
	  ▪ Low phosphate
	  ▪ Elevated FGF23
	  ▪ Low 1,25-(OH)2D
	  ▪ Normal calcium or parathyroid hormone (PTH)
	  ○ A urine test demonstrating decreased tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR)
	  ○ Evidence of skeletal abnormalities, confirmed by radiographic evaluation
	
	<u>Tumor-Induced Osteomalacia</u>
	• Documentation that tumor cannot be located or is unresectable
	• Alternative renal phosphate-wasting disorders have been ruled out

Appropriate Treatment Regimen & Other Criteria:	**<u>All Indications:</u>** • Documentation of treatment failure with at least 12 months of oral phosphate and calcitriol supplementation in combination, unless contraindicated or not tolerated • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **<u>Reauthorization</u>**: requires: • Documentation of normalization of serum phosphate levels • If established on therapy for 12 months or more, improvement in radiographic imaging of skeletal abnormalities
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a nephrologist, endocrinologist, or provider experienced in managing patients with metabolic bone disease
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CALCIFEDIOL
Affected Medications: RAYALDEE (calcifediol)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of secondary hyperparathyroidism in adult patients with stage 3 or 4 chronic kidney disease (CKD) and serum total 25-hydroxyvitamin D levels less than 30 ng/mL

Required Medical Information:	• A confirmed diagnosis of secondary hyperparathyroidism with persistently elevated or progressively rising serum intact parathyroid hormone (iPTH) that is 2.3 times (or more) above the upper limit of normal for the assay used
	• Documentation of all the following prior to treatment initiation:
	  ○ Stage 3 or 4 CKD
	  ○ Serum total 25-hydroxyvitamin D level is less than 30 ng/mL
	  ○ Corrected serum calcium is below 9.8 mg/dL

Appropriate Treatment Regimen & Other Criteria:	• Documentation of persistent vitamin D deficiency (level below 30 ng/mL), despite at least 12 weeks of adherent treatment with each of the following at an appropriate dose, unless contraindicated or not tolerated:
	  ○ Vitamin D2 (ergocalciferol) or Vitamin D3 (cholecalciferol)
	  ○ Calcitriol
	  ○ Doxercalciferol
	  ○ Paricalcitol
	
	Reauthorization will require documentation of a clinically significant response to therapy, evidenced by increased serum total 25-hydroxyvitamin D level (to at least 30 ng/mL) and reduced plasma iPTH to goal therapeutic range (or an approximate 30% reduction compared to baseline)

Exclusion Criteria:	• A diagnosis of stage 1, 2, or 5 chronic kidney disease or end-stage renal disease (ESRD) on dialysis
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a nephrologist or endocrinologist.
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CALCITONIN GENE-RELATED PEPTIDE (CGRP) INHIBITORS
Affected Medications: Eptinezumab (Vyepti), Erenumab (Aimovig), Galcanezumab (Emgality), Rimegepant (Nurtec)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Chronic or episodic migraine, prevention
	  ○ Episodic cluster headache, prevention **(Emgality)**
	  ○ Acute treatment of migraine in adults **(Nurtec)**

Required Medical Information:	**Chronic Migraine**
	• Diagnosis of chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine at baseline
	
	Episodic Migraine
	• Diagnosis of episodic migraine with at least 8 migraines per month at baseline
	
	Episodic Cluster Headache (Emgality)
	• History of episodic cluster headache with at least two cluster periods lasting from 7 days to 1 year (when untreated) separated by pain-free remission periods of at least one month
	
	All Uses
	• Headaches are not due to medication overuse: headaches occurring 15 or more days each month in a patient with pre-existing headache-causing condition possibly due to:
	  ○ Use of ergotamines, triptans, opioids, or combination analgesics at least 10 days per month for at least three months
	  ○ Use of simple analgesics (acetaminophen, aspirin, or an NSAID) at least 15 days per month for at least 3 months
	  ○ Use of combination of any previously mentioned products without overuse of any one agent if no causative pattern can be established

Appropriate Treatment Regimen & Other Criteria:	**Chronic or Episodic Migraine**
	• Documented treatment failure with an adequate trial (at least 8 weeks) of an oral migraine preventive therapy as follows:
	  ○ Candesartan 16 mg daily
	  ○ Antiepileptic (divalproex sodium 500 mg daily, valproic acid 500 mg daily, topiramate 50 mg daily)
	  ○ Beta-blocker (metoprolol 100 mg daily, propranolol 40 mg daily, timolol 20 mg daily, nadolol 80 mg daily)
	  ○ Antidepressants (amitriptyline 25 mg daily, nortriptyline 25 mg daily, venlafaxine 75 mg daily, duloxetine 60 mg daily)
	• Documented treatment failure with 6 months (two treatments) of Botox therapy (chronic migraine only)
	• Vyepti requests:
	  ○ Documented treatment failure with the above trials (adequate trial of an oral migraine preventive therapy, Botox)
	  ○ Documented treatment failure or intolerance to **ONE** of the following: Emgality or Aimovig
	• Nurtec requests:
	  ○ Documented treatment failure with the above trials (adequate trial of an oral

	migraine preventive therapy, Botox) ○ Documented treatment failure or intolerance with each of the following: Aimovig, Emgality ○ Quantity limit: 16 tablets per 30 days **Episodic Cluster Headache (Emgality)** • Documented treatment failure with an adequate trial of verapamil (dose of at least 480 mg daily for a minimum of 3 weeks), or if unable to tolerate verapamil or contraindications apply, another oral preventative therapy (lithium, topiramate) **Acute Treatment of Migraine (Nurtec)** • Documented treatment failure with each of the following: ○ An oral triptan (such as sumatriptan, naratriptan, rizatriptan, zolmitriptan) ○ A non-oral triptan (such as sumatriptan, zolmitriptan) ○ Reyvow ○ Ubrelvy • Quantity limit: 8 tablets per 30 days • Initial approvals are limited to 8 tablets per month. Requests for quantities greater than 8 tablets require the following: ○ Currently receiving treatment with a migraine prophylactic treatment ○ The current quantity limit is not effective for treating your number of migraines ○ Quantity limit: 18 tablets per 30 days **QL** • **Emgality** ○ Availability: 120 mg/1 mL syringe or auto-injector; 100 mg/mL syringe (carton of 3) ○ Dosing: ▪ Chronic migraine: 240 mg single loading dose then 120 mg every 30 days ▪ Episodic cluster headache: 300 mg at the start of a cluster period and then 300 mg monthly until the end of the cluster period – Maximum 6 fills annually • **Aimovig** ○ Availability: 70 mg/mL & 140 mg/mL auto-injector or syringe ○ Dosing: 70 mg once monthly, some may benefit from a dosage of 140 mg monthly • **Vyepti** ○ Availability: 100 mg/1 mL single-use vial Dosing: 100 mg infusion every 3 months. Some patients may benefit from a dosage of 300 mg every 3 months **Reauthorization:** • Preventative treatment: documentation of treatment success defined as a 50% reduction in monthly headache frequency since starting therapy • Acute treatment: documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Combined use with Botox or another calcitonin gene-related peptide (CGRP) inhibitor for the prevention of migraine
Age Restriction:	
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

POLICY NAME:
CANNABIDIOL
Affected Medications: EPIDIOLEX (cannabidiol)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Lennox-Gastaut Syndrome (LGS)
	  ○ Dravet Syndrome (DS)
	  ○ Tuberous Sclerosis Complex (TSC)

Required Medical Information:	**All Indications** • Patient weight • Documentation that cannabidiol will be used as adjunctive therapy • Baseline seizure type and seizure frequency
Appropriate Treatment Regimen & Other Criteria:	**LGS** • Documented treatment failure with at least **two** antiepileptic drugs (e.g. valproate, lamotrigine, rufinamide, topiramate, felbamate, clobazam) • Dosing not to exceed 20 mg/kg per day **DS** • Documented treatment failure with at least **two** antiepileptic drugs (e.g. valproate, clobazam, topiramate, levetiracetam) • Dosing not to exceed 20 mg/kg per day **TSC** • Documented treatment failure with at least **two** antiepileptic drugs • Dosing not to exceed 25 mg/kg per day **Reauthorization** will require documentation of treatment success and a reduction in seizure severity, frequency, and/or duration
Exclusion Criteria:	• Use as monotherapy for seizure control
Age Restriction:	• 1 year of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CAPLACIZUMAB-YHDP
Affected Medications: CABLIVI (caplacizumab-yhdp)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy

Required Medical Information:	• Diagnosis or suspected diagnosis of aTTP, meeting all the following:
	  ○ Severe thrombocytopenia (platelet count less than 100 x 10^9/L)
	  ○ Microangiopathic hemolytic anemia (MAHA) confirmed by red blood cell fragmentation (e.g., schistocytes) on peripheral blood smear
	  ○ Baseline ADAMTS13 activity level of less than 10%
	• Documentation of **ONE** of the following:
	  ○ Failure of at least one initial treatment for aTTP, such as therapeutic plasma exchange (TPE), glucocorticoids, or rituximab
	  ○ Documentation of high-risk disease meeting **ONE** of the following:
	  ▪ Neurologic abnormalities (seizures, focal weakness, aphasia, dysarthria, confusion, coma)
	  ▪ Altered mental status
	  ▪ Elevated serum troponin levels
	• Documentation that Cablivi will be used in combination with standard-of-care treatment for aTTP (TPE and glucocorticoid)

Appropriate Treatment Regimen & Other Criteria:	• Total treatment duration will be limited to 58 days beyond the last TPE treatment **Reauthorization** requires documented signs of ongoing disease (such as, suppressed ADAMTS13 activity levels) and no more than 2 recurrences of aTTP while on Cablivi. Recurrence is defined as thrombocytopenia after initial recovery of platelet count (platelet count greater than or equal to 150,000) that requires re-initiation of daily plasma exchange.
Exclusion Criteria:	• Use for other causes of thrombocytopenia, such as other TTP-like disorders (congenital or hereditary TTP)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematology specialist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 3 months (for new episode), unless otherwise specified

POLICY NAME:
CAPSAICIN KIT
Affected Medications: QUTENZA (capsaicin kit)

Covered Uses:	• All Food and Drug Administration (FDA) – approved indications not otherwise excluded by plan design
	  ○ Neuropathic pain associated with postherpetic neuralgia (PHN)
	  ○ Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet

Required Medical Information:	

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with at least 12 weeks of ALL the following:
	  ○ Gabapentin
	  ○ Pregabalin
	  ○ Carbamazepine or oxcarbazepine or valproic acid/divalproex sodium
	  ○ Amitriptyline or nortriptyline
	  ○ Topical lidocaine
	• Dose limited to single treatment (up to 4 patches) once every 90 days
	• For renewal, your doctor must send in notes showing that this drug has worked well for you

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pain management specialist
Coverage Duration:	• Initial approval: 3 months (single treatment), unless otherwise specified • Reauthorization: 12 months (up to 4 treatments), unless otherwise specified

POLICY NAME:
CARGLUMIC ACID
Affected Medications: CARBAGLU, CARGLUMIC ACID

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Acute hyperammonemia due to one of the following:
	  ▪ N-Acetylglutamate Synthase (NAGS) deficiency
	  ▪ Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)
	  ○ Chronic hyperammonemia due to N-Acetylglutamate Synthase (NAGS) deficiency

Required Medical Information:	• Diagnosis is confirmed by enzymatic, biochemical, or genetic testing • Ammonia level above the upper limit of normal (ULN) reference range for the patient's age
Appropriate Treatment Regimen & Other Criteria:	• Current weight **<u>Acute hyperammonemia</u>** • Prescribed in combination with at least one other ammonia-lowering therapy (examples include: sodium phenylacetate and sodium benzoate, intravenous glucose, insulin, L-arginine, L-carnitine, protein restriction, dialysis) • For disease due to PA or MMA: Prescribed treatment course does not exceed 7 days • **Reauthorization** for acute disease will require: documentation of reoccurrence of acute hyperammonemia meeting initial criteria **<u>Chronic hyperammonemia due to N-Acetylglutamate Synthase (NAGS) deficiency</u>** • Prescribed in combination with a protein-restricted diet **Reauthorization** for chronic disease will require: • Documentation of treatment success and a clinically significant response to therapy as evidenced by reduction in ammonia levels • Documentation of member's current weight and continuation of appropriate treatment course

Exclusion Criteria:	• Hyperammonemia caused by other enzyme deficiencies in the urea cycle:
	  ○ Carbamyl phosphate synthetase I (CPSI) deficiency
	  ○ Ornithine transcarbamylase (OTC) deficiency
	  ○ Argininosuccinate synthetase (ASS) deficiency
	  ○ Argininosuccinate lyase (ASL) deficiency
	  ○ Arginase deficiency
	• Chronic treatment (use beyond 7 days) of acute or chronic hyperammonemia due to MMA or PA

Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a metabolic disease specialist
Coverage Duration:	**<u>Acute Hyperammonemia due to PA or MMA:</u>** • Approval: 7 days, unless otherwise specified **<u>Acute Hyperammonemia due to NAGs deficiency:</u>** • Approval: 1 month, unless otherwise specified

	Chronic Hyperammonemia: • Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
CAYSTON
Affected Medications: CAYSTON (aztreonam inhalation)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. ○ Cystic fibrosis
Required Medical Information:	• Documentation of confirmed diagnosis of cystic fibrosis • Culture and sensitivity report confirming presence of Pseudomonas aeruginosa in the lungs • Baseline FEV1 greater than 25% but less than 75% predicted
Appropriate Treatment Regimen & Other Criteria:	• Documented failure, contraindication, or resistance to inhaled tobramycin • Dosing: 28 days on and 28 days off **Reauthorization**: requires documentation of improved respiratory symptoms and need for long-term use
Exclusion Criteria:	• Baseline FEV1 less than 25% or greater than 75% predicted
Age Restriction:	• Age 7 years or older
Prescriber Restrictions:	
Coverage Duration:	• Initial approval: 1 month, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
CENOBAMATE
Affected Medications: XCOPRI (cenobamate)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Partial-onset seizures in adult patients
Required Medical Information:	• Documentation of baseline seizure frequency • Documentation of treatment failure with at least three adjunctive therapies for seizure management (carbamazepine, lamotrigine, levetiracetam, oxcarbazepine, topiramate, lamotrigine, divalproex, lacosamide, zonisamide, phenytoin, valproic acid, gabapentin, pregabalin)
Appropriate Treatment Regimen & Other Criteria:	Dosing not to exceed 400 mg daily **Reauthorization** will require documentation of treatment success and clinically significant response as determined by provider
Exclusion Criteria:	• Familial short QT syndrome
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
CERLIPONASE ALFA
Affected Medications: BRINEURA (cerliponase alfa)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ To slow the loss of ambulation in pediatric patients with neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase-1 (TPP1) deficiency

Required Medical Information:	• Diagnosis of CLN2 disease confirmed by BOTH the following:
	  ○ Enzyme assay demonstrating deficient TPP1 activity
	  ○ Genetic testing that has detected two pathogenic variants/mutations in the TPP1/CLN2 gene (one on each parental allele of the TPP1/CLN2 gene)
	• Documentation of mild to moderate functional impairment at baseline using the CLN2 Clinical Rating Scale, defined as ALL the following:
	  ○ Combined score of 3 to 6 in the motor and language domains
	  ○ Score of at least 1 in the motor domain
	  ○ Score of at least 1 in the language domain

Appropriate Treatment Regimen & Other Criteria:	• Dosing is in accordance with FDA labeling **<u>Reauthorization:</u>** • Documentation of clinical responsiveness to therapy defined as disease stabilization OR a score of at least 1 in the motor domain of the CLN2 Clinical Rating Scale
Exclusion Criteria:	• Any sign or symptom of acute or unresolved localized infection on or around the device insertion site (e.g., cellulitis or abscess); or suspected or confirmed CNS infection (e.g., cloudy CSF or positive CSF gram stain, or meningitis) • Any acute intraventricular access device-related complication (e.g., leakage, extravasation of fluid, or device failure) • Other forms of neuronal ceroid lipofuscinosis • Patients with ventriculoperitoneal shunts
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of CLN2
Coverage Duration:	• Authorization: 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CERTOLIZUMAB
Affected Medications: CIMZIA KIT, CIMZIA PREFILLED SYRINGE KIT, CIMZIA PREFILLED SYRINGE STARTER KIT

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis (PP)
	  ○ Rheumatoid Arthritis (RA)
	  ○ Psoriatic Arthritis (PsA)
	  ○ Ankylosing Spondylitis (AS)
	  ○ Non-radiographic Axial Spondyloarthritis (NR-axSPA)
	  ○ Crohn's Disease (CD)
	  ○ Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Required Medical Information:	**<u>Rheumatoid Arthritis</u>**
	• Documentation of current disease activity with one of the following (or equivalent objective scale)
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted Routine Assessment of Patient Index Data 3 (RAPID3) of at least 2.3
	
	<u>Plaque Psoriasis</u>
	• Documentation that the skin disease is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	AND
	• Documentation of one or more of the following:
	  ○ At least 10% body surface area involvement despite current treatment
	OR
	  ○ Hand, foot, or mucous membrane involvement
	
	<u>Psoriatic Arthritis</u>
	• Documentation of Classification for Psoriatic Arthritis (CASPAR) criteria score of 3 or greater based on chart notes:
	  ○ Skin psoriasis: present – two points, OR previously present by history – one point, OR a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxta-articular bone formation on radiographs (distinct from osteophytes): one point
	
	<u>Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis, and Psoriatic Arthritis with Axial Involvement</u>
	• Diagnosis of axial spondyloarthritis (SpA) confirmed by sacroiliitis on imaging AND at least one spondyloarthritis feature:
	  ○ Inflammatory back pain (4 of 5 features met):
	  ▪ Onset of back discomfort before the age of 40 years
	  ▪ Insidious onset
	  ▪ Improvement with exercise
	  ▪ No improvement with rest

	▪ Pain at night (with improvement upon arising) o Arthritis o Enthesitis o Uveitis o Dactylitis (inflammation of entire digit) o Psoriasis o Crohn's disease/ulcerative colitis o Good response to nonsteroidal anti-inflammatory drugs (NSAIDs) o Family history of SpA o Elevated C-reactive protein (CRP) **OR** o HLA-B27 genetic test positive AND at least TWO SpA features • Documentation of active disease defined by Bath ankylosing spondylitis disease activity index (BASDAI) at least 4 or equivalent objective scale **Crohn's disease** • Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy • Documentation of moderate to severely active disease despite current treatment **Polyarticular Juvenile Idiopathic Arthritis** • Documented current level of disease activity with physician global assessment (MD global score) or active joint count
Appropriate Treatment Regimen & Other Criteria:	**All indications** • Exception for pregnancy requires documentation of actively attempting to conceive **Rheumatoid Arthritis** • Documented failure with at least 12 weeks of treatment with methotrexate o If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: o One of following: Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis), tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV) **AND** o Two of the following: Olumiant, Kevzara, Simponi Aria, Actemra SQ, Kineret, rituximab (preferred biosimilar products Truxima, Riabni, and Ruxience), Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) **Plaque Psoriasis** • Documented treatment failure with 12 weeks of at least TWO systemic therapies: methotrexate, cyclosporine, acitretin, phototherapy [UVB, PUVA] • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: o Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis) **AND** o One of the following: Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **Psoriatic Arthritis** • Documented treatment failure with at least 12 weeks of treatment with methotrexate

	○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Simponi Aria, Orencia IV, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **<u>Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis, and Psoriatic Arthritis with Axial Involvement</u>** • Documented treatment failure with two daily prescription strength nonsteroidal anti-inflammatory drugs (ibuprofen, naproxen, diclofenac, meloxicam, etc.) with minimum 1 month trial each **OR** • For peripheral arthritis: documented treatment failure with locally administered parenteral glucocorticoid • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of: ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Simponi Aria or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) **<u>Crohn's Disease</u>** • Documented treatment failure with at least one oral treatment for a minimum 12 week trial: azathioprine, 6-mercaptopurine, methotrexate, sulfasalazine, balsalazide **OR** • Documentation of previous surgical intervention for Crohn's disease **OR** • Documentation of severe, high-risk disease on colonoscopy defined by one of the following: ○ Fistulizing disease ○ Stricture ○ Presence of abscess/phlegmon ○ Deep ulcerations ○ Large burden of disease including ileal, ileocolonic, or proximal gastrointestinal involvement • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of: ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Entyvio, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **<u>Polyarticular Juvenile Idiopathic Arthritis</u>** • Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide AND • Documented failure with glucocorticoid joint injections or oral corticosteroids • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of two of the following therapies: ○ tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV), Adalimumab (preferred

	biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), and Simponi Aria
	
	QL
	• Induction
	  ○ CD/RA/PsA/AS/PP: 400 mg (2 injections) at week 0, 2 and 4
	  ○ pJIA:
	  ▪ 10 to <20 kg: 100 mg week 0, 2, 4
	  ▪ 20 to <40 kg: 200 mg week 0, 2, 4
	  ▪ ≥40 kg: 400 (2 injections) week 0, 2, 4
	• Maintenance
	  ○ CD/RA/PsA/AS: 400 mg (2 injections) per 28 days
	  ○ PP:
	  ▪ 90 kg or less: 400 mg (2 injections) per 28 days
	  ▪ >90 kg: 400 mg every other week
	  ○ pJIA:
	  ▪ 10 to <20 kg: 50 mg every 2 weeks
	  ▪ 20 to <40 kg: 100 mg every 2 weeks
	  ▪ ≥40 kg: 200 mg every 2 weeks
	
	Reauthorization
	• Documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/dermatologist/gastroenterologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CFTR MODULATORS
Affected Medications: ALYFTREK (vanzacaftor/tezacaftor/deutivacaftor), KALYDECO (ivacaftor), ORKAMBI (lumacaftor/ivacaftor), SYMDEKO (tezacaftor/ivacaftor), TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Cystic fibrosis (CF) in patients with mutation(s) in the F508del cystic fibrosis transmembrane conductance regulator (CFTR) gene or another responsive mutation in the CFTR gene
	  ○ CF in patients who are homozygous for the F508del mutation in the CFTR gene (Orkambi)

Required Medical Information:	• Documentation of cystic fibrosis (CF) diagnosis confirmed by appropriate genetic or diagnostic testing (FDA approved CF mutation test) ○ Please provide the diagnostic testing report and/or Cystic Fibrosis Foundation Patient Registry Report • Documentation of mutation(s) in the CFTR gene for which the drug has been FDA-approved to treat
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success
Exclusion Criteria:	• Kalydeco: Homozygous F508del mutation • Concurrent use with another CFTR modulator
Age Restriction:	• Alyftrek: 6 years of age and older • Kalydeco: one month of age and older • Orkambi: 1 year of age and older • Symdeko: 6 years of age and older • Trikafta: 2 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a pulmonologist or provider who specializes in CF
Coverage Duration:	• Initial Authorization: 12 months, unless otherwise specified • Reauthorization: 24 months unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CHELATING AGENTS

PA policy applicable to: deferasirox, deferiprone		
1. Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #2
2. Is the request to treat a diagnosis according to one of the Food and Drug Administration (FDA)-approved indications?	Yes – Go to appropriate section below	No – Criteria not met
Chronic Iron Overload Due to Blood Transfusions in Myelodysplastic Syndromes		
1. Documentation of International Prognostic Scoring System (IPSS) low or intermediate-1 risk level?	Yes – Document and go to #2	No – Criteria not met
2. Documentation of a history of more than 20 red blood cell (RBC) transfusions OR that it is anticipated that more than 20 would be required?	Yes – Document and go to #3	No – Criteria not met
3. Documentation of serum ferritin levels greater than 2500 ng/ml?	Yes – Document and go to # 4	No – Criteria not met
4. Is the request for deferasirox soluble tablet?	Yes – Go to #6	No- Go to #5
5. Is there documented failure with deferasirox?	Yes – Document and go to #6	No – Criteria not met
6. Is the drug prescribed by, or in consultation with, a hematologist specialist?	Yes – Go to #7	No – Criteria not met
7. Is the requested dose within the Food and Drug Administration (FDA) approved label?	Yes – Approve up to 12 months	No – Criteria not met
Chronic Iron Overload Due to Blood Transfusions in Thalassemia syndromes, Sickle Cell Disease, or other anemias		
1. Documentation of pretreatment serum ferritin level within the last 60 days of at least 1000 mcg/L?	Yes – Document and go to #2	No – Criteria not met
2. Is the request for deferasirox soluble tablet?	Yes – Document and go to #4	No – Go to #3

3. Is there documented failure with deferasirox?	Yes – Document and go to #4	No – Criteria not met
4. Documentation of platelet counts greater than 50,000 per microliter?	Yes – Go to #5	No – Criteria not met
5. Is the drug prescribed by, or in consultation with, a hematologist specialist?	Yes – Document and go to #6	No – Criteria not met
6. Is the requested dose within the Food and Drug Administration (FDA) approved label?	Yes – Approve up to 12 months	No – Criteria not met
Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndromes		
1. Documentation of liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight	Yes – Document and go to #2	No – Criteria not met
2. Documentation of serum ferritin levels consistently greater than 300 mcg/L prior to initiation of treatment	Yes – Document and go to #3	No – Criteria not met
3. Is the requested dose within the Food and Drug Administration (FDA) approved label?	Yes – Approve up to 12 months	No – Criteria not met
Renewal Criteria		
1. Is there documentation of treatment success and a clinically significant response to therapy defined as a reduction from baseline liver iron concentration (LIC) or serum ferritin level? (LIC and serum ferritin must still be above 3 mg Fe per gram of dry weight and 500 mcg/L, respectively)	Yes – Go to #2	No – Criteria not met
2. Is the requested dose within the Food and Drug Administration (FDA)-approved label and PacificSource quantity limitations?	Yes – Approve up to 12 months	No – Criteria not met
Quantity Limitations		

• **Exjade (deferasirox soluble tablet) – available in 125mg, 250mg, 500mg tablets**
  ○ **20-40 mg/kg/day**
• **Jadenu (deferasirox tablet or granules) – available in 90mg, 180mg, 360mg tablets**
  ○ **14-28 mg/kg/day**
• **Ferriprox (deferiprone) – 100mg/ml oral solution, 500mg, 1000mg tablets**
  ○ **75-99 mg/kg/day**		

- **Can be used in adult and pediatric patients 8 years of age and older (tablets), or 3 years of age and older (solution)**

PacificSource Community Solutions

POLICY NAME:
CHENODIOL
Affected Medications: CTEXLI (chenodiol)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of cerebrotendinous xanthomatosis (CTX) in adults

Required Medical Information:	• Diagnosis of CTX (Bogaert-Scherer-Epstein syndrome) confirmed by genetic testing that detects pathogenic variants in the *CYP27A1* gene
	• Documentation with all the following:
	  ○ Plasma cholestanol 5 to 10 times greater than normal
	  ○ Elevated urine bile alcohol levels (23s-pentol)

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires improvement or stabilization of cognitive function and decrease in cholestanol or urine bile alcohol levels compared to baseline
Exclusion Criteria:	• Combined use with Chenodal (chenodeoxycholic acid) or Cholbam (cholic acid)
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist, endocrinologist, or other metabolic specialist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CHOLBAM
Affected Medications: CHOLBAM (cholic acid)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs)
	  ○ Adjunctive treatment of peroxisomal disorders, including Zellweger spectrum disorders, in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption

Required Medical Information:	• Documentation of all prior therapies, patient weight, and anticipated treatment course • Baseline liver function tests (AST, ALT, GGT, ALP, total bilirubin, INR) **Bile acid synthesis disorder** • Diagnosis confirmed by assessment of serum or urinary bile acid levels using mass spectrometry (Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis) **Peroxisomal disorders including Zellweger spectrum disorders** • Diagnosis confirmed by clinical features, elevated very long-chain fatty acid (VLCFA) levels, peroxisomal biomarkers, genetic testing • Prothrombin time (vitamin K), serum levels of vitamins A, D, and E. • Hepatic injury or at risk of liver injury (elevations in liver enzymes or atypical bile acids) OR • If normal liver function tests, must show manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption
Appropriate Treatment Regimen & Other Criteria:	• Will not be used for treatment of extrahepatic manifestations (such as neurologic symptoms) of bile acid synthesis disorders **Reauthorization** requires documentation of clinically significant improvement in liver function as determined by meeting TWO of the following criteria: • Improvement in abnormal liver chemistries (AST, ALT, bilirubin) • Reduction or stabilization of hepatic inflammation and fibrosis • Reduced levels of the toxic C27-bile acid intermediates dihydroxycholestanoic acid (DHCA) and trihydroxycholestanoic acid (THCA) in plasma and urine • Improvement in prothrombin time (as a result of improved vitamin K absorption) and serum levels of vitamins A, D, and E • No evidence of cholestasis on liver biopsy • Body weight increased or stabilized • Treatment should be discontinued if liver function does not improve after 3 months of start of treatment
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hepatologist, gastroenterologist, or metabolic specialist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CHOLESTATIC LIVER DISEASE
Affected Medications: BYLVAY (odevixibat), LIVMARLI (Maralixibat)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Pruritus due to progressive familial intrahepatic cholestasis (PFIC)
	  ○ Cholestatic pruritus in patients with Alagille syndrome (ALGS)

Required Medical Information:	• Documentation of experiencing moderate to severe pruritis associated with PFIC or ALGS
	• Documentation of serum bile acid concentration above the upper limit of normal (ULN) reference range for the reporting laboratory
	
	PFIC
	• Documentation of confirmed molecular diagnosis of PFIC type 1 or type 2
	  ○ Documentation of absence of ABCB11 gene variant if PFIC type 2
	
	ALGS
	• Documentation of ALGS confirmed by:
	  ○ Genetic test detecting a JAG1 or NOTCH2 mutation **OR**
	  ○ Liver biopsy and at least three clinical features:
	  ▪ Chronic cholestasis
	  ▪ Cardiac disease
	  ▪ Ocular or skeletal abnormalities
	  ▪ Characteristic facial features
	  ▪ Renal and vascular disease

Appropriate Treatment Regimen & Other Criteria:	• Documentation of current weight and dosing in accordance with FDA labeling
	• Documented treatment failure with **ALL** the following for at least 30 days:
	  ○ Rifampin
	  ○ Ursodiol
	  ○ Cholestyramine (or colesevelam if requesting for ALGS)
	
	Reauthorization:
	• Documented treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Prior hepatic decompensation events • Decompensated cirrhosis (such as ALT or total bilirubin greater than 10-times the ULN) • Concomitant liver disease (e.g., biliary atresia, liver cancer, non- PFIC related cholestasis) • Prior liver transplant
Age Restriction:	• Age is in accordance with FDA labeling
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hepatologist or a specialist with experience in the treatment of PFIC or ALGS
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified


PacificSource
Community Solutions

POLICY NAME:
CLADRIBINE
Affected Medications: MAVENCLAD (cladribine)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following:
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)

Required Medical Information:	**MS** • Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS
Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with (or intolerance to) a minimum 12-week trial of at least two disease-modifying therapies for MS **Reauthorization** (one time only) requires provider attestation of treatment success • Eligible to initiate second treatment cycle 43 weeks after last dose was administered
Exclusion Criteria:	• Concurrent use of other disease-modifying medications indicated for the treatment of MS • Current malignancy • Human immunodeficiency virus (HIV) infection • Active chronic infections (e.g., hepatitis, tuberculosis) • Pregnancy • Treatment beyond 2 years
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Initial Authorization: 2 months, unless otherwise specified • Reauthorization: 2 months, unless otherwise specified

POLICY NAME:
COAGADEX
Affected Medications: COAGADEX (Factor X)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Indicated in children and adults with hereditary Factor X (FX) deficiency for:
	  ▪ Routine prophylaxis to reduce frequency of bleeding episodes
	  ▪ On-demand treatment and control of bleeding episodes
	  ▪ Perioperative management of bleeding in mild, moderate, or severe disease

Required Medical Information:	• Documented diagnosis of hereditary Factor X (FX) deficiency, confirmed by baseline plasma FX levels (FX:C) less than or equal to 10% • Patient weight **<u>Routine Prophylaxis</u>** • Documented baseline frequency of bleeding episodes **<u>Perioperative Management</u>** • Documentation of scheduled procedure with intent to use Coagadex for perioperative management of bleeding episodes
Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **<u>Reauthorization</u>** • **Prophylaxis:** Reauthorization requires documentation of treatment plan and responsiveness to therapy, defined as a reduction in spontaneous bleeds requiring treatment • **On-demand:** Reauthorization requires documentation of treatment plan, number of acute bleeds since last approval, and number of doses on-hand (not to exceed 6 total doses) • **Perioperative:** N/A
Prescriber Restrictions:	Prescribed by, or in consultation with, a hematologist

Coverage Duration:	• **Prophylaxis/On-demand:**
	  ○ Initial Authorization: 3 months, unless otherwise specified
	  ○ Reauthorization: 12 months, unless otherwise specified
	• **Perioperative:** 1 month, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
COMPOUNDED MEDICATIONS
Affected Medications: ALL COMPOUNDED MEDICATIONS

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• All compounded ingredients must be submitted on the pharmacy claim
Appropriate Treatment Regimen & Other Criteria:	• Compounded medications will only be payable after **ALL** commercially available or formulary products have been exhausted. • In the case of a payable claim, only compound ingredients that are covered on the applicable formulary will be reimbursed under this policy. ○ Compounds above a certain dollar threshold will be stopped by the claim adjudication system.
Exclusion Criteria:	• Compounds for experimental or investigational uses will not be covered. • Compounds containing non-FDA approved ingredients will not be covered • Non-FDA approved compounded medications will not be covered when an FDA approved, commercially available medication is on the market for treatment of requested condition
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• 3 months unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CONCIZUMAB
Affected Medications: ALHEMO (concizumab-mtci)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with:
	  ▪ Hemophilia A (congenital factor VIII deficiency) with or without FVIII inhibitors
	  ▪ Hemophilia B (congenital factor IX deficiency) with or without FIX inhibitors

Required Medical Information:	• Diagnosis of FVIII deficiency (hemophilia A) or FIX deficiency (hemophilia B) • Documentation of baseline factor level less than 1% AND prophylaxis required OR • Baseline factor level 1% to 3% and a documented history of at least two episodes of spontaneous bleeding into joints • Prescribed for routine prophylaxis to prevent or reduce the frequency of bleeding episodes • Documentation if inhibitors present • Number of bleeds in the past 3 months with severity and cause of bleed • Documentation of current weight
Appropriate Treatment Regimen & Other Criteria:	• **Hemophilia A**: Documentation treatment failure or contraindication to FVIII prophylaxis with 1 or more preferred therapies: Advate, Adynovate, Eloctate, Altuviiio, Kogenate FS, Kovaltry, Novoeight, Jivi (with bypassing agent if inhibitors present) OR Hemlibra • **Hemophilia B**: Documentation treatment failure or contraindication to FIX prophylaxis with 1 or more preferred therapies: Rixubus, BeneFIX, Alprolix, Idelvion, Rebinyn (with bypassing agent if inhibitors present) • Prophylactic agents must be discontinued • Documentation of planned treatment dose based on reasonable projections, current dose utilization, and disease severity **<u>Reauthorization:</u>** • Documentation of bleeding episodes (number and severity) showing reduction in spontaneous bleeds requiring treatment • Documentation that Alhemo plasma concentration is above 200 ng/mL to decrease the risk of bleeding episodes • Documentation of planned treatment dose, past treatment history, and titer inhibitor level to factor VIII and FIX as appropriate
Exclusion Criteria:	
Age Restriction:	• 12 years of age and up
Prescriber/Site of Care Restrictions:	• Hematologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CONTINUOUS GLUCOSE MONITORS (CGM)
Affected Medications: FREESTYLE LIBRE, DEXCOM

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Type 1 diabetes mellitus
	  ○ Type 2 diabetes mellitus requiring rapid, short, or intermediate acting insulin
	  ○ Gestational diabetes requiring rapid, short, or intermediate acting insulin

Required Medical Information:	**For type 1 diabetes, type 2 diabetes, gestational diabetes:**
	• Documentation of one of the following:
	  ○ Currently on an insulin pump
	  ○ Baseline HbA1c Level 8.0% or higher
	  ○ Frequent or severe hypoglycemia
	  ○ Impaired awareness of hypoglycemia
	  ○ Diabetes related complications (e.g., peripheral neuropathy, end organ damage)
	OR
	• Children and adolescents under 21
	OR
	• Documentation of type 1 diabetes for women who are pregnant or actively attempting to conceive

Appropriate Treatment Regimen & Other Criteria:	**When requested through the PHARMACY benefit:** Coverage for a CGM that is not Freestyle Libre or Dexcom is provided when the member meets the following criteria: • Documentation of current use of an insulin pump that is compatible with a CGM that is not Freestyle Libre or Dexcom **For type 2 diabetes, gestational diabetes:** • Documentation of current use of rapid, short, or intermediate acting insulin **Reauthorization** requires documentation of improved glycemic control and continued use of rapid, short, or intermediate acting insulin
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 1 year, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
COPPER CHELATING AGENTS
Affected Medications: Penicillamine, Trientine hydrochloride, CUVRIOR (trientine tetrahydrochloride)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Wilson's disease
	  ○ Cystinuria (penicillamine only)
	  ○ Rheumatoid arthritis (penicillamine only)
	  ○ Copper measurement in urine (penicillamine only)

Required Medical Information:	• For penicillamine: Documented treatment plan including routine urinalysis, WBCs, hemoglobin, platelet count, liver function tests, renal function tests due to risk of fatalities due to aplastic anemia, agranulocytosis, thrombocytopenia, myasthenia gravis, and Goodpasture's Syndrome
	
	<u>Wilson's Disease</u>
	• Diagnosis confirmed by **ONE** of the following:
	  ○ Genetic testing results confirming biallelic pathogenic *ATP7B* mutations (in either symptomatic or asymptomatic individuals)
	  ○ Liver biopsy findings consistent with Wilson's disease
	  ○ Presence of Kayser-Fleischer (KF) rings **AND** serum ceruloplasmin level less than 20 mg/dL **AND** 24-hour urinary copper excretion greater than **40** mcg
	  ○ Presence of Kayser-Fleischer (KF) rings **AND** 24-hour urinary copper excretion greater than **100** mcg
	  ○ Absence of KF rings with serum ceruloplasmin level less than 10 mg/dL **AND** 24-hour urinary copper excretion greater than **100** mcg
	
	<u>Rheumatoid arthritis</u>
	• Documentation of severe, active disease defined by one of the following:
	  ○ The Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ The Simplified Disease Activity Index (SDAI) greater than 11
	  ○ The Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted Routine Assessment of Patient Index Data 3 (RAPID3) of at least 2.3

Appropriate Treatment Regimen & Other Criteria:	**<u>Wilson's Disease</u>**
	• For Cuvrior, must meet both of the following:
	  ○ Documented treatment failure with a minimum 6-month trial of penicillamine that was not due to tolerability
	  AND
	  ○ Documented intolerable adverse event to a maximally tolerated dosage of generic trientine hydrochloride and the adverse event was not an expected adverse event attributed to the active ingredient
	
	<u>Rheumatoid arthritis</u>
	• Has failed to respond to an adequate trial of conventional therapies (such as methotrexate, sulfasalazine, hydroxychloroquine, leflunomide)
	
	<u>Reauthorization:</u> Documentation of treatment success and a clinically significant response to therapy

	○ For Wilson's Disease, this is defined as normalization of free serum copper (non-ceruloplasmin bound copper) to less than 15 mcg/dL and 24-hour urinary copper in the range of 200 to 500 mcg
Exclusion Criteria:	• For trientine hydrochloride: ○ Treatment of rheumatoid arthritis ○ Treatment of cystinuria ○ Treatment of biliary cirrhosis • Use of penicillamine during pregnancy (except for treatment of Wilson's disease or cystinuria)
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hepatologist, gastroenterologist, or liver transplant physician
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CORLANOR
Affected Medications: CORLANOR (ivabradine) 5 mg/5mL oral solution

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Stable, symptomatic chronic heart failure with reduced ejection fraction in adult patients (adjunctive therapy)
	  ○ Stable, symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients 6 months and older
	• Compendia-supported uses that will be covered
	  ○ Inappropriate sinus tachycardia

Required Medical Information:	**<u>Chronic heart failure in adult patients</u>** • Documentation of chronic heart failure with left ventricular ejection fraction (LVEF) 35% or less AND • Resting heart rate of at least 70 beats per minute (bpm) **<u>Heart failure in pediatric patients</u>** • Documentation of stable symptomatic disease due to DCM • Currently in sinus rhythm with an elevated heart rate **<u>Inappropriate sinus tachycardia</u>** • Documented resting heart rate of at least 100 beats per minute, with a mean heart rate of at least 90 beats per minute over 24 hours, that is not due to appropriate physiologic response or primary abnormality (such as hyperthyroidism or anemia) • Symptoms are present (such as palpitations, shortness of breath, dizziness, and/or decreased exercise capacity) • Documented absence of identifiable causes of sinus tachycardia and exclusion of atrial tachycardia

Appropriate Treatment Regimen & Other Criteria:	**<u>Chronic heart failure in adult patients</u>**
	• Documented treatment failure with a beta blocker (metoprolol succinate extended release, carvedilol, or carvedilol extended release) at the maximally tolerated dose for heart failure treatment OR
	• Documentation of contraindication to beta-blocker use
	
	<u>Heart failure in pediatric patients</u>
	• Treatment failure with beta blocker or digoxin, or contraindication to beta blocker and digoxin use
	
	<u>All Indications</u>
	• Requests for Corlanor oral solution will require at least **ONE** of the following:
	  ○ Request is for a pediatric patient
	  ○ Request is for an adult patient who is unable to swallow tablets
	  ○ Documentation of an adverse event with generic ivabradine tablets (and the adverse event was not an expected adverse event attributed to the active ingredient)

	Reauthorization will require documentation of treatment success and a clinically significant response to therapy • Development of atrial fibrillation while on therapy will exclude patient from reauthorization
Exclusion Criteria:	• Acute, decompensated heart failure • Blood pressure less than 90/50 mm Hg • Sick sinus syndrome, sinoatrial block, third-degree atrioventricular block (unless stable with functioning demand pacemaker) • Severe hepatic impairment (Child-Pugh class C) • Heart rate maintained exclusively by pacemaker
Age Restriction:	• Heart failure due to DCM: 6 months to less than 18 years of age
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a cardiologist
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

POLICY NAME:
CORTICOTROPIN INJECTION GEL
Affected Medications: ACTHAR Gel (repository corticotripin injection), PURIFIED CORTROPHIN GEL (repository corticotropin injection)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design • Diagnostic adrenocortical function
Required Medical Information:	• **ACTHAR GEL ONLY**: Diagnosis of infantile spasms and currently receiving treatment with Acthar gel and has shown substantial clinical benefit from therapy, OR the patient has not received previous treatment with Acthar gel and the patient is less than 2 years of age **(If yes, skip directly to exclusion criteria)** **<u>All other indications:</u>** **Coverage of Acthar Gel requires a documented intolerable adverse event to a trial of Purified Cortrophin Gel and one of the following**: • Use for diagnostic testing of adrenocortical function and the patient cannot be tested with Cosyntropin, OR • For use in serum sickness and the patient had an inadequate response to parenteral corticosteroids, OR • For use in rheumatic diseases, used as adjunctive treatment, and the patient had an inadequate response to parenteral corticosteroids, OR • The patient has a diagnosis of nephrotic syndrome, the therapy is being requested for induction of diuresis or for remission proteinuria, and the patient had an inadequate response to parenteral corticosteroids, OR • The therapy is requested for multiple sclerosis (MS) exacerbation and the patient had an inadequate response to parenteral corticosteroids, OR • The patient has Collagen diseases (eg, systemic lupus erythematosus (SLE), dermatomyositis, or polymyositis), Dermatologic disorders (eg, severe erythema multiforme, Stevens-Johnson syndrome), Ophthalmic disorders, acute or chronic (eg, iritis, keratitis, optic neuritis), or Symptomatic sarcoidosis AND the patient had an inadequate response to parenteral corticosteroids
Appropriate Treatment Regimen & Other Criteria:	• **MS exacerbation:** Failure to generic oral **AND** intravenous glucocorticoids • **SLE:** Failure to hydroxychloroquine or chloroquine **AND** generic glucocorticoids **<u>Reauthorization</u>** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Receipt of live or live attenuated vaccines within 6 weeks of corticotropin gel administration • Suspected congenital infection (infants) • Scleroderma • Osteoporosis • Systemic fungal infections • Peptic ulcer disease • Ocular herpes simplex • Congestive heart failure • Recent surgery • Uncontrolled hypertension

	• Known hypersensitivity to porcine proteins • Primary adrenocortical insufficiency or hyperfunction
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approvals: Infantile Spasms (ACTHAR GEL ONLY), Rheumatic Diseases, Nephrotic Syndrome, Collagen Diseases, Dermatologic Diseases, Ophthalmic Disorders, or Symptomatic Sarcoidosis = 6 months, unless otherwise specified Diagnostic Use = 1 dose, (30 days), unless otherwise specified Serum Sickness = 1 month, unless otherwise specified MS Exacerbation = 3 weeks, unless otherwise specified

POLICY NAME:
COVID-19 DIAGNOSTIC AT HOME TESTING (PHARMACY BENEFIT)
Affected Medications: COVID-19 DIAGNOSTIC AT HOME TESTING (PHARMACY BENEFIT)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design

Required Medical Information:	• Documentation of the type of test requested including:
	  ○ Molecular testing or antigen testing
	  ○ Rapid testing or sample collection
	  ○ Manufacturer of test or kit
	• Documentation of symptoms consistent with COVID-19 or who have confirmed or suspected exposure to COVID-19

Appropriate Treatment Regimen & Other Criteria:	• Authorized by the Food and Drug Administration (including emergency use authorization)
Exclusion Criteria:	• Tests not approved or cleared by the FDA
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 10 days

PacificSource Community Solutions

POLICY NAME:
CRINECERFONT
Affected Medications: CRENESSITY (crinecerfont)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Congenital adrenal hyperplasia (CAH)

Required Medical Information:	• Confirmed diagnosis of classic CAH due to 21-hydroxylase deficiency (21-OHD) confirmed by one of the following
	  ○ Elevated 17-hydroxyprogestone level
	  ○ Confirmed cytochrome CYP21A2 genotype
	  ○ Positive newborn screening with confirmatory second-tier testing (such as liquid chromatography tandem mass spectrometry)
	  ○ Cosyntropin stimulation test
	• Documentation of being used concurrently with a systemic glucocorticoid (such as hydrocortisone, prednisone, prednisolone, dexamethasone)
	• Body surface area (BSA)

Appropriate Treatment Regimen & Other Criteria:	• Requests for oral solution must have documented inability to swallow tablets • Documentation of being on a supraphysiologic systemic glucocorticoid dose to control disease (total glucocorticoid dose of at least 10 mg/m^2/day in hydrocortisone dose equivalents) • Dosing is in accordance with FDA labeling **Reauthorization** required documentation of treatment success defined by a reduction in serum androstenedione (A4) or reduction in glucocorticoid dose
Exclusion Criteria:	
Age Restriction:	• 4 years of age or older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an endocrinologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization:12 months, unless otherwise specified

POLICY NAME:
CRIZANLIZUMAB
Affected Medications: ADAKVEO (crizanlizumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ To reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease
Required Medical Information:	• Diagnosis of sickle cell disease confirmed by genetic testing • Two or more sickle cell-related crises in the past 12 months • Therapeutic failure of 6-month trial on maximum tolerated dose of hydroxyurea or intolerable adverse event to hydroxyurea
Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** requires documentation of treatment success defined by a decrease in the number of vaso-occlusive crises
Exclusion Criteria:	• Long-term red blood cell transfusion therapy • Hemoglobin is less than 4.0 g/dL • Chronic anticoagulation therapy (e.g., warfarin, heparin) other than aspirin • History of stroke within the past 2 years • Combined use with Endari (L-glutamine)
Age Restriction:	• 16 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CROVALIMAB
Affected Medications: PIASKY (crovalimab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Paroxysmal nocturnal hemoglobinuria (PNH)

Required Medical Information:	• Detection of PNH clones of at least 5% by flow cytometry diagnostic testing
	  ○ Presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least 2 different cell lines (e.g., granulocytes, monocytes, erythrocytes)
	• Baseline lactate dehydrogenase (LDH) levels greater than or equal to 2 times the upper limit of normal range
	• One of the following PNH-associated clinical findings:
	  ○ Presence of a thrombotic event
	  ○ Presence of organ damage secondary to chronic hemolysis
	  ○ History of 4 or more blood transfusions required in the previous 12 months
	• Body weight

Appropriate Treatment Regimen & Other Criteria:	• Documented inadequate response, contraindication, or intolerance to ravulizumab-cwvz (Ultomiris) • Dosing is in accordance with FDA labeling and most recent body weight **Reauthorization** requires documentation of treatment success defined as a decrease in serum LDH, stabilized/improved hemoglobin, decreased transfusion requirement, and reduction in thromboembolic events compared to baseline
Exclusion Criteria:	• Concurrent use with other biologics for PNH (Soliris, Ultomiris, Empaveli, Fabhalta) • Current meningitis infection or other unresolved serious infection caused by encapsulated bacteria
Age Restriction:	• 13 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
CYSTEAMINE
Affected Medications: PROCYSBI (cysteamine bitartrate delayed release)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Nephropathic cystinosis

Required Medical Information:	• Diagnosis of nephropathic cystinosis confirmed by **ONE** of the following:
	  ○ Molecular genetic testing showing mutations in the CTNS gene
	  ○ Leukocyte cystine concentration above the laboratory reference range
	  ○ Presence of cysteine corneal crystals by slit lamp examination

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure or intolerable adverse event with Cystagon
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
DALFAMPRIDINE
Affected Medications: dalfampridine

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment to improve walking in adult patients with multiple sclerosis (MS)
Required Medical Information:	• Diagnosis of Multiple Sclerosis (MS) with documented impairment, but able to walk with or without assistance • Documentation of baseline Timed 25-foot walk test (T25-FW)
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of treatment success compared to baseline walking ability as determined by treating provider
Exclusion Criteria:	• History of seizures • Creatinine clearance less than or equal to 50mL/min
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or after consultation with, a neurologist or an MS specialist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
DANICOPAN
Affected Medications: VOYDEYA (danicopan)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH)
Required Medical Information:	• Patients complete or update vaccination with meningococcal vaccine at least two weeks prior to initiation of Voydeya the requested therapy and revaccinated according to current Advisory Committee on Immunization Practices (ACIP) guidelines
Appropriate Treatment Regimen & Other Criteria:	• Must be used in combination with ravulizumab-cwvz (Ultomiris) or eculizumab (Soliris) [separate authorization required] • Documentation of clinically significant extravascular hemolysis (EVH) defined as persistent anemia (Hgb less than or equal to 9.5 gram/deciliter) with absolute reticulocyte count greater than or equal to 120 x 10^9/liter despite use of Ultomiris or Soliris for at least 6 months **Reauthorization:** documentation of treatment success defined as a decrease in serum LDH, stabilized/improved hemoglobin, decreased transfusion requirement, and reduction in thromboembolic events compared to baseline
Exclusion Criteria:	• Use without Ultomiris or Soliris • Concurrent use with biologics for PNH other than Ultomiris and Soliris (such as pegcetacoplan or iptacopan) • Current meningitis infection
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
DAPTOMYCIN
Affected Medications: Daptomycin Solution Reconstituted 350 mg Intravenous, Daptomycin Solution Reconstituted 500 mg Intravenous

Covered Uses:	• Empiric outpatient intravenous treatment of a suspected gram-positive bacterial infection
	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Bacteremia, including right-sided infective endocarditis caused by:
	  ▪ Methicillin-susceptible Staphylococcus aureus (MSSA)
	  ▪ Methicillin-resistant Staphylococcus aureus (MRSA)
	  ○ Complicated Skin and Skin Structure Infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria:
	  ▪ MSSA
	  ▪ MRSA
	  ▪ Streptococcus pyogenes
	  ▪ Streptococcus agalactiae
	  ▪ Streptococcus dysgalactiae subsp. equisimilis
	  ▪ Enterococcus faecalis
	• Compendia-supported uses including
	  ○ Vancomycin resistant enterococci (VRE) or vancomycin resistant staph aureus (VRSA) infections
	  ○ Bacteremia associated with intravascular line
	  ○ Osteomyelitis
	  ○ Septic arthritis
	  ○ Acute Hematogenous Osteomyelitis (Pediatric only)
	  ○ Vertebral osteomyelitis

Required Medical Information:	• Documentation of confirmed or suspected gram-positive bacterial infection • Documentation of treatment history and current treatment regimen • Documentation of therapy intention (empiric, pathogen directed) • Documentation of culture and sensitivity data or plan to adjust from empiric to definitive therapy once culture results are available • Documentation of planned treatment duration as applicable • Documentation of planned dosing, current weight, and patient renal function • Avoidance of vancomycin due to nephrotoxicity will require documentation of multiple (at least 2 consecutive) increased serum creatinine concentrations (increase of 0.5 mg/dL (44 mcmol/L) or at least 50 percent increase from baseline, whichever is greater), without an alternative explanation

Appropriate Treatment Regimen & Other Criteria:	• Empiric outpatient intravenous treatment of a suspected gram-positive bacterial infection for up to 7 days
	
	<u>Bacteremia, including right-sided infective endocarditis</u>
	• Documentation of MRSA or VRE infection
	• Documentation of treatment failure or pathogen resistance to linezolid and vancomycin or contraindication or rationale for avoidance to therapy with each
	• Adult dosing:
	  ○ 6 to 12 mg/kg once daily
	  ○ CrCl less than 30 mL/min: adjust dose frequency to once every 48 hours
	• Pediatric dosing:
	  ○ 1 to 6 years of age: 12mg/kg once daily
	  ○ 7 to 11 years of age: 9mg/kg once daily

	○ 12 to 17 years of age: 7mg/kg once daily • Duration of therapy: 2 to 6 weeks **Bacteremia associated with intravascular line** • Documentation of treatment failure or pathogen resistance to linezolid and vancomycin or contraindication or rationale for avoidance to therapy with each. • Adult dosing ○ For infections caused by MRSA: 6 to 8mg/kg once daily ○ For infections caused by ▪ methicillin-resistant, coagulase-negative staphylococci: 6mg/kg once daily ▪ ampicillin-resistant, vancomycin-susceptible Enterococcus faecalis/faecium: 6mg/kg once daily ▪ ampicillin-resistant, vancomycin-resistant Enterococcus faecalis/faecium: 6mg/kg once daily ○ CrCl less than 30 mL/min: adjust dose frequency to once every 48 hours **cSSSI** • Documentation of MSSA or MRSA infection • Documentation of treatment failure or pathogen resistance to beta-lactams (e.g., cefazolin), clindamycin, doxycycline, linezolid, sulfamethoxazole/trimethoprim, and vancomycin, or contraindication or rationale for avoidance to therapy with each • Adult dosing: ○ 4mg/kg once daily for 7 to 14 days ○ CrCl less than 30 mL/min: adjust dose frequency to once every 48 hours • Pediatric dosing: ○ 1 to less than 2 years of age: 10mg/kg once daily ○ 2 to 6 years of age: 9mg/kg once daily ○ 7 to 11 years of age: 7mg/kg once daily ○ 12 to 17 years of age: 5mg/kg once daily • Duration of therapy: 7 to 14 days **Osteomyelitis and Septic arthritis** • Documentation of MRSA and VRE infection • Documentation of treatment failure or pathogen resistance to vancomycin and linezolid or contraindication or rationale for avoidance to therapy with each • Adult dosing: 6 to 10 mg/kg ○ CrCl less than 30 mL/min: adjust dose frequency to once every 48 hours • Pediatric dosing: 6 to 10mg/kg once daily • Duration of therapy ○ Osteomyelitis: 8 weeks ○ Septic arthritis: 3 to 4 weeks **Acute Hematogenous Osteomyelitis (Pediatric only)** • Documentation of MRSA infection • Documentation of treatment failure or pathogen resistance to clindamycin and vancomycin or contraindication or rationale for avoidance to therapy with each • Pediatric dosing: ○ 1 to 6 years of age: 12mg/kg once daily ○ 7 to 11 years of age: 9mg/kg once daily

	○ 12 to 17 years of age: 7mg/kg once daily • Duration of therapy: 3 to 6 weeks **<u>Vertebral osteomyelitis</u>** • Documentation of MRSA or VRE infection • Documentation of treatment failure or pathogen resistance to vancomycin and linezolid or contraindication or rationale for avoidance to therapy with each • Adult dosing: 6 to 8 mg/kg once daily ○ CrCl less than 30 mL/min: adjust dose frequency to once every 48 hours • Duration: 6 weeks
Exclusion Criteria:	• Treatment of pneumonia • Treatment of left-sided infective endocarditis or prosthetic valve endocarditis due to Staphylococcus aureus • Treatment of VRE colonization of urine or respiratory tract • Empiric therapy for patients discharged from a higher level of care on vancomycin
Age Restriction:	• At least 1 year of age
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist
Coverage Duration:	• Empiric treatment of an infection caused by an undefined pathogen on an outpatient basis, approval: 7 days • Other, approval: 1 month

PacificSource Community Solutions

POLICY NAME:
DEFLAZACORT
Affected Medications: Deflazacort

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of Duchenne Muscular Dystrophy
Required Medical Information:	• A confirmed diagnosis of Duchenne muscular dystrophy (DMD) with documentation of genetic testing to confirm diagnosis
Appropriate Treatment Regimen & Other Criteria:	• Documented trial of prednisone with intolerable side-effects that would not be associated with deflazacort or the corticosteroid class **Reauthorization** requires documentation of treatment success
Exclusion Criteria:	
Age Restriction:	• 2 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a specialist with experience in the treatment of Duchenne muscular dystrophy
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
DEFIBROTIDE
Affected Medications: DEFITELIO (defibrotide sodium)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation (HSCT)
Required Medical Information:	• Diagnosis of, or high suspicion for, classical or late-onset hepatic VOD • Weight prior to HSCT, dose, and frequency
Appropriate Treatment Regimen & Other Criteria:	• Requested dose within the FDA-approved label
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 2 months with no reauthorization, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
DELANDISTROGENE MOXEPARVOVEC-ROKL
Affected Medications: ELEVIDYS (delandistrogene moxeparvovec-rokl)

Covered Uses:	• Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of patients ages 4 and up with Duchenne muscular dystrophy (DMD)
Required Medical Information:	• Confirmed mutation of DMD gene between exons 18-58 • North Star Ambulatory Assessment (NSAA) scale total score of 17 or more • Receiving physical and/or occupational therapy • Baseline anti-AAVrh74 total binding antibody titer of less than 1:400 as measured by ELISA • Current weight
Appropriate Treatment Regimen & Other Criteria:	• Documentation of being on a stable dose of an oral corticosteroid such as prednisone for at least 12-weeks, and will continue prior to and following Elevidys infusion, according to FDA approved labeling • Does not exceed FDA approved dosing based on weight and maximum of 70 vials • Number of vials needed = patient body weight (kg) rounded to nearest number of vials
Exclusion Criteria:	• Exon 8 and/or exon 9 deletion in DMD gene • Concomitant therapy or within the past 6 months with DMD-directed antisense oligonucleotides such as golodirsen, casimersen, viltolarsen, eteplirsen • Current active infection • Previous Elevidys treatment in their lifetime • Acute liver disease or impaired liver function
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Authorization: 1 month (one-time dose, no reauthorization)

POLICY NAME:
DENOSUMAB
Affected Medications: PROLIA (denosumab), JUBBONTI (denosumab-bbdz), STOBOCLO (denosumab-bmwo), CONEXXENCE (denosumab-bnht)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Treatment of osteoporosis in men and postmenopausal women at high risk for fracture
	  ○ Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
	  ○ Treatment of bone loss in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
	  ○ Treatment of bone loss in men at high risk for fracture receiving androgen deprivation therapy for prostate cancer

Required Medical Information:	**<u>Osteoporosis</u>**
	• Diagnosis of osteoporosis as defined by at least one of the following:
	  ○ T-score less than or equal to -2.5 (current or past) at the lumbar spine, femoral neck, total hip, or 1/3 radius site.
	  ○ T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, or 1/3 radius site AND increased risk of fracture as defined by at least one of the following Fracture Risk Assessment Tool (FRAX) scores:
	  ▪ FRAX 10-year probability of major osteoporotic fracture is 20% or greater
	  ▪ FRAX 10-year probability of hip fracture is 3% or greater
	  ○ History of non-traumatic fractures in the absence of other metabolic bone disorders (postmenopausal women with osteoporosis only)
	
	<u>Glucocorticoid-Induced Osteoporosis</u>
	• If 50 years old and greater, must provide documentation of one of the following:
	  ○ Baseline bone mineral density (BMD) T-score of less than or equal to -2.0 at the lumbar spine, total hip, or femoral neck
	  ○ BMD T-score less than or equal to -1.0 at the lumbar spine, total hip, or femoral neck AND a history of osteoporotic fracture
	• If less than 50 years old, must provide documentation of a history of osteoporotic fracture
	• In addition to the above, must also provide documentation of the following:
	  ○ Initiation or continuation of systemic glucocorticoids equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months
	
	<u>Bone Loss in Women Receiving Adjuvant Aromatase Inhibitor Therapy for Breast Cancer</u>
	• Documentation of baseline BMD T-score at minimum -1.0 at the lumbar spine, total hip, or femoral neck
	
	<u>Bone Loss in Men Receiving Androgen Deprivation Therapy for Prostate Cancer</u>
	• If less than 70 years old, must provide documentation of one of the following:
	  ○ BMD T-score at minimum -1.0 at the lumbar spine, total hip, or femoral neck
	  ○ History of osteoporotic fracture

Appropriate Treatment Regimen & Other Criteria:	**<u>Osteoporosis and Glucocorticoid-Induced Osteoporosis</u>**
	• Documentation of one of the following:
	  ○ Treatment failure or intolerable adverse event with an oral or intravenous bisphosphonate (e.g., alendronate, risedronate, zoledronic acid or ibandronate)
	  ○ Severe renal impairment (e.g., creatinine clearance less than 35 mL/min)
	  ○ Multiple osteoporotic fractures in the setting of T-scores less than -3.5
	
	<u>Reauthorization:</u> requires documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Concurrent use of bisphosphonate therapy or antineoplastic therapy apart from aromatase inhibitors or androgen deprivation therapy. • Preexisting hypocalcemia • Pregnancy
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
DIABETIC TEST STRIPS
Affected Medications: DIABETIC TEST STRIPS (all brands)

<table>
<tr><td>Covered Uses:</td><td>

All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design

Diabetes Mellitus (DM)

</td></tr>
<tr><td>Required Medical Information:</td><td>

Documentation of complete & current treatment course

</td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>

If a patient requires a new meter, please call PacificSource pharmacy help desk at 541-330-4999
Preferred products must be prescribed:

Freestyle Lite
Freestyle Precision Neo
Freestyle InsuLinx

Non-FreeStyle products will require a formulary exception request and will adhere to the following quantity limits below

Standard Quantity Limits:
<table>
<tr><th></th><th>Standard Quantity Limit</th></tr>
<tr><td>Insulin dependent DM</td><td rowspan="2">100 test strips per 25 days (4x/day)</td></tr>
<tr><td>Non-insulin dependent DM</td></tr>
</table>
Quantity Limit exceptions:
<table>
<tr><th>Exception</th><th>Quantity Limit</th></tr>
<tr><td>Gestational DM</td><td rowspan="4">150 test strips per 25 days (6x/day)</td></tr>
<tr><td>Insulin administration of 4 times daily or greater</td></tr>
<tr><td>New onset Adult DM</td></tr>
<tr><td>Uncontrolled DM (HbA1c greater than 10%)</td></tr>
</table>
<table>
<tr><th>Exception</th><th>Quantity Limit</th></tr>
<tr><td>Insulin Pump Start</td><td rowspan="2">250 test strips per 25 days (10x/day)</td></tr>
<tr><td>New onset Pediatric DM</td></tr>
</table>
</td></tr>
<tr><td>Exclusion Criteria:</td><td>

Patients actively utilizing continuous glucose monitors (CGM) will not be approved for greater than 4 times daily testing (#100/25 days)

</td></tr>
<tr><td>Age Restriction:</td><td></td></tr>
<tr><td>Prescriber Restrictions:</td><td></td></tr>
<tr><td>Coverage Duration:</td><td>

Approval: 12 months

</td></tr>
</table>

PacificSource Community Solutions

POLICY NAME:
DIAZOXIDE CHOLINE
Affected Medications: VYKAT XR (diazoxide choline)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded: ○ Hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS)
Required Medical Information:	• Diagnosis of PWS confirmed by genetic testing • Provider attests that patient experiences moderate to severe symptoms of hyperphagia related to PWS and provides documentation of associated symptoms (e.g. food-seeking behaviors) • Caregiver has implemented and intends to continue strategies to establish a food-secure environment (e.g. locked food storage) • Patient is able to swallow tablets whole • Recent weight documentation (within 30 days) to ensure appropriate dose
Appropriate Treatment Regimen & Other Criteria:	**Dosing**: within FDA-approved label **Reauthorization** will require documentation of the following: • Patient has experienced an improvement in hyperphagic symptoms, such as a decrease in food-related aggression or manipulation, or lessened food preoccupation that interferes with normal daily activities, etc. • Patient is adherent to therapy and able to successfully swallow the prescribed number of tablets daily • Recent weight documentation (within 30 days) to ensure appropriate dose • For adult patients, provider has determined that patient is likely to still benefit from therapy (i.e. patient has not entered the phase of symptom improvement sometimes observed in adulthood)
Exclusion Criteria:	• Use for eating disorders without PWS
Age Restriction:	• 4 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with an endocrinologist, psychiatrist, or other physician with expertise in the treatment of PWS
Coverage Duration:	• Initial Authorization: 6 months • Reauthorization: 6 months

PacificSource Community Solutions

POLICY NAME:
DOJOLVI
Affected Medications: DOJOLVI (triheptanoin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ A source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders.

Required Medical Information:	• Diagnosis of long chain fatty acid oxidation disorder (LC-FAOD) confirmed by molecular genetic testing or enzyme assay
	• Documentation of total prescribed daily caloric intake
	• Documentation of severe disease despite dietary management as evidenced by one of the following:
	  ○ Hypoglycemia after short periods of fasting
	  ○ Evidence of functional cardiomyopathy with poor ejection fraction requiring ongoing management
	  ○ Frequent severe major medical episodes requiring emergency room visits, acute care, or hospitalization (3 within the past year or 5 within the past 2 years)
	  ○ Elevated creatinine kinase (chronic or episodic)

Appropriate Treatment Regimen & Other Criteria:	• Documentation of inadequate response or intolerance to an over the counter (OTC) medium-chain triglyceride (MCT) product • Dose not to exceed 35% of daily caloric intake • Reauthorization will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Concurrent use of another medium chain triglyceride product • Medium chain acyl-dehydrogenase deficiency
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist or provider experienced in the management of metabolic disorders
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
DONANEMAB-AZBT
Affected Medications: KISUNLA (donanemab-azbt)

<table>
<tr><td>Covered Uses:</td><td>• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
  ○ Alzheimer’s disease</td></tr>
<tr><td>Required Medical Information:</td><td>• Documentation of mild cognitive impairment due to Alzheimer’s disease or mild Alzheimer’s dementia as evidenced by ALL of the following:
  ○ Clinical Dementia Rating (CDR) global score of 0.5 – 1.0
  ○ Evidence of cognitive impairment at baseline using validated objective scales
  ○ Mini-Mental Status Exam (MMSE) score between 20 and 28
  ○ Positron Emission Tomography (PET) scan positive for amyloid beta plaque
• Documentation of baseline brain magnetic resonance (MRI) within the last year with no superficial siderosis or brain hemorrhage
• Provider attestation that monitoring for ARIA will be conducted with MRI prior to initiation and prior to the 2nd, 3rd, 4th, and 7th infusion</td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>• Current weight

<u>Dosing</u>
• Availability: 350 mg/20 mL single-dose vial
• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced

Dosing and monitoring schedule:
<table><tr><th>Intravenous infusion (every 4 weeks)</th><th>Dose</th></tr><tr><td>Infusions 1, 2, and 3</td><td>700 mg</td></tr><tr><td>Infusion 4 and beyond</td><td>1400 mg</td></tr></table>
<u>Reauthorization (76 weeks total allowed)</u>
• Documentation of clinically significant amyloid reduction compared to baseline confirmed by post-infusion PET scan
• Documentation of updated surveillance MRI showing absence of clinically significant microhemorrhage and superficial siderosis since prior approval
• Documentation of one of the following when compared to baseline:
  ○ Cognitive or functional improvement
  ○ Disease stabilization
  ○ Reduction in clinical decline compared to natural disease progression</td></tr>
<tr><td>Exclusion Criteria:</td><td>• Prior stroke or brain hemorrhage
• Current treatment with immunoglobulin G (IgG) therapy
• Evidence of moderate to severe Alzheimer’s disease
• Non-Alzheimer’s dementia</td></tr>
<tr><td>Age Restriction:</td><td>• 59 years of age and older</td></tr>
<tr><td>Prescriber/Site of Care Restrictions:</td><td>• Prescribed by, or in consultation with, a neurologist</td></tr>
</table>

Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified (76 weeks total approval)

PacificSource Community Solutions

POLICY NAME:
DONISLECEL
Affected Medications: LANTIDRA (donislecel solution)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information:	• Diagnosis of type 1 diabetes for 5 or more years
	• Documentation of inability to achieve target HbA1c despite adherence to intensive insulin management with all the following:
	  ○ Multiple daily injections of prandial and basal insulin or on an insulin pump
	  ○ Performing at least four blood glucose tests per day or using a continuous glucose monitor
	• Documentation of 2 or more episodes of severe hypoglycemia (blood glucose level less than 50 mg/dL) in the past three years requiring assistance of another person with either an oral carbohydrate, intravenous glucose, or glucagon administration
	• Documentation of hypoglycemia unawareness, defined by the absence of adequate autonomic symptoms during an episode of severe hypoglycemia

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of not achieving exogenous insulin independence within one year of infusion or within one year of losing independence from exogenous insulin (maximum of three infusions per lifetime)
Exclusion Criteria:	• Pregnancy • Malignancy • Active infection • Previous kidney or pancreas transplant • Prior portal vein thrombosis
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an endocrinologist
Coverage Duration:	• Authorization: 3 months (single treatment), unless specified otherwise

POLICY NAME:
DORNASE ALFA
Affected Medications: PULMOZYME (dornase alfa)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	• The diagnosis of Cystic Fibrosis (CF) has been confirmed by appropriate diagnostic or genetic testing ○ Additional testing should include evaluation of overall clinical lung status and respiratory function (e.g., pulmonary function tests, lung imaging, etc.)
Appropriate Treatment Regimen & Other Criteria:	• Pulmozyme will be used in conjunction with standard therapies for cystic fibrosis **Reauthorization** will require documentation of a clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	• 1 month or older
Prescriber Restrictions:	
Coverage Duration:	• Approval: 24 months, unless otherwise specified.

PacificSource Community Solutions

POLICY NAME:
DUOPA
Affected Medications: DUOPA (carbidopa/levodopa enteral suspension)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of motor fluctuations in patients with advanced Parkinson's disease (PD)

Required Medical Information:	• Documentation of all the following:
	  ○ Diagnosis of advanced PD
	  ○ Clear response to levodopa treatment with evidence of "On" periods
	  ○ Persistent motor fluctuations with "Off" time occurring 3 hours or more per day while awake despite an optimized PD treatment regimen
	  ○ Has undergone or has planned placement of a nasojejunal (NJ) tube for temporary administration of Duopa OR gastrostomy-jejunostomy (PEG-J) tube for long-term administration of Duopa

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with both of the following:
	  ○ Oral levodopa/carbidopa
	  ○ Two additional agents from different anti-PD drug classes:
	  ▪ Monoamine oxidase-B (MAO-B) inhibitors (ex: selegiline, rasagiline)
	  ▪ Dopamine agonists (ex: amantadine, pramipexole, ropinirole)
	  ▪ Catechol-O-methyltransferase (COMT) inhibitors (ex: entacapone)
	
	Reauthorization will require documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Atypical Parkinson's syndrome ("Parkinson's Plus" syndrome) or secondary Parkinson's • Non-levodopa responsive PD • Contraindication to percutaneous endoscopic gastro-jejunal (PEG-J) tube placement or long-term use of a PEG-J • Concomitant use with nonselective MAO inhibitors or have recently (within 2 weeks) taken a nonselective MAO inhibitor
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• 12 months, unless otherwise specified

POLICY NAME:
DUPILUMAB
Affected Medications: DUPIXENT (dupilumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Add-on maintenance treatment of patients aged 6 years and older with moderate-to-severe asthma with an eosinophilic phenotype or oral corticosteroid dependent asthma
	  ○ Treatment of patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD)
	  ○ Treatment of patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE)
	  ○ Add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)
	  ○ Treatment of adult patients with prurigo nodularis (PN)
	  ○ Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype
	  ○ Treatment of patients 12 to a maximum age of 20 years with chronic spontaneous urticaria (CSU) who remain symptomatic despite histamine-1 receptor (H1) antihistamine treatment
	  ○ Treatment of adult patients with bullous pemphigoid (BP)

Required Medical Information:	**<u>Eosinophilic asthma</u>**
	• Diagnosis of moderate-to-severe asthma with an eosinophilic phenotype, defined by both of the following:
	  ○ Baseline eosinophil count of at least 150 cells/µL **AND**
	  ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal
	
	<u>AD</u>
	• Diagnosis of severe atopic dermatitis with functional impairment, defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	AND one of the following:
	  ○ Body surface area (BSA) involvement of at least 10%
	  ○ Hand, foot, face, or mucous membrane involvement
	
	<u>EoE</u>
	• Diagnosis confirmed by endoscopic biopsy with greater than or equal to 15 eosinophils per high power field (HPF)
	• Documented history of two or more dysphagia episodes per week despite current treatment

	CRSwNP
	• Documented diagnosis of chronic rhinosinusitis with nasal polyps
	• History of sinus surgery (Functional Endoscopic Sinus Surgery [FESS] or similar)
	• Documentation of both of the following:
	  ○ Presence of bilateral nasal polyps
	  ○ Symptoms of sinonasal obstruction/congestion for over 12 weeks (decreased/absent sense of smell, facial pressure/pain, rhinorrhea/postnasal drip)
	
	PN
	• Documentation of all the following:
	  ○ Diagnosis confirmed by skin biopsy
	  ○ Presence of at least 20 PN lesions for at least 3 months
	  ○ Severe itching
	
	COPD
	• Diagnosis of COPD with moderate to severe airflow limitation
	• FEV1/FVC ratio less than 0.7 and FEV1 of 30-70% predicted
	• Baseline eosinophil count at least 300 cells/µL
	• Symptoms of chronic productive cough for at least 3 months
	
	CSU
	• Documentation of active CSU where the underlying cause is not considered to be any other allergic condition or other form of urticaria
	• Documentation of presence of recurrent urticaria, angioedema, or both, for a period of six weeks or longer
	• Documented avoidance of triggers (such as nonsteroidal anti-inflammatory drugs [NSAIDs])
	• Documentation of pruritus severe enough to interfere with the ability to grow, develop and participate in school despite treatment with at least 80% adherence
	
	BP
	• Documented diagnosis of bullous pemphigoid confirmed by one of the following:
	  ○ Biopsy using direct immunofluorescence (DIF) microscopy
	  ○ Serum tests using indirect immunofluorescence (IIF) assay or enzyme-linked immunosorbent assay (ELISA), detecting circulating anti-basement membrane zone antibodies
	• Documentation of pruritic, eczematous, papular, urticaria-like skin lesions or tense blisters and erosions
	• Bullous Pemphigoid Disease Area Index (BPDAI) activity score of 24 or greater

Appropriate Treatment Regimen & Other Criteria:	**Eosinophilic asthma** • Documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms AND • Documentation of one of the following: ○ Documented history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months while on combination inhaler treatment and at least 80% adherence

	○ Documentation that chronic daily oral corticosteroids are required **AD** • Documented treatment failure with at least 4 weeks of a topical non-steroidal agent (e.g., tacrolimus ointment, pimecrolimus cream) OR • Documented treatment failure with at least 12 weeks of one of the following: phototherapy, cyclosporine, azathioprine, methotrexate, mycophenolate **EoE** • Documented treatment failure with at least 12 weeks of **ONE** of the following: ○ High dose (twice daily dosing) proton pump inhibitor (PPI) ○ Swallowed corticosteroid (such as fluticasone or budesonide) **CRSwNP** • Documented treatment failure with a minimum 3-month trial of one intranasal corticosteroid after sinus surgery **PN** • Documented treatment failure with at least 12 weeks of one of the following: phototherapy, methotrexate, cyclosporine **COPD** • Documented use of inhaled triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) for at least 12 weeks with continued symptoms • Documentation of one of the following: ○ History of at least two moderate COPD exacerbations requiring treatment with a systemic corticosteroid and/or an antibiotic in the past year while on triple therapy and at least 80% adherence ○ History of at least one severe COPD exacerbation requiring hospitalization in the past year while on triple therapy and at least 80% adherence **CSU** • Documented treatment failure with 4-fold standard dosing of one second generation H1-antihistamine products for at least one month: cetirizine, fexofenadine, loratadine, desloratadine, or levocetirizine **BP** • Documented treatment failure with a minimum 8-week trial with at least two of the following: ○ High potency topical corticosteroid (clobetasol, betamethasone, halobetasol, fluocinonide) ○ Oral corticosteroid ○ Oral doxycycline ○ Azathioprine, mycophenolate, methotrexate **Reauthorization:** documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Use in combination with another monoclonal antibody (e.g., Fasenra, Nucala, Xolair, Tezspire, Cinqair)
Age Restriction:	• **AD:** 6 months of age and older • **Asthma:** 6 years of age and older • **CRSwNP:** 12 years of age and older • **EoE:** 1 year of age and older • **PN:** 18 years of age and older • **COPD:** 18 years of age and older • **CSU:** 12 to 20 years of age • **BP:** 18 years of age and older
Prescriber/Site of Care Restrictions:	• **Eosinophilic asthma**: Prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist • **AD**: Prescribed by, or in consultation with, a dermatologist • **EoE**: Prescribed by, or in consultation with, an allergist, immunologist, or gastroenterologist • **CRSwNP**: Prescribed by, or in consultation with, an otolaryngologist • **PN**: Prescribed by, or in consultation with, an allergist, immunologist, or dermatologist • **COPD**: prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ECULIZUMAB
Affected Medications: SOLIRIS (eculizumab), EPYSQLI (eculizumab- aagh), BKEMV (eculizumab-aeeb)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
	  ○ Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy
	  ○ Generalized myasthenia gravis (gMG) in adult and pediatric patients six years of age and older who are anti-acetylcholine receptor (AchR) antibody positive
	  ○ Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive

Required Medical Information:	**PNH**
	• Detection of PNH clones of at least 5% by flow cytometry diagnostic testing
	  ○ Presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least 2 different cell lines (e.g., granulocytes, monocytes, erythrocytes)
	• Baseline lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal range
	• One of the following PNH-associated clinical findings:
	  ○ Presence of a thrombotic event
	  ○ Presence of organ damage secondary to chronic hemolysis
	  ○ History of 4 or more blood transfusions required in the previous 12 months
	
	aHUS
	• Clinical presentation of microangiopathic hemolytic anemia, thrombocytopenia, and acute kidney injury
	• Patient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.)
	• ADAMTS13 activity level greater than or equal to 10%
	• Shiga toxin E. coli related hemolytic uremic syndrome (ST-HUS) has been ruled out
	• History of 4 or more blood transfusions required in the previous 12 months
	
	gMG
	• Diagnosis of gMG confirmed by:
	  ○ A history of abnormal neuromuscular transmission test OR
	  ○ A positive edrophonium chloride test OR
	  ○ Improvement in gMG signs or symptoms with an acetylcholinesterase inhibitor
	• Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
	• Positive serologic test for AChR antibodies
	• Documentation of **ONE** of the following:
	  ○ MG-Activities of Daily Living (MG-ADL) total score of 6 or greater
	  ○ Quantitative Myasthenia Gravis (QMG) total score of 12 or greater

PacificSource Community Solutions

<table>
<tr><td></td><td>

NMOSD

- Diagnosis of seropositive aquaporin-4 immunoglobulin G (AQP4-IgG) NMOSD confirmed by all the following:
  - Documentation of AQP4-IgG-specific antibodies on cell-based assay
  - Exclusion of alternative diagnoses (such as multiple sclerosis)
  - At least **one** core clinical characteristic:
    - Acute optic neuritis
    - Acute myelitis
    - Acute area postrema syndrome (episode of otherwise unexplained hiccups or nausea/vomiting)
    - Acute brainstem syndrome
    - Symptomatic narcolepsy **OR** acute diencephalic clinical syndrome with NMOSD-typical diencephalic lesion on magnetic resonance imaging (MRI) [*see table below*]
    - Acute cerebral syndrome with NMOSD-typical brain lesion on MRI [*see table below*]

<table>
<tr><th>Clinical presentation</th><th>Possible MRI findings</th></tr>
<tr><td>Diencephalic syndrome</td><td>• Periependymal lesion
• Hypothalamic/thalamic lesion</td></tr>
<tr><td>Acute cerebral syndrome</td><td>• Extensive periependymal lesion
• Long, diffuse, heterogenous, or edematous corpus callosum lesion
• Long corticospinal tract lesion
• Large, confluent subcortical or deep white matter lesion</td></tr>
</table>

</td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>

PNH

- Documented inadequate response, contraindication, or intolerance to ravulizumab-cwvz (Ultomiris)

aHUS

- Failure to respond to plasma therapy within 10 days
  - Trial of plasma therapy not required if one of the following is present:
    - Life-threatening complications of HUS such as seizures, coma, or heart failure
    - Confirmed presence of a high-risk complement genetic variant (e.g., CFH or CFI)
- Documented inadequate response, contraindication, or intolerance to ravulizumab-cwvz (Ultomiris)

gMG

- Documentation of one of the following:
  - Treatment failure with an adequate trial (one year or more) of at least 2 immunosuppressive therapies (azathioprine, mycophenolate, tacrolimus, cyclosporine, methotrexate)

</td></tr>
</table>

	○ Has required three or more courses of rescue therapy (plasmapheresis/plasma exchange and/or intravenous immunoglobulin), while on at least one immunosuppressive therapy, over the last 12 months • Documented inadequate response, contraindication, or intolerance to each of the following: ○ Efgartigimod-alfa (Vyvgart) ○ Ravulizumab-cwvz (Ultomiris) **NMOSD** • Documented inadequate response, contraindication, or intolerance to **ALL** of the following: ○ Rituximab (preferred products: Riabni, Ruxience, Truxima) ○ Satralizumab-mwge (Enspryng) ○ Inebilizumab-cdon (Uplizna) ○ Ravulizumab-cwvz (Ultomiris) **Reauthorization requires:** • gMG: documentation of treatment success defined as an improvement in MG-ADL and QMG scores from baseline • NMOSD: documentation of treatment success defined as the stabilization or improvement in neurological symptoms as evidenced by a decrease in acute relapses, Expanded Disability Status Scale (EDSS) score, hospitalizations, or plasma exchange treatments • PNH: documentation of treatment success defined as a decrease in serum LDH, stabilized/improved hemoglobin, decreased transfusion requirement, and reduction in thromboembolic events compared to baseline • aHUS: documentation of treatment success defined as a decrease in serum LDH, stabilized/improved serum creatinine, increased platelet count, and decreased plasma exchange/infusion requirement compared to baseline
Exclusion Criteria:	• Concurrent use with other disease-modifying biologics for requested indication, unless indicated by the FDA for combination use with Soliris • Current meningitis infection
Age Restriction:	• PNH, NMOSD: 18 years of age or older • gMG: 6 years of age and older • aHUS: 2 months of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist: ○ PNH: hematologist ○ aHUS: hematologist or nephrologist ○ gMG: neurologist ○ NMOSD: neurologist or neuro-ophthalmologist
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
EDARAVONE
Affected Medication: RADICAVA (edaravone), RADICAVA ORS (edaravone)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Amyotrophic lateral sclerosis (ALS)
Required Medical Information:	• Documentation of "definite" or "probable" ALS diagnosis based on revised El Escorial (Airlie House) or Awaji criteria • Disease duration of 2 years or less • Normal respiratory function (defined as percent-predicted forced vital capacity values [% FVC] of at least 80%) • Patient currently retains most activities of daily living (ADLs) defined as at least 2 points on all 12 items of the ALS functional rating scale-revised (ALSFRS-R)

Appropriate Treatment Regimen & Other Criteria:	For Radicava ORS requests:
	• Documented intolerable adverse event to Radicava (given intravenously) and the adverse event was not an expected adverse event attributed to the active ingredient
	
	• Reauthorization requires **both** of the following:
	  ○ Documentation of treatment success, as determined by prescriber (e.g., retention of most ADLs)
	  ○ Patient is not dependent on invasive mechanical ventilation (e.g., intubation, tracheostomy)

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or provider with experience in treating ALS
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ELADOCAGENE EXUPARVOVEC-TNEQ
Affected Medications: KEBILIDI (eladocagene exuparvovec-tneq)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of aromatic L-amino acid decarboxylase (AADC) deficiency

Required Medical Information:	• Diagnosis of AADC deficiency confirmed by genetic testing showing bilateral/biallelic mutations in the DDC gene
	• Reduced AADC enzyme activity in plasma
	• Cerebrospinal fluid (CSF) shows all the following:
	  ○ Reduced levels of 5-hydroxyindoleacetic acid (5-HIAA), homovanillic acid (HVA), and 3-methoxy-4-hydroxyphenylglycol (MHPG)
	  ○ Elevated levels of 3-O-methyldopa (3-OMD), levodopa (L-Dopa), and 5-hydroxytryptophan (5-HTP)
	  ○ Normal levels of pterins (neopterin and biopterin)
	• Clinical symptoms of AADC deficiency such as movement disorders, hypotonia, autonomic dysfunction, and developmental delay
	• Documented achieved skull maturity assessed by neuroimaging

Appropriate Treatment Regimen & Other Criteria:	• Dosing is in accordance with FDA labeling
Exclusion Criteria:	• Prior gene therapy administration • Anti-AAV2 neutralizing antibody titer over 1,200 folds
Age Restriction:	• 1 to 17 years of age
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist or geneticist
Coverage Duration:	• Authorization: 3 months, (one-time infusion only), unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ELAGOLIX
Affected Medications: Orilissa (elagolix), Oriahnn (elagolix/estradiol/norethindrone acetate)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Moderate to severe endometriosis-associated pain (Orilissa)
	  ○ Heavy menstrual bleeding associated with uterine leiomyomas (Oriahnn)

Required Medical Information:	**Pain due to endometriosis**
	• Documentation of both the following:
	  ○ Diagnosis of moderate to severe pain associated with endometriosis
	  ○ Attestation that patient is premenopausal
	
	Heavy menstrual bleeding due to uterine leiomyomas
	• Documentation of both the following:
	  ○ Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas
	  ○ Attestation that patient is premenopausal

Appropriate Treatment Regimen & Other Criteria:	**Pain due to endometriosis**
	• Documentation of a trial and inadequate relief (or contraindication) after at least 3 months of both of the following first-line therapies:
	  ○ Nonsteroidal anti-inflammatory drugs (NSAIDs)
	  ○ Continuous (no placebo pills) hormonal contraceptives
	
	Reauthorization requires documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• History of osteoporosis • Pregnancy • Severe (Child-Pugh Class C) hepatic impairment (Orilissa) • Mild, moderate, and severe (Child-Pugh Class A, B, and C) hepatic impairment (Oriahnn)
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a specialist in obstetrics/gynecology or reproductive endocrinology
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 18 months (Orilissa 150 mg once daily* and Oriahnn only), unless otherwise specified *Maximum treatment duration for Orilissa 150 mg once daily in patients with moderate hepatic impairment (Child-Pugh Class B) and Orilissa 200 mg twice daily is 6 months. Reauthorization not allowed.

PacificSource Community Solutions

POLICY NAME:
ELIVALDOGENE AUTOTEMCEL
Affected Medications: Skysona (elivaldogene autotemcel)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Early, active cerebral adrenoleukodystrophy (CALD) in male patients

Required Medical Information:	• Confirmed diagnosis of CALD with all of the following:
	  ○ Confirmed *ABCD1* gene mutation
	  ○ Elevated very-long-chain fatty acid (VLCFA) values for ALL of the following:
	  ▪ Concentration of C26:0
	  ▪ Ratio of C24:0 to C22:0
	  ▪ Ratio of C26:0 to C22:0
	  ○ Neurologic function score (NFS) less than or equal to 1 (asymptomatic or mildly symptomatic disease)
	  ○ Active central nervous system disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating both of the following:
	  ▪ Gadolinium enhancement on MRI of demyelinating lesions
	  ▪ Loes scores between 0.5 and 9 on the 34-point scale

Appropriate Treatment Regimen & Other Criteria:	• Coverage of Skysona is provided if the patient does not have access to a hematopoietic stem cell transplant with a matched sibling donor **Approved for one-time single infusion only**
Exclusion Criteria:	• Female gender • Previously received an allogeneic transplant or gene therapy
Age Restriction:	• 4 to 17 years of age
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist, endocrinologist, or hematologist/oncologist
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified (one infusion only)

PacificSource Community Solutions

POLICY NAME:
ELTROMBOPAG DERIVATIVES
Affected Medications: eltrombopag olamine, PROMACTA PACKET, ALVAIZ (eltrombopag choline)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of thrombocytopenia in patients with persistent or chronic immune thrombocytopenia (ITP)
	  ○ Treatment of thrombocytopenia in patients with hepatitis C infection
	  ○ Treatment of severe aplastic anemia

Required Medical Information:	**<u>Thrombocytopenia in patients with chronic ITP</u>**
	• Documentation of **ONE** of the following:
	  ○ Platelet count less than 20,000/microliter
	  ○ Platelet count less than 30,000/microliter AND symptomatic bleeding
	  ○ Platelet count less than 50,000/microliter AND increased risk for bleeding (such as peptic ulcer disease, use of antiplatelets or anticoagulants, history of bleeding at higher platelet count, need for surgery or invasive procedure)
	
	<u>Thrombocytopenia in patients with chronic hepatitis C</u>
	• Documentation of plan to initiate interferon-based therapy
	• Documentation of platelet count less than 75,000/microliter
	
	<u>Severe aplastic anemia</u>
	• Diagnosis confirmed by bone marrow biopsy
	• Documentation of at least two of the following:
	  ○ Absolute reticulocyte count (ARC) less than 60,000/microliter
	  ○ Platelet count less than 20,000/microliter
	  ○ Absolute neutrophil count (ANC) less than 500/microliter

Appropriate Treatment Regimen & Other Criteria:	• Promacta packet formulation requires documented medical inability to use oral tablet formulation
	
	<u>Thrombocytopenia in patients with persistent or chronic ITP</u>
	• Documentation of one of the following:
	  ○ Failure (defined as platelets did not increase to at least 50,000/microliter) with at least 2 therapies for immune thrombocytopenia, including corticosteroids or immunoglobulin
	  ○ Splenectomy
	
	Reauthorization:
	• Response to treatment with platelet count of at least 50,000/microliter (not to exceed 400, 000/microliter) **OR**
	• The platelet counts have not increased to a platelet count of at least 50,000/microliter and the patient has NOT been on the maximum dose for at least 4 weeks
	
	<u>Thrombocytopenia in patients with chronic hepatitis C</u>
	
	Reauthorization:
	• Response to treatment with platelet count of at least 90,000/microliter (not to exceed 400,000/microliter) and eltrombopag used in combination with antiviral therapy

	<u>Severe aplastic anemia</u> • Documentation of refractory severe aplastic anemia as indicated by insufficient response to at least one prior immunosuppressive therapy **OR** • For those less than 40 years old without a rapidly available matched related donor (MRD) or 40 years old or older: ○ Documentation that eltrombopag is being used as first line treatment in combination with standard immunosuppressive therapy (Atgam and cyclosporine) **Reauthorization (refractory severe aplastic anemia only):** Requires hematologic response to treatment defined as meeting **ONE** or more of the following criteria: • Platelet count increases to 20,000/microliter above baseline, or stable platelet counts with transfusion independence for a minimum of 8 weeks • Hemoglobin increases by greater than 1.5 g/dL, or a reduction in greater than or equal to 4 units red blood cell (RBC) transfusions for 8 consecutive weeks • ANC increase of 100% or an ANC increase greater than 500/microliter
Exclusion Criteria:	• Use in combination with another thrombopoietin receptor agonist, spleen tyrosine kinase inhibitor, or similar treatments (Nplate, Tavalisse, Doptelet)
Age Restriction:	**<u>Thrombocytopenia in patients with ITP</u>** • 1 year of age and older (eltrombopag olamine) • 6 years of age and older (Alvaiz) **<u>Thrombocytopenia in patients with chronic hepatitis C and patients with severe aplastic anemia</u>** • 18 years of age and older (eltrombopag olamine and Alvaiz) **<u>Severe Aplastic Anemia (initial therapy)</u>** • 2 years of age and older • 18 years of age and older (Alvaiz)
Prescriber Restrictions:	• Prescribed by, or consultation with, a hematologist or gastroenterology/liver specialist
Coverage Duration:	**<u>Thrombocytopenia in patients with ITP</u>** • Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified **<u>Thrombocytopenia in patients with chronic hepatitis C</u>** • Initial Authorization: 2 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified **<u>Severe aplastic anemia</u>** • Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified **<u>Severe aplastic anemia in combination with cyclosporine and Atgam</u>** • Approval: 6 months, no reauthorization, unless otherwise specified


PacificSource
Community Solutions

PacificSource Community Solutions

POLICY NAME:
EMICIZUMAB
Affected Medications: HEMLIBRA (Emicizumab-kxwh)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• Documented diagnosis of hemophilia A with or without inhibitors • Prescribed for routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Appropriate Treatment Regimen & Other Criteria:	• Baseline factor level less than 1% AND prophylaxis required OR
	• Baseline factor level 1% to 3% AND a documented history of at least two episodes of spontaneous bleeding into joints
	• Prophylactic agents must be discontinued
	  ○ Factor VIII Inhibitors: after the first week of HEMBLIRA
	  ○ Bypassing Agents: one day before starting HEMBLIRA
	
	Loading Dose:
	• 3 mg/kg once every week for 4 weeks
	  ○ Maximum 1,380 mg per 28 day supply
	
	Maintenance dose:
	• 1.5 mg/kg once every week **or**
	• 3 mg/kg once every 2 weeks **or**
	• 6 mg/kg once every 4 weeks
	• Any increases in dose must be supported by an acceptable clinical rationale (i.e. weight gain, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.)
	
	Product Availability:
	• Single-dose vials for injection: 30 mg/mL, 60 mg/0.4 mL, 105 mg/0.7 mL, 150 mg/mL
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization requires documentation of treatment success defined as a reduction in spontaneous bleeds requiring treatment, as well as documentation of bleed history since last approval

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Approval duration: 6 months, unless otherwise specified

POLICY NAME:
EMAPALUMAB
Affected Medications: GAMIFANT (emapalumab-lzsg)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of primary hemophagocytic lymphohistiocytosis (HLH) in patients (newborn and older) intolerant to conventional HLH therapy or with refractory, recurrent, or progressive disease
	  ○ Treatment of HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA) in patients (newborn and older) with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS

Required Medical Information:	• Documentation confirming status as a hematopoietic stem cell transplant (HSCT) candidate
	
	HLH
	• Diagnosis confirmed by presence of a genetic mutation known to cause primary HLH (e.g., PRF1, UNC13D, STX11, STXBP2) **OR** documentation showing at least 5 of the following are present:
	  ○ Prolonged fever (lasting over 7 days)
	  ○ Splenomegaly
	  ○ **Two** of the following cytopenias in the peripheral blood:
	  ▪ Hemoglobin less than 9 g/dL
	  ▪ Platelet count less than 100,000/mcL
	  ▪ Neutrophils less than 100 mcL
	  ○ **One** of the following:
	  ▪ Hypertriglyceridemia defined as fasting triglycerides 3 mmol/L or higher (equivalent to 265 mg/dL or higher)
	  ▪ Hypofibrinogenemia defined as fibrinogen 1.5 g/L or lower
	  ○ Hemophagocytosis in bone marrow, spleen, or lymph nodes (with no evidence of malignancy)
	  ○ Low or absent natural killer cell activity (according to local laboratory reference)
	  ○ Ferritin 500 mcg/L or higher
	  ○ Soluble CD25 (i.e., soluble IL-2 receptor) 2,400 U/ml or higher
	
	HLH with MAS
	• Diagnosis of HLH and documentation of active MAS in the setting of Adult Onset Still's disease or sJIA with ferritin levels greater than 684 ng/mL
	• Documentation showing at least 2 of the following are present:
	  ○ Platelet count is 181,000/mcL or lower
	  ○ AST is greater than 48 U/L
	  ○ Triglycerides is greater than 156 mg/dL
	  ○ Fibrinogen is 360 mg/dL or lowercell transplant (HSCT) candidate

Appropriate Treatment	**HLH** • Documentation of refractory, recurrent, or progressive disease (or intolerable adverse event) on conventional HLH therapy (e.g., dexamethasone, etoposide, methotrexate, hydrocortisone)

Regimen & Other Criteria:	• Must be used in combination with dexamethasone, unless currently established on and planning to continue one of the following: cyclosporine, glucocorticoids, and/or intrathecal methotrexate **HLH with MAS** • Documentation of refractory, recurrent, or progressive disease (or intolerable adverse event) on high dose intravenous glucocorticoids and Kineret (anakinra) • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization:** documentation of disease responsiveness to therapy AND patient has not yet received HSCT
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist, oncologist, transplant specialist, or provider with experience in the management of HLH
Coverage Duration:	• Initial Authorization: 2 months, unless otherwise specified • Reauthorization: 4 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ENDOTHELIN RECEPTOR ANTAGONISTS
Affected Medications: BOSENTAN (bosentan), AMBRISENTAN (ambrisentan), Tracleer suspension

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO) Group 1

Required Medical Information:	• Documentation of Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO) Group 1 confirmed by right heart catheterization meeting the following criterias:
	  ○ Mean pulmonary artery pressure of at least 20 mm Hg
	  ○ Pulmonary capillary wedge pressure less than or equal to 15 mm Hg AND
	  ○ Pulmonary vascular resistance of at least 2.0 Wood units
	• New York Heart Association (NYHA)/WHO Functional Class II or higher symptoms
	• Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blocker) unless there are contraindications:
	  ○ Low systemic blood pressure (systolic blood pressure less than 90)
	  ○ Low cardiac index OR
	  ○ Presence of severe symptoms (functional class IV)

Appropriate Treatment Regimen & Other Criteria:	• Documentation that the drug will be used in combination with a phosphodiesterase-5 (PDE-5) inhibitor • Documentation of inadequate response or intolerance to oral calcium channel blocking agents if postitive Acute Vasoreactivity Test • Requests for Tracleer oral suspension must have documented inability to swallow tablets **Reauthorization** requires documentation of treatment success defined as one or more of the following: • Improvement in exercise ability • Improvement in pulmonary function • Improvement or stability in WHO functional class
Exclusion Criteria:	
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ENTERAL NUTRITION/ORAL NUTRITION SUPPLEMENTS
Affected Medications: ENTERAL NUTRITION

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information:	**Enteral nutrition may be approved when one of the following is met:**
	• Documentation of chronic and permanent illness/trauma resulting in inability to be maintained through oral feeding and must rely on enteral/parenteral nutrition therapy. (i.e., permanent enteral/parenteral prosthetic device is required)
	• Documentation of functioning GI tract who, due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract (oral feeding), cannot maintain weight and strength commensurate with his/her general condition. (ex. head/neck cancer with reconstructive surgery and CNS disease leading to interference with the neuromuscular mechanism)
	• Documentation of use for training in the ketogenic diet for children with epilepsy in cases where the child has failed or not tolerated conventional therapy
	• Enteral access device (tube) is required to provide sufficient nutrients to maintain weight and strength otherwise not possible by dietary adjustments and/or oral supplements
	
	Oral nutritional supplements may be approved when the following criteria has been met:
	
	For those 21 years of age and older:
	• An assessment performed by a registered dietitian (RD) or treating practitioner, at onset and annually thereafter, documenting the client is unable to meet their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form
	• Documentation showing the prescribed oral nutritional formula and/or nutritional supplements are an integral part of treatment for a nutritional deficiency as identified by one of the following conditions:
	  ○ Diagnosed acute or chronic malnutrition
	  ○ Documentation of weight, either currently or historically, supported by oral nutritional supplements
	  ○ Increased metabolic need resulting from severe trauma
	  ○ Malabsorption difficulties (e.g., short-gut syndrome, fistula, cystic fibrosis, renal dialysis)
	  ○ Inborn errors of metabolism (e.g., fructose intolerance, galactosemia, maple syrup urine disease [MSUD], or phenylketonuria [PKU])
	  ○ Ongoing cancer treatment, advanced Acquired Immune Deficiency Syndrome (AIDS), or pulmonary insufficiency
	  ○ Oral aversion or other psychological condition making it difficult for a client to consume their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form
	
	For those under 21 years of age:

	• An assessment performed by a registered dietitian (RD) or treating practitioner, at onset and annually thereafter, documenting the prescribed nutritional formula and/or nutritional supplementation is medically necessary and appropriate as identified by one of the following:
	  ○ Diagnosed acute or chronic malnutrition
	  ○ Documentation of weight, either currently or historically, supported by oral nutritional supplements
	  ○ Increased metabolic need resulting from severe trauma
	  ○ Malabsorption difficulties (e.g., short-gut syndrome, fistula, cystic fibrosis, renal dialysis)
	  ○ Inborn errors of metabolism (e.g., fructose intolerance, galactosemia, maple syrup urine disease [MSUD], or phenylketonuria [PKU])
	  ○ Ongoing cancer treatment, advanced Acquired Immune Deficiency Syndrome (AIDS), or pulmonary insufficiency
	  ○ Oral aversion or other psychological condition making it difficult for a client to consume their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form
	  ○ Documentation showing the client is unable to meet their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form
	  ○ Malabsorption or other diagnosed medical condition which involves dietary restriction as part of the treatment, including but not limited to food allergy, Eosinophilic disorders (EoE), Food Protein Induced Enterocolitis (FPIES)
	  ○ Documented delayed growth or failure to thrive
	
	Reauthorization:
	A recent assessment (within the last year) by the prescriber or RD documenting the continued need for nutrition supplementation.

Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Initial approval: 12 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ENZYME REPLACEMENT THERAPY (ERT) FOR GAUCHER DISEASE TYPE 1
Affected Medications: CERDELGA (eliglustat), VPRIV (velaglucerase alfa), CEREZYME (imiglucerase), ELELYSO (taliglucerase alfa)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Vpriv: Gaucher disease type 1 (GD1)
	  ○ Elelyso: GD1 for ages 4 years and older
	  ○ Cerdelga: GD1 in adults who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test
	  ○ Cerezyme: GD1 for ages 2 years and older that results in one or more of the following conditions:
	  ▪ Anemia
	  ▪ Thrombocytopenia
	  ▪ Bone disease
	  ▪ Hepatomegaly or splenomegaly

Required Medical Information:	• Diagnosis confirmed by enzyme assay showing deficiency of beta-glucocerebrosidase glucosidase enzyme activity **OR** genetic testing indicating mutation of two alleles of the glucocerebrosidase genome
	  ○ For Cerdelga, must also have documentation of cytochrome P450 2D6 (CYP2D6) genotype by an FDA-approved test indicating CYP2D6 EM, IM, or PM status
	• Documentation of baseline tests such as hemoglobin level, platelet count, liver function tests, renal function tests
	• Documentation of at least one clinically significant disease complication of GD1:
	  ○ Anemia (low hemoglobin and hematocrit levels)
	  ○ Thrombocytopenia (platelet count less than 120,000 mm^3)
	  ○ Bone disease (T-score less than -2.5 or bone pain)
	  ○ Hepatomegaly or splenomegaly
	  ○ For symptomatic children: symptoms of early presentation, such as malnutrition, growth retardation, impaired psychomotor development, and/or fatigue

Appropriate Treatment Regimen & Other Criteria:	**Cerdelga** Extensive or Intermediate Metabolizers of CYP2D6 • Quantity limit - 84 mg capsules #60 per 30 days Poor Metabolizers of CYP2D6 • Quantity limit - 84 mg capsules #30 per 30 days **Elelyso, Vpriv, and Cerezyme** • Dosing is in accordance with FDA labeling and patient's most recent weight • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced

	Reauthorization will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Concomitant use with another ERT for GD1 or with miglustat **Cerdelga** • CYP2D6 ultrarapid metabolizers • Moderate or severe hepatic impairment • Pre-existing cardiac disease (congestive heart failure, myocardial infarction, bradycardia, heart block, arrhythmias,and long QT syndrome) • Presence of moderate to severe renal impairment or end stage renal disease
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a specialist in the management of Gaucher disease (hematologist, oncologist, hepatologist, geneticist or orthopedic specialist)
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
EPLONTERSEN, PATISIRAN, VUTRISIRAN
Affected Medications: WAINUA (eplontersen), ONPATTRO (patisiran), AMVUTTRA (vutrisiran)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of hereditary transthyretin amyloidosis with polyneuropathy (hATTR-PN) in adults
	  ○ Treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits

Required Medical Information:	**ATTR-CM (Amvuttra)**
	• Diagnosis of ATTR-CM supported by **ONE** of the following (a, b, or c):
	  a. Cardiac tissue biopsy confirms presence of ATTR amyloid deposits by immunohistochemistry (IHC) or mass spectrometry
	  b. Documentation of **BOTH** of the following (i and ii):
	  i. Noncardiac tissue biopsy confirms presence of ATTR amyloid deposits by IHC or mass spectrometry
	  ii. Imaging consistent with cardiac amyloidosis (echocardiogram [ECG], cardiac magnetic resonance [CMR], or positron emission tomography [PET])
	  c. Documentation of **ALL** the following (i, ii, and iii):
	  i. Grade 2 to 3 uptake on cardiac scintigraphy (utilizing Tc-PYP, Tc-DPD, or Tc-HMDP radiotracers)
	  ii. Normal serum kappa/lambda free light chain (sFLC) ratio, serum protein immunofixation, **AND** urine protein immunofixation
	  iii. Imaging consistent with cardiac amyloidosis (ECG, CMR, or PET)
	• Documentation of New York Heart Association (NYHA) Functional Class I to III
	
	ATTR-PN
	• Documented diagnosis of hATTR confirmed by **BOTH** of the following:
	  ○ Amyloid deposition on biopsy
	  ○ Presence of pathogenic transthyretin (TTR) variant on genetic testing
	• Presence of clinical manifestations of the disease, confirmed by presence of peripheral neuropathy on nerve conduction studies **OR** 2 of the following:
	  ○ Autonomic dysfunction (bladder/urinary tract infections, gastrointestinal disturbances, erectile dysfunction, orthostatic hypotension)
	  ○ Documented symptoms of sensorimotor polyneuropathy (e.g., paresthesia, balance issues, weakness/numbness in the hands/feet, or loss of sensation for pain, temperature, proprioception)
	  ○ Cardiomyopathy, ocular involvement, or renal involvement
	• Documentation of **ONE** of the following:
	  ○ Baseline polyneuropathy disability (PND) score of less than or equal to IIIb
	  ○ Baseline neuropathy impairment score (NIS) between 10 and 130
	  ○ Baseline familial amyloid polyneuropathy (FAP) stage 1 or 2

Appropriate Treatment	• **Amvuttra** requests require one of the following:
	  ○ ATTR-PN diagnosis
	  ○ ATTR-CM diagnosis only: treatment failure with Attruby (acoramidis) evidenced

Regimen & Other Criteria:	by worsening of heart failure signs/symptoms, increase in NYHA class, and increase in cardiovascular related hospitalizations • **Onpattro:** Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization:** **ATTR-CM (Amvuttra)** • Documentation of disease responsiveness (improvement in symptoms, quality of life, or 6-Minute Walk Test; slowing or stabilization of disease progression; reduced cardiovascular-related hospitalizations, etc.) **ATTR-PN** • Documentation of a positive clinical response (e.g., stabilized or improved neurologic impairment, motor function, cardiac function, quality of life assessment, serum TTR levels)
Exclusion Criteria:	• Prior or planned liver transplantation • NYHA Functional Class III or IV (Wainua) • NYHA Functional Class IV (Amvuttra) • Combined use with TTR-lowering or stabilizing therapy
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist or specialist experienced in the treatment of amyloidosis
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
EPOPROSTENOL
Affected Medications: EPOPROSTENOL, VELETRI (epoprostenol), FLOLAN (epoprostenol)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1

Required Medical Information:	**<u>Pulmonary arterial hypertension (PAH) WHO Group 1</u>**
	• Documentation of PAH confirmed by right-heart catheterization meeting the following criteria:
	  ○ Mean pulmonary artery pressure of at least 20 mm Hg
	  ○ Pulmonary capillary wedge pressure less than or equal to 15 mm Hg
	  ○ Pulmonary vascular resistance of at least 2.0 Wood units
	• New York Heart Association (NYHA)/World Health Organization (WHO) Functional Class III or higher symptoms
	• Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blockers) unless there are contraindications:
	  ○ Low systemic blood pressure (systolic blood pressure less than 90)
	  ○ Low cardiac index
	  ○ Presence of severe symptoms (functional class IV)
	• Documentation of current patient weight
	• Documentation of a clear treatment plan

Appropriate Treatment Regimen & Other Criteria:	• Documentation of inadequate response or intolerance to the following therapy classes is required:
	  ○ PDE5 inhibitors AND
	  ○ Endothelin receptor antagonists (exception WHO Functional Class IV)
	
	<u>Reauthorization</u> requires documentation of treatment success defined as one or more of the following:
	• Improvement in walking distance
	• Improvement in exercise ability
	• Improvement in pulmonary function
	• Improvement or stability in WHO functional class

Exclusion Criteria:	• Congestive heart failure due to severe left ventricular systolic dysfunction • Long-term use in patients who develop pulmonary edema during dose initiation
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
ERGOT ALKALOIDS
Affected Medications: Dihydroergotamine Mesylate Injection, Dihydroergotamine Mesylate Nasal Solution

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	• Documentation of moderate to severe migraines
Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure, intolerance, or contraindication to all the following: o At least **two** prescription strength non-steroidal anti-inflammatory drugs (NSAIDs) or combination analgesics (such as ibuprofen, naproxen, acetaminophen/aspirin/caffeine) o At least **one** oral 5-hydroxytryptamine-1 (5-HT_1) receptor agonist (such as sumatriptan, naratriptan, rizatriptan, zolmitriptan) o At least **one** non-oral 5-HT_1 receptor agonist (such as sumatriptan, zolmitriptan) **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Hemiplegic or basilar migraine • Uncontrolled hypertension • Ischemic heart disease (e.g., angina pectoris, history of myocardial infarction, history of silent ischemia) • Peripheral artery disease • Pregnancy or breastfeeding • Documented severe chronic liver disease • Severe renal impairment • Use in combination with 5HT1 receptor agonist such as sumatriptan
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ERYTHROPOIESIS STIMULATING AGENTS (ESAs)
Affected Medications: Epogen (epoetin alfa), Mircera (methoxy polyethylene glycol-epoetin beta), Procrit (epoetin alfa)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design **Epogen & Procrit & Mircera** • Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion **Epogen & Procrit** • Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy **Epogen & Procrit only** • To reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin greater than 10 to 13 or less g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery • Treatment of anemia due to zidovudine administered at ≤ 4200 mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL **Compendia-supported uses** • Symptomatic anemia in Myelodysplastic syndrome • Allogenic bone marrow transplantation • Anemia associated with Hepatitis C (HCV) treatment • Anemia associated with rheumatoid arthritis (RA)/ rheumatic disease
Required Medical Information:	• One of the following in accordance with FDA (Food and Drug Administration)-approved label or compendia support: ○ Anemia associated with chronic renal failure ○ Anemia secondary to chemotherapy with a minimum of two additional months of planned chemotherapy ○ Anemia secondary to zidovudine-treated Human Immunodeficiency Virus (HIV) patients ○ Anemia in patients scheduled to undergo elective, non-cardiac, nonvascular surgery ○ Symptomatic anemia in Myelodysplastic syndrome ○ Allogenic bone marrow transplantation ○ Anemia associated with Hepatitis C (HCV) treatment ○ Anemia associated with rheumatoid arthritis (RA)/ rheumatic disease
Appropriate Treatment Regimen & Other Criteria:	• Coverage for the non-preferred drugs (Epogen, Procrit, Mircera) is provided when any of the following criteria is met: • For Epogen or Procrit, a documented intolerable adverse event to the preferred product Retacrit, and the adverse event was not an expected adverse event attributed to the active ingredient • For Mircera, a documented inadequate response or intolerable adverse event to the preferred products, Aranesp & Retacrit • Currently receiving treatment with Mircera, excluding via samples or manufacturer's patient assistance programs
Exclusion Criteria:	• Use in combination with another erythropoiesis stimulating agent (ESA)
Age Restriction:	

Prescriber Restrictions:	• Must be prescribed by, or in consultation with, a specialist (hematologist, oncologist, nephrologist)
Coverage Duration:	• Approval: 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ETA RECEPTOR ANTAGONISTS
Affected Medications: FILSPARI (sparsentan), VANRAFIA (atrasentan)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression
Required Medical Information:	• Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed with biopsy • Documentation of proteinuria equal to or greater than 1 g/day (labs taken within 30 days of request) • Documented estimated glomerular filtration rate (eGFR) equal to or greater than 30 mL/min/1.73m^2

Appropriate Treatment Regimen & Other Criteria:	• Persistent proteinuria (greater than or equal to 1 g/day) despite a minimum 12-week trial with **each** of the following:
	  ○ Maximally tolerated angiotensin-converting enzyme (ACE) inhibitor **OR** angiotensin receptor II blocker (ARB)
	  ○ High dose glucocorticoid therapy, such as prednisone or methylprednisolone (or adverse effect with two or more glucocorticoid therapies, which is not associated with the corticosteroid class)
	• For Vanrafia requests: documented trial and failure of Filspari (sparsentan)
	
	Reauthorization requires documentation of treatment success, defined as reduction in proteinuria

Exclusion Criteria:	• Concurrent use of an endothelin A (ETA) receptor antagonist
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a nephrologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ETANERCEPT
Affected Medications: ENBREL SOLUTION, ENBREL KIT

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis
	  ○ Polyarticular Juvenile Idiopathic Arthritis
	  ○ Psoriatic Arthritis
	  ○ Ankylosing Spondylitis
	  ○ Non-radiographic axial spondyloarthritis
	  ○ Plaque Psoriasis
	  ○ Juvenile Psoriatic Arthritis

Required Medical Information:	**<u>Rheumatoid Arthritis</u>**
	• Documentation of current disease activity with one of the following (or equivalent objective scale):
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ The Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted RAPID3 of at least 2.3
	
	<u>Plaque Psoriasis</u>
	• Documentation that the skin disease is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DQLI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	AND
	• Documentation of one or more of the following:
	  ○ At least 10% body surface area involvement despite current treatment **OR**
	  ○ Hand, foot or mucous membrane involvement
	
	<u>Psoriatic Arthritis</u>
	• Documentation of CASPAR criteria score of 3 or greater based on chart notes:
	  ○ Skin psoriasis: present – two points, OR previously present by history – one point, OR a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxta-articular bone formation on radiographs (distinct from osteophytes): one point
	
	<u>Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (NR-axSPA)</u>
	• Diagnosis of axial spondyloarthritis (SpA) confirmed by Sacroiliitis on imaging AND at least 1 Spondyloarthritis (SpA) feature:
	  ○ Inflammatory back pain (4 of 5 features met):
	  ▪ Onset of back discomfort before the age of 40 years
	  ▪ Insidious onset
	  ▪ Improvement with exercise
	  ▪ No improvement with rest
	  ▪ Pain at night (with improvement upon arising)

	○ Arthritis ○ Enthesitis ○ Uveitis ○ Dactylitis (inflammation of entire digit) ○ Psoriasis ○ Crohn's disease/ulcerative colitis ○ Good response to NSAIDs ○ Family history of SpA ○ Elevated CRP **OR** ○ HLA-B27 genetic test positive AND at least TWO SpA features • Documentation of active disease defined by Bath ankylosing spondylitis disease activity index (BASDAI) at least 4 or equivalent objective scale **Polyarticular Juvenile Idiopathic Arthritis** • Documented current level of disease activity with physician global assessment (MD global score) or active joint count **Juvenile Psoriatic Arthritis (JPsA)** • Diagnosis of JPsA confirmed by presence of: ○ Arthritis and psoriasis **OR** ○ Arthritis and at least 2 of the following: ▪ Dactylitis ▪ Nail pitting or onycholysis ▪ Enthesitis ▪ Psoriasis in a first-degree relative
Appropriate Treatment Regimen & Other Criteria:	**Rheumatoid Arthritis** • Documented failure with at least 12 weeks of treatment with methotrexate ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ One of the following: Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis), tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV) **AND** ○ Two of the following: Olumiant, Kevzara, Simponi Aria, Actemra SQ, Kineret, rituximab (preferred biosimilar products Truxima, Riabni, and Ruxience), Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) **Plaque Psoriasis** • Documented treatment failure with 12 weeks of at least TWO systemic therapies: Methotrexate, Cyclosporine, Acitretin, Phototherapy [UVB, PUVA] • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **Psoriatic Arthritis** • Documented failure with at least 12 weeks of treatment with methotrexate

	○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Simponi Aria, Orencia IV, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **<u>Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (NR-axSPA)</u>** • Documented failure with two daily prescription strength nonsteroidal anti-inflammatory drugs (ibuprofen, naproxen, diclofenac, meloxicam, etc.) with minimum 1 month trial each **OR** • For peripheral arthritis: documented treatment failure with locally administered parenteral glucocorticoid • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of: ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Simponi Aria or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) **<u>Juvenile Idiopathic Arthritis</u>** • Documented failure with glucocorticoid joint injections or oral corticosteroids AND at least one of methotrexate or leflunomide for a minimum of 12 weeks • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of two of the following therapies: ○ tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV), Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), and Simponi Aria **<u>Juvenile Psoriatic Arthritis</u>** • Documented treatment failure with a nonsteroidal anti-inflammatory drug (ibuprofen, naproxen, diclofenac, meloxicam, etc.) with a minimum trial of 1 month • Documented treatment failure with at least one of the following disease-modifying antirheumatic drugs (DMARDs) with a minimum trial of 12 weeks: methotrexate, sulfasalazine, leflunomide **<u>QL:</u>** • Induction (Plaque Psoriasis only): 50mg twice weekly for first 3 months • Maintenance: 50mg once weekly **<u>Reauthorization</u>** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other biologic therapy or Otezla is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/dermatologist as appropriate for diagnosis

Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

POLICY NAME:
ETELCALCETIDE
Affected Medications: PARSABIV (etelcalcetide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Secondary hyperparathyroidism in adults with chronic kidney disease (CKD) on dialysis

Required Medical Information:	• Documentation of both of the following:
	  ○ Currently on dialysis
	  ○ Intact parathyroid (iPTH) level greater than 300 pg/mL
	• Documentation of iPTH that is persistently elevated above target range despite at least 12 weeks of adherent treatment with each of the following at an appropriate dose, unless contraindicated or not tolerated:
	  ○ Calcitriol
	  ○ Doxercalciferol
	  ○ Paricalcitol
	  ○ Cinacalcet

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Diagnosis of parathyroid carcinoma, primary hyperparathyroidism or with chronic kidney disease who are not on hemodialysis
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist or nephrologist
Coverage Duration:	• 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ETRANACOGENE
Affected Medications: Hemgenix

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Hemophilia B (congenital factor IX deficiency)

Required Medical Information:	• Documentation of diagnosis of Hemophilia B
	• Documentation of current negative inhibitor testing and history defined as two tests in the last five years separated by at least 12 months
	• Documentation of baseline circulating level of factor IX less than or equal to 2% AND requiring prophylactic treatment
	• Baseline lab values (less than 2 times upper limit of normal):
	  ○ ALT
	  ○ AST
	  ○ Total bilirubin
	  ○ Alkaline phosphatase (ALP)
	  ○ Creatinine

Appropriate Treatment Regimen & Other Criteria:	**<u>Dosing</u>** • 2×10^{13} genome copies (gc) per kilogram of body weight
Exclusion Criteria:	• History or current presence of IX inhibitors • Prior gene therapy administration • Active Hepatitis B or C infection or uncontrolled HIV • Life expectancy less than 1 year due to other advanced medical conditions
Age Restriction:	• Ages 18 and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation, with a hematologist or specialist with experience in treatment of hemophilia
Coverage Duration:	• Initial Authorization: 2 months (one-time infusion)

POLICY NAME:
EVKEEZA
Affected Medications: EVKEEZA (evinacumab-dgnb)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Homozygous familial hypercholesterolemia (HoFH)

Required Medical Information:	• Documentation of baseline untreated low-density lipoprotein cholesterol (LDL-C)
	• Diagnosis confirmed by **ONE** of the following:
	  ○ Baseline LDL-C greater than 560 mg/dL
	  ○ Baseline LDL-C of 400 mg/dL and at least 1 parent with familial hypercholesterolemia
	  ○ Baseline LDL-C of 400 md/dL with aortic valve disease or xanthomata in ages less than 20 years
	  ○ Presence of two abnormal LDL-C-raising gene defects (excluding double-null LDL receptor [LDLR] mutations)

Appropriate Treatment Regimen & Other Criteria:	• Documented intent to take alongside maximally tolerated doses of statin and/or ezetimibe, unless otherwise contraindicated
	OR
	• History of statin intolerance requires documentation of **ONE** of the following:
	  ○ Statin-associated rhabdomyolysis occurred with statin use and was confirmed by a creatinine kinase (CK) level at least 10 times the upper limit of normal
	  ○ Statin-associated muscle symptoms (e.g., myopathy, myalgia) occurred with statin use and was confirmed by **BOTH** of the following:
	  ▪ A minimum of three different statin trials, with at least one being a hydrophilic statin (rosuvastatin, pravastatin)
	  ▪ A re-challenge of each statin (muscle symptoms stopped when each was discontinued and restarted upon re-initiation)
	• Documented treatment failure, defined as an inability to achieve LDL-C reduction of 50% or greater **OR** LDL-C less than 100 mg/dL, despite at least six months of adherent therapy with all the following, unless contraindicated or not tolerated:
	  ○ Maximally tolerated statin therapy
	  ○ Ezetimibe
	  ○ PCSK9 monoclonal antibody unless double-null or LDLR activity 15% or less
	• Dose rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization: Documentation of treatment success and a clinically significant response to therapy defined by an LDL-C level at goal or decreased by at least 30% from baseline

Exclusion Criteria:	
Age Restriction:	• 5 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist, cardiologist, or lipid specialist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
EXAGAMGLOGENE AUTOTEMCEL
Affected Medications: CASGEVY (exagamglogene autotemcel)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of sickle cell disease in adults and pediatric patients at least 12 years of age with recurrent vaso-occlusive crises
	  ○ Treatment of transfusion-dependent beta-thalassemia in adults and pediatric patients at least 12 years of age

Required Medical Information:	**<u>SICKLE CELL DISEASE</u>**
	• Documentation of sickle cell disease confirmed by genetic testing to show the presence of βS/βS, βS/β0 or βS/β+ genotype as follows:
	  ○ Identification of significant quantities of HbS with or without an additional abnormal β-globin chain variant by hemoglobin assay
	  OR
	  ○ Identification of biallelic *HBB* pathogenic variants where at least one allele is the p.glu6Val or p.glu7val pathogenic variant on molecular genetic testing
	  AND
	  ○ Patient does NOT have disease with more than two α-globin gene deletions
	
	• Documentation of severe disease defined as 2 or more severe vaso-occlusive crises (VOCs) or vaso-occlusive events (VOEs) within the previous 1 years (4 events over 2 years will also meet this requirement)
	  ○ VOC/VOEs defined as:
	  ▪ Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or IV NSAIDs) or RBC transfusions
	  ▪ Acute chest Syndrome
	  ▪ Priapasm lasting more than 2 hours and requiring visit to medical facility
	  ▪ Splenic Sequestration
	
	• Clinically stable and eligible to undergo hematopoietic stem cell transplant (HSCT) but unable to find a human leukocyte antigen (HLA) matched, related donor
	• Adequate bone marrow, lung, heart and liver function to undergo myeloablative conditioning regimen
	
	<u>TRANSFUSION DEPENDENT BETA THALASSEMIA</u>
	• Documented diagnosis of homozygous beta thalassemia or compound heterozygous beta thalassemia including β-thalassemia/hemoglobin E (HbE) (excludes alpha-thalassemia and hemoglobin S/ß-thalassemia variants) as outlined by the following:
	  ○ Patient diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants
	  OR
	  ○ Patient has severe microcytic hypochromic anemia, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A and increased amounts of hemoglobin F
	• Documented transfusion-dependent disease defined as a history of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs) or with 10 or more transfusions of pRBCs *per year* in the 2 years preceding therapy

	• Clinically stable and eligible to undergo hematopoietic stem cell transplant (HSCT) but unable to find a human leukocyte antigen (HLA) matched, related donor
Appropriate Treatment Regimen & Other Criteria:	• Must weigh a minimum of 6 kilograms and able to provide a minimum number of cells (3,000,000 CD34+ cells/kg) • Documentation that cardiac iron overload has been evaluated and there is no evidence of severe iron overload. (cardiac T2* less than 10 msec by magnetic resonance imaging [MRI] or left ventricular ejection fraction [LVEF] less than 45% by echocardiogram) • No evidence of advanced liver disease [i.e., AST or ALT more than 3 times the upper limit of normal (ULN), or direct bilirubin value more than 2.5 times the ULN, or if a liver biopsy demonstrated bridging fibrosis or cirrhosis]
Exclusion Criteria:	• Prior HSCT or other gene therapy
Age Restriction:	• Ages 12 and above
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 6 months (one time infusion), unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
FABRY DISEASE AGENTS
Affected Medications: ELFABRIO (pegunigalsidase alfa), FABRAZYME (agalsidase beta), GALAFOLD (migalastat)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Fabry disease

Required Medical Information:	• Diagnosis of Fabry disease confirmed by one of the following:
	  ○ Males: enzyme assay demonstrating undetectable (less than 3 percent) alpha-galactosidase A enzyme activity
	  ○ Males: deficiency of alpha-galactosidase A enzyme activity(less than 35 percent) and genetic testing showing a mutation in the galactosidase alpha (GLA) gene
	  ○ Females: genetic testing showing a mutation in the GLA gene
	• For Galafold: Genetic testing confirming the presence of at least one amenable GLA variant
	
	• Clinical signs and symptoms of Fabry disease, such as:
	  ○ Severe neuropathic pain
	  ○ Dermatologic manifestations (telangiectasias and angiokeratomas)
	  ○ Corneal opacities
	  ○ Kidney manifestations (proteinuria, polyuria, polydipsia)
	  ○ Cardiac involvement (left ventricular hypertrophy, myocardial fibrosis, heart failure)
	  ○ Cerebrovascular involvement (transient ischemic attacks, ischemic strokes)
	  ○ Other manifestations common in Fabry disease (sweating abnormalities, hearing loss, or intolerance to heat, cold, or exercise)

Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with another agent on this policy (Galafold or enzyme replacement therapy for Fabry disease) • For Galafold: Severe renal impairment (eGFR less than 30) or end-stage renal disease requiring dialysis
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a geneticist or specialist experienced in the treatment of Fabry disease
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
FDA APPROVED DRUG – MEDICAL NECESSITY

Covered Uses:	• Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information:	• **For age 20 or younger and Young Adults with Special Health Care Needs (YSHCN):**
	• Medications used to treat a condition are covered by PacificSource Community Solutions if treatment is medically necessary, per the Early and Periodic Screening, Diagnostic and Treatment Program (EPSDT)
	
	• **For all other members:**
	• Medications used to treat an unfunded condition are **not** covered by PacificSource Community Solutions unless it can be shown that:
	  ○ The unfunded condition is causing or exacerbating a medically related funded condition AND
	  ○ Treating the unfunded condition would significantly improve the outcome of treating the medically related funded condition
	
	Definitions:
	• **Unfunded condition** is a condition that is below the Oregon Health Authority (OHA)-funded line of the Prioritized List of Health Services
	• **Funded condition** is a condition that is above the OHA-funded line of the Prioritized List of Health Services
	
	To review the line as well as examine guidelines to see if patient meets certain criteria for approval, please refer to the following website: https://intouch.pacificsource.com/LineFinder/

Appropriate Treatment Regimen & Other Criteria:	• Drug must be dosed according to package insert requirements • Documented intolerance or treatment failure with all formulary alternatives for the submitted diagnosis • Diagnostic criteria for the submitted diagnosis is met based on established guidelines or compendia • The submitted diagnosis is for a funded condition or treatment is considered medically necessary under EPSDT or YSCHN
Exclusion Criteria:	• Exclusion based on package insert requirements
Age Restriction:	• Age based on package insert requirements
Prescriber Restrictions:	• Prescriber restrictions based on package insert requirements
Coverage Duration:	• Case by case

PacificSource Community Solutions

POLICY NAME:
FDA APPROVED DRUG – Drug or Indication Not Yet Reviewed By Plan for Formulary Placement
Affected Medications: New Medications, Formulations, or Indications of Existing Drugs that are Under Review by Plan for Formulary Placement

Covered Uses:	• Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	• Documentation of disease state, level of control, and therapies failed • Documentation of failure with all available formulary products for treatment of disease state • Documentation that a delay in treatment will cause loss of life, limb, function or other extreme pain
Appropriate Treatment Regimen & Other Criteria:	• Drug must be dosed according to package insert requirements
Exclusion Criteria:	• Exclusion based on package insert requirements
Age Restriction:	• Age based on package insert requirements
Prescriber Restrictions:	• Prescribed by, or in consultation with, a provider experienced in the management of the diagnosis
Coverage Duration:	• Case by case based on member need

PacificSource Community Solutions

POLICY NAME:
FECAL MICROBIOTA
Affected Medications: REBYOTA (fecal microbiota, live-jslm), VOWST (fecal microbiota spores, live-brpk)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Prophylaxis of *Clostridioides difficile* (C.diff) infection recurrence following antibiotic treatment

Required Medical Information:	• Documentation confirming a current diagnosis of recurrent C.diff infection (CDI) with a history of at least 2 recurrent episodes (initial episode + a minimum of 2 recurrences)
	  ○ Recurrent CDI is defined as a resolution of CDI symptoms while on appropriate therapy, followed by a reappearance of symptoms within 8 weeks of discontinuing treatment
	• Current episode of CDI must be controlled (less than 3 unformed or loose stools per day for 2 consecutive days)
	• Administration will occur following completion of antibiotic course for CDI treatment
	  ○ Within 24 to 72 hours for Rebyota
	  ○ Within 2 to 4 days for Vowst
	• Positive stool test for C. diff within 30 days prior to request

Appropriate Treatment Regimen & Other Criteria:	**<u>Rebyota</u>** • Previous treatment with at least **two** of the following in the setting of CDI recurrence: Oral vancomycin, fidaxomicin (Dificid), or fecal microbiota transplant (FMT) **<u>Vowst</u>** • Previous treatment with at least **two** of the following in the setting of CDI recurrence: Oral vancomycin, fidaxomicin (Dificid), or FMT • Documented treatment failure with Rebyota
Exclusion Criteria:	• Retreatment with Rebyota or Vowst
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist or gastroenterologist
Coverage Duration:	• Authorization: 1 month with no reauthorization

PacificSource Community Solutions

POLICY NAME:
FENFLURAMINE
Affected Medications: FINTEPLA (fenfluramine)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of seizures associated with Dravet syndrome (DS)
	  ○ Treatment of seizures associated with Lennox-Gastaut syndrome (LGS)

Required Medical Information:	• Documented diagnosis of Dravet syndrome (DS) or Lennox-Gastaut Syndrome (LGS) • Current weight • Documentation that therapy is being used as adjunct therapy for seizures **Dravet Syndrome** • Documentation of at least 6 convulsive seizures in the last 6 weeks while on stable antiepileptic drug therapy **Lennox-Gastaut Syndrome (LGS)** • Documentation of at least 8 drop seizures per month while on stable antiepileptic drug therapy

Appropriate Treatment Regimen & Other Criteria:	**Dravet Syndrome**
	• Documented treatment and inadequate control of seizures with Epidiolex **AND** at least four of the following therapies:
	  ○ Valproate, clobazam, clonazepam, levetiracetam, zonisamide or topiramate
	
	Lennox-Gastaut Syndrome (LGS)
	• Documented treatment and inadequate control of seizures with Epidiolex **AND** at least three guideline directed therapies including:
	  ○ Valproate, lamotrigine, rufinamide, topiramate, felbamate, or clobazam
	
	Dosing: not to exceed 26 mg daily
	
	Reauthorization: documentation of treatment success and a reduction in seizure severity, frequency, or duration

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
FIDAXOMICIN
Affected Medications: DIFICID (fidaxomicin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ *Clostridioides difficile*-associated diarrhea

Required Medical Information:	• Documented diagnosis of *C. difficile* infection (CDI) with associated diarrhea, confirmed by **all** the following:
	  ○ Enzyme immunoassay positive for toxin A/B
	  ○ Positive GDH antigen test or nucleic acid amplification test (NAAT)
	  ○ Greater than 3 unformed bowel movements in 24 hours

Appropriate Treatment Regimen & Other Criteria:	• Documentation of at least one trial/failure of an appropriate oral vancomycin regimen for CDI in the previous 6 months
	• At least one of the following risk factors for recurrent or severe CDI:
	  ○ Age greater than 65 years
	  ○ Healthcare-associated CDI
	  ○ Severe underlying medical disorders
	  ○ Immunocompromised status
	  ○ Clinically severe CDI (as defined by Zar score greater than or equal to 2)
	
	Reauthorization:
	• Documentation of current active CDI with associated diarrhea
	• Documentation of past treatment success with fidaxomicin, defined as symptom resolution at the end of treatment course

Exclusion Criteria:	• Asymptomatic colonization with *C. difficile*
Age Restriction:	• 6 months of age and older
Prescriber/Site of Care Restrictions:	
Coverage Duration:	Initial Authorization: 14 days, unless otherwise specified Reauthorization: 14 days, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
FINERENONE
Affected Medications: KERENDIA (finerenone)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Chronic kidney disease (CKD) associated with type 2 diabetes (T2DM) to reduce the risk of:
	  ▪ Sustained estimated glomerular filtration rate (eGFR) decline
	  ▪ End-stage kidney disease
	  ▪ Cardiovascular death
	  ▪ Non-fatal myocardial infarction
	  ▪ Hospitalization for heart failure
	  ○ Heart failure with left ventricular ejection fraction (LVEF) greater than or equal to 40% to reduce the risk of:
	  ▪ Cardiovascular death
	  ▪ Hospitalization for heart failure
	  ▪ Urgent heart failure visits

Required Medical Information:	**<u>CKD associated with T2DM</u>**
	• Documentation of all the following:
	  ○ eGFR greater than or equal to 25 mL/min/1.73 m^2
	  ○ Urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g
	  ○ Serum potassium level less than or equal to 5.0 mEq/L
	
	<u>Heart Failure with LVEF greater than or equal to 40%</u>
	• Documentation of all the following:
	  ○ Heart failure with left ventricular ejection fraction (LVEF) of 40% or more
	  ○ eGFR greater than or equal to 25 mL/min/1.73 m^2
	  ○ Serum potassium level less than or equal to 5.0 mEq/L

Appropriate Treatment Regimen & Other Criteria:	**<u>CKD associated with T2DM</u>**
	• Currently receiving maximally tolerated dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), unless intolerant or contraindicated
	• Documented treatment failure or intolerable adverse event to at least 12 weeks of sodium-glucose cotransporter 2 (SGLT2) inhibitor therapy, such as dapagliflozin
	
	<u>Heart Failure with LVEF greater than or equal to 40%</u>
	• Documented treatment failure or intolerable adverse event to at least 12 weeks of each of the following, unless intolerant or contraindicated:
	  ○ Sodium-glucose cotransporter 2 (SGLT2) inhibitor therapy, such as dapagliflozin
	  ○ Mineralocorticoid receptor antagonist (MRA) therapy, such as spironolactone or eplerenone
	
	<u>Reauthorization</u> requires documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a nephrologist, endocrinologist, or cardiologist

PacificSource Community Solutions

Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
FITUSIRAN
Affected Medications: QFITLIA (fitusiran)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with:
	  ▪ Hemophilia A (congenital factor VIII deficiency) or
	  ▪ Hemophilia B (congenital factor IX deficiency)

Required Medical Information:	• Diagnosis of FVIII deficiency (hemophilia A) or FIX deficiency (hemophilia B) • Documentation of baseline factor level less than 1% AND prophylaxis required OR • Baseline factor level 1% to 3% and a documented history of at least two episodes of spontaneous bleeding into joints • Prescribed for routine prophylaxis to prevent or reduce the frequency of bleeding episodes • Documentation of inhibitor status • Documentation of antithrombin (AT) activity over 60% prior to treatment initiation and documentation of planned follow-up and monitoring of antithrombin (AT) activity to adjust dose • Number of bleeds in the past 3 months with severity and cause of bleed • Documentation of current weight
Appropriate Treatment Regimen & Other Criteria:	• **Hemophilia A**: Documentation treatment failure or contraindication to factor VIII prophylaxis with 1 or more preferred therapies: Advate, Adynovate, Eloctate, Altuviiio, Kogenate FS, Kovaltry, Novoeight, Jivi (with bypassing agent if inhibitors are present) OR Hemlibra or Hympavzi • **Hemophilia B**: Documentation treatment failure or contraindication to factor IX prophylaxis with 1 or more preferred therapies: Rixubus, BeneFIX, Alprolix, Idelvion, Rebinyn (with bypassing agent if inhibitors are present) OR Hympavzi • Prophylactic agents must be discontinued **<u>Reauthorization:</u>** • Documentation of bleeding episodes (number and severity) showing reduction in spontaneous bleeds requiring treatment • Documentation of antithrombin (AT) activity at 15%–35% and clinical benefit
Exclusion Criteria:	
Age Restriction:	• 12 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
FLUCYTOSINE
Affected Medications: FLUCYTOSINE

Covered Uses:	• All Food and Drug Administration (FDA)-approved or compendia supported indications not otherwise excluded by plan design
	  ○ Treatment of systemic Candida infections
	  ▪ Cardiac infection, native or prosthetic valve endocarditis, or device infection
	  ▪ Central nervous system (e.g., meningitis)
	  ▪ Endophthalmitis
	  ▪ Urinary tract infection (symptomatic cystitis, pyelonephritis)
	  ○ Treatment of systemic Cryptococcus infections
	  ▪ Meningitis
	  ▪ Disseminated disease
	  ▪ Severe pulmonary infection

Required Medical Information:	• Susceptibility cultures matching flucytosine activity • Candida urinary tract infection: Documentation of fluconazole-resistant C. glabrata • Endophthalmitis: Documentation of fluconazole- or voriconazole-resistant isolates
Appropriate Treatment Regimen & Other Criteria:	• FDA-approved or compendia supported dose, frequency, and duration of therapy
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an Infectious Disease specialist
Coverage Duration:	• Approval: 8 weeks, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
FOSTAMATINIB
Affected Medications: TAVALISSE (fostamatinib)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment

Required Medical Information:	**Thrombocytopenia in patients with chronic ITP**
	• Documentation of **ONE** of the following:
	  ○ Platelet count less than 20,000/microliter
	  ○ Platelet count less than 30,000/microliter AND symptomatic bleeding
	  ○ Platelet count less than 50,000/microliter AND increased risk for bleeding (such as peptic ulcer disease, use of antiplatelets or anticoagulants, history of bleeding at higher platelet count, need for surgery or invasive procedure)

Appropriate Treatment Regimen & Other Criteria:	**Thrombocytopenia in patients with chronic ITP**
	• Documentation of inadequate response, defined as platelets did not increase to at least 50,000/microliter, to the following therapies:
	  ○ **ONE** of the following:
	  ▪ Inadequate response with at least 2 therapies for immune thrombocytopenia, including corticosteroids, rituximab, or immunoglobulin
	  ▪ Splenectomy
	  ○ eltrombopag olamine
	Reauthorization requires response to treatment with platelet count of at least 50,000/microliter or above (not to exceed 400,000 microliter)

Exclusion Criteria:	• Use in combination with a thrombopoietin receptor agonist, spleen tyrosine kinase inhibitor, or similar treatment for thrombocytopenia (such as eltrombopag olamine, Doptelet, or Nplate)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
FLUOCINOLONE OCULAR IMPLANT
Affected Medications: ILUVIEN, RETISERT, YUTIQ (fluocinolone acetonide intravitreal implant)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Diabetic macular edema (DME)
	  ○ Chronic, non-infectious posterior uveitis

Required Medical Information:	**<u>Iluvien (DME)</u>** • Diagnosis of clinically significant diabetic macular edema • Documentation of past treatment with corticosteroids without a clinically significant rise in intraocular pressure **<u>Retisert, Iluvien and Yutiq (Uveitis)</u>** • Diagnosis of chronic, non-infectious posterior uveitis confirmed by slit lamp and fundoscopic examination

Appropriate Treatment Regimen & Other Criteria:	**<u>Iluvien (DME)</u>**
	• Documentation of inadequate response or intolerance to an intravitreal vascular endothelial growth factor (VEGF) inhibitor (preferred products: Avastin, Byooviz, Lucentis)
	• Documentation of inadequate response to laser photocoagulation
	
	<u>Retisert, Iluvien and Yutiq</u>
	• Documentation of inadequate response or intolerance to all of the following:
	  ○ Minimum 12-week trial with oral systemic corticosteroid
	  ○ At least one corticosteroid-sparing immunosuppressive therapy (methotrexate, azathioprine, or mycophenolate mofetil)
	  ○ At least one calcineurin inhibitor (cyclosporine, tacrolimus)
	• **Retisert:** Documentation of treatment failure with Yutiq

Exclusion Criteria:	• Active or suspected ocular or periocular infections • Concurrent use of intravitreal implants and injections (corticosteroid, anti-VEGF) • **Iluvien:** Glaucoma (with cup to disc ratios greater than 0.8)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an ophthalmologist
Coverage Duration:	**Iluvien:** 36 months, unless otherwise specified **Retisert:** 30 months, unless otherwise specified **Yutiq:** 36 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
FUMARATES FOR MULTIPLE SCLEROSIS
Affected Medications: BAFIERTAM (monomethyl fumarate), VUMERITY (diroximel fumarate)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following:
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)

Required Medical Information:	**MS** • Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS
Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure with (or intolerance to) **TWO** of the following: dimethyl fumarate, fingolimod, teriflunomide **Reauthorization** requires provider attestation of treatment success
Exclusion Criteria:	• Concurrent use of other disease-modifying medications indicated for the treatment of MS
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Authorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
FYARRO
Affected Medications: FYARRO (nab-sirolimus)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course

Appropriate Treatment Regimen & Other Criteria:	**Perivascular Epithelioid Cell Tumor (PEComa)**
	• Presence of malignant locally advanced unresectable or metastatic disease confirmed by pathology.
	• History of intolerable adverse event with trial of each of the following agents:
	  ○ Sirolimus oral tablet
	  ○ Everolimus or temsirolimus
	
	Reauthorization: documentation of disease responsiveness to therapy

Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • History of disease progression with prior mechanistic target of rapamycin (mTOR) inhibitor treatment.
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 4 months • Reauthorization: 12 months

POLICY NAME:
GIVOSIRAN
Affected Medications: GIVLAARI (givosiran)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of adults with acute hepatic porphyria (AHP)
Required Medical Information:	• Documentation of elevated urine porphobilinogen (PBG) levels based on specific lab test utilized • Diagnosis confirmed based on Porphyria Genomic testing • Documentation of baseline acute attack frequency • Evaluation for avoidance of exacerbating factors of porphyria attacks, including certain medications, smoking, drinking, and infections
Appropriate Treatment Regimen & Other Criteria:	• Documentation of active disease defined as at least 2 documented porphyria attacks within the last six months which can include hospitalization, urgent healthcare visits, or requiring intravenous Hemin administration • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** will require documentation of a positive clinical response and a reduction in acute attack frequency from baseline
Exclusion Criteria:	• Active HIV, Hepatitis C, or Hepatitis B infection(s) • History of Pancreatitis • Concomitant use with prophylactic hemin • History of liver transplant
Age Restriction:	• Greater than or equal to 18 years of age
Prescriber Restrictions:	• Prescribed by, or in consultation with, physicians that specialize in the treatment of acute hepatic porphyria
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
GLATIRAMER
Affected Medications: GLATIRAMER, GLATOPA

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following:
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)

Required Medical Information:	**MS** • Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS
Appropriate Treatment Regimen & Other Criteria:	• Documentation of dose and frequency as the 20 mg/mL and 40 mg/mL formulations are not interchangeable **Reauthorization** requires provider attestation of treatment success
Exclusion Criteria:	• Concurrent use of other disease-modifying medications indicated for the treatment of MS
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Authorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
GLUCAGON-LIKE PEPTIDE-1 AGONISTS (DIABETES)
Affected Medications: BYETTA Subcutaneous (Exenatide), BYDUREON Subcutaneous (Exenatide), BYDUREON BCise Subcutaneous (Exenatide), OZEMPIC (semaglutide), Liraglutide Subcutaneous, TRULICITY Subcutaneous (dulaglutide)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus (T2DM)
	  ○ To reduce risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with T2DM and chronic kidney disease (CKD)

Required Medical Information:	**T2DM**
	• Diagnosis of Type 2 diabetes
	• A recent hemoglobin A1c greater than or equal to 7%
	
	CKD and T2DM (Ozempic)
	• Diagnosis of CKD and T2DM at risk of progression with one of the following:
	  ○ Estimated glomerular filtration rate (eGFR) greater than 50 mL/min/1.73m^2 **AND** Urine Albumin-to-Creatinine Ratio (UACR) greater than 300 mg/g
	  ○ eGFR 25 to less than 50 mL/min/1.73m^2 **AND** UACR greater than 100 mg/g
	
	T2DM with Metabolic dysfunction–associated steatohepatitis (MASH):
	• Diagnosis of Type 2 diabetes
	• Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or MASH with moderate to advanced (F2 to F3) liver fibrosis confirmed by ONE of the following:
	  ○ Conclusive result from a well-validated non-invasive test such as:
	  ▪ Fibroscan-AST (FAST) score
	  ▪ MAST (score from MRI–proton density fat fraction, Magnetic resonance elastography [MRE], and serum AST)
	  ▪ MEFIB (Fibrosis-4 Index greater than or equal to 1.6 and MRE greater than or equal to 3.3 kPa)
	  ○ Liver biopsy (also required if non-invasive testing is inconclusive or other causes for liver disease have not been ruled out)
	• Other causes for liver steatosis have been ruled out (such as alcohol-associated liver disease, chronic hepatitis C, Wilson disease, drug-induced liver disease)
	• Baseline lab values for AST and ALT

Appropriate Treatment Regimen & Other Criteria:	**Ozempic, Trulicity, Bydureon, Byetta (T2DM New Starts)** Documentation of one of the following: • Inadequate treatment response following a minimum 12-week trial of liraglutide • Evidence of adverse effect with liraglutide (not attributable to the GLP-1 class) after an adequate dose titration **T2DM and CKD (Ozempic)** • Documentation of being on a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) for at least 4 weeks • Documented treatment failure or adverse event with one Sodium-Glucose Cotransporter 2 (SGLT2) inhibitor such as: dapagliflozin

	<u>T2DM with MASH:</u>
	• Documentation of abstinence from alcohol consumption
	• Documentation of comprehensive comorbidity management being undertaken, including all the following:
	  ○ Use of diet and exercise for weight management
	  ○ Medications to manage associated comorbid conditions, such as thyroid disease (must not have active disease), diabetes, dyslipidemia, hypertension, or cardiovascular conditions
	
	<u>Reauthorization:</u>
	• Documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Weight Loss
Age Restriction:	• Byetta, Bydureon, liraglutide and Trulicity – greater than or equal to 10 years • Ozempic – greater than or equal to 18 years
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
GLUCAGON-LIKE PEPTIDE-1 AGONISTS (non-diabetic indications)
Affected Medications: SAXENDA (liraglutide), WEGOVY (semaglutide), ZEPBOUND (tirzepatide)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design

Required Medical Information:	**Major Adverse Cardiovascular Event (MACE) Risk Reduction (Wegovy only):**
	• Documented history of prior cardiovascular event defined as one of the following:
	  ○ Myocardial infarction
	  ○ Stroke (ischemic or hemorrhagic stroke)
	  ○ Symptomatic peripheral artery disease (PAD) such as intermittent claudication with ankle-brachial index (ABI) less than 0.85 at rest, or history of peripheral arterial revascularization procedure
	• Body mass index (BMI) of 27 kg/m^2 or greater
	• Used in combination with caloric restriction (diet), increased physical activity, and behavioral modification
	
	Metabolic dysfunction-associated steatohepatitis (MASH) (Wegovy only):
	• Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or MASH with moderate to advanced (F2 to F3) liver fibrosis confirmed by ONE of the following:
	  ○ Conclusive result from a well-validated non-invasive test such as:
	  ▪ Fibroscan-AST (FAST) score
	  ▪ MAST (score from MRI–proton density fat fraction, Magnetic resonance elastography [MRE], and serum AST)
	  ▪ MEFIB (Fibrosis-4 Index greater than or equal to 1.6 and MRE greater than or equal to 3.3 kPa)
	  ○ Liver biopsy (also required if non-invasive testing is inconclusive or other causes for liver disease have not been ruled out)
	• Other causes for liver steatosis have been ruled out (such as alcohol-associated liver disease, chronic hepatitis C, Wilson disease, drug-induced liver disease)
	• Baseline lab values for AST and ALT
	
	Weight Loss:
	• Patient age of 12 to 20 years and Young Adults with Special Health Care Needs (YSHCN)
	• Severe obesity defined as one of the following:
	  ○ Body mass index (BMI) of greater than or equal to 35 kg/m^2
	  ○ Equal to or greater than 120% of the 95th percentile for age and sex
	
	Obstructive Sleep Apnea (Zepbound only)
	• Diagnosis of moderate to severe obstructive sleep apnea (OSA) with Apnea-Hypopnea Index (AHI) of at least 15 on polysomnography or home sleep study
	• Body mass index (BMI) of greater than or equal to 30 kg/m^2

Appropriate Treatment	**MACE Risk Reduction (Wegovy only):** • Currently established on standard of care treatment of cardiovascular disease (CVD) at therapeutic doses (one from each category): ○ Lipid-lowering therapy: statins, ezetimibe, Repatha, Praluent

PacificSource Community Solutions

Regimen & Other Criteria:	○ Antiplatelet/anticoagulant therapy: aspirin, clopidogrel, ticagrelor, Xarelto **<u>MASH (Wegovy only):</u>** • Documented treatment failure (or intolerable adverse event) with at least 12 weeks of one of the following: liraglutide, Ozempic, Trulicity for concurrent type 2 diabetes diagnosis • Documentation of abstinence from alcohol consumption • Documentation of comprehensive comorbidity management being undertaken, including all the following: ○ Use of diet and exercise for weight management ○ Medications to manage associated comorbid conditions, such as thyroid disease (must not have active disease), diabetes, dyslipidemia, hypertension, or cardiovascular conditions. **<u>Weight Loss:</u>** • Current intensive health behavior and lifestyle treatment which includes ○ Physical activity goals ○ Nutrition education ○ Behavior change counseling • Documentation of treatment failure with phentermine-topiramate, defined as failure to experience 5% reduction in BMI after 12 weeks at max tolerated dosage **<u>OSA (Zepbound only)</u>** • Documentation of current nonpharmacologic interventions, including caloric restriction (diet), increased physical activity, and behavioral modification/support **Zepbound Reauthorization:** • Documentation of treatment success defined by an improvement in AHI score or OSA symptoms (such as less daytime sleepiness, fewer sleep arousals, fewer pauses in breathing) **Saxenda Reauthorization:** • Documentation of at least 2.4mg daily dose and reduction of weight of at least 1% of BMI since initiation (pediatric weight loss) **Wegovy MACE Reauthorization:** • Documentation of at least 1.7mg once weekly dose and reduction of weight of at least 1% of BMI since initiation (pediatric weight loss) • Documentation of treatment success (MACE risk reduction) **Wegovy MASH Reauthorization:** • Documentation of disease responsiveness to therapy based on improvements or stability in laboratory results, such as ALT and AST, or fibrosis as evaluated by a non-invasive test
Exclusion Criteria:	• Personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (Zepbound)
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a cardiologist (MACE reduction) • Prescribed by, or in consultation with, a gastroenterologist or hepatologist (MASH/NASH)

	• Prescribed by, or in consultation with, a pediatrician or weight loss specialist
Coverage Duration:	• Initial Authorization: 12 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
GOLIMUMAB
Affected Medications: SIMPONI ARIA INTRAVENOUS (IV) SOLUTION

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis (RA)
	  ○ Psoriatic Arthritis (PsA)
	  ○ Ankylosing Spondylitis (AS)
	  ○ Non-radiographic axial spondyloarthritis (NR-axSPA)
	  ○ Polyarticular Juvenile Idiopathic Arthritis (JIA)

Required Medical Information:	**Rheumatoid Arthritis**
	• Documentation of current disease activity with one of the following (or equivalent objective scale)
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted Routine Assessment of Patient Index Data 3 (RAPID3) of at least 2.3
	
	Psoriatic Arthritis
	• Documentation of Classification for Psoriatic Arthritis (CASPAR) criteria score of 3 or greater based on chart notes:
	  ○ Skin psoriasis: present – two points, OR previously present by history – one point, OR a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxta-articular bone formation on radiographs (distinct from osteophytes): one point
	
	Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis
	• Diagnosis of axial spondyloarthritis (SpA) confirmed by sacroiliitis on imaging AND at least 1 spondyloarthritis feature:
	  ○ Inflammatory back pain (4 of 5 features met):
	  ▪ Onset of back discomfort before the age of 40 years
	  ▪ Insidious onset
	  ▪ Improvement with exercise
	  ▪ No improvement with rest
	  ▪ Pain at night (with improvement upon arising)
	  ○ Arthritis
	  ○ Enthesitis
	  ○ Uveitis
	  ○ Dactylitis (inflammation of entire digit)
	  ○ Psoriasis
	  ○ Crohn's disease/ulcerative colitis
	  ○ Good response to nonsteroidal anti-inflammatory drugs (NSAIDs)
	  ○ Family history of SpA
	  ○ Elevated C-reactive protein (CRP)
	  OR
	  ○ HLA-B27 genetic test positive AND at least TWO SpA features
	• Documentation of active disease defined by Bath ankylosing spondylitis disease activity index (BASDAI) at least 4 or equivalent objective scale

	<u>Juvenile Idiopathic Arthritis</u> • Documentation of current level of disease activity with physician global assessment (MD global score) or active joint count

Appropriate Treatment Regimen & Other Criteria:	**<u>Rheumatoid Arthritis</u>**
	• Documented failure with at least 12 weeks of treatment with methotrexate
	  ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide)
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola)
	
	<u>Psoriatic Arthritis</u>
	• Documented failure with at least 12 weeks of treatment with methotrexate
	  ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide)
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola)
	
	<u>Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis</u>
	• Documented failure with two daily prescription strength nonsteroidal anti-inflammatory drugs (ibuprofen, naproxen, diclofenac, meloxicam, etc.) with minimum 1 month trial each
	OR
	• For peripheral arthritis: documented treatment failure with locally administered parenteral glucocorticoid
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola)
	
	<u>Juvenile Idiopathic Arthritis</u>
	• Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide
	• Documented failure with glucocorticoid joint injections or oral corticosteroids
	
	<u>QL</u>
	• RA/PsA/AS: 2 mg/kg at weeks 0 and 4, followed by every 8 weeks
	• Pediatric PsA and JIA: 80 mg/m2 at weeks 0 and 4, then every 8 weeks thereafter
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	<u>Reauthorization:</u>
	• Documentation of treatment success and clinically significant response to therapy

Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
GOSERELIN ACETATE IMPLANT
Affected Medications: ZOLADEX (goserelin acetate implant)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Endometriosis
	  ○ Endometrial thinning
	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better

Required Medical Information:	**Endometriosis** • Documentation of moderate to severe pain due to endometriosis

Appropriate Treatment Regimen & Other Criteria:	**Endometriosis**
	• Documentation of a trial and inadequate relief (or contraindication) after at least 3 months of both of the following first-line therapies:
	  ○ Nonsteroidal anti-inflammatory drugs (NSAIDs)
	  ○ Continuous (no placebo pills) hormonal contraceptives
	
	Endometrial thinning
	• Documentation of both the following:
	  ○ Diagnosis of dysfunctional uterine bleeding
	  ○ Planning to use as an endometrial-thinning agent prior to endometrial ablation
	
	Reauthorization for oncologic uses requires documentation of disease responsiveness to therapy

Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • For endometriosis, prior use of Zoladex for a 6-month period
Age Restriction:	• 18 years and older
Prescriber Restrictions:	• For oncologic uses: Prescribed by, or in consultation with, an oncologist • For gynecologic uses: Prescribed by, or in consultation with, a gynecologist
Coverage Duration:	Oncologic uses • Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified Endometriosis • Approval: 6 months with no reauthorization, unless otherwise specified Endometrial thinning • Approval: 4 months (up to 2 doses only), unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
GROWTH HORMONES
Affected Medications: GENOTROPIN, GENOTROPIN MINIQUICK, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, ZOMACTON, SKYTROFA, SOGROYA, NGENLA

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	• Pediatric indications:
	  ○ Growth Hormone Deficiency
	  ○ Pituitary dwarfism (short stature disorder due to growth hormone deficiency)
	  ▪ Growth hormone deficiency without short stature NOT a funded indication
	  ○ Turner's syndrome
	  ○ Prader-Willi syndrome
	  ○ Noonan's syndrome
	  ○ Short stature homeobox-containing gene (SHOX) deficiency
	  ○ Growth failure secondary to chronic kidney disease (stages 3, 4, 5 or ESRD) or renal transplant
	  ○ Small for gestational age
	• Adult indications:
	  ○ Growth Hormone Deficiency

Required Medical Information:	<u>All indications:</u>
	• Documentation of baseline height, height velocity, and bone age (pediatrics), and patient weight
	
	<u>Pediatric growth hormone deficiency or Pituitary dwarfism</u>
	• For initial approval, documentation of the following is required:
	  ○ Diagnosis of growth hormone deficiency or pituitary dwarfism AND
	  ○ Low serum values for GH stimulation test, IGF-1, and IGFBP-3 with delayed bone age AND
	  ▪ Height standard deviation score (SDS) of -2.5 (0.6th percentile)
	  OR
	  ▪ Height velocity impaired AND
	  ▪ Height SDS of -2 (2.3rd percentile) for bone age
	
	<u>Turner's syndrome</u>
	• For initial approval, documentation of the following is required:
	  ○ Diagnosis of Turner Syndrome done through genetic testing AND
	  ▪ For patients less than 2 years of age:
	  • Documented 50% delay in growth from projected based on WHO growth curves at equivalent age, AND
	  • No secondary factor present that would explain observed growth delays
	  ▪ For patients greater than or equal to 2 years of age:
	  • Height below the 5th percentile for bone age, AND
	  • No secondary factor present that would explain observed growth delays
	
	<u>Noonan's syndrome</u>
	• For initial approval, documentation of the following is required:
	  ○ Diagnosis of Noonan's syndrome done through genetic testing AND
	  ▪ Height standard deviation score (SDS) of -2.5 (0.6th percentile)
	  OR

	▪ Height velocity impaired AND ▪ Height SDS of -2 (2.3rd percentile) for bone age <u>Short stature homeobox-containing gene (SHOX) deficiency</u> • For initial approval, documentation of the following is required: o Diagnosis of SHOX deficiency done through genetic testing AND ▪ Height standard deviation score (SDS) of -2.5 (0.6^{th} percentile) OR ▪ Height velocity impaired AND ▪ Height SDS of -2 (2.3rd percentile) for bone age <u>Growth failure secondary to chronic kidney disease stage 3 and greater OR kidney transplant</u> • For initial approval, documentation of the following is required: o Diagnosis of chronic kidney disease stage 3 or higher (CrCl less than 60mL/min) o Height velocity (SDS) less than -1.88 for bone age. <u>Prader-Willi syndrome</u> • For initial approval, documentation of the following is required: o Diagnosis of Prader-Willi syndrome through genetic testing AND o Height velocity impaired <u>Small for gestational age</u> • For initial approval, documentation of the following is required: o Documentation of weight and/or length of at least 2 standard deviations (SD) from the mean for gestational age and sex at birth o At least two years old o Height standard deviation score of at least -2.5 at the start of therapy o Documentation of lab work ruling out other physiological and genetic conditions that cause short stature including: ▪ IGF-1 and IGFBP-3 values within normal range ▪ Evaluation for growth inhibiting medications ▪ Absence of chronic illness impacting growth velocity ▪ Absence of genetic condition impacting growth velocity <u>Adult Growth Hormone</u> • For initial approval, documentation of the following is required: o Growth hormone deficiency defined as IGF-1 outside of reference range for patients' sex and age o Failure of a growth hormone stimulation test (insulin tolerance test ITT or glucagon stimulation test) **<u>Reauthorization:</u>** • Pediatric: requires a documented growth rate increase of at least 2.5 cm over baseline per year AND evaluation of epiphyses (growth plates) documenting they remain open • Adult: requires documented clinical improvement and IGF-1 within normal reference range for age and sex
Appropriate Treatment Regimen & Other Criteria:	• Documentation of clinical failure with an adequate trial (at least 12 weeks) of Norditropin prior to any other growth hormone agent **<u>Skytrofa and Ngenla</u>**

	• Documentation of clinical failure with an adequate trial (at least 12 weeks each) of all formulary growth hormone options **<u>Sogroya</u>** • Documented clinical failure with an adequate trial (at least 12 weeks each) of Norditropin AND one additional daily growth hormone agent • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an age-appropriate endocrinologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
HEPATITIS C DIRECT-ACTING ANTIVIRALS
Affected Medications: EPCLUSA (Sofosbuvir/Velptasvir), VOSEVI (Sofosbuvir/Velpatasvir/Voxilaprevir), MAVYRET (Glecaprevir/Pibrentasvir)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for treatment of Hepatitis C infection?	**Yes:** Go to #3 Document baseline quantitative HCV RNA level	**No:** Pass to RPh. Deny; medical appropriateness.
• Has all the following pre-treatment testing been documented: ○ Genotype testing in past 3 years is required if the patient has decompensated cirrhosis, prior treatment experience with a DAA regimen, and if prescribed a regimen which is not pan-genotypic ○ History of previous HCV treatment, viral load after treatment, and outcome are required only if there is documentation of treatment experience	**Yes:** Record results of each test and go to #4	**No**: Pass to RPh. Request updated testing.
4. Which regimen is requested?	Document and go to #5	
5. Has the patient been treated with a direct acting antiviral regimen previously?	**Yes:** Go to #6	**No:** Go to #8

PacificSource Community Solutions

Approval Criteria		
6. Did the patient achieve a sustained virological response (SVR) at week 12 or longer following the completion of their last DAA regimen?	**Yes:** Go to #7	**No:** Document as treatment failure and treat as indicated for treatment experienced. Go to #8
• Is this likely a reinfection, indicated by at least one of the following: ○ Does the patient have ongoing risk factors for hepatitis C reinfection (e.g., sexually active men who have sex with men, persons who inject drugs), OR ○ Is the hepatitis C infection a different genotype than previous	**Yes:** Document as reinfection. Use regimens recommended for treatment naïve patients. Go to #8	**No:** Document as treatment failure and treat as indicated for treatment experienced. Go to #8
• Is the prescribed drug: ○ Elbasvir/grazoprevir for GT 1a infection; or ○ Ledipasvir/sofosbuvir for GT 1a treatment-experienced infection; or ○ Sofosbuvir/velpatasvir for GT 3 in cirrhosis or treatment-experienced infection	**Yes:** Go to #9	**No:** Go to #10
9. Has the patient had a baseline NS5a resistance test that documents a resistant variant to one of the agents in #8? Note: Baseline NS5A resistance testing is required.	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #10 Document test and result.

10. Is the prescribed drug regimen a recommended regimen based on the patient's genotype, age, treatment status (retreatment or treatment naïve) and cirrhosis status (see **Table 1 and Table 2**)? Note: Safety and efficacy of DAAs for children < 3 years of age have not been established Pediatric dosing available in **Table 3** and **Table 4**	**Yes:** Approve for 8-24 weeks based on duration of treatment indicated for approved regimen Referral will be made for optional case management (patient may choose to opt-in).	**No:** Pass to RPh. Deny; medical appropriateness.

Table 1: Recommended Treatment Regimens for Adults, and Adolescents 12 years of age and older with Hepatitis C virus.

Treatment History	Cirrhosis Status	Recommended Regimen
Treatment Naïve (Genotype 1-6)		
Treatment naïve, confirmed reinfection or prior treatment with PEGylated interferon/ribavirin	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	G/P x 8 weeks SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3)
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 weeks SOF/VEL x 24 weeks (if ribavirin ineligible*)
Treatment Experienced (Genotype 1-6)		
Sofosbuvir based regimen treatment failures, including: Sofosbuvir + ribavirin Ledipasvir/sofosbuvir Velpatasvir/sofosbuvir	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x12 weeks G/P x 16 weeks (except GT3)
Elbasvir/grazoprevir treatment failures	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks
Glecaprevir/pibrentasvir treatment failures	Non-cirrhotic or compensated cirrhosis	G/P + SOF + RBV x 16 weeks SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis)

Multiple DAA Treatment Failures, including: sofosbuvir/velpatasvir/voxilaprevir glecaprevir/pibrentasvir + sofosbuvir	Non-cirrhotic or compensated cirrhosis	G/P + SOF + RBV x 16-24 weeks SOF/VEL/VOX x 24 weeks
Abbreviations: DAA = direct acting antiviral; EBV/GZR = elbasvir/grazoprevir; G/P = glecaprevir and pibrentasvir; PEG = pegylated interferon; RAV = resistance-associated variant; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir; SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir * Ribavirin ineligible/intolerance may include: 1) neutrophils < 750 mm^3, 2) hemoglobin < 10 g/dl, 3) platelets <50,000 cells/mm^3, autoimmune hepatitis or other autoimmune condition, hypersensitivity or allergy to ribavirin		
^ Rarely, genotyping assays may indicate the presence of a mixed infection (e.g., genotypes 1a and 2). Treatment data for mixed genotypes with direct-acting antivirals are limited. However, in these cases, a pangenotypic regimen is appropriate.		
Ribavirin-containing regimens are absolutely contraindicated in pregnant women and in the male partners of women who are pregnant. Documented use of two forms of birth control in patients and sex partners for whom a ribavirin containing regimen is chosen is required.		
All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C).		
There is limited data supporting DAA regimens in treatment- experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director.		
Definitions of Treatment Candidates • Treatment-naïve: Patients without prior HCV treatment. • Treat as treatment-naïve: Patients who discontinued HCV DAA therapy within 4 weeks of initiation or have confirmed reinfection after achieving SVR following HCV treatment. • Treatment-experienced: Patients who received more than 4 weeks of HCV DAA therapy.		

Table 2: Recommended Treatment Regimens for children ages 3 - 12 years of age with Hepatitis C virus.

Treatment History	Cirrhosis Status	Recommended Regimen
Treatment Naïve Genotype 1-6		
Treatment naïve, confirmed reinfection or prior treatment with pegylated interferon/ribavirin	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 8 weeks
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 weeks
Treatment Experienced with DAA regimen		
Note: Efficacy and safety extremely limited in treatment experienced to other DAAs in this population. Can consider recommended treatment regimens in adults if FDA approved for pediatric use. Recommend consulting with hepatologist.		

Abbreviations: DAA = direct acting antiviral; G/P = glecaprevir and pibrentasvir; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir

- All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C).
- There is limited data supporting DAA regimens in treatment- experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director.

Table 3: Recommended dosage of sofosbuvir/velpatasvir in pediatric patients 3 years of age and older:

Body weight	Dosing of sofosbuvir/velpatasvir
Less than 17 kg	One 150 mg/37.5 mg pellet packet once daily
17 kg to less than 30 kg	One 200 mg50 mg pellet packet OR tablet once daily
At least 30 kg	Two 200 mg/50 mg pellet packets once daily OR one 400 mg/100 mg tablet once daily

Table 4: Recommended dosage of glecaprevir/pibrentasvir in pediatric patients 3 years of age and older:

Body weight	Dosing of glecaprevir/pibrentasvir
Less than 20 kg	Three 50mg/20 mg pellet packets once daily
20 kg to less than 30 kg	Four 50 mg/20 mg pellet packets once daily
30 kg to less than 45 kg	Five 50 mg/20 mg pellet packets once daily
45 kg and greater OR 12 years of age and older	Three 100mg/40 mg tablets once daily

PacificSource Community Solutions

POLICY NAME:
HEREDITARY ANGIOEDEMA (HAE)
Affected Medications: BERINERT, CINRYZE, ICATIBANT ACETATE, SAJAZIR, HAEGARDA**,** RUCONEST, KALBITOR, TAKHZYRO, ORLADEYO

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design

Required Medical Information:	• Hereditary angioedema (HAE) official diagnosis documented in member's chart **AND**
	• Laboratory confirmed diagnosis for HAE Type I or II:
	  ○ Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing test) AND one of the following:
	  ○ C1-inhibitor functional level less than 50% of the lower limit of normal as defined by the laboratory performing test OR
	  ○ C1-inhibitor antigenic level less than 50% of the lower limit of normal as defined by the laboratory performing test
	OR
	• Family history of angioedema and the angioedema was refractory to a trial of antihistamine (e.g., diphenhydramine) for at least one month or confirmed factor 12 (FXII) mutation
	• All other causes of acquired angioedema (e.g., medications, auto-immune diseases) have been excluded
	• Documentation of requested number of units or doses and current weight

Appropriate Treatment Regimen & Other Criteria:	**<u>Acute Treatment</u>**
	• For requests to treat 3 or less attacks per month:
	  ○ Documentation of requested number of units or doses and current weight.
	  ○ Documentation of number of attacks requiring treatment in the past year. Authorization for therapy for acute treatment will provide a sufficient quantity to cover the number of attacks experienced in the last year plus 1 additional dose. Limited to having medication on hand to treat average number of acute attacks per month plus 1 additional dose.
	• **Berinert**: Treatment of acute attacks 20 units/kg IV
	  ○ If 18 years or older, requires documented treatment failure (or documented intolerable adverse event) to icatibant acetate
	  OR
	  ○ Currently receiving treatment with Berinert, excluding via samples or manufacturer's patient assistance programs
	• **Icatibant Acetate**: Treatment of acute attacks 30mg SQ. Additional doses may be administered at 6-hour intervals if response is inadequate or symptoms recur. Maximum 3 doses in 24 hours

	• **Ruconest**: 50 units/kg IV, not to exceed 4200 units per dose. If attack symptoms persist, a second dose may be administered. Not to exceed 2 doses in 24 hours. (Effectiveness not demonstrated in patients with laryngeal attacks) ○ If 18 years or older, requires documented treatment failure (or documented intolerable adverse event) to icatibant acetate **OR** ○ If under 18 years of age, requires documented treatment failure (or documented intolerable adverse event) to Berinert **OR** ○ Currently receiving treatment with Ruconest, excluding via samples or manufacturer's patient assistance programs. • **Kalbitor**: Treatment of acute attacks 30mg SQ. If attack persists, an additional dose of 30mg may be given within 24 hours. ○ If 18 years or older, requires documented treatment failure (or documented intolerable adverse event) to icatibant acetate **OR** ○ If under 18 years of age, requires documented treatment failure (or documented intolerable adverse event) to Berinert **OR** ○ Currently receiving treatment with Kalbitor, excluding via samples or manufacturer's patient assistance programs • For requests to treat more than 3 attacks per month: ○ Documentation of number of attacks requiring treatment in the past year ○ Documentation of current treatment or failure, intolerance, or clinical rationale for avoidance of prophylactic therapies such as Haegarda, Takhzyro, Cinryze ○ Authorization for therapy for acute treatment will provide a sufficient quantity to cover the number of attacks experienced in the last year plus 1 additional dose. Limited to having medication on hand to treat average number of acute attacks per month plus 1 additional dose **Reauthorization** requires documentation of number of acute attacks treated in the past year AND documentation of treatment success defined as reduction of frequency and severity of HAE attack episodes by greater than or equal to 50% from baseline **Prophylaxis** • Documentation of number of attacks requiring treatment in the past year • At least ONE of the following: ○ Disabling symptoms for at least 5 days per month ○ Laryngeal edema or history of laryngeal edema ○ A history of self-limiting, non-inflammatory subcutaneous angioedema, without urticaria, which is recurrent and lasts greater than 12 hours ○ Self-limiting, recurrent abdominal pain without a clear organic cause lasting

	greater than 6 hours **AND** • A history of TWO or more severe attack(s) per month on average for the past 3 months (defined as an attack that significantly interrupts daily activities despite short-term treatment) • **Cinryze Prophylaxis**: 1000 units IV twice a week. o Requires documented treatment failure (or documented intolerable adverse event) to Haegarda AND Takhzyro **OR** o Currently receiving treatment with Cinryze for prophylaxis, excluding via samples or manufacturer's patient assistance programs and have had a greater than or equal to 50% reduction of frequency and severity of HAE attacks requiring acute therapy from baseline o Doses up to 2,500 units (not exceeding 100 units/kg) may be appropriate if inadequate response with 1000 units • **Orladeyo Prophylaxis**: 150 mg once daily. o Requires documented treatment failure (or documented intolerable adverse event) to Haegarda AND Takhzyro **OR** o Currently receiving treatment with Orladeyo for prophylaxis, excluding via samples or manufacturer's patient assistance programs and have had a greater than or equal to 50% reduction of frequency and severity of HAE attacks requiring acute therapy from baseline • **Haegarda Prophylaxis**: 60 units/kg SC twice a week • **Takhzyro Prophylaxis**: If patient is dosing every 2 weeks and has been attack free for 6 months, dosing will be reduced to every 4 weeks o 2 years of age to less than 6: 150 mg SC every 4 weeks o 6 years of age to less than 12: 150 mg SC every 2 weeks o 12 years of age and older: 300 mg SC every 2 weeks **Reauthorization** requires documentation of number of acute HAE attacks treated in the past year AND documentation of treatment success defined as reduction of frequency and severity of HAE attack episodes requiring acute therapy by greater than or equal to 50% from baseline • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced for all medical infusion drugs
Exclusion Criteria:	• Documentation that the requested acute treatment drug will not be used in combination with another acute HAE drug such as Berinert, Ruconest or Icatibant Acetate • Documentation that the requested prophylactic treatment drug will not be used in combination with another prophylactic HAE drug such as Haegarda, Takhzyro, Cinryze • Orladeyo in the setting of End-Stage Renal Disease or those requiring hemodialysis

Age Restriction:	• **Berinert**: Approved for acute treatment of HAE attacks in adult and pediatric patients • **Cinryze**: Approved for routine prophylaxis of HAE attacks in patients 6 years and older • **Icatibant Acetate**: Approved for acute treatment of HAE attacks in patients 18 and older • **Haegarda**: Approved for routine prophylaxis of HAE attacks in patients 6 years and older • **Ruconest**: Approved for acute treatment of HAE attacks (non-laryngeal) in patients 13 and older • **Kalbitor**: Approved for acute treatment of HAE attacks in patients 12 years and older • **Takhzyro**: Approved for routine prophylaxis of HAE attacks in patients 2 years and older • **Orladeyo**: Approved for routine prophylaxis of HAE attacks in patients 12 years and older
Prescriber Restrictions:	• Must be prescribed by, or in consultation with, an allergist/immunologist or physician that specializes in HAE or related disorders.
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
HISTRELIN
Affected Medications: SUPPRELIN LA (histrelin acetate)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. ○ Central precocious puberty (CPP) • Gender dysphoria

Required Medical Information:	**<u>Central Precocious puberty</u>**
	• Documentation of CPP confirmed by basal luteinizing hormone (LH), follicle-stimulating hormone (FSH), and either estradiol or testosterone concentrations
	
	<u>Gender Dysphoria</u>
	• Documentation of all the following:
	  ○ Current Tanner stage 2 or greater OR baseline and current estradiol and testosterone levels to confirm onset of puberty
	  ○ Confirmed diagnosis of gender dysphoria that is persistent
	  ○ The patient has the capacity to make a fully informed decision and to give consent for treatment
	  ○ Any significant medical or mental health concerns are reasonably well controlled
	  ○ A comprehensive mental health evaluation has been completed by a licensed mental health professional (LMHP) and provided in accordance with the most current version of the World Professional Association for Transgender Health (WPATH) Standards of Care

Appropriate Treatment Regimen & Other Criteria:	**<u>All Indications</u>** • Approval requires rationale for avoidance of Lupron formulations **<u>Reauthorization</u>** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	• Equal or greater than 2 years old
Prescriber Restrictions:	• Central Precocious Puberty: Prescribed by, or in consultation with, an endocrinologist • Gender Dysphoria: Diagnosis made and prescribed by, or in consultation with, a specialist in the treatment of gender dysphoria
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
Hormone supplementation under 18 years of age
Affected Medications: Depo-Estradiol oil, estradiol twice weekly patch, estradiol weekly patch, estradiol tablets, estradiol valerate oil, Testosterone Cypionate solution, Testosterone Enanthate solution, Testosterone gel

PA applies to New Starts only

Covered Uses:	• Gender dysphoria ○ Applies to patients under the age of 18

Required Medical Information:	**Gender dysphoria**
	• Documentation of all the following:
	  ○ Current Tanner stage 2 or greater OR baseline and current estradiol and testosterone levels to confirm onset of puberty
	  ○ Confirmed diagnosis of gender dysphoria that is persistent
	  ○ The patient has the capacity to make a fully informed decision and to give consent for treatment
	  ○ Any significant medical or mental health concerns are reasonably well controlled
	  ○ A comprehensive mental health evaluation has been completed by a licensed mental health professional (LMHP) and provided in accordance with the most current version of the World Professional Association for Transgender Health (WPATH) Standards of Care
	• Note: For requests following pubertal suppression therapy, an updated or new comprehensive mental health evaluation must be provided prior to initiation of hormone supplementation

Appropriate Treatment Regimen & Other Criteria:	**Transdermal Testosterone** • Requires documented failure, intolerance, or clinical rationale for avoidance of the testosterone injections **Reauthorization** requires documentation of treatment success
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Gender Dysphoria: Diagnosis made and prescribed by, or in consultation with, a specialist in the treatment of gender dysphoria
Coverage Duration:	• Authorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
HYALURONIC ACID DERIVATIVES
Affected Medications: EUFLEXXA, GENVISC 850, GEL-ONE, GEL-SYN, HYALGAN, HYMOVIS, MONOVISC, ORTHOVISC, SUPARTZ, SYNVISC, SYNVISC-ONE, TRI-VISC, DUROLANE, SYNOJOYNT, TRILURON, VISCO-3

Covered Uses:	• Hyaluronic Acid products are excluded from coverage per the Oregon Health Authority ○ See Guideline Note #104, which states "CPT 20610 and 20611 are included on these lines only for interventions other than viscosupplementation for osteoarthritis of the knee."
Required Medical Information:	
Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	

PacificSource Community Solutions

POLICY NAME:
HYDROCORTISONE ORAL GRANULES
Affected Medications: ALKINDI SPRINKLE (hydrocortisone oral granules)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Glucocorticoid replacement therapy in pediatric patients with adrenocortical insufficiency
Required Medical Information:	• Diagnosis of adrenal insufficiency confirmed with an adrenal stimulation test • Current body surface area (or height and weight to calculate) • Current height and weight velocity • For adolescents, evaluation of epiphyses (growth plates) documenting they remain open • Complete treatment plan including dose in mg/m^2/day

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with a 6-month trial of two or more of the following:
	  ○ Hydrocortisone tablets
	  ○ Cortisone acetate tablets
	  ○ Prednisolone or prednisone tablets
	  ○ Compounded hydrocortisone oral capsules or solution
	• **Dosing** is in accordance with FDA labeling and does not exceed the following:
	  ○ Starting dose: 8-10 mg/m^2/day in 3 divided doses
	  ○ When switching from other oral hydrocortisone formulations, use the same total hydrocortisone dosage
	  ○ Infants with Congenital Adrenal Hyperplasia may start at a dose of 8-15 mg/m^2/day in 3 divided doses
	
	Reauthorization requires documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Use in adolescents who have achieved their adult height • Use for stress dosing • Use in acute treatment of adrenal crisis or acute adrenal insufficiency • Long term use with strong CYP3A4 inducers, unless medically necessary
Age Restriction:	• Less than 18 years of age
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pediatric endocrinologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
HYPOXIA-INDUCIBLE FACTOR PROLYL HYDROXYLASE (HIF PH) INHIBITORS
Affected Medications: JESDUVROQ (daprodustat), VAFSEO (vadadustat)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis

Required Medical Information:	• Diagnosis of anemia due to CKD
	• Documentation of dialysis use for:
	  ○ Jesduvroq: 4 or more months
	  ○ Vafseo: 3 or more months
	• Documentation of pretreatment hemoglobin level greater than 8 g/dL and less than 12 g/dL
	• Adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%

Appropriate Treatment Regimen & Other Criteria:	• Documentation of **ONE** of the following:
	  ○ Documented hypo-responsiveness to an erythropoiesis stimulating agent (ESA), defined as the need for **ONE** of the following:
	  ▪ Greater than 300 IU/kg per week of epoetin alfa
	  ▪ Greater than 1.5 mcg/kg per week of darbepoetin
	  ○ Intolerance to all ESAs
	
	Reauthorization will require documentation of treatment success and hemoglobin of greater than 8 g/dL and less than 12 g/dL

Exclusion Criteria:	• Use in combination with ESAs • Current uncontrolled hypertension • Active malignancy • For Jesduvroq: Major adverse cardiac events (such as myocardial infarction, acute coronary syndrome, stroke, transient ischemic attack, venous thromboembolism) within 3 months prior to starting treatment
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by or in consultation with a specialist, such as a hematologist or nephrologist
Coverage Duration:	• Initial authorization: 6 months • Reauthorization: 12 months

PacificSource Community Solutions

POLICY NAME:
IBREXAFUNGERP
Affected Medications: BREXAFEMME (ibrexafungerp)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Treatment of vulvovaginal candidiasis (VVC)
	  ○ Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC)

Required Medical Information:	**All Indications** • Documented presence of signs/symptoms of current acute vulvovaginal candidiasis with a positive potassium hydroxide (KOH) test • Documentation confirming that the patient is not pregnant and is on contraceptive for length of planned treatment **RVVC** • Documentation of three or more episodes of symptomatic vulvovaginal candidiasis infection within the past 12 months

Appropriate Treatment Regimen & Other Criteria:	**VVC**
	• Documented treatment failure with both of the following for the current VVC episode:
	  ○ Vaginally administered treatment (such as clotrimazole cream, miconazole cream, terconazole cream or suppository)
	  ○ A 7-day course of fluconazole taken orally every third day for a total of 3 doses (days 1, 4, and 7)
	
	RVVC
	• Documented disease recurrence following 10 to 14 days of induction therapy with a topical antifungal agent or oral fluconazole, followed by fluconazole 150 mg once per week for 6 months
	
	Reauthorization requires documentation of treatment success defined as a reduction in symptomatic vulvovaginal candidiasis episodes, and documentation supporting the need for additional treatment.

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	Authorization (VVC): 3 months, unless otherwise specified Authorization (RVVC): 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ICOSAPENT ETHYL
Affected Medications: icosapent ethyl

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Cardiovascular risk reduction with hypertriglyceridemia
	  ○ Severe hypertriglyceridemia

Required Medical Information:	**<u>Cardiovascular Risk Reduction with Hypertriglyceridemia</u>**
	• Documented current triglyceride level of at least 150 mg/dL, despite current therapy
	• Documentation of **ONE** of the following:
	  ○ Established cardiovascular disease (CVD) (e.g., coronary artery disease, cerebrovascular disease, peripheral artery disease)
	  ○ Diabetes mellitus and 2 or more risk factors for CVD (e.g., hypertension, cigarette smoking, chronic kidney disease, family history of CVD)
	
	<u>Severe Hypertriglyceridemia</u>
	• Documented current triglyceride level of at least 500 mg/dL

Appropriate Treatment Regimen & Other Criteria:	**<u>Cardiovascular Risk Reduction with Hypertriglyceridemia</u>** • Documentation of minimum 12 weeks of consistent statin therapy at maximum tolerated dose prior to request **AND** treatment plan includes intent to continue statin therapy with icosapent ethyl **<u>Severe Hypertriglyceridemia</u>** • Documentation of inadequate response with minimum 12-week trial of fenofibrate **AND** omega-3-acid ethyl esters (generic Lovaza) **<u>Reauthorization</u>:** Documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• Authorization: 12 months, unless otherwise specified.

PacificSource Community Solutions

POLICY NAME:
ILOPROST
Drug Name: VENTAVIS (iloprost)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1

Required documentation:	**<u>Pulmonary arterial hypertension (PAH) WHO Group 1</u>**
	• Documentation of PAH confirmed by right-heart catheterization meeting the following criterias:
	  ○ Mean pulmonary artery pressure of at least 20 mm Hg,
	  ○ Pulmonary capillary wedge pressure less than or equal to 15 mm Hg,
	  ○ Pulmonary vascular resistance of at least 2.0 Wood units
	• New York Heart Association (NYHA)/World Health Organization (WHO) Functional Class III or higher symptoms
	• Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blockers) unless there are contraindications:
	  ○ Low systemic blood pressure (systolic blood pressure less than 90)
	  ○ Low cardiac index
	  ○ Presence of severe symptoms (functional class IV)

Appropriate Treatment Regimen:	• Documentation of inadequate response or intolerance to the following therapy classes is required:
	  ○ PDE5 inhibitors **AND**
	  ○ Endothelin receptor antagonists (exception WHO Functional Class IV)
	
	<u>Reauthorization</u> requires documentation of treatment success defined as one or more of the following:
	• Improvement in walking distance
	• Improvement in exercise ability
	• Improvement in pulmonary function
	• Improvement or stability in WHO functional class

Exclusion Criteria:	
Age Restriction:	
Provider Restriction:	• Prescribed by, or in consultation with, a cardiologist or a pulmonologist
Approval Duration:	• 12 months, unless otherwise specified

POLICY NAME:
ILARIS
Affected Medications: ILARIS (canakinumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF), Adult-Onset Still's Disease (AOSD), Systemic Juvenile Idiopathic Arthritis (SJIA), Cryopyrin-Associated Periodic Syndromes (CAPS), Gout Flares

Required Medical Information:	**Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)**
	• Confirmed diagnosis of TRAPS with frequent and/or severe recurrent disease (such as recurrent fevers, prominent myalgias, migratory rash, periorbital edema) AND documented genetic defect of TNFRSF1A gene
	
	Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
	• Confirmed diagnosis with one of the following:
	  ○ Elevated serum IgD with or without elevated IgA
	  ○ Genetic testing showing presence of heterozygous or homozygous mutation in the mevalonate kinase (MVK) gene
	• Documentation of 3 or more febrile acute flares within a 6 month period
	
	Still's Disease
	• Confirmed diagnosis of Still's Disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older
	• Documented clinical signs and symptoms including fever, rash, arthritis, arthralgia, myalgia, pharyngitis, pulmonary disease, elevated liver enzymes, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), serum ferritin
	
	Cryopyrin-Associated Periodic Syndromes (CAPS)
	• Confirmed diagnosis of CAPS in patients 4 years and older including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) with one of the following:
	  ○ Elevated inflammatory markers such as CRP and serum amyloid A with two of the following manifestations:
	  ▪ Urticaria-like rash, cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
	  ○ Genetic testing showing presence of NALP3 mutations
	
	Gout Flares
	• Confirmed diagnosis of gout that is refractory to standard therapies
	• Documentation of having 3 or more gout flares in the past 12 months

Appropriate Treatment Regimen & Other Criteria:	**TRAPS** • Documented clinical failure to episodic treatment with Nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids (prednisone or prednisolone) and at least a 12-week trial with Enbrel **HIDS/MKD** • Documented treatment failure to episodic treatment with nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and anakinra **FMF**

	• Documented treatment failure with maximal tolerable dose of colchicine (3 mg daily in adults and 2 mg daily in children)
	AND
	• Documentation of frequent and/or severe recurrence disease despite adequate treatment with at least 12 weeks of Anakinra
	
	Still's Disease
	• Documentation of frequent and/or severe recurrence disease despite adequate treatment with a minimum 12-week trial with each of the following:
	  ○ NSAIDs or Glucocorticoids
	  ○ Methotrexate or leflunomide
	  ○ Kineret (anakinra)
	  ○ Actemra (tocilizumab)
	
	CAPS
	• Documentation of failure with a minimum 12-week trial with anakinra or contraindication to use
	
	Gout Flares
	• Documented treatment failure with all the following for the symptomatic treatment of gout flares:
	  ○ Prescription strength NSAIDs (naproxen, indomethacin, diclofenac, meloxicam, or celecoxib)
	  ○ Colchicine
	  ○ Glucocorticoids (oral or intraarticular)
	
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization requires documentation of treatment success

Exclusion Criteria:	• Treatment of neonatal onset multisystem inflammatory disorder (NOMID) or chronic infantile neurological cutaneous and articular syndrome (CINCA), rheumatoid arthritis, chronic obstructive pulmonary disease (COPD), type 2 diabetes mellitus • When used in combination with tumor necrosis factor (TNF) blocking agents (e.g., Enbrel, Humira, Cimzia, Infliximab, Simponi), Kineret, Arcalyst • Coverage is not recommended for circumstances not listed under covered uses
Age Restriction:	• FMF, HIDS/MKD, juvenile idiopathic arthritis, TRAPS: 2 years of age and older • CAPS: 4 years of age and older • Gout Flares: 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an allergist/Immunologist/Rheumatologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
IMMUNE GLOBULIN
Affected Medications: ASCENIV, BIVIGAM, FLEBOGAMMA, GAMMAGARD LIQUID/S-D, GAMMAPLEX, GAMUNEX-C, GAMASTAN, OCTAGAM, PRIVIGEN, PANZYGA, ALYGLO

Covered Uses:	• Food and Drug Administration-approved and compendia-supported uses not otherwise excluded by plan design as follows:
	  ○ Primary immunodeficiency (PID)/Wiskott - Aldrich syndrome
	  ○ Idiopathic thrombocytopenia purpura (ITP)
	  ○ Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
	  ○ Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)
	  ○ Pediatric HIV: Bacterial control or prevention
	  ○ Myasthenia Gravis
	  ○ Dermatomyositis/Polymyositis
	  ○ Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant
	  ○ Allogeneic Bone Marrow or Stem Cell Transplant
	  ○ Kawasaki's disease (Pediatric)
	  ○ Fetal alloimmune thrombocytopenia (FAIT)
	  ○ Hemolytic disease of the newborn
	  ○ Auto-immune Mucocutaneous Blistering Diseases
	  ○ Chronic lymphocytic leukemia with associated hypogammaglobulinemia (CLL)
	  ○ Toxic Shock Syndrome
	  ○ Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infections (PANDAS)

Initial Approval Criteria:	**Primary immunodeficiency (PID)/Wiskott - Aldrich syndrome**
	Includes but not limited to: X-linked agammaglobulinemia, common variable immunodeficiency (CVID), transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels) and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome)
	• Documentation of one of the following:
	  ○ IgG level less than 200
	  ○ Low IgG levels (below the laboratory reference range lower limit of normal) AND a history of multiple hard to treat infections as indicated by at least one of the following:
	  ▪ Four or more ear infections within 1 year
	  ▪ Two or more serious sinus infections within 1 year
	  ▪ Two or more months of antibiotics with little effect
	  ▪ Two or more pneumonias within 1 year
	  ▪ Recurrent or deep skin abscesses
	  ▪ Need for intravenous antibiotics to clear infections
	  ▪ Two or more deep-seated infections including septicemia; AND
	• Documentation showing a deficiency in producing antibodies in response to vaccination including all the following:
	  ○ Titers that were drawn before challenging with vaccination

PacificSource Community Solutions

	○ Titers that were drawn between 4 and 8 weeks after vaccination **Idiopathic thrombocytopenia purpura (ITP)** <u>For Acute disease state:</u> • Documented use to manage acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/microliter) **OR** • To increase platelet counts prior to invasive surgical procedures, such as splenectomy. (Platelet counts less than 100,000/microliter) **OR** • Documented severe thrombocytopenia (platelet counts less than 20,000/microliter) and is considered to be at risk for intracerebral hemorrhage <u>Chronic Immune Thrombocytopenia (CIT):</u> • Documentation of increased risk for bleeding as indicated by a platelet count less than 30,000/microliter • History of failure, contraindication, or intolerance with corticosteroids • Duration of illness more than 6 months **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):** • Documented baseline in strength/weakness using objective clinical measuring tool (INCAT, Medical Research Council (MRC) muscle strength, 6 MWT, Rankin, Modified Rankin) • Documented disease course is progressive or relapsing and remitting for 2 months or longer • Abnormal or absent deep tendon reflexes in upper or lower limbs • Electrodiagnostic testing indicating demyelination with one of the following: ○ Motor distal latency prolongation in 2 nerves ○ Reduction of motor conduction velocity in 2 nerves ○ Prolongation of F-wave latency in 2 nerves ○ Absence of F-waves in at least 1 nerve ○ Partial motor conduction block of at least 1 motor nerve ○ Abnormal temporal dispersion in at least 2 nerves ○ Distal CMAP duration increase in at least 1 nerve • Cerebrospinal fluid (CSF) analysis indicates all the following (if electrophysiologic findings are nondiagnostic): ○ CSF white cell count of less than 10 cells/mm3 ○ CSF protein is elevated (greater than 45 mg/dL) • Refractory to or intolerant of corticosteroids (prednisolone, prednisone) given in therapeutic doses over at least three months **Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)** • Documentation that the disease is severe (aid required to walk) • Onset of symptoms are recent (less than 1 month) **Pediatric HIV: Bacterial control or prevention** • Approved for those 13 years of age and younger with HIV diagnosis • Documented hypogammaglobulinemia (IgG less than 400mg/dL)

PacificSource Community Solutions

	OR
	• Functional antibody deficiency as demonstrated by either poor specific antibody titers or recurrent bacterial infections
	
	Myasthenia Gravis
	• Documented myasthenic crisis (impending respiratory or bulbar compromise)
	• Documented use for an exacerbation (difficulty swallowing, acute respiratory failure, functional disability leading to discontinuation of physical activity)
	• Documented failure with conventional therapy alone (azathioprine, cyclosporine and/or cyclophosphamide)
	
	Dermatomyositis/Polymyositis
	• Documented severe active disease state on physical exam
	• Documentation of at least two of the following:
	  ○ Proximal muscle weakness in all upper and/or lower limbs
	  ○ Elevated serum creatine kinase (CK) or aldolase level
	  ○ Interstitial lung disease (ILD)
	  ○ Skin findings such as Gottron papules, Gottron sign, heliotrope eruption, poikiloderma
	  ○ Nailfold abnormalities
	  ○ Hyperkeratosis and fissuring of palms and lateral fingers
	• Documented failure with a trial of corticosteroids (such as prednisone)
	• Documented failure with a trial of an immunosuppressant (Methotrexate, azathioprine, cyclophosphamide)
	
	Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant
	Coverage is provided for one or more of the following:
	• Suppression of panel reactive anti-HLA antibodies prior to transplantation
	• Treatment of antibody mediated rejection of solid organ transplantation
	• Prevention of cytomegalovirus (CMV) induced pneumonitis
	
	Allogeneic Bone Marrow or Stem Cell Transplant
	• Approved in use for prevention of acute Graft- Versus- Host Disease (GVHD) or infection (such as cytomegalovirus)
	• Documentation that the bone marrow transplant (BMT) was allogeneic
	• Transplant was less than 100 days ago
	
	Kawasaki's Disease (Pediatric)
	• Diagnosis or suspected diagnosis of Kawasaki's disease
	• 13 years of age or under
	
	Fetal alloimmune thrombocytopenia (FAIT)
	• Documentation of one or more of the following:
	  ○ Previous FAIT pregnancy
	  ○ Family history of the disease

	○ Screening reveals platelet alloantibodies • Authorization is valid until delivery date only **Hemolytic disease of the newborn** • Diagnosis or suspected diagnosis of hemolytic disease in newborn patient **Auto-immune Mucocutaneous Blistering Diseases** • Diagnosis confirmed by biopsy of one of the following: ○ Pemphigus vulgaris ○ Pemphigus foliaceus ○ Bullous Pemphigoid ○ Mucous Membrane Pemphigoid (Cicatricial Pemphigoid) ○ Epidermolysis bullosa aquisita ○ Pemphigus gestationis (Herpes gestationis) ○ Linear IgA dermatosis • Documented severe disease that is extensive and debilitating • Disease is progressive and refractory to a trial of conventional combination therapy with corticosteroids and immunosuppressive treatment (azathioprine, cyclophosphamide, mycophenolate mofetil) **Chronic lymphocytic leukemia (CLL) with associated hypogammaglobulinemia** • Documentation of an IgG level less than 500 mg/dL • A documented history of recurrent or chronic infections that have required intravenous antibiotics or hospitalization **Toxic Shock Syndrome** • Diagnosis or suspected diagnosis of toxic shock syndrome **Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infections (PANDAS)** • A clinically appropriate trial of two or more less-intensive treatments was either not effective, not tolerated, or did not result in sustained improvement in symptoms, as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient's primary symptom complex. Treatments may be given concurrently or sequentially and may include: ○ Selective-serotonin reuptake inhibitor SSRI (e.g., Fluoxetine, fluvoxamine, sertraline) ○ Behavioral therapy ○ Nonsteroidal anti-inflammatory (NSAID) drugs (e.g., naproxen, diclofenac, ibuprofen) ○ Oral and IV corticosteroids (e.g., prednisone, methylprednisolone) • Documentation of a consultation with a pediatric subspecialist (or adult subspecialist for adolescents) and the consulted subspecialist and the patient's primary care provider recommend the treatment
Renewal Criteria:	**Primary immunodeficiency (PID)** • Renewal requires disease response as evidenced by a decrease in the frequency and/or severity of infections

	Chronic Immune Thrombocytopenia (Chronic ITP or CIT)
	• Renewal requires disease response as indicated by the achievement and maintenance of a platelet count of at least 50 as necessary to reduce the risk for bleeding
	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
	• Renewal requires documentation of a documented clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6 Minute walk test, Rankin, Modified Rankin)
	Pediatric HIV: Bacterial control or prevention
	• Age 13 years or less
	Dermatomyositis/Polymyositis
	• Renewal requires documentation that CPK (Creatine phosphokinase) levels are lower upon renewal request AND
	• Documentation of clinically significant improvement above baseline per physical exam
	Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant
	• Renewal requires documentation of clinically significant disease response
	Allogeneic Bone Marrow or Stem Cell Transplant
	• Renewal requires documentation that the IgG is less than or equal to 400mg/dL; AND
	• Therapy does not exceed one year past date of allogeneic bone marrow transplantation
	Auto-immune mucocutaneous blistering diseases:
	• Renewal requires a documented clinically significant improvement over baseline per physical exam
	Chronic lymphocytic leukemia (CLL) with associated hypogammaglobulinemia
	• Renewal requires disease response as evidenced by a decrease in the frequency and/or severity of infections
	Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infections (PANDAS)
	• Renewal requires all the following:
	  ○ Documentation of a clinical reevaluation at three months after treatment initiation
	  ○ Documentation of clinically meaningful improvement in the results of clinical testing with a validated instrument (which must be performed pretreatment and posttreatment)

PacificSource Community Solutions

Dosing and Coverage Duration:

- Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
- Approval durations are as stated below, unless otherwise specified

Indication	Dose	Approval Duration
PID	Up to 800 mg/kg every 3 to 4 weeks	Initial: up to 3 months Reauthorization: up to 12 months
CIDP	2 g/kg divided over 2-5 days for one dose then maintenance dosing of 1 g/kg every 21 days	Initial: up to 3 months Reauthorization: up to 12 months
ITP	1 g/kg once daily for 1-2 days May be repeated monthly for chronic ITP	Acute ITP: • Approval: 1 month only Chronic ITP: • Initial: up to 3 months • Reauthorization: up to 12 months
FAIT	1 g/kg/week until delivery	Authorization is valid until delivery date only
Kawasaki's Disease (pediatric patients)	Up to 2 g/kg x 1 single dose	Approval: 1 month only
CLL	400 mg/kg every 3 to 4 weeks	Approval: up to 6 months
Pediatric HIV	400 mg/kg every 28 days	Initial: up to 3 months Reauthorization: up to 12 months
Guillain-Barre	400 mg/kg once daily for 5 days	Approval: maximum of 2 rounds of therapy within 6 weeks of onset; 2 months maximum
Myasthenia Gravis	Up to 2 g/kg x 1 dose (acute attacks)	Approval: 1 month (one course of treatment)
Auto-immune blistering diseases	Up to 2 g/kg divided over 5 days in a 28-day cycle	Approval: up to 6 months
Dermatomyositis /Polymyositis	2 g/kg given over 2-5 days in a 28-day cycle	Initial: up to 3 months Reauthorization: up to 6 months

PacificSource Community Solutions

Allogeneic Bone Marrow or Stem Cell Transplant	500 mg/kg/week x 90 days, then 500 mg/kg/month up to one-year post-transplant	Initial: up to 3 months Reauthorization: until up to one-year post-transplant
Complications of transplanted solid organ: (kidney, liver, lung, heart, pancreas) transplant	2 g/kg divided over 5 days in a 28-day cycle	Initial: up to 3 months Reauthorization: up to 12 months
Toxic shock syndrome	1 g/kg on day 1, followed by 500 mg/kg once daily on days 2 and 3	Approval: 1 month (one course of treatment)
Hemolytic disease of the newborn	1 g/kg x 1 dose, may be repeated once if needed	Approval: 1 month (one course of treatment)
PANS/PANDAS	Each dose: Up to 2 g/kg divided over 2-5 days	Initial: up to 3 months (3 monthly doses) Reauthorization: up to 3 months (3 monthly doses) Total 6 monthly doses only

Prescriber/Site of Care Restrictions:	• Must be prescribed by a specialist for the condition being treated (such as neurologist, rheumatologist, immunologist, hematologist)

PacificSource Community Solutions

POLICY NAME:
INCLISIRAN
Affected Medications: LEQVIO (inclisiran subcutaneous injection)

Covered Uses:	• All Food and Drug Administration (FDA)-approved or compendia-supported indications not otherwise excluded by plan design
	  ○ Primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH])
	  ○ Secondary prevention in atherosclerotic cardiovascular disease (ASCVD)

Required Medical Information:	**<u>All Indications</u>**
	• Documentation of baseline (untreated) low-density lipoprotein cholesterol (LDL-C)
	
	<u>Primary Hyperlipidemia (non-familial)</u>
	• Documentation of baseline (untreated) LDL-C of at least 190 mg/dL
	
	<u>HeFH</u>
	• Diagnosis confirmed by **ONE** of the following:
	  ○ Minimum baseline LDL-C of 160 mg/dL in adolescents or 190 mg/dL in adults **AND** 1 first-degree relative affected
	  ○ Presence of one abnormal LDL-C-raising gene defect (e.g., LDL receptor [LDLR], apolipoprotein B [apo B], proprotein convertase subtilisin kexin type 9 [PCSK9] loss-of-function mutation, or LDL receptor adaptor protein 1 [LDLRAP1])
	  ○ World Health Organization (WHO)/Dutch Lipid Network criteria score of at least 8 points
	  ○ Definite FH diagnosis per the Simon Broome criteria
	
	<u>Clinical ASCVD</u>
	• Documentation of established ASCVD, confirmed by at least **ONE** of the following:
	  ○ Acute coronary syndromes (ACS)
	  ○ History of myocardial infarction (MI)
	  ○ Stable or unstable angina
	  ○ Coronary or other arterial revascularization
	  ○ Stroke or transient ischemic attack
	  ○ Peripheral artery disease (PAD) presumed to be of atherosclerotic origin

Appropriate Treatment Regimen & Other Criteria:	**<u>All Indications</u>**
	• History of statin intolerance requires documentation of **ONE** of the following:
	  ○ Statin-associated rhabdomyolysis occurred with statin use and was confirmed by a creatinine kinase (CK) level at least 10 times the upper limit of normal
	  ○ Statin-associated muscle symptoms (e.g., myopathy, myalgia) occurred with statin use and was confirmed by **BOTH** of the following:
	  ▪ A minimum of three different statin trials, with at least one being a hydrophilic statin (rosuvastatin, pravastatin)
	  ▪ A re-challenge of each statin (muscle symptoms stopped when each was discontinued and restarted upon re-initiation)
	
	<u>Primary Hyperlipidemia/HeFH</u>
	• Documented treatment failure with minimum 12-week trial with **ALL** the following, shown by an inability to achieve LDL-C reduction of 50% or greater **OR** LDL-C less than 100 mg/dL:
	  ○ Maximally tolerated combination statin/ezetimibe therapy

<table>
<tr><td></td><td>
Repatha OR Praluent
<u>Clinical ASCVD</u>

Documented treatment failure with minimum 12 weeks of consistent maximally tolerated combination statin/ezetimibe therapy, as shown by ONE of the following:
Current LDL-C of at least 70 mg/dL
Current LDL-C of at least 55 mg/dL in patients at very high risk of future ASCVD events, based on history of multiple major ASCVD events OR 1 major ASCVD event + multiple high-risk conditions (see below)
Documented treatment failure or intolerance to minimum 12-week trial of Repatha OR Praluent

<table>
<tr><th>Major ASCVD Events</th><th>High-Risk Conditions</th></tr>
<tr><td>ACS within the past 12 months
History of MI (distinct from ACS event)
Ischemic stroke
Symptomatic PAD</td><td>Age 65 years and older
HeFH
Prior coronary artery bypass or percutaneous intervention (outside of major ASCVD events)
Diabetes
Hypertension
Chronic kidney disease
Current smoking
History of congestive heart failure</td></tr>
</table>
<u>Reauthorization</u> will require an updated lipid panel showing a clinically significant reduction in baseline LDL-C and continued adherence to therapy
</td></tr>
<tr><td>Exclusion Criteria:</td><td>Concurrent use with PCSK9 monoclonal antibodies (e.g., Repatha, Praluent)</td></tr>
<tr><td>Age Restriction:</td><td>18 years of age and older</td></tr>
<tr><td>Prescriber Restrictions:</td><td>Prescribed by, or in consultation with, a cardiologist, endocrinologist, or lipid specialist</td></tr>
<tr><td>Coverage Duration:</td><td>Approval: 12 months, unless otherwise specified</td></tr>
</table>

POLICY NAME:
INEBILIZUMAB-CDON
Affected Medications: UPLIZNA (inebilizumab-cdon)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded from plan design
	  ○ Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive
	  ○ Immunoglobulin G4-related disease (IgG4-RD) in adults

Required Medical Information:	**NMOSD**
	• Diagnosis of seropositive aquaporin-4 immunoglobulin G (AQP4-IgG) NMOSD confirmed by all the following:
	  ○ Documentation of AQP4-IgG-specific antibodies on cell-based assay
	  ○ Exclusion of alternative diagnoses (such as multiple sclerosis)
	  ○ At least **one** core clinical characteristic:
	  ▪ Acute optic neuritis
	  ▪ Acute myelitis
	  ▪ Acute area postrema syndrome (episode of otherwise unexplained hiccups or nausea/vomiting)
	  ▪ Acute brainstem syndrome
	  ▪ Symptomatic narcolepsy **OR** acute diencephalic clinical syndrome with NMOSD-typical diencephalic lesion on magnetic resonance imaging (MRI) [*see table below*]
	  ▪ Acute cerebral syndrome with NMOSD-typical brain lesion on MRI [*see table below*]

Clinical presentation	Possible MRI findings
Diencephalic syndrome	• Periependymal lesion • Hypothalamic/thalamic lesion
Acute cerebral syndrome	• Extensive periependymal lesion • Long, diffuse, heterogenous, or edematous corpus callosum lesion • Long corticospinal tract lesion • Large, confluent subcortical or deep white matter lesion

• History of at least 1 attack in the past year, or at least 2 attacks in the past 2 years, requiring rescue therapy

IgG4-RD
• Diagnosis of IgG4-RD per American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) classification criteria that meets inclusion criteria, has no exclusion criteria, AND has equal to or greater than 20 classification criteria inclusion points
• The condition affects two or more organs or sites at any time, including at least one of the following: pancreas, bile ducts/biliary tree, orbits, lungs, kidneys, lacrimal glands, major salivary glands, retroperitoneum, aorta, pachymeninges, or thyroid gland

	• Member is experiencing (or has recently experienced) an IgG4-RD flare that requires glucocorticoid treatment

Appropriate Treatment Regimen & Other Criteria:	**NMOSD**
	• Documentation of inadequate response, contraindication, or intolerance to each of the following:
	  ○ Rituximab (preferred products: Truxima, Riabni, Ruxience)
	  ○ Satralizumab-mwge (Enspryng)
	
	Reauthorization requires documentation of treatment success
	
	IgG4-RD
	• Documentation of inadequate response, contraindication, or intolerance to each of the following:
	  ○ Glucocorticoids
	  ○ Rituximab (preferred products: Truxima, Riabni, Ruxience)
	
	Reauthorization requires documentation of treatment success

Exclusion Criteria:	• Active Hepatitis B Virus (HBV) infection • Active or untreated latent tuberculosis • Concurrent use with other disease-modifying biologics for requested indication
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	**NMOSD** • Prescribed by, or in consultation with, a neurologist or neuro-ophthalmologist **IgGR-RD** • Prescribed by, or in consultation with, a rheumatologist, immunologist, endocrinologist, nephrologist, hepatologist, or other providers with experience in treating IgG4-RD
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
INFLIXIMAB
Affected Medications: INFLECTRA, AVSOLA, REMICADE, INFLIXIMAB (J1745) INTRAVENOUS (IV) SOLUTION, RENFLEXIS

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis (PP)
	  ○ Rheumatoid Arthritis (RA)
	  ○ Psoriatic Arthritis (PsA)
	  ○ Ankylosing Spondylitis (AS)
	  ○ Non-radiographic axial spondyloarthritis (NR-axSPA)
	  ○ Crohn's Disease (CD)
	  ○ Ulcerative Colitis (UC)
	• Compendia-supported uses that will be covered
	  ○ Uveitis
	  ○ Hidradenitis Suppurativa (HS)
	  ○ Generalized Pustular Psoriasis (GPP) Flare

Required Medical Information:	**<u>Rheumatoid Arthritis</u>**
	• Documentation of current disease activity with one of the following (or equivalent objective scale)
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted Routine Assessment of Patient Index Data 3 (RAPID3) of at least 2.3
	
	<u>Plaque Psoriasis</u>
	• Documentation that the skin disease is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	AND
	• Documentation of one or more of the following:
	  ○ At least 10% body surface area involvement despite current treatment
	OR
	  ○ Hand, foot, or mucous membrane involvement
	
	<u>Psoriatic Arthritis</u>
	• Documentation of Classification for Psoriatic Arthritis (CASPAR) criteria score of 3 or greater based on chart notes:
	  ○ Skin psoriasis: present – two points, OR previously present by history – one point, OR a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxta-articular bone formation on radiographs (distinct from osteophytes): one point

	Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis
	• Diagnosis of axial spondyloarthritis (SpA) confirmed by sacroiliitis on imaging AND at least 1 spondyloarthritis feature:
	  ○ Inflammatory back pain (4 of 5 features met):
	  ▪ Onset of back discomfort before the age of 40 years
	  ▪ Insidious onset
	  ▪ Improvement with exercise
	  ▪ No improvement with rest
	  ▪ Pain at night (with improvement upon arising)
	  ○ Arthritis
	  ○ Enthesitis
	  ○ Uveitis
	  ○ Dactylitis (inflammation of entire digit)
	  ○ Psoriasis
	  ○ Crohn's disease/ulcerative colitis
	  ○ Good response to nonsteroidal anti-inflammatory drugs (NSAIDs)
	  ○ Family history of SpA
	  ○ Elevated C-reactive protein (CRP)
	  OR
	  ○ HLA-B27 genetic test positive AND at least TWO SpA features
	• Documentation of active disease defined by Bath ankylosing spondylitis disease activity index (BASDAI) at least 4 or equivalent objective scale
	
	Ulcerative Colitis and Crohn's Disease
	• Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy
	• Documentation of moderate to severely active disease despite current treatment
	
	Uveitis
	• Documented diagnosis of noninfectious intermediate, posterior, or panuveitis
	
	Hidradenitis Suppurativa
	• Diagnosis of moderate to severe HS as defined by Hurley stage II or stage III disease
	• Documentation of baseline count of abscesses and inflammatory nodules
	
	Generalized Pustular Psoriasis Flare
	• Diagnosis of generalized pustular psoriasis as confirmed by the following:
	  ○ The presence of widespread sterile pustules arising on erythematous skin
	  ○ Pustulation is not restricted to psoriatic plaques
	• Signs and symptoms of an acute GPP flare of moderate-to-severe intensity as follows:
	  ○ A Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of greater than or equal to 3
	  ○ A GPPGA pustulation score of greater than or equal to 2 (moderate to very high-density pustules)
	  ○ Greater than or equal to 5% body surface are (BSA) covered with erythema and the presence of pustules

Appropriate Treatment Regimen & Other Criteria:	**All Indications** • Coverage of Remicade or Infliximab (J1745) requires documentation of one of the following: ○ A documented intolerable adverse event to the preferred products, Inflectra, Avsola, Renflexis and the adverse event was not an expected adverse event attributed to the active ingredient

	Rheumatoid Arthritis
	• Documented failure with at least 12 weeks of treatment with methotrexate
	  ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide)
	
	Plaque Psoriasis
	• Documented treatment failure with 12 weeks of at least TWO systemic therapies: methotrexate, cyclosporine, acitretin, phototherapy [UVB, PUVA]
	
	Psoriatic Arthritis
	• Documented failure with at least 12 weeks of treatment with methotrexate
	  ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide)
	
	Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis
	• Documented failure with two daily prescription strength nonsteroidal anti-inflammatory drugs (ibuprofen, naproxen, diclofenac, meloxicam, etc.) with minimum 1 month trial each
	OR
	• For peripheral arthritis: documented treatment failure with locally administered parenteral glucocorticoid
	
	Crohn's disease
	• Documented treatment failure with at least one oral treatment for a minimum 12-week trial: azathioprine, 6-mercaptopurine, methotrexate, sulfasalazine, balsalazide
	OR
	• Documentation of previous surgical intervention for Crohn's disease
	OR
	• Documentation of severe, high-risk disease on colonoscopy defined by one of the following:
	  ○ Fistulizing disease
	  ○ Stricture
	  ○ Presence of abscess/phlegmon
	  ○ Deep ulcerations
	  ○ Large burden of disease including ileal, ileocolonic, or proximal gastrointestinal involvement
	Uveitis
	• Documented failure with at least 12 weeks of TWO of the following: an immunosuppressive agent such as: methotrexate, azathioprine, mycophenolate or a calcineurin inhibitor such as cyclosporine, tacrolimus
	
	Hidradenitis Suppurativa
	• Documented failure with at least 12 weeks of oral antibiotics (such as doxycycline, tetracycline, minocycline, or clindamycin plus rifampin)
	• Documented failure with 8 weeks on a systemic retinoid (isotretinoin or acitretin)
	
	Ulcerative Colitis
	• Documented failure with at least two oral treatments for a minimum of 12 weeks: corticosteroids, sulfasalazine, mesalamine, balsalazide, cyclosporine, azathioprine, 6-mercaptopurine
	OR
	• Documentation of severely active disease despite current treatment defined by greater than or equal to 6 bloody, loose stools per day with severe cramps and evidence of systemic toxicity

	(fever, tachycardia, anemia, and/or elevated CRP/ESR), or recent hospitalization for ulcerative colitis **<u>Generalized Pustular Psoriasis Flare</u>** • Documented 1 week treatment failure of acute disease flare (or documented intolerable adverse event) with: ○ Cyclosporine **<u>QL</u>** • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced • CD/UC/HS: 5 mg/kg at 0, 2 and 6 weeks followed by 5 mg/kg every 8 weeks thereafter. For those who respond and lose response, consideration may be given to treatment with 10 mg/kg • PsA/PP/GPP: 5 mg/kg at 0, 2 and 6 weeks followed by 5 mg/kg every 8 weeks thereafter • RA: 3 mg/kg at 0, 2 and 6 weeks followed by 3 mg/kg every 8 weeks thereafter. For those with an incomplete response, consideration may be given for dosing up to 10 mg/kg or as often as every 4 weeks • AS: 5 mg/kg at 0, 2 and 6 weeks followed by 5 mg/kg every 6 weeks thereafter **<u>Reauthorization</u>** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/ dermatologist/ophthalmologist/gastroenterologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
INFUSIONS FOR ADVANCED PARKINSON'S DISEASE
Affected Medications: ONAPGO (apomorphine hydrochloride infusion), VYALEV (carbidopa-levodopa infusion)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of motor fluctuations in adults with advanced Parkinson's disease (PD)
Required Medical Information:	• Diagnosis of advanced PD • Clear response to levodopa treatment with evidence of "On" periods **Onapgo** • Persistent motor fluctuations with "Off" time occurring 3 hours or more per day while awake despite an optimized PD treatment regimen **Vyalev** • Persistent motor fluctuations with "Off" time occurring 2.5 hours or more per day while awake despite an optimized PD treatment regimen

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with both of the following:
	  ○ Oral carbidopa/levodopa extended release
	  ○ Two additional agents from different anti-PD drug classes:
	  ▪ Monoamine oxidase-B (MAO-B) inhibitors (ex: selegiline, rasagiline)
	  ▪ Dopamine agonists (ex: amantadine, pramipexole, ropinirole)
	  ▪ Catechol-O-methyltransferase (COMT) inhibitors (ex: entacapone)
	
	Onapgo
	• Dosing is in accordance with FDA labeling and does not exceed 98 mg/20 mL per day
	
	Vyalev
	• Dosing is in accordance with FDA labeling and does not exceed 3,525 mg of foslevodopa component per day
	
	Reauthorization requires documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	**Onapgo** • PD not responsive to levodopa • Use for atypical Parkinson's syndrome (such as "Parkinson's Plus" syndrome) or secondary PD • Previous neurosurgical treatment for PD **Vyalev** • PD not responsive to levodopa • Concomitant or recent (within 2 weeks) use of nonselective MAO inhibitors • Concomitant use with carbidopa/levodopa extended-release products
Age Restriction:	**Onapgo** • 30 years of age or older **Vyalev** • 18 years of age or older

Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
INHALED MANNITOL
Affected Medications: MANNITOL (BRONCHITOL)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Add-on maintenance therapy to improve pulmonary function in cystic fibrosis
Required Medical Information:	• Documentation of cystic fibrosis (CF) diagnosis confirmed by appropriate genetic or diagnostic testing ○ Additional testing should include evaluation of overall clinical lung status and respiratory function (e.g., pulmonary function tests, lung imaging, etc.)

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with 6-month trial of twice daily inhaled hypertonic saline (at least 80% adherence), unless contraindicated or intolerable. Treatment failure defined as one or more of the following:
	  ○ Increased pulmonary exacerbations from baseline
	  ○ Decrease in FEV1
	• Requests for Bronchitol 7-day and 4-week treatment packs for add-on maintenance therapy:
	  ○ Documentation confirming successful completion of the Bronchitol Tolerance Test (BTT)
	  ○ Prescribed in conjunction with a short-acting bronchodilator and standard therapies for CF
	
	Reauthorization requires documentation of a clinically significant response to therapy

Exclusion Criteria:	
Age Restriction:	
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• **Authorization:** 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
INTERFERONS FOR MULTIPLE SCLEROSIS
Affected Medications: AVONEX (interferon beta-1a), BETASERON (interferon beta-1b), PLEGRIDY (pegylated interferon beta-1a), REBIF (interferon beta-1a)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following:
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)

Required Medical Information:	**MS** • Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS

Appropriate Treatment Regimen & Other Criteria:	• **Avonex and Plegridy:** Documentation of treatment failure with (or intolerance to) **BOTH** of the following:
	  ○ Glatiramer OR Glatopa
	  ○ Dimethyl fumarate, fingolimod OR teriflunomide
	• **Rebif and Betaseron:** Documentation of treatment failure with (or intolerance to) **ALL** the following:
	  ○ Glatiramer OR Glatopa
	  ○ Dimethyl fumarate, fingolimod OR teriflunomide
	  ○ Avonex OR Plegridy
	
	Reauthorization: provider attestation of treatment success

Exclusion Criteria:	• Concurrent use of other disease-modifying medications indicated for the treatment of MS
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Approval: 24 months, unless otherwise specified

POLICY NAME:
INTRAVITREAL ANTI-VEGF THERAPY
Affected Medications: EYLEA (aflibercept), EYLEA HD (aflibercept), BEOVU (brolucizumab), SUSVIMO (ranibizumab implant), VABYSMO (faricimab), PAVBLU (aflibercept-ayyh), ranibizumab (Lucentis, Byooviz)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
	  ○ Neovascular (Wet) Age-Related Macular Degeneration (AMD)
	  ▪ Eylea, Eylea HD, Pavblu, Lucentis, Susvimo, Beovu, Vabysmo
	  ○ Macular Edema Following Retinal Vein Occlusion (RVO)
	  ▪ Eylea, Pavblu, Lucentis, Vabysmo
	  ○ Diabetic Macular Edema (DME)
	  ▪ Eylea, Eylea HD, Pavblu, Lucentis, Vabysmo, Beovu, Susvimo
	  ○ Diabetic Retinopathy (DR) in patients with Diabetes Mellitus
	  ▪ Eylea, Eylea HD, Pavblu, Lucentis, Susvimo
	  ○ Myopic Choroidal Neovascularization (mCNV)
	  ▪ Lucentis
	  ○ Retinopathy of Prematurity (ROP)
	  ▪ Eylea

Required Medical Information:	• Anticipated treatment course with dose and frequency clearly stated in chart notes.

Appropriate Treatment Regimen & Other Criteria:	• Initial approval of any of the following drugs requires documented failure to intravitreal Avastin (bevacizumab) after a minimum 3-month trial, defined as worsening vision, such as losing greater than 15 letters of visual acuity
	  ○ Exception: treatment of ROP
	
	<u>Eylea/Pavblu Dosing</u>
	• Approval requires documentation of one of the following:
	  ○ Treatment failure or intolerable adverse event with at least 3 months of ranibizumab (preferred products: Byooviz, Lucentis)
	  ○ Documentation of treatment-naïve ROP in preterm infant 32 weeks or younger
	
	• **AMD** - 2mg (0.05 ml) every 4 weeks for the first 3 injections, followed by 2 mg (0.05ml) every 8 weeks
	  ○ Continued every 4-week dosing requires documented clinical failure to minimum 3 months of every 8-week maintenance dosing
	• **RVO** - 2 mg (0.05 mL) every 4 weeks
	• **DME and DR**- 2mg (0.05 ml) every 4 weeks for the first 5 injections followed by 2 mg (0.05ml) every 8 weeks
	• **ROP** – 0.4 mg (0.01 mL) single injection per affected eye(s); may repeat dose after a minimum interval of 10 days
	
	<u>Eylea HD Dosing</u>
	• Approval requires documentation of one of the following:
	  ○ Treatment failure or intolerable adverse event with at least 3 months of ranibizumab (preferred products: Byooviz, Lucentis)
	• **AMD and DME** – 8 mg (0.07 mL) every 4 weeks for the first 3 injections followed by 8 mg

	(0.07 mL) every 8 to 16 weeks ○ Every 4-week dosing is limited to the first 3 injections only • **DR -** 8 mg (0.07 mL) every 4 weeks for the first 3 injections followed by 8 mg (0.07 mL) every 8 weeks to 12 weeks ○ Every 4-week dosing is limited to the first 3 injections only <u>Lucentis Dosing</u> • **AMD and RVO** – maximum 0.5mg every 4 weeks • **DME and DR** – 0.3 mg every 28 days • **mCNV** - 0.5 mg monthly for up to 3 months • **ROP** – 0.1 to 0.3 mg as a single injection in the affected eye(s); dose may be repeated up to 2 times at a minimum of 28-day intervals <u>Beovu Dosing</u> • **AMD** – 6 mg every month for the first three doses, followed by 6 mg every 8-12 weeks • **DME** – 6 mg every six weeks for the first five doses, followed by 6 mg every 8-12 weeks <u>Susvimo Dosing</u> • Must be established on ranibizumab (preferred products: Byooviz, Lucentis) injections with response to treatment for a minimum of 6 months at standard dosing (0.5mg every 4 weeks) • **AMD and DME**– 2mg administered continuously via ocular implant with refills every 24 weeks • **DR** – 2 mg administered continuously via ocular implant with refills every 36 weeks <u>Vabysmo Dosing</u> • Approval requires documented treatment failure or intolerable adverse event with at least 3 months of ranibizumab (preferred products: Byooviz, Lucentis) • **AMD** – 6 mg every 4 weeks for the first 4 injections, followed by 6 mg every 8 to 16 weeks ○ Some patients may require continued every 4-week injections following the initial doses • **DME** ○ Fixed interval regimen: 6 mg every 4 weeks for the first 6 injections, followed by 6 mg every 8 weeks ○ Variable interval regimen: 6 mg once every 4 weeks for at least the first 4 injections, followed by 6 mg every 4 to 16 weeks (based on visual assessments) ○ Some patients may require continued every 4-week injections following the initial doses • **RVO** - 6 mg (0.05 mL) every 4 weeks for up to 6 months **<u>Reauthorization</u>** requires documentation of vision stability defined as losing fewer than 15 letters of visual acuity and/or improvements in visual acuity with evidence of decreased leakage and/or fibrosis (central retinal thickness)
Exclusion Criteria:	• Evidence of a current ocular or periocular infections • Active intraocular inflammation (aflibercept)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an ophthalmologist

Coverage Duration:	**Macular Edema Following Retinal Vein Occlusion (RVO) for Vabysmo:** • Approval: 6 months with no reauthorization, unless otherwise specified **Retinopathy of Prematurity (ROP):** • Approval: 3 months with no reauthorization, unless otherwise specified **All other indications:** • Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
INTRAVITREAL COMPLEMENT INHIBITORS
Affected Medications: SYFOVRE (pegcetacoplan), IZERVAY (avacincaptad pegol)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

Required Medical Information:	• Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) confirmed by all the following:
	  ○ Fundus Autofluorescence (FAF) imaging showing:
	  ▪ Total GA area size between 2.5 and 17.5 mm^2
	  ▪ If GA is multifocal, at least 1 focal lesion that is 1.25 mm^2 or greater
	• Best-corrected visual acuity (BCVA) between 24 and 83 Early Treatment Diabetic Retinopathy Study (ETDRS) letters (20/25 and 20/320 Snellen equivalent)

Appropriate Treatment Regimen & Other Criteria:	• Dosing not to exceed:
	  ○ Every 25-day dosing for Syfovre
	  ○ Every 28-day dosing for Izervay
	
	Reauthorization requires documentation of treatment success and for BCVA to remain at 24 letters or better (20/320 Snellen equivalent)

Exclusion Criteria:	• Presence of choroidal neovascularization in the affected eye(s) receiving treatment
Age Restriction:	• 60 years of age and older for Syfovre • 50 years of age and older for Izervay
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an ophthalmologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
INTRON-A
Affected Medications: INTRON A (Interferon Alfa-2B)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher • Hypereosinophilic Syndrome (HES) in patients that are consistently symptomatic or with evidence of end-organ damage.
Required Medical Information:	• For Hepatitis B and C: Documentation of intolerance to or clinical rationale for avoidance of PEGylated interferon. • HES: documentation of steroid resistant disease OR disease responding only to high-dose steroids and the addition of a steroid-sparing agent would be beneficial. ○ Non-lymphocytic variants of HES will also require documented failure with at least 12 weeks of hydroxyurea prior to interferon-alfa approval. • Recent liver function tests, comprehensive metabolic panel, complete blood count with differential, TSH (within past 3 months) • Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • **Reauthorization**: documentation of disease responsiveness to therapy
Appropriate Treatment Regimen & Other Criteria:	• Patients with preexisting cardiac abnormalities and/or advanced cancer: recent electrocardiogram • Chest X ray for patients with pulmonary disorders • Recent ophthalmologic exam at baseline for all patients • Uncontrolled severe mental health illness should be addressed before use and monitored during treatment
Exclusion Criteria:	• Autoimmune hepatitis • Decompensated liver disease • Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	• Hepatitis B greater than or equal to 1 year of age • Hepatitis C greater than or equal to 3 years of age • All other indications greater than or equal to 18 years of age
Prescriber Restrictions:	
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
ISAVUCONAZONIUM SULFATE
Affected Medications: CRESEMBA (isavuconazonium sulfate)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of invasive aspergillosis
	  ○ Treatment of invasive mucormycosis

Required Medical Information:	**Invasive Aspergillosis**
	• Documented diagnosis supported by clinical manifestations of disease and at least one of the following:
	  ○ Features of *Aspergillus* spp. on histopathology or cytology (tissue or fluid staining)
	  ○ Positive culture or biopsy
	  ○ Two or more positive polymerase chain reaction (PCR) tests from serum, plasma, bronchoalveolar lavage (BAL), or a combination
	  ○ Elevated galactomannan (GM) index
	  ▪ Greater than or equal to 1.0 from serum, plasma, BAL, or cerebrospinal fluid (CSF)
	  OR
	  ▪ Greater than or equal to 0.7 from serum or plasma **and** greater than or equal to 0.8 from BAL
	
	Invasive Mucormycosis
	• Documented diagnosis of invasive mucormycosis supported by clinical manifestations of disease and at least one of the following:
	  ○ Positive tissue culture or biopsy
	  ○ Features of Mucorales on histopathology
	  ○ Positive polymerase chain reaction (PCR) test (serum, plasma, or histological specimens with fungal elements)

Appropriate Treatment Regimen & Other Criteria:	**Invasive Aspergillosis**
	• Documentation treatment failure with minimum 2-week trial of the following, unless intolerable or contraindicated:
	  ○ Voriconazole
	  ○ Posaconazole
	
	Invasive Mucormycosis
	• Documented treatment failure or intolerable adverse event with one of the following:
	  ○ Amphotericin B (if request is for initial therapy)
	  ○ Posaconazole (if request is for oral step-down therapy after initial therapy)
	
	Reauthorization will require documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Familial short QT syndrome
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist, transplant physician, or oncologist
Coverage Duration:	• Authorization: 3 months, unless otherwise specified

POLICY NAME:
ISOTRETINOIN ORAL
Affected Medications: AMNESTEEM ORAL, ISOTRETINOIN ORAL, MYORISAN ORAL, ZENATANE ORAL

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Severe acne
	• Compendia-supported uses
	  ○ Hidradenitis suppurative (HS)

Required Medical Information:	**<u>For all indications</u>** • Current Weight **<u>Severe Acne</u>** For age 21 and above: • Documentation of persistent or recurrent inflammatory nodules and cysts AND ongoing scarring OR • Documentation of acne fulminans OR • For Acne Conglobata: documentation of recurrent abscesses or communicating sinuses **<u>Hidradenitis Suppurativa (HS)</u>** For age 21 and above: • Diagnosis of moderate to severe HS as defined by Hurley stage II or stage III disease AND • Documentation of baseline count of abscesses and inflammatory nodules

Appropriate Treatment Regimen & Other Criteria:	**<u>Severe Acne</u>**
	• Documented trial and failure with at least 80% adherence to 12 continuous weeks of treatment with one of the following:
	  ○ Oral antibiotic (such as doxycycline or minocycline)
	  ○ Topical combination therapy (such as topical antibiotic with topical retinoid)
	
	<u>Hidradenitis Suppurativa</u>
	• Documented trial and failure of at least 12 weeks of oral antibiotics (such as doxycycline, minocycline, or clindamycin plus rifampin)
	
	<u>Reauthorization</u> will require documentation of treatment success and current cumulative isotretinoin dose

Exclusion Criteria:	• Dosing above 150mg/kg cumulative lifetime dose. • Symptoms of depression, mood disturbance, psychosis, or aggression.
Age Restriction:	• 12 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a Dermatologist
Coverage Duration:	• Initial approval: 5 months • Reauthorization: determined by cumulative lifetime dose

PacificSource Community Solutions

POLICY NAME:
ITRACONAZOLE
Affected Medications: ITRACONAZOLE 100 mg oral capsule, ITRACONAZOLE 10 mg/mL oral solution

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Pulmonary and extrapulmonary aspergillosis – salvage therapy
	  ○ Pulmonary and extrapulmonary blastomycosis
	  ○ Disseminated, non-meningeal histoplasmosis
	  ○ Pulmonary histoplasmosis
	  ○ Onychomycosis
	  ○ Oropharyngeal and esophageal candidiasis (oral solution)
	• Compendia-supported uses that will be covered (if applicable)
	  ○ Superficial tinea infections
	  ○ Coccidioidomycosis
	  ○ Prophylaxis against invasive fungal infections
	  ○ Sporotrichosis
	  ○ Talaromycosis

Required Medical Information:	**<u>Onychomycosis and superficial tinea infections</u>** • Documentation of a confirmed diagnosis of onychomycosis or tinea infection ○ Onychomycosis diagnosis must be confirmed by potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy • Documentation of a secondary risk factor that is covered by the Oregon Health Authority (OHA), such as diabetes mellitus, peripheral vascular disease, immunocompromised status
Appropriate Treatment Regimen & Other Criteria:	• **Itraconazole oral solution:** Documentation of inability to swallow capsules/tablets AND therapeutic alternatives available in other formulations (such as oral solutions or suspensions, injections, topicals) have been exhausted. Not applicable to oropharyngeal and esophageal candidiasis. **<u>Superficial tinea infections</u>** • Documented treatment failure with an adequate trial of a topical antifungal agent (such as terbinafine, naftifine, tolnaftate, clotrimazole) **<u>Oropharyngeal and Esophageal Candidiasis (Oral Solution)</u>** • Documented treatment failure (defined as no response to therapy) with fluconazole
Exclusion Criteria:	
Coverage Duration:	**<u>Onychomycosis</u>** • Authorization: 6 weeks (fingernails) or 12 weeks (toenails), unless otherwise specified **<u>Superficial tinea infections and oropharyngeal/esophageal candidiasis</u>** • Authorization: 1 month, unless otherwise specified **<u>All other indications:</u>** • Authorization: 6 months, unless otherwise specified

POLICY NAME:
KESIMPTA
Affected Medications KESIMPTA (ofatumumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following:
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)

Required Medical Information:	**RRMS** • Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS **CIS** • Documentation of a monophasic clinical episode, with patient-reported symptoms and corresponding objective clinical evidence as follows: One or more T2-hyperintense lesions that are characteristic of MS in at least two of four MS-typical regions (periventricular, cortical or juxtacortical, infratentorial brain regions, and the spinal cord) **Active SPMS** • Documented history of RRMS, followed by gradual and persistent worsening in neurologic function over at least 6 months (independent of relapses) • Evidence of active SPMS, as shown by ongoing clinical relapses and/or inflammatory activity (i.e., gadolinium enhancing lesions **OR** new or enlarging lesions) • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure or intolerance to one of the following:
	  ○ Rituximab (preferred biosimilar products: Truxima, Ruxience, Riabni)
	  ○ Ocrevus (ocrelizumab), if previously established on treatment (excluding via samples or manufacturer's patient assistance programs)
	• No concurrent use of other disease-modifying medications indicated for the treatment of MS
	
	Reauthorization requires provider attestation of treatment success

Exclusion Criteria:	• Active hepatitis B virus infection
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

POLICY NAME:
LAROTRECTINIB
Affected Medications: VITRAKVI (larotrectinib)

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Documentation of positive neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, as determined by an FDA approved test
Appropriate Treatment Regimen & Other Criteria:	• Documentation of an intolerance to, or clinical rationale for avoidance of Rozlytrek (entrectinib) **Reauthorization:** Documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LAZERTINIB
Affected Medications: Lazcluze (lazertinib)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Documentation of confirmed non-small cell lung cancer (NSCLC) that is metastatic or unresectable with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations.
Appropriate Treatment Regimen & Other Criteria:	• Documented intolerable adverse event to Tagrisso (osimertinib) with or without chemotherapy **Reauthorization:** documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	• At least 18 years of age
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LECANEMAB
Affected Medications: LEQEMBI (lecanemab)

<table>
<tr><td>Covered Uses:</td><td>

All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design

Alzheimer’s disease

</td></tr>
<tr><td>Required Medical Information:</td><td>

Documentation of mild cognitive impairment due to Alzheimer’s disease or mild Alzheimer’s dementia as evidenced by ALL of the following:

Clinical Dementia Rating (CDR) global score of 0.5
Evidence of cognitive impairment at baseline using validated objective scales
Mini-Mental Status Exam (MMSE) score of at least 22
Positron Emission Tomography (PET) scan positive for amyloid beta plaque

Documentation of baseline brain magnetic resonance (MRI) within the last year with no superficial siderosis or brain hemorrhage

</td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>

Current weight

<u>Dosing</u>

Availability: 500 mg/5 mL vial and 200 mg/2 mL vial
Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced

Dosing and Monitoring Schedule:
<table>
<tr><th>Infusion (every 2 weeks)</th><th>Dose</th><th>Monitoring</th></tr>
<tr><td>Infusion 1</td><td>10 mg/kg</td><td>Baseline MRI prior to Infusion 1</td></tr>
<tr><td>Infusions 2-5</td><td>10 mg/kg</td><td>MRI between Infusion 4 and 5</td></tr>
<tr><td>Infusions 5-7</td><td>10 mg/kg</td><td>MRI between Infusion 6 and 7</td></tr>
<tr><td>Infusions 8-14</td><td>10 mg/kg</td><td>MRI between Infusion 13 and 14</td></tr>
<tr><td>Infusions 15 and after</td><td>10 mg/kg</td><td>MRI annually</td></tr>
</table>
<u>Reauthorization</u>

Documentation of clinically significant amyloid reduction compared to baseline confirmed by post-infusion PET scan (3rd authorization only)
Documentation of updated surveillance MRI showing absence of clinically significant microhemorrhage and superficial siderosis since prior approval
Documentation of one of the following when compared to baseline:

Cognitive or functional improvement
Disease stabilization
Reduction in clinical decline compared to natural disease progression

</td></tr>
<tr><td>Exclusion Criteria:</td><td>

Prior stroke or brain hemorrhage
Evidence of moderate to severe Alzheimer’s disease
Non-Alzheimer’s dementia
Concurrent anticoagulant use

</td></tr>
<tr><td>Age Restriction:</td><td>

50 years of age and older

</td></tr>
<tr><td>Prescriber/Site of Care Restrictions:</td><td>

Prescribed by, or in consultation with, a neurologist

</td></tr>
</table>

Coverage Duration:	Initial Authorization: 6 months, unless otherwise specified Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LENACAPAVIR
Affected Medications: SUNLENCA

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of human immunodeficiency virus type 1 (HIV-1) infection, in combination with other antiretrovirals, in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

Required Medical Information:	• Documentation of multidrug resistance within at least 3 of the 4 following antiretroviral classes (as defined by resistance to at least 2 agents within each of the 3 classes), unless contraindicated or clinically significant adverse effects are experienced:
	  ○ Nucleoside reverse-transcriptase inhibitors (NRTIs)
	  ○ Non-nucleoside reverse-transcriptase inhibitors (NNRTIs)
	  ○ Protease inhibitors (PIs)
	  ○ Integrase strand transfer inhibitors (INSTIs)
	• Documentation of current (within the past 30 days) HIV-1 RNA viral load of at least 200 copies/mL

Appropriate Treatment Regimen & Other Criteria:	• Must be used in combination with an optimized background antiretroviral regimen that contains at least one agent demonstrating full viral susceptibility, as confirmed by resistance testing
	
	<u>Reauthorization</u>:
	• Treatment plan includes continued use of optimized background antiretroviral regimen
	• Documentation of treatment success, as evidenced by one of the following:
	  ○ Reduction in viral load from baseline or maintenance of undetectable viral load
	  ○ Absence of postbaseline emergence of lenacapavir resistance-associated mutations confirmed by resistance testing

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Must be prescribed by, or in consultation with, an infectious disease or HIV specialist
Coverage Duration:	• Oral Tablet Initial Authorization: 1 month, unless otherwise specified • Injection Initial Authorization: 6 months, unless otherwise specified • Injection Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LENIOLISIB
Affected Medications: JOENJA (leniolisib)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Activated phosphoinositide 3-kinase delta syndrome (APDS)

Required Medical Information:	• Documentation of an APDS-associated PIK3CD/PIK3R1 mutation without concurrent use of immunosuppressive medication
	• Presence of at least one measurable nodal lesion on a CT or MRI scan
	• Documentation of both of the following:
	  ○ Nodal and/or extranodal lymphoproliferation
	  ○ History of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g., lung, liver)
	• Current member weight (must be at least 45 kg)

Appropriate Treatment Regimen & Other Criteria:	• Females of reproductive potential should have pregnancy ruled out and use effective contraception during therapy **Reauthorization** will require documentation of treatment success as shown by both of the following: • Improvement in lymphoproliferation as measured by a change from baseline in lymphadenopathy • Normalization of immunophenotype as measured by the percentage of naïve B cells out of total B cells
Exclusion Criteria:	
Age Restriction:	• 12 to 75 years of age
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an immunologist, hematologist, oncologist, or specialist with experience in the treatment of APDS
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LETERMOVIR
Affected Medications: PREVYMIS (letermovir)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Prophylaxis of cytomegalovirus (CMV) infection and disease in CMV-seropositive recipients [R+] of an allogeneic hematopoietic cell transplant for adults and pediatric patients 6 months of age and older and weighing at least 6 kg
	  ○ Prophylaxis of CMV disease in kidney transplant recipients at high risk for adult and pediatric patients 12 years of age and older and weighing at least 40 kg

Required Medical Information:	**CMV Prophylaxis in Allogeneic HSCT [R+]** • Documentation confirming receipt of allogeneic HSCT • Documentation of recipient CMV-seropositive status **CMV Prophylaxis in Kidney Transplant [D+/R-]** • Documentation confirming receipt of kidney transplant • Evidence of high-risk for CMV disease, defined as donor CMV-seropositive/recipient CMV-seronegative mismatch
Appropriate Treatment Regimen & Other Criteria:	**CMV Prophylaxis in Allogeneic HSCT [R+]** • **Dosing:** Up to 480 mg (or 240 mg) once daily beginning between Day 0 and 28 post-allogeneic HSCT; continue through Day 100 post-transplantation **CMV Prophylaxis in Kidney Transplant [D+/R-]** • Documented intolerance or contraindication to valganciclovir • **Dosing:** Up to 480 mg once daily beginning between Day 0 and 7 post-kidney transplant; continue through Day 200 post-transplantation
Exclusion Criteria:	
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a specialist in transplant medicine, infectious disease, or hematology
Coverage Duration:	• HSCT: 4 months, unless otherwise specified • Kidney transplant: 7 months, unless otherwise specified

POLICY NAME:
LEUPROLIDE
Affected Medications: Leuprolide Acetate, LUPRON DEPOT, LUPRON DEPOT-PED, ELIGARD, FENSOLVI, CAMCEVI

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Endometriosis
	  ○ Uterine leiomyomata (fibroids)
	  ○ Central precocious puberty (CPP)
	• National Comprehensive Cancer Network (NCCN) indications with evidence level 2A or higher
	• Gender dysphoria

Required Medical Information:	**Endometriosis**
	• Documentation of moderate to severe pain due to endometriosis
	
	Uterine leiomyomata (fibroids)
	• Documentation of all the following:
	  ○ Preoperative anemia due to uterine leiomyomata (fibroids)
	  ○ Planning to undergo leiomyomata-related surgery in the next 6 months or less
	  ○ Planning to use in combination with iron supplements
	
	Gender dysphoria
	• Documentation of all the following:
	  ○ Current Tanner stage 2 or greater OR baseline and current estradiol and testosterone levels to confirm onset of puberty
	  ○ Confirmed diagnosis of gender dysphoria that is persistent
	  ○ The patient has the capacity to make a fully informed decision and to give consent for treatment
	  ○ Any significant medical or mental health concerns are reasonably well controlled
	  ○ A comprehensive mental health evaluation has been completed by a licensed mental health professional (LMHP) and provided in accordance with the most current version of the World Professional Association for Transgender Health (WPATH) Standards of Care
	
	Central precocious puberty
	• Documentation of CPP confirmed by basal luteinizing hormone (LH), follicle-stimulating hormone (FSH), and either estradiol or testosterone concentrations

Appropriate Treatment Regimen & Other Criteria:	**Endometriosis**
	• Documentation of a trial and inadequate relief (or contraindication) after at least 3 months of both of the following first-line therapies:
	  ○ Nonsteroidal anti-inflammatory drugs (NSAIDs)
	  ○ Continuous (no placebo pills) hormonal contraceptives
	
	Central precocious puberty
	• Approval of Fensolvi requires rationale for avoidance of Lupron and Supprelin LA

Exclusion Criteria:	• Undiagnosed abnormal vaginal bleeding • Management of uterine leiomyomata without intention of undergoing surgery. • Pregnancy or breastfeeding

	• Use for infertility
Age Restriction:	• Endometriosis and preoperative uterine leiomyomata: 18 years or older • Central precocious puberty (CPP): age 11 or younger (females), age 12 or younger (males)
Prescriber Restrictions:	• Gender Dysphoria: Diagnosis made and prescribed by, or in consultation with, a specialist in the treatment of gender dysphoria • All other indications: prescribed by, or in consultation with, an oncologist, endocrinologist, or gynecologist as appropriate for diagnosis
Coverage Duration:	• Uterine leiomyomata: maximum of 6 months, unless otherwise specified • Endometriosis: 6 months, unless otherwise specified • All other diagnoses: 12 months, unless otherwise specified

POLICY NAME:
LEVOKETOCONAZOLE
Affected Medications: RECORLEV (levoketoconazole)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Cushing syndrome

Required Medical Information:	• Diagnosis of Cushing's syndrome due to one of the following:
	  ○ Adrenocorticotropic hormone (ACTH)-secreting pituitary adenoma (Cushing's disease)
	  ○ Ectopic ACTH secretion (EAS) by a non-pituitary tumor
	  ○ Cortisol secretion by an adrenal adenoma
	• Mean 24-hour urine free cortisol (mUFC) greater than 1.5 times the upper limit of normal (ULN) for the assay (at least two measurements)

Appropriate Treatment Regimen & Other Criteria:	• Documentation confirming surgery is not an option **OR** previous surgery has not been curative
	• Documentation of **one** of the following:
	  ○ Clinical failure to maximally tolerated dose of oral ketoconazole for at least 8 weeks
	  ○ Intolerable adverse event to oral ketoconazole, and the adverse event was not an expected adverse event attributed to the active ingredient
	Reauthorization requires documentation of treatment success defined as mUFC normalization (i.e., less than or equal to the ULN)

Exclusion Criteria:	• Adrenal or pituitary carcinoma
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist, neurologist, or adrenal surgeon
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LIDOCAINE PATCH
Affected Medications: Lidocaine Patch

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. • Diabetic neuropathic pain
Required Medical Information:	• Diagnosis of post-herpetic neuralgia **OR** • Diagnosis of diabetes (for diabetic neuropathy) • All medications tried/failed for indicated diagnosis
Appropriate Treatment Regimen & Other Criteria:	**Post Herpetic Neuralgia:** • Documented inadequate treatment response or intolerance to gabapentin **Diabetic Neuropathic Pain:** • Documented inadequate treatment response or intolerance to a minimum of 3 other pharmacologic therapies commonly used to treat neuropathic pain such as gabapentin, serotonin norepinephrine reuptake inhibitors (SNRIs): duloxetine, venlafaxine, desvenlafaxine, and tricyclic antidepressants (TCAs) **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LIFILEUCEL
Affected Medications: AMTAGVI (lifileucel)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Diagnosis of unresectable or Stage IV metastatic melanoma • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • ECOG PS of 0 or 1 • Left ventricular ejection fraction (LVEF) greater than 45% • Forced expiratory volume (FEV1) greater than 60% • New York Heart Association (NYHA) classification not more than Class I

Appropriate Treatment Regimen & Other Criteria:	• At least one resectable lesion (or aggregate of lesions resected) of 1.5 cm or more in diameter post-resection to generate tumor-infiltrating lymphocytes (TILs)
	• Disease progression after 1 or more prior systemic therapy including
	  ○ A PD-1–blocking antibody and
	  ○ If BRAF V600 mutation–positive, a BRAF inhibitor or BRAF inhibitor plus a MEK inhibitor

Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Melanoma of uveal or ocular origin • Untreated or active brain metastasis
Age Restriction:	• At least 18 years of age
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Approve for 6 months (one dose per patient's lifetime), unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LONAFARNIB
Affected Medications: Zokinvy (lonafarnib)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome
	  ○ For treatment of processing-deficient Progeroid Laminopathies

Required Medical Information:	• A diagnosis of Hutchinson-Gilford Progeria Syndrome (HGPS) confirmed by mutational analysis (G608G mutation in the lamin A gene)
	OR
	• A diagnosis of processing-deficient Progeroid Laminopathies with one of the following:
	  ○ Heterozygous LMNA mutation with progerin-like protein accumulation
	  ○ Homozygous or compound heterozygous ZMPSTE24 mutations

Appropriate Treatment Regimen & Other Criteria:	• Documented height and weight, or body surface area (BSA)
	• Documentation of medication review and avoidance of drugs that significantly affect the metabolism of lonafarnib (e.g., strong or moderate CYP3A4 inhibitors/inducers)
	• Females of reproductive potential should have pregnancy ruled out and use effective contraception during treatment
	
	Labs:
	• Absolute Phagocyte Count (sum of absolute neutrophil count, bands, and monocytes) greater than 1,000/microliters
	• Platelets greater than 75,000/microliters (transfusion independent)
	• Hemoglobin greater than 9g/dl.
	
	Dosing:
	• Available as oral capsules: 50 mg, 75 mg
	• Initial, 115 mg/m2/dose twice daily for 4 months, then increase to 150 mg/m2/dose twice daily
	  ○ Do not exceed 115 mg/m2/dose twice daily when used in combination with a weak CYP3A4 inhibitor
	  ○ Round all total daily doses to the nearest 25 mg increment
	
	Reauthorization: Documentation of treatment success and initial criteria to be met.

Exclusion Criteria:	• Use for other progeroid syndromes or processing-proficient progeroid laminopathies • Concomitant use with strong or moderate CYP3A4 inhibitors/inducers, midazolam, lovastatin, atorvastatin, or simvastatin • Overt renal, hepatic, pulmonary disease or immune dysfunction • BSA less than to 0.39 m2
Age Restriction:	• Age 12 months or older with a BSA of greater than or equal to 0.39 m2
Prescriber Restrictions:	• Prescribed by, or in consultation with, a provider with experience in treating progeria and/or progeroid laminopathies
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
LONG-ACTING INJECTABLE RISPERIDONE
Affected Medications: PERSERIS (risperidone subcutaneous injection), RISPERDAL CONSTA (risperidone intramuscular injection), RYKINDO (risperidone intramuscular injection) (*Medical benefit only)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Schizophrenia
	  ○ Bipolar I disorder maintenance treatment as monotherapy or as adjunctive therapy to lithium and valproate (Risperdal Consta and Rykindo only)

Required Medical Information:	**Treatment Initiation** • A documented history of non-compliance, refusal to utilize oral medication, or cannot be stabilized on oral medications • Documentation of established tolerability to oral risperidone (if risperidone-naïve) **Continuation of Therapy** • Documentation showing that member is stable on current treatment with Perseris, Rykindo or Risperdal Consta
Appropriate Treatment Regimen & Other Criteria:	• Requests for Perseris require documentation of treatment failure or clinical rationale for avoidance of Risperdal Consta or Rykindo **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a psychiatrist or receiving input from a psychiatry practice
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LOVOTIBEGLOGENE AUTOTEMCEL
Affected Medications: LYFGENIA (lovotibeglogene autotemcel)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of sickle cell disease in adults and pediatric patients at least 12 years of age with a history of recurrent vaso-occlusive crises

Required Medical Information:	• Documentation of sickle cell disease confirmed by genetic testing to show the presence of βS/βS, βS/β0 or βS/β+ genotype as follows:
	  ○ Identification of significant quantities of HbS with or without an additional abnormal β-globin chain variant by hemoglobin assay **OR**
	  ○ Identification of biallelic *HBB* pathogenic variants where at least one allele is the p.glu6Val or p.glu7val pathogenic variant on molecular genetic testing
	  AND
	  ○ Patient does NOT have disease with more than two α-globin gene deletions
	
	• Documentation of severe disease defined as 2 or more severe vaso-occlusive crises (VOCs) or vaso-occlusive events (VOEs) within the previous 1 years (4 events over 2 years will also meet this requirement)
	  ○ VOC/VOEs defined as an event requiring a visit to a medical facility for evaluation AND necessitating subsequent interventions such as opioid pain management, non-steroidal anti-inflammatory drugs, red blood cell (RBC) transfusions, which results in a diagnosis of such being documented due to one (or more) of the following:
	  ▪ Acute pain event
	  ▪ Acute chest Syndrome
	  ▪ Priapasm lasting more than 2 hours
	  ▪ Acute splenic sequestration
	  ▪ Acute hepatic sequestration
	
	• For patients under 18 years of age, the patient does not have a known and suitable (10/10) human leukocyte antigen (HLA) matched related donor willing to participate in an allogeneic hematopoietic stem cell transplant (HSCT)
	• Adequate bone marrow, lung, heart, and liver function to undergo myeloablative conditioning regimen
	• Confirmed HIV negative as confirmed by a negative HIV test prior to mobilization

Appropriate Treatment Regimen & Other Criteria:	• Able to provide the minimum recommended dose of Lyfgenia: 3,000,000 CD34+ cells/kg
Exclusion Criteria:	• Previous treatment with gene therapy for sickle cell disease • Prior hematopoietic stem cell transplant (HSCT) • History of hypersensitivity to dimethyl sulfoxide (DMSO) or dextran 40
Age Restriction:	• 12 years of age and older

Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 12 months (one-time infusion), unless otherwise specified

POLICY NAME:
LUSPATERCEPT-AAMT
Affected Medications: REBLOZYL (luspatercept-aamt)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of anemia in adults with beta thalassemia who require regular red blood cell (RBC) transfusions
	  ○ Treatment of anemia in adults without previous erythropoiesis stimulating agent use (ESA-naïve) with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular RBC transfusions
	  ○ Treatment of anemia failing an ESA and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk MDS with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

Required Medical Information:	**Beta Thalassemia**
	• Documented diagnosis of beta thalassemia OR hemoglobin E/beta thalassemia
	• Documentation of transfusion dependence as evidenced by BOTH of the following in the previous 24 weeks:
	  ○ Has required regular transfusions of at least 6 RBC units
	  ○ No transfusion-free period greater than 35 days
	• Pre-treatment or pre-transfusion hemoglobin (Hgb) level is less than or equal to 11 g/dL
	
	Myelodysplastic Syndromes
	• Documented diagnosis of MDS, MDS-RS or MDS/MPN-RS-T with very low, low, or intermediate risk as classified by the International Prognostic Scoring System-Revised (IPSS-R)
	• Documentation of requiring at least 2 RBC units over the previous 8 weeks
	• Pre-treatment or pre-transfusion level is less than or equal to 11 g/dL

Appropriate Treatment Regimen & Other Criteria:	**Myelodysplastic Syndromes** • For those with MDS-RS or MDS/MPN-RS-T, must have documentation of treatment failure with an ESA (e.g., Retacrit, Procrit, Epogen, Mircera), unless intolerant or current endogenous serum erythropoietin (sEPO) level is greater than 500 U/L **Reauthorization** • **Beta thalassemia:** requires documentation of treatment success, defined as a reduction in RBC transfusion burden from baseline by at least 20% • **MDS:** requires documentation of treatment success, defined as achieving transfusion independence and/or an improvement in Hgb level from baseline
Exclusion Criteria:	• Diagnosis of non-transfusion-dependent beta thalassemia • Use as immediate correction as a substitute for RBC transfusions • Diagnosis of alpha thalassemia • Known pregnancy
Age Restriction:	• 18 years of age and older

Prescriber Restrictions:	• **Beta thalassemia:** Prescribed by, or in consultation with, a hematologist • **MDS:** Prescribed by, or in consultation with, a hematologist or oncologist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
LUSUTROMBOPAG
Affected Medications: MULPLETA (lusutrombopag)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure

Required Medical Information:	• Documentation of ALL the following:
	  ○ Planned procedure including date
	  ○ Baseline platelet count of less than 50,000/microliter

Appropriate Treatment Regimen & Other Criteria:	• Approved for one time 7-day dosing regimen
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist or gastroenterology/liver specialist
Coverage Duration:	• Approval: 1 month (7 days of treatment), based on planned procedure date

PacificSource Community Solutions

POLICY NAME:
MARIBAVIR
Affected Medications: LIVTENCITY (maribavir)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet
Required Medical Information:	• Documentation of treatment refractory CMV infection or disease following hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT) • Documentation of current weight
Appropriate Treatment Regimen & Other Criteria:	• Documented clinical failure (defined as detectable plasma CMV DNA) after a minimum 3-week trial with at least one of the following: valganciclovir, ganciclovir, foscarnet, cidofovir **<u>Reauthorization:</u>** • Documented treatment success and a clinically significant response to therapy and continued need for treatment.
Exclusion Criteria:	• CMV infection involving the central nervous system, including the retina • Prophylaxis of CMV infection/disease
Age Restriction:	• 12 years and older
Prescriber/Site of Care Restrictions:	• Prescribed by an infectious disease provider or a specialist with experience in the treatment of CMV infection
Coverage Duration:	Authorization: 2 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MARSTACIMAB
Affected Medications: HYMPAVZI (marstacimab-hncq)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Hemophilia A (congenital factor VIII deficiency)
	  ○ Hemophilia B (congenital factory IX deficiency)

Required Medical Information:	• Diagnosis of congenital factor VIII deficiency (hemophilia A) or congenital factory IX deficiency (hemophilia B) without inhibitors • Documentation of baseline factor level less than 1% AND prophylaxis required OR • Baseline factor level 1% to 3% and a documented history of at least two episodes of spontaneous bleeding into joints • Prescribed for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
Appropriate Treatment Regimen & Other Criteria:	**Hemophilia A** • Documented treatment failure with Hemlibra (emicizumab-kxwh) **Hemophilia B** • Documented treatment failure to factor IX prophylaxis for at least 6 months Dose escalation to 300 mg once weekly: • Documented treatment failure of weighing at least 50 kg and experiencing at least 2 breakthrough bleeds while on 150 mg dose for at least 6 months **Reauthorization** requires documentation of treatment success defined as a reduction in spontaneous bleeds requiring treatment, and documentation of bleed history since last approval
Exclusion Criteria:	• Concurrent use with bypassing agents • Prior gene therapy administration • Pregnancy
Age Restriction:	• 12 years of age and older
Prescriber/Site of Care Restrictions:	• Hematologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MAVACAMTEN
Affected Medications: CAMZYOS (mavacamten)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. ○ Hypertrophic cardiomyopathy with left ventricular outflow tract obstruction
Required Medical Information:	• Documented diagnosis of obstructive hypertrophic cardiomyopathy (OHCM) • New York Heart Association (NYHA) class II or III symptoms • Left ventricular ejection fraction (LVEF) of 55% or greater prior to starting therapy • Valsalva left ventricular outflow tract (LVOT) peak gradient of 50 mmHg or greater at rest or with provocation, prior to starting therapy

Appropriate Treatment Regimen & Other Criteria:	• Documentation of negative pregnancy test AND use of effective contraception in females of reproductive potential
	• Documented treatment failure, intolerance, or contraindication, to **ALL** the following:
	  ○ Non-vasodilating beta-blocker (e.g., atenolol, metoprolol, bisoprolol,
	  ○ propranolol)
	  ○ Non-dihydropyridine calcium channel blocker (e.g., verapamil, diltiazem)
	
	Reauthorization will require documentation of symptomatic improvement and that LVEF remains above 50%

Exclusion Criteria:	• History of two measurements of LVEF less than 50% while on mavacamten 2.5 mg tablets
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by a cardiologist or a specialist with experience in the treatment of obstructive hypertrophic cardiomyopathy
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MAVORIXAFOR
Affected Medications: XOLREMDI (mavorixafor)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) in patients 12 years of age and older to increase the number of circulating mature neutrophils and lymphocytes
Required Medical Information:	• Diagnosis of WHIM syndrome confirmed by genotype variant of CXCR4 and ANC (absolute neutrophil count) of 400 cells/μL or less • Documentation of symptoms and complications associated with WHIM syndrome requiring medical treatment
Appropriate Treatment Regimen & Other Criteria:	• Documentation of weight to assess appropriate dosing • Documentation of baseline ALC (absolute lymphocyte count) and ANC (absolute neutrophil count) to assess clinical response to treatment **Reauthorization** requires documentation of disease responsiveness to therapy with sustained improvement in ALC and ANC
Exclusion Criteria:	• Concomitant use with drugs that are highly dependent on CYP2D6 for clearance
Age Restriction:	• 12 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an immunologist or hematologist
Coverage Duration:	• Initial Authorization: 6 months • Reauthorization: 12 months

PacificSource Community Solutions

POLICY NAME:
MEBENDAZOLE
Affected Medications: EMVERM (mebendazole)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Gastrointestinal (GI) infections caused by any of the following:
	  ▪ *Ancylostoma duodenale* (hookworm)
	  ▪ *Ascaris lumbricoides* (roundworm)
	  ▪ *Enterobius vermicularis* (pinworm)
	  ▪ *Necator americanus* (hookworm)
	  ▪ *Trichuris trichiura* (whipworm)
	• Compendia-supported uses that will be covered (if applicable)
	  ○ Capillariasis (*C. hepatica, C. philippinensis*)
	  ○ Cystic echinococcus
	  ○ Toxocariasis
	  ○ Trichinellosis (aka trichinosis)
	  ○ Trichostrongyliasis

Required Medical Information:	• Documentation of current helminth infection confirmed with appropriate lab testing

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure, clinically significant intolerance, or contraindication to albendazole is required for the following conditions:
	  ○ *Ancylostoma duodenale* (hookworm)
	  ○ *Ascaris lumbricoides* (roundworm)
	  ○ Capillariasis
	  ○ *Necator americanus* (hookworm)
	  ○ Toxocariasis (roundworm)
	  ○ Trichinellosis (aka trichinosis)
	• Documented treatment failure, clinically significant intolerance, or contraindication to albendazole AND pyrantel pamoate is required for the following conditions:
	  ○ *Enterobius vermicularis* (pinworm)

Exclusion Criteria:	
Age Restriction:	• 2 years of age and older
Prescriber/Site of Care Restrictions:	

Coverage Duration:	• Authorization:
	  ○ Cystic echinococcus: 6 months
	  ○ Other indications: 2 months

PacificSource Community Solutions

POLICY NAME:
MECASERMIN
Affected Medications: INCRELEX (mecasermin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Severe primary insulin-like growth factor-1 (IGF-1) deficiency (Primary IGFD)
	  ○ Patient with growth hormone (GH) gene deletion with neutralizine antibodies to GH

Required Medical Information:	• Prior to starting therapy, a height at least 3 standard deviations below the mean for chronological age and sex, and an IGF-1 level at least 3 standard deviations below the mean for chronological age and sex. • One stimulation test showing patient has a normal or elevated GH level.
Appropriate Treatment Regimen & Other Criteria:	• Initial: 0.04-0.08 mg/kg SQ twice daily. • Maintenance: Up to 0.12 mg/kg SQ twice daily **Reauthorization:** requires a documented growth rate increase of at least 2.5 cm over baseline per year AND evaluation of epiphyses (growth plates) documenting they remain open.
Exclusion Criteria:	• Epiphyseal closure, active or suspected neoplasia malignancy, or concurrent use with GH therapy. • Patient has secondary causes of IGF1 deficiency (e.g., hypothyroidism, malignancy, chronic systemic disease, skeletal disorders, malnutrition, celiac disease).
Age Restriction:	• For patients 2 to 18 years of age.
Prescriber Restrictions:	• Prescribed by, or in consultation with, a Pediatric Endocrinologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MEK INHIBITORS FOR NEUROFIBROMATOSIS TYPE 1 (NF1)
Affected Medications KOSELUGO (selumetinib), GOMEKLI (mirdametinib)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Neurofibromatosis type 1 with symptomatic, inoperable plexiform neurofibromas in pediatric patients 1 year of age and older • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better

Required Medical Information:	• Documented body surface area (BSA) and requested dose (all indications)
	
	<u>Neurofibromatosis type 1 (NF1) with inoperable plexiform neurofibromas</u>
	• Documentation of diagnosis of symptomatic and/or progressive, inoperable NF1, defined as one or more plexiform neurofibromas that cannot be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity
	
	• Documentation of 2 or more of the following clinical diagnostic criteria as evaluated by a multidisciplinary specialist care team (A child of a parent with NF1 can be diagnosed if one or more of these criteria are met):
	  ○ Six or more café-au-lait macules over 5 mm in greatest diameter in prepubertal individuals and over 15 mm in greatest diameter in post pubertal individuals
	  ○ Freckling in the axillary or inguinal region
	  ○ Two or more neurofibromas of any type or one plexiform neurofibroma
	  ○ Optic pathway glioma
	  ○ Two or more iris Lisch nodules identified by slit lamp examination or two or more choroidal abnormalities
	  ○ A distinctive osseous lesion such as sphenoid dysplasia, anterolateral bowing of the tibia, or pseudarthrosis of a long bone
	  ○ A heterozygous pathogenic NF1 variant with a variant allele fraction of 50% in apparently normal tissue such as white blood cells
	
	<u>NCCN Indications</u>
	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course

Appropriate Treatment Regimen & Other Criteria:	• Coverage of Gomekli requires documentation of the following:
	  ○ Documented of intolerable adverse event to Koselugo OR
	  ○ Age 18 years and above
	  ○ Dosing is limited to 2 mg/m^2
	
	<u>Reauthorization:</u> documentation of disease responsiveness to therapy

Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	**<u>Neurofibromatosis type 1 (NF1) with inoperable plexiform neurofibromas</u>** • 1 to 18 years of age (Koselugo) • 2 years of age and above (Gomekli)

Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
MEPOLIZUMAB
Affected Medications: NUCALA (mepolizumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Add-on maintenance treatment of patients with severe asthma aged 6 years and older with an eosinophilic phenotype
	  ○ Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
	  ○ Treatment of patients aged 12 years and older with hypereosinophilic syndrome (HES)
	  ○ Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids (NCS)
	  ○ Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

Required Medical Information:	**<u>Eosinophilic asthma</u>**
	• Diagnosis of severe asthma with an eosinophilic phenotype, defined by both of the following:
	  ○ Baseline eosinophil count of at least 150 cells/µL **AND**
	  ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal
	
	<u>EGPA</u>
	• Documented diagnosis of EGPA confirmed by:
	  ○ Eosinophilia at baseline (blood eosinophil level over 10% or absolute count over 1,000 cells/mcL)
	  ○ At least **two** of the following:
	  ▪ Asthma
	  ▪ Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
	  ▪ Peripheral neuropathy (not due to radiculopathy)
	  ▪ Pulmonary infiltrates
	  ▪ Sinonasal abnormality/obstruction
	  ▪ Cardiomyopathy (confirmed on imaging)
	  ▪ Glomerulonephritis
	  ▪ Alveolar hemorrhage
	  ▪ Palpable purpura
	  ▪ Antineutrophil cytoplasmic antibody (ANCA) positive (anti-MPO-ANCA or anti-PR3-ANCA)
	• Documentation that manifestations of EGPA are active and nonsevere (respiratory/sinonasal disease, uncomplicated skin manifestations, arthralgias, mild systemic symptoms, etc.)
	• Documentation of **one** of the following:
	  ○ Refractory disease, defined as inability to achieve remission within the prior 6 months, following induction treatment with a standard regimen
	  ○ Relapsing disease, defined as needing an increased glucocorticoid dose, initiation/increased dose of immunosuppressant, or hospitalization while on oral glucocorticoid therapy

	HES
	• Diagnosis of HES with all the following:
	  ○ Blood eosinophil count greater than or equal to 1,000 cells/mcL
	  ○ Disease duration greater than 6 months
	  ○ At least 2 flares within the past 12 months
	  ○ Lab work showing Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRα) mutation negative disease
	  ○ Non-hematologic secondary HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) has been ruled out
	• Documentation that disease is currently controlled on the highest tolerated glucocorticoid dose (defined as an improvement in clinical symptoms and a decrease in eosinophil count by at least 50% from baseline)
	
	CRSwNP
	• Documented diagnosis of chronic rhinosinusitis with nasal polyps
	• History of sinus surgery (Functional Endoscopic Sinus Surgery [FESS] or similar)
	• Documentation of both of the following:
	  ○ Presence of bilateral nasal polyps
	  ○ Symptoms of sinonasal obstruction/congestion for over 12 weeks (decreased/absent sense of smell, facial pressure/pain, rhinorrhea/postnasal drip)
	
	COPD
	• Diagnosis of COPD with moderate to very severe airflow limitation
	• FEV1/FVC ratio less than 0.7 and FEV1 of 20-80% predicted
	• Blood eosinophil count of at least 150 cells/µL (within last 30 days) or at least 300 cells/µL in the previous 12 months
	• Symptoms of chronic bronchitis (productive cough) and/or emphysema (shortness of breath) for at least 3 months

Appropriate Treatment Regimen & Other Criteria:	**Eosinophilic asthma**
	• Documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms
	AND
	• Documentation of one of the following:
	  ○ Documented history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months while on combination inhaler treatment and at least 80% adherence
	  ○ Documentation that chronic daily oral corticosteroids are required
	
	EGPA
	• Documented treatment failure or contraindication to at least two oral immunosuppressant drugs (azathioprine, methotrexate, mycophenolate) for at least 12 weeks each
	
	HES
	• Documented treatment failure or contraindication to at least 12 weeks of hydroxyurea (not required if patient has a lymphocytic variant of HES [L-HES])

	CRSwNP
	• Documented treatment failure with at least 3 months of two intranasal corticosteroids after sinus surgery
	
	COPD
	• Documented use of inhaled triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) for at least 12 weeks with continued symptoms
	• Documentation of one of the following:
	  ○ History of at least two moderate COPD exacerbations requiring treatment with a systemic corticosteroid and/or an antibiotic in the past year while adherent on triple therapy and at least 80% adherence
	  ○ History of at least one severe COPD exacerbation requiring hospitalization in the past year while adherent on triple therapy and at least 80% adherence
	
	Reauthorization: documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Use in combination with another monoclonal antibody (e.g., Dupixent, Fasenra, Xolair, Cinqair, Tezspire)
Age Restriction:	• **Eosinophilic asthma**: 6 years of age and older • **EGPA**: 18 years of age and older • **HES**: 12 years of age and older • **CRSwNP**: 18 years of age and older • **COPD**: 18 years of age and older
Prescriber Restrictions:	• **Eosinophilic asthma**: prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist • **EGPA**: prescribed by, or in consultation with, a specialist in the treatment of EGPA (such as a rheumatologist, nephrologist, pulmonologist, or immunologist) • **HES**: prescribed by, or in consultation with, a specialist in the treatment of HES (such as an immunologist or hematologist) • **CRSwNP**: prescribed by, or in consultation with, an otolaryngologist • **COPD**: prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
METRELEPTIN
Affected Medications: MYALEPT (metreleptin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Congenital or acquired generalized lipodystrophy as a result of leptin deficiency

Required Medical Information:	• Current weight
	• Baseline serum leptin levels, hemoglobin A1c (HbA1c), fasting glucose, fasting triglycerides, fasting serum insulin
	• Prior Myalept use will require testing for anti-metrepeptin antibodies
	• Documented leptin deficiency confirmed by laboratory testing (serum leptin of less than 12 ng/mL)
	• Documentation of congenital or acquired generalized lipodystrophy with least **ONE** of the following:
	  ○ Concurrent hypertriglyceridemia
	  ○ Concurrent diabetes

Appropriate Treatment Regimen & Other Criteria:	**Generalized lipodystrophy with concurrent hypertriglyceridemia** • Triglycerides of 500 mg/dL or higher despite optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses for at least 12 weeks each **Generalized lipodystrophy with concurrent diabetes** • Persistent hyperglycemia (HgbA1C 7 percent or greater) despite dietary intervention and optimized insulin therapy at maximally tolerated doses for at least 12 weeks **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy documented by increased metabolic control defined by improvement in HgbA1c, fasting glucose, and fasting triglyceride levels
Exclusion Criteria:	• Partial lipodystrophy • General obesity not associated with leptin deficiency • HIV-related lipodystrophy • Metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent documentation of generalized lipodystrophy
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist
Coverage Duration:	• Initial: 4 months, unless otherwise specified • Subsequent: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MIACALCIN
Affected Medications: MIACALCIN Injection (calcitonin-salmon)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Paget's disease of bone
	  ○ Hypercalcemia

Required Medical Information:	**Hypercalcemia** • Documented calcium level greater than or equal to 14 mg/dL (3.5 mmol/L) **Paget's disease of bone** • Documented baseline radiographic findings of osteolytic bone lesions • Abnormal liver function test (LFT), including alkaline phosphatase • Documented lack of malignancy within the past 3 months

Appropriate Treatment Regimen & Other Criteria:	**Hypercalcemia**
	  ○ Documentation that additional methods for lowering calcium (such as intravenous fluids) did not result in adequate efficacy **OR**
	  ○ Clinical judgement necessitated immediate administration without waiting for other methods to show efficacy
	Paget's disease of bone
	• Documented trial and failure (or intolerable adverse event) with an adequate trial of both of the following:
	  ○ Zoledronic acid (at least one dose)
	  ○ Oral bisphosphonate (e.g., alendronate, risedronate) for at least 8 weeks
	OR
	• Documentation that the patient has severe renal impairment (e.g., creatinine clearance less than 35 mL/min)
	AND
	• Documentation of all of the following:
	  ○ Normal vitamin D and calcium levels and/or supplementation
	  ○ Symptoms that necessitate treatment with medication (e.g., bone pain, bone deformity)
	
	Re-Authorization criteria – Paget's disease of bone:
	• Documentation of treatment success and a clinically significant response to therapy (such as stable or lowered alkaline phosphatase level, resolution of bone pain or other symptoms)

Exclusion Criteria:	• Related to Paget's disease of bone
	  ○ History of a skeletal malignancy or bone metastases
	  ○ Concurrent use of zoledronic acid or oral bisphosphonates
	  ○ Asymptomatic Paget's Disease of the bone
	• Treatment of prevention of osteoporosis

Age Restriction:	• 18 years or older - for Paget's disease of bone only
Prescriber Restrictions:	
Coverage Duration:	• Approval = 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MIGLUSTAT
Affected Medications: MIGLUSTAT

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of adult patients with mild to moderate type 1 Gaucher disease
	• Compendia-supported uses that will be covered:
	  ○ Niemann-Pick disease type C (NPC)

Required Medical Information:	**Gaucher Disease**
	• Diagnosis of Gaucher disease confirmed by ONE of the following:
	  ○ An enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity
	  ○ Detection of biallelic pathogenic variants in the GBA gene by molecular genetic testing
	• Enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access)
	
	NPC
	• Diagnosis of NPC confirmed by genetic testing showing biallelic pathogenic variants in either the NPC1 gene or NPC2 gene
	• Documentation of at least one neurological symptom of Niemann-Pick disease type C, such as:
	  ○ Loss of motor function
	  ○ Problems with swallowing or speech
	  ○ Cognitive impairment
	• Documentation of being ambulatory without needing an assistive device such as a wheelchair, walker, or cane
	• Documentation of baseline signs and symptoms of NPC

Appropriate Treatment Regimen & Other Criteria:	**Gaucher Disease:** Reauthorization will require documentation of treatment success and a clinically significant response to therapy **NPC:** Reauthorization requires: • Documentation of treatment success defined as stability or improvement of Niemann-Pick disease type C signs and symptoms • Documentation that patient is still ambulatory
Exclusion Criteria:	• Female of childbearing potential who is pregnant or planning a pregnancy
Age Restriction:	

Prescriber Restrictions:	• Prescribed by, or in consultation with, one of the following:
	  ○ A specialist in the management of Gaucher disease (hematologist, oncologist, hepatologist, geneticist or orthopedic specialist)
	  ○ A specialist in the management of NPC (such as a geneticist, endocrinologist, metabolic disorder subspecialist, or neurologist)

Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MILTEFOSINE
Affected Medications: IMPAVIDO (miltefosine)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Treatment of the following in adults and pediatric patients 12 years of age and older weighing greater than or equal to 30 kg (66 lbs):
	  ▪ Visceral leishmaniasis caused by *Leishmania donovani*
	  ▪ Cutaneous leishmaniasis caused by *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*
	  ▪ Mucosal leishmaniasis caused by *Leishmania braziliensis*

Required Medical Information:	**<u>All Indications</u>** • Current weight **<u>Visceral leishmaniasis</u>** • Documentation of diagnosis confirmed by smear or culture in tissue (usually bone marrow or spleen) **<u>Cutaneous and Mucosal leishmaniasis</u>** • Documentation of diagnosis confirmed by histology, culture, or molecular analysis via polymerase chain reaction (PCR)
Appropriate Treatment Regimen & Other Criteria:	**<u>Dosing:</u>** • 30 to 44 kg: 50 mg twice daily for 28 days • 45 kg or greater: 50 mg three times daily for 28 days
Exclusion Criteria:	• Pregnancy • Sjögren-Larsson syndrome • Weight less than 30 kg (66 lbs) • Treatment of leishmaniasis outside of the visceral, cutaneous, or mucosal settings • Treatment of other *Leishmania* species
Age Restriction:	• 12 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist
Coverage Duration:	• Approval: 1 month, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MITAPIVAT
Affected Medications: MITAPIVAT (pyrukynd tablet)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Hemolytic anemia due to pyruvate kinase deficiency (PKD)

Required Medical Information:	• Documented diagnosis of pyruvate kinase deficiency (PKD), confirmed by **BOTH** of the following:
	  ○ Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (*PLKR*) gene
	  ○ At least one variant allele is a missense mutation
	• Documentation of **ONE** of the following:
	  ○ Regularly receiving red blood cell (RBC) transfusions, defined as 6 or more transfusions in the previous 12 months
	  ○ Baseline hemoglobin level of less than or equal to 10 g/dL with a history of no more than 4 transfusions in the previous 12 months
	• Documentation of baseline transfusion count, including dates and number of units transfused

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization:** documentation of treatment success and a clinically significant response to therapy, defined as: • For patients receiving regular transfusions at baseline: must document greater than or equal to a 33% reduction in RBC units transfused compared to baseline • For patients not receiving regular transfusions at baseline: must document greater than or equal to a 1.5 g/dL increase in Hb from baseline sustained at 2 or more scheduled visits AND no transfusions were needed
Exclusion Criteria:	• Splenectomy scheduled during treatment or have undergone within the 12-month period prior to starting treatment • Previous bone marrow or stem cell transplant
Age Restriction:	• Must be 18 years or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MOLLUSCUM CONTAGIOSUM AGENTS
Affected Medications: YCANTH, ZELSUVMI

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Molluscum contagiosum (MC)

Required Medical Information:	• Diagnosis of MC confirmed by one of the following:
	  ○ Presence of lesions that are consistent with MC (small, firm, pearly, with pitted centers, 2-5 millimeters in diameter, not associated with systemic symptoms such as fever)
	  ○ For lesions with unclear cause or otherwise not consistent with MC, confirmation of diagnosis using dermoscopy, microscopy, histological examination, or biopsy
	• Documentation persistent itching or pain AND one of the following:
	  ○ Concomitant bacterial infection
	  ○ Concomitant atopic dermatitis
	  ○ Significant concern for contagion (such as daycare setting) and prevention cannot be reasonably prevented through good hygiene and covering lesions with bandages or clothing
	  ○ Continued presence of lesions after 12 months

Appropriate Treatment Regimen & Other Criteria:	• Trial of at least two cycles of one of the following procedures for the removal of MC lesions:
	  ○ Cryotherapy
	  ○ Curettage
	  ○ Laser therapy
	• Adequate trial and failure of one additional treatment for MC that has evidence supporting use, such as:
	  ○ Topical podofilox (Condylox) for at least 1 month
	  ○ Oral cimetidine for at least 2 months
	• **Dosing:** Two applicators per treatment every 21 days, limit to 4 total treatments
	  ○ Ycanth: Two applicators per treatment every 21 days, limit to 4 total treatments
	  ○ Zelsuvmi: One kit for 12 weeks

Exclusion Criteria:	• Molloscum contagiosum is considered a below the line (non-funded) diagnosis per Oregon Health Authority (OHA) for those 21 years of age and older.
Age Restriction:	• Ycanth: 2 to under 21 years of age • Zelsuvmi: 1 to under 21 years of age
Prescriber/Site of Care Restrictions:	• Prescribed and administered by a dermatologist
Coverage Duration:	• Approval: 3 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MOMETASONE SINUS IMPLANT
Affected Medications: SINUVA (mometasone sinus implant)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of chronic rhinosinusitis with nasal polyps in patients who have had ethmoid sinus surgery

Required Medical Information:	• Documented diagnosis of chronic rhinosinusitis with nasal polyps
	• History of bilateral total ethmoidectomy
	• Documented diagnosis of both of the following:
	  ○ Presence of bilateral nasal polyps
	  ○ Symptoms of sinonasal obstruction/congestion for over 12 weeks (decreased/absent sense of smell, facial pressure/pain, rhinorrhea/postnasal drip)

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with at least 3 months of two intranasal corticosteroids after ethmoidectomy **Reauthorization:** documentation of treatment success (reduction in symptoms, polyp size/obstruction, etc.), at least 9 months after previous treatment with Sinuva
Exclusion Criteria:	
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an otolaryngologist
Coverage Duration:	• Authorization: 1 month, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MOTIXAFORTIDE
Affected Medications: APHEXDA (motixafortide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ In combination with filgrastim (granulocyte colony-stimulating factor [G-CSF]) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood circulation to facilitate their collection for subsequent autologous stem cell transplantation (ASCT) in patients with multiple myeloma (MM). • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better (autologous HSCT must be NCCN recommended)
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Documentation of diagnosis of multiple myeloma in first or second remission • Eligible for Autologous stem cell transplantation (ASCT) • At least 7 days from most recent high dose induction therapy • No single agent chemotherapy or maintenance therapy within 7 days • Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1

Appropriate Treatment Regimen & Other Criteria:	• Inadequate stem cell collection amount despite previous trial with ALL the following:
	  ○ Single agent Granulocyte colony stimulating factor (G-CSF)
	  ○ Granulocyte colony stimulating factor (G-CSF) in combination with plerixafor
	• No reauthorization

Exclusion Criteria:	• Karnofsky Performance Status 50% or less or Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 2 or greater
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Authorization: 2 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MUCOPOLYSACCHARIDOSIS (MPS) AGENTS
Affected Medications: VIMIZIM (elosulfase alfa), NAGLAZYME (galsulfase), MEPSEVII (vestronidase alfa-vjbk), MEPSEVII (vestronidase alfa-vjbk), ALDURAZYME (laronidase), ELAPRASE (idursulfase)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Vimizim: Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)
	  ○ Naglazyme: Mucopolysaccharidosis type VI (MPS VI, Maroteaux-Lamy syndrome)
	  ○ Mepsevii: Mucopolysaccharidosis VII (MPS VII; Sly Syndrome)
	  ○ Aldurazyme:
	  ▪ Hurler Mucopolysaccharidosis type I (MPS I H)
	  ▪ Herler-Scheie Mucopolysaccharidosis type I (MPS I H/S)
	  ▪ Scheie form of Mucopolysaccharidosis (MPS I S) with moderate to severe symptoms
	  ○ Elaprase: Mucopolysaccharidosis type II (MPS II; Hunters syndrome)

Required Medical Information:	• Diagnosis of specific MPS type confirmed by enzyme assay showing deficient activity of the relevant enzyme **OR** detection of pathogenic mutations in the relevant gene by molecular genetic testing, as follows:
	  ○ For Vimizim: N-acetylgalactosamine 6-sulfatase (GALNS) enzyme or GALNS gene
	  ○ For Naglazyme: N-acetylgalactosamine 4-sulfatase (ASB) enzyme or Arylsulfatase B (ARSB) gene
	  ○ For Mepsevii: beta-glucuronidase (GUSB) enzyme or GUSB gene
	  ○ For Aldurazyme: alpha-L-iduronidase (IDUA) enzyme or IDUA gene
	  ○ For Elaprase: iduronate 2-sulfatase (I2S or IDS) enzyme or IDS gene
	• Documented clinical signs and symptoms of MPS, such as soft tissue abnormality, skeletal abnormality, joint abnormality, respiratory disease, gait abnormality, motor issues, or cardiac abnormality
	• Baseline value for one or more of the following:
	  ○ Function test such as the Bruininks-Oseretsky Test of Motor Proficiency (BOT-2), 6-minute walk test (6MWT), three-minute stairclimb test (3-MSCT), or pulmonary function tests (PFTs)
	  ○ Liver and/or spleen volume
	  ○ Urinary glycosaminoglycan (GAGs) level

Appropriate Treatment Regimen & Other Criteria:	• Dose does not exceed the recommended dosing according to the FDA label • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** requires documentation of treatment success defined as **ONE** or more of the following: • Stability or improvement in function tests such as BOT-2, 6MWT, 3-MSCT, **or** PFTs • Reduction in liver and/or spleen volume • Reduction in urinary GAG level • Other clinically significant improvement in MPS signs and symptoms

Exclusion Criteria:	• Treatment of central nervous system manifestation of the disorder • Severe, irreversible cognitive impairment
Age Restriction:	• Vimizim and Naglazyme: 5 years of age and older • Elaprase: 16 months of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a specialist in the treatment of inherited metabolic disorders, such as a geneticist or endocrinologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
MUSCULAR DYSTROPHY
Affected Medications: Amondys 45 (casimersen), Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Viltepso (viltolarsen), Duvyzat (givinostat)

Covered Uses:

- All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Casimersen (Amondys 45)

- Duchenne muscular dystrophy with mutations amenable to exon 45 skipping, including the following exon deletions:

7-44	12-44	44	46-51	46-60	46-75
	18-44	46	46-53	46-67	46-78
		46-47	46-55	46-69	
		46-48	46-57		
		46-49	46-59		

Eteplirsen (Exondys 51)

- Duchenne muscular dystrophy with mutations amenable to exon 51 skipping, including the following exon deletions:

3-50	10-50	21-50	30-50	40-50	50
4-50	11-50	23-50	31-50	41-50	52
5-50	13-50	24-50	32-50	42-50	52-61
6-50	14-50	25-50	33-50	43-50	52-63
9-50	15-50	26-50	34-50	45-50	52-64
	16-50	27-50	35-50	47-50	52-66
	17-50	28-50	36-50	48-50	52-76
	19-50	29-50	37-50	49-50	
			38-50		
			39-50		

Golodirsen (Vyondys 53)

- Duchenne muscular dystrophy with mutations amenable to exon 53 skipping, including the following exon deletions:

3-52	10-52	21-52	30-52	40-52	50-52
4-52	11-52	23-52	31-52	41-52	52
5-52	13-52	24-52	32-52	41-52	54-58
6-52	14-52	25-52	33-52	43-52	54-61
9-52	15-52	26-52	34-52	45-52	54-63
	16-52	27-52	35-52	47-52	54-64
	17-52	28-52	36-52	48-52	54-66
	19-52	29-52	37-52	49-52	54-76
			38-52		54-77
			39-52		

Viltolarsen (Viltepso)

- Duchenne muscular dystrophy with mutations amenable to exon 53 skipping (see above)

Givinostat (Duvyzat)

- Duchenne muscular dystrophy

Required Medical Information:	• A confirmed diagnosis of Duchenne muscular dystrophy (DMD) with documentation of genetic testing to confirm appropriate use • A baseline functional assessment using a validated tool (e.g., the 6- minute walk test or North Star Ambulatory Assessment, etc.) • Documentation of being ambulatory without needing an assistive device such as a wheelchair, walker, or cane (Duvyzat) • Current weight
Appropriate Treatment Regimen & Other Criteria:	• Documentation of being on a stable dose of an oral corticosteroid such as prednisone for at least 12 weeks prior to treatment **Reauthorization** requires that the patient's functional status has been maintained at or above baseline level or not declined more than expected given the natural disease progression *Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
Exclusion Criteria:	• Treatment with more than one exon-skipping therapy • Combined use of Duvyzat and exon-skipping therapy **Duvyzat** • Prior to starting therapy, platelet count less than 150,000 cells/microliter • During therapy, QTc interval exceeds 500 ms or increases by more than 60 ms from baseline
Age Restriction:	• 6 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist with experience in the treatment of Duchenne muscular dystrophy • Required to utilize pharmacy benefit
Coverage Duration:	• Initial Approval: 6 months, unless otherwise specified • Continuation: 12 months, unless otherwise specified

POLICY NAME:
MYELOID GROWTH FACTORS
Affected Medications: FULPHILA (pegfilgrastim-jmdb), LEUKINE (sargramostim), NEULASTA (pegfilgrastim), NEUPOGEN (filgrastim), NIVESTYM (filgrastim-aafi), NYVEPRIA (pegfilgrastim – apgf), GRANIX (tbo-filgrastim), ZARXIO (filgrastim-sndz), RELEUKO (filgrastim-ayow), FYLNETRA (Pegfilrastim-pbbk), ROLVEDON (Eflapegrastim-xnst), STIMUFEND (Pegfilgrastim-fpgk), UDENYCA (pegfilgrastim-cbqv), NYPOZI (filgrastim-txid), RYZNEUTA (efbemalenograstim alfa)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design **Neupogen, Nivestym, Releuko, and Zarxio** <u>Patients with Cancer Receiving Myelosuppressive Chemotherapy</u> • Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever <u>Patients With Acute Myeloid Leukemia Receiving Induction or Consolidation Chemotherapy</u> • Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia <u>Patients with Cancer Receiving Bone Marrow Transplant</u> • Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, (e.g., febrile neutropenia) in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation <u>Patients Undergoing Autologous Peripheral Blood Progenitor Cell Collection and Therapy (Neupogen, Nivestym, Zarxio)</u> • Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis <u>Patients With Severe Chronic Neutropenia</u> • Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia <u>Patients Acutely Exposed to Myelosuppressive Doses of Radiation (Hematopoietic Syndrome of Acute Radiation Syndrome) (Neupogen)</u> • Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation **Leukine** <u>Use Following Induction Chemotherapy in Acute Myelogenous Leukemia</u> • Indicated for use following induction chemotherapy in older adult patients with acute myelogenous leukemia to shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death <u>Use in Mobilization and Following Transplantation of Autologous Peripheral Blood Progenitor Cells</u>

	• Indicated for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis. <u>Use in Myeloid Reconstitution After Autologous Bone Marrow Transplantation</u> • Indicated for acceleration of myeloid recovery in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's disease undergoing autologous bone marrow transplantation (BMT) <u>Use in Myeloid Reconstitution After Allogeneic Bone Marrow Transplantation</u> • Indicated for acceleration of myeloid recovery in patients undergoing allogeneic BMT from human leukocyte antigen (HLA)-matched related donors <u>Use in Bone Marrow Transplantation Failure or Engraftment Delay</u> • Indicated in patients who have undergone allogeneic or autologous BMT in whom engraftment is delayed or has failed **Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, Stimufend, Ryzneuta and Rolvedon** <u>Patients with Cancer Receiving Myelosuppressive Chemotherapy</u> • Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever <u>Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome (Neulasta, Udenyca, Ziextenzo)</u> • Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation **Granix** • Granix is indicated to reduce the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia **Compendia supported uses that will be covered (if applicable)** **Neupogen/Granix/Zarxio/Nivestym/Leukine:** • Treatment of chemotherapy-induced febrile neutropenia in patients with non-myeloid malignancies • Treatment of anemia in patients with myelodysplastic syndromes (MDS) • Treatment of neutropenia in patients with MDS • Following chemotherapy for acute lymphocytic leukemia (ALL) • Stem cell transplantation-related indications • Agranulocytosis • Aplastic anemia • Neutropenia related to human immunodeficiency virus (HIV) • Neutropenia related to renal transplantation
Required Medical Information:	• Complete blood counts with differential and platelet counts will be monitored at baseline and regularly throughout therapy • Documentation of therapy intention (curative, palliative) for prophylaxis of febrile neutropenia • Documentation of patient specific risk factors for febrile neutropenia

	• Documentation of febrile neutropenia risk associated with the chemotherapy regimen • Documentation of planned treatment course • Documentation of current patient weight

Appropriate Treatment Regimen & Other Criteria:	**<u>Filgrastim products: Neupogen, Nivestym, Releuko, Zarxio, Granix, Nypozi</u>**
	
	When requested via the MEDICAL benefit:
	Coverage for the non-preferred products, Neupogen, Releuko, Nypozi and Granix, is provided when the member meets the following criteria:
	• Documented treatment failure or intolerable adverse event to **Zarxio and Nivestym**
	
	When requested through the specialty PHARMACY benefit:
	Coverage for the non-preferred products, Neupogen, Releuko, Nypozi and Granix, is provided when the member meets the following criteria:
	• Documented treatment failure or intolerable adverse event to **Nivestym and Zarxio**
	
	<u>Sargramostim product: Leukine</u>
	Coverage for the non-preferred product, Leukine, is provided when the member meets one of the following criteria:
	• Leukine will be used for myeloid reconstitution after autologous or allogenic bone marrow transplant or bone marrow transplant engraftment delay or failure
	• A documented treatment failure or intolerable adverse event to preferred products listed above
	
	<u>Pegfilgrastim products: Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, Stimufend, Rolvedon</u>
	
	When requested via the PHARMACY benefit:
	Coverage for the non-preferred products, Neulasta, Fylnetra, Rolvedon, Stimufend, and Nyvepria is provided when the member meets one of the following criteria:
	• Documented treatment failure or intolerable adverse event to **Ziextenzo, Fulphila and Udenyca**
	
	When requested via the MEDICAL benefit:
	Coverage for the non-preferred products, Neulasta, Nyvepria, Fulphila, and Flynetra is provided when the member meets the following criteria:
	• Documented treatment failure or intolerable adverse event to **Ziextenzo or Udenyca**
	
	<u>Eflapegrastim product: Rolvedon and Efbemalenograstim product: Ryzneuta</u>
	Coverage for the non-preferred products, Rolvedon and Ryzneuta, is provided when the member meets the following criteria:
	• Documented treatment failure or intolerable adverse event to the preferred pegfilgrastim products
	
	<u>For prophylaxis of febrile neutropenia (FN) or other dose-limiting neutropenic events for patients receiving myelosuppressive anticancer drugs:</u>
	Meets **ONE** of the following:
	• **Curative Therapy:**
	  ○ High risk (greater than 20% risk) for febrile neutropenia based on chemotherapy regimen **OR**
	  ○ Intermediate risk (10-20% risk) for febrile neutropenia based on chemotherapy regimen with documentation of significant patient risk factors for serious medical consequences **OR**

	○ Has experienced a dose-limiting neutropenic event on a previous cycle of current chemotherapy to be continued • **Palliative Therapy:** ○ Myeloid growth factors will not be approved upfront for prophylaxis of febrile neutropenia in the palliative setting. Per the NCCN (National Comprehensive Cancer Network), chemotherapy regimens with a 20% or greater risk of neutropenic events should not be used. If, however, a dose limiting neutropenic event occurs on a previous cycle of chemotherapy, and the effectiveness of chemotherapy will be reduced with dose reduction, growth factor will be approved for secondary prophylaxis on a case by case basis **For Treatment of Severe Chronic Neutropenia:** • Must meet ALL the following: ○ Congenital neutropenia, cyclic neutropenia, OR idiopathic neutropenia ○ Current documentation of absolute neutrophil count (ANC) less than 500 cells/microL ○ Neutropenia symptoms (fever, infections, oropharyngeal ulcers)
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist or hematologist
Coverage Duration:	• 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
NATALIZUMAB
Affected Medications: TYSABRI (natalizumab)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following:
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)
	  ○ Crohn's disease (CD)

Required Medical Information:	• Screening for anti-JC virus (JCV) antibodies prior to initiating Tysabri therapy **RRMS** • Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS **CIS** • Documentation of a monophasic clinical episode, with patient-reported symptoms and corresponding objective clinical evidence as follows: One or more T2-hyperintense lesions that are characteristic of MS in at least two of four MS-typical regions (periventricular, cortical or juxtacortical, infratentorial brain regions, and the spinal cord) **Active SPMS** • Documented history of RRMS, followed by gradual and persistent worsening in neurologic function over at least 6 months (independent of relapses) • Evidence of active SPMS, as shown by ongoing clinical relapses and/or inflammatory activity (i.e., gadolinium enhancing lesions **OR** new or enlarging lesions) • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5 **Crohn's disease** • Moderate to severely active disease despite current treatment

Appropriate Treatment Regimen & Other Criteria:	**Relapsing Forms of MS**
	• Documentation of treatment failure (or documented intolerable adverse event) to:
	  ○ Rituximab (preferred biosimilar products: Riabni, Truxima and Ruxience) OR
	  ○ Ocrevus (ocrelizumab) if previously established on treatment, excluding via samples or manufacturer's patient assistance program OR
	  ○ Documentation of pregnancy and severe disease
	
	Crohn's disease
	• Documented treatment failure with at least one oral treatment for a minimum 12 week trial: azathioprine, 6-mercaptopurine, methotrexate, sulfasalazine, balsalazide
	OR
	• Documentation of previous surgical intervention for Crohn's disease
	OR

	• Documentation of severe, high-risk disease on colonoscopy defined by one of the following:
	  ○ Fistulizing disease
	  ○ Stricture
	  ○ Presence of abscess/phlegmon
	  ○ Deep ulcerations
	  ○ Large burden of disease including ileal, ileocolonic, or proximal gastrointestinal involvement
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of:
	  ○ Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis)
	  AND
	  ○ One of the following: Entyvio, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek)
	
	Reauthorization:
	• **Anti-JCV antibody negative:** documentation of positive clinical response to therapy
	• **Anti-JCV antibody positive:** documentation of positive clinical response to therapy and periodic MRI to monitor for progressive multifocal leukoencephalopathy (PML)

Exclusion Criteria:	• Current or prior history of PML • MS: concurrent use of disease-modifying medications indicated for the treatment of MS • CD: concurrent use of other targeted immune modulators for the treatment of CD
Age Restriction:	
Prescriber Restrictions:	• MS: prescribed by, or in consultation with, a neurologist or MS specialist • CD: prescribed by, or in consultation with, a gastroenterologist
Coverage Duration:	**MS** • Approval: 12 months, unless otherwise specified **CD** • Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
NAUSEA & VOMITING IN PREGNANCY
Affected Medications: BONJESTA (doxylamine-pyridoxine extended-release tablet 20-20mg), doxylamine-pyridoxine delayed release tablet 10-10 mg

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. ○ Pregnancy associated nausea and vomiting
Required Medical Information:	• Estimated Delivery Date • Documentation of all therapies tried/failed

Appropriate Treatment Regimen & Other Criteria:	• Documentation of trial and education on non-pharmacologic methods of controlling nausea and vomiting related to pregnancy (avoidance of triggers, proper rest, etc.)
	
	• Documented treatment failure, intolerance, or clinical rationale for avoidance of **ALL** the following:
	  ○ Over the counter (OTC) pyridoxine with OTC doxylamine
	  AND
	  ○ One of the following:
	  ▪ Dopamine antagonist (prochlorperazine, metoclopramide, etc.)
	  ▪ H1 antagonist (promethazine, meclizine, dimenhydrinate, diphenhydramine, etc.)
	  ▪ Ondansetron

Exclusion Criteria:	
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	
Coverage Duration:	• Approval: Until estimated delivery date (no more than 9 months), unless otherwise specified

POLICY NAME:
NEMOLIZUMAB-ILTO
Affected Medications: NEMLUVIO

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Prurigo nodularis (PN)
	  ○ Atopic dermatitis (AD)

Required Medical Information:	**PN**
	• Documentation of all the following:
	  ○ Diagnosis confirmed by skin biopsy
	  ○ Presence of at least 20 PN lesions for at least 3 months
	  ○ Severe itching
	AD
	• Diagnosis of severe atopic dermatitis with functional impairment, defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	AND one of the following:
	  ○ Body surface area (BSA) involvement of at least 10%
	  ○ Hand, foot, face, or mucous membrane involvement

Appropriate Treatment Regimen & Other Criteria:	**PN** • Documented treatment failure with at least 2 weeks of a super high potency topical corticosteroid (such as clobetasol propionate 0.05%, halobetasol propionate 0.05%) • Documentation of treatment failure with at least 12 weeks of one of the following: phototherapy, methotrexate, cyclosporine • Documented treatment failure with at least 12 weeks of Dupixent (dupilumab) **AD** • Documented treatment failure with at least 4 weeks of a topical non-steroidal agent (e.g., tacrolimus ointment, pimecrolimus cream) • Documented treatment failure with at least 12 weeks of one of the following: phototherapy, cyclosporine, azathioprine, methotrexate, mycophenolate • Documented treatment failure with at least 12 weeks of Dupixent (dupilumab)
Exclusion Criteria:	• Concurrent use with another therapeutic immunomodulator agent
Age Restriction:	• PN: 18 years of age and older • AD: 12 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
NEONATAL FC RECEPTOR ANTAGONISTS
Affected Medications: VYVGART (efgartigimod alfa), VYVGART HYTRULO (efgartigimod alfa and hyaluronidase vial), RYSTIGGO (rozanolixizumab), IMAAVY (nipocalimab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design **Vyvgart** o Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive **Rystiggo** o Generalized myasthenia gravis (gMG) in adult patients who are AChR or anti-muscle-specific tyrosine kinase (MuSK) antibody positive **Vyvgart Hytrulo** o Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive o Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) **Imaavy** o Generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti muscle-specific tyrosine kinase (MuSK) antibody positive
Required Medical Information:	**Myasthenia Gravis** • Diagnosis of generalized Myasthenia Gravis (gMG) confirmed by one of the following: o A history of abnormal neuromuscular transmission test o A positive edrophonium chloride test o Improvement in gMG signs or symptoms with an acetylcholinesterase inhibitor • Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV • Documentation of **ONE** of the following: o MG-Activities of Daily Living (MG-ADL) total score of 6 or greater o Quantitative Myasthenia Gravis (QMG) total score of 12 or greater • For Rystiggo and Imaavy: Positive serologic test for AChR or MuSK antibodies **CIDP (Vyvgart Hytrulo only)** • Documented baseline in strength/weakness using an objective clinical measuring tool (INCAT, Medical Research Council (MRC) muscle strength, 6 Minute Walk Test, Rankin, Modified Rankin) • Documented disease course is progressive or relapsing and remitting for 2 months or longer • Abnormal or absent deep tendon reflexes in upper or lower limbs • Electrodiagnostic evidence of demyelination indicated by one of the following: o Motor distal latency prolongation in 2 nerves o Reduction of motor conduction velocity in 2 nerves o Prolongation of F-wave latency in 2 nerves o Absence of F-waves in at least 1 nerve o Partial motor conduction block of at least 1 motor nerve o Abnormal temporal dispersion in at least 2 nerves o Distal CMAP duration increase in at least 1 nerve • Cerebrospinal fluid (CSF) analysis indicates all of the following (if electrophysiologic findings are non-diagnostic): o CSF white cell count of less than 10 cells/mm^3 o CSF protein is elevated (greater than or equal to 45mg/dL)

PacificSource Community Solutions

Appropriate Treatment Regimen & Other Criteria:	**<u>Myasthenia Gravis</u>**
	• Currently on a stable dose of at least one gMG therapy (acetylcholinesterase inhibitor, corticosteroid, or non-steroidal immunosuppressive therapy (NSIST)) that will be continued during initial treatment with Vyvgart, Vyvgart Hytrulo, Imaavy, or Rystiggo
	
	• Documentation of one of the following:
	  ○ Treatment failure with an adequate trial (one year or more) of at least 2 immunosuppressive therapies (azathioprine, mycophenolate, tacrolimus, cyclosporine, methotrexate)
	  ○ Has required three or more courses of rescue therapy (plasmapheresis/plasma exchange and/or intravenous immunoglobulin), while on at least one immunosuppressive therapy, over the last 12 months
	
	• Coverage for Rystiggo or Imaavy is provided when one of the following is met:
	  ○ Currently receiving treatment with Rystiggo or Imaavy, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
	  ○ Documented treatment failure or intolerable adverse event with Vyvgart for AChR antibody positive gMG, if age appropriate
	  ○ Documented treatment failure to rituximab for MuSK antibody positive MG (preferred products: Truxima, Riabni, Ruxience), if age appropriate
	
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	<u>Reauthorization</u> requires:
	• Documentation of treatment success and clinically significant response to therapy defined as:
	  ○ A minimum 2-point reduction in MG-ADL score from baseline or improvement in QMG total score
	  ○ Absent or reduced need for rescue therapy compared to baseline
	• That the patient requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity
	
	✧ Note: a minimum of 50 days for Vyvgart/ Vyvgart Hytrulo or 63 days for Rystiggo must have elapsed from the start of the previous treatment cycle
	
	<u>CIDP (Vyvgart Hytrulo only)</u>
	• Documented trial and failure of at least 3 months of intravenous or subcutaneous immune globulin
	
	<u>Reauthorization:</u>
	Documentation of a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-Minute walk test, Rankin, Modified Rankin)

Exclusion Criteria:	• Immunoglobulin G (IgG) levels less than 600 mg/dL at baseline • Concurrent use with other disease-modifying biologics for treatment of gMG
Age Restriction:	• **Vyvgart, Vyvgart Hytrulo, and Rystiggo:** 18 years of age and older • **Imaavy**: 12 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist

PacificSource Community Solutions

Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
NIROGACESTAT
Affected Medications: OGSIVEO (nirogacestat)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Progressive desmoid tumor(s) requiring systemic therapy • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or higher
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Diagnosis of biopsy proven desmoid tumor/aggressive fibromatosis (DT/AF) with documentation of tumor progression. (Tumor growth causing chronic pain, disfigurement, internal bleeding, and/or impaired range of motion)
Appropriate Treatment Regimen & Other Criteria:	• Documentation of clinical failure with sorafenib **Reauthorization:** documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
NITISINONE
Affected Medications: NITISINONE, ORFADIN SUSPENSION

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Hereditary tyrosinemia type 1 (HT-1)
	  ○ Alkaptonuria (AKU)

Required Medical Information:	• Diagnosis of hereditary tyrosinemia type 1 confirmed by:
	  ○ Presence of succinylacetone (SA) in urine or blood
	  ○ Genetic testing showing a mutation in the gene encoding fumarylacetoacetate hydrolase (FAH)
	• Current patient weight
	• Diagnosis of alkaptonuria confirmed by:
	  ○ Quantitative measurement of homogentisic acid (HGA) in urine
	  ○ Genetic testing showing a mutation in the homogentisic acid dioxygenase (HGD) gene

Appropriate Treatment Regimen & Other Criteria:	• Use as an adjunct to dietary restriction of tyrosine and phenylalanine • Orfadin suspension requires: ○ A documented medical inability to use nitisinone capsules **Reauthorization:** documentation of treatment success confirmed by: • Reduction in urine or plasma succinylacetone (for HT-1) or homogentisic acid (for AKU) from baseline • Documentation of dietary restriction of tyrosine and phenylalanine
Exclusion Criteria:	• Use without dietary restriction of tyrosine and phenylalanine
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, physicians that specializes in the treatment of hereditary tyrosinemia or related disorders
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
NON-PREFERRED MEDICAL DRUG CODES
Affected Medications: BORTEZOMIB, PEMETREXED

<table>
<tr><td>Covered Uses:</td><td>• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
• For oncology indications: National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher</td></tr>
<tr><td>Required Medical Information:</td><td></td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>• Approval of a non-preferred medical drug listed below requires documentation of an intolerable adverse event to all the preferred alternatives, and the adverse event was not an expected adverse event attributed to the active ingredient

<table>
<tr><th>Drug</th><th>Non-Preferred code</th><th>Preferred Alternatives</th></tr>
<tr><td>Bortezomib (Boruzu, Velcade)</td><td>J9046, J9054</td><td>J9041, J9048, J9049</td></tr>
<tr><td>Pemetrexed (Pemfexy, Alimta, Pemrydi RTU, Axtle)</td><td>J9304, J9292</td><td>J9294, J9296, J9297, J9305, J9314, J9324</td></tr>
</table>

<u>Reauthorization</u> requires documentation of disease responsiveness to therapy</td></tr>
<tr><td>Exclusion Criteria:</td><td></td></tr>
<tr><td>Age Restriction:</td><td></td></tr>
<tr><td>Prescriber/Site of Care Restrictions:</td><td></td></tr>
<tr><td>Coverage Duration:</td><td>• Authorization: 12 months, unless otherwise specified</td></tr>
</table>

PacificSource Community Solutions

POLICY NAME:
NON-PREFERRED SODIUM-GLUCOSE CO-TRANSPORTERS (SGLT2)
Affected Medications: JARDIANCE (empagliflozin), INVOKANA (canagliflozin), INVOKAMET (canagliflozin/metformin), INVOKAMET XR (canagliflozin/metformin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Type 2 Diabetes Mellitus
	  ○ Heart failure regardless of ejection fraction (dapagliflozin, Jardiance)
	  ○ Chronic kidney disease at risk of progression (dapagliflozin, Jardiance)

Required Medical Information:	• Documentation of diagnosis of one of the following:
	  ○ Type 2 Diabetes
	  ○ Heart failure (dapagliflozin, Jardiance)
	  ○ Chronic kidney disease (dapagliflozin, Jardiance)

Appropriate Treatment Regimen & Other Criteria:	**<u>Jardiance</u>**
	• Documentation of one of the following:
	  ○ Documented treatment failure (or intolerable adverse event) with Steglatro
	  ○ Documented treatment failure (or intolerable adverse event) with dapagliflozin
	
	<u>Invokana/Invokamet</u>
	• Documentation of one of the following:
	  ○ Documented treatment failure (or intolerable adverse event) with Steglatro
	  ○ Documented treatment failure (or intolerable adverse event) with dapagliflozin
	
	<u>Reauthorization:</u>
	• Documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Concurrent use of more than one SGLT2 • Weight Loss
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 36 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
NIEMANN-PICK DISEASE TYPE C (NPC) AGENTS
Affected Medications: Miplyffa (arimoclomol citrate), Aqneursa (levacetylleucine)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Niemann-Pick disease type C (NPC)

Required Medical Information:	• Diagnosis of NPC confirmed by genetic testing showing biallelic pathogenic variants in either the NPC1 gene or NPC2 gene
	• Documentation of at least one neurological symptom of Niemann-Pick disease type C, such as:
	  ○ Loss of motor function
	  ○ Problems with swallowing or speech
	  ○ Cognitive impairment
	• Documentation of being ambulatory without needing an assistive device such as a wheelchair, walker, or cane
	• Documentation of baseline signs and symptoms of NPC

Appropriate Treatment Regimen & Other Criteria:	**For Miplyffa**: • Documentation that patient has been receiving miglustat with a stable dose for at least the past 6 consecutive months • Documentation that Miplyffa will be taken in combination with miglustat **Reauthorization** requires: • Documentation of treatment success defined as stability or improvement of Niemann-Pick disease type C signs and symptoms • Documentation that patient is still ambulatory • For Miplyffa: that the drug continues to be used in combination with miglustat
Exclusion Criteria:	• Use of Miplyffa and Aqneursa in combination
Age Restriction:	• Miplyffa: 2 years of age and older • Aqneursa: Adults and pediatric patients weighing 15 kilograms or greater
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a specialist in the management of NPC (such as a geneticist, endocrinologist, metabolic disorder subspecialist, or neurologist)
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
NULIBRY
Affected Medications: NULIBRY (fosdenopterin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ To reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A

Required Medical Information:	• Documentation of presumptive or genetically confirmed molybdenum cofactor deficiency (MoCD) Type A diagnosis
	
	<u>Presumptive diagnosis of Molybdenum cofactor deficiency (MoCD) Type A</u>
	• Documentation of family history meeting **ONE** of the following:
	  ○ Affected sibling(s) with confirmed MoCD Type A; or a history of deceased sibling(s) with classic MoCD presentation
	  ○ One or both parents are known to carry a copy of the mutated gene [Molybdenum Cofactor Synthesis 1 (MOCS1)]
	  ○ Child has consanguineous parents with a family history of MoCD
	• Onset of clinical and/or laboratory signs and symptoms consistent with MoCD Type A, such as:
	  ○ Clinical presentation: intractable seizures, exaggerated startle response, high-pitched cry, axial hypotonia, limb hypertonia, feeding difficulties
	  ○ Biochemical findings: elevated urinary sulfite and/or S-sulfocysteine (SSC), elevated xanthine in urine or blood, or low/absent uric acid in the urine or blood
	• Genetic testing to confirm diagnosis of MoCD Type A is scheduled or in progress
	
	<u>Confirmed diagnosis of MoCD Type A</u>:
	• Diagnosis of MoCD Type A confirmed by genetic testing showing the presence of mutation in molybdenum cofactor synthesis gene 1 (MOSC1)

Appropriate Treatment Regimen & Other Criteria:	**<u>Reauthorization</u>**: • Documentation of clinically significant response to therapy as determined by prescribing physician • Documentation of genetically confirmed MoCD Type A (MOCS1 mutation) if initially approved for presumptive diagnosis
Exclusion Criteria:	• Molybdenum cofactor deficiency (MoCD) Type B (MOCS2 mutation) • MoCD Type C (gephyrin or GPHN mutation)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, one of the following: neonatologist, pediatrician, pediatric neurologist, neonatal neurologist, or geneticist.
Coverage Duration:	**<u>Presumptive diagnosis:</u>** • Approval: 1 month, unless otherwise specified. Must have confirmed diagnosis for continued approval **<u>Confirmed diagnosis:</u>** • Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
NUSINERSEN
Affected Medications: SPINRAZA (nusinersen)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Spinal muscular atrophy (SMA)

Required Medical Information:	• Diagnosis of SMA type 1, 2, or 3 confirmed by genetic testing of chromosome 5q13.2 demonstrating ONE of the following:
	  ○ Homozygous gene deletion of SMN1 (survival motor neuron 1)
	  ○ Homozygous gene mutation of SMN1
	  ○ Compound heterozygous gene mutation of SMN1
	• Documentation of 2 or more copies of the SMN2 (survival motor neuron 2) gene
	• Documentation of previous treatment history
	• Documentation of one of the following baseline motor assessments appropriate for patient age and motor function:
	  ○ Hammersmith Infant Neurological Examination (HINE-2)
	  ○ Hammersmith Functional Motor Scale (HFSME)
	  ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
	  ○ Upper Limb Module (ULM) test
	  ○ 6-Minute Walk Test (6MWT)
	• Documentation of ventilator use status
	  ○ Patient is NOT ventilator-dependent (defined as using a ventilator at least 16 hours per day on at least 21 of the last 30 days)
	  ○ This does not apply to patients who require non-invasive ventilator assistance
	• Planned treatment regimen

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with or intolerable adverse event on Evrysdi **Reauthorization:** documentation of improvement in baseline motor assessment score, clinically meaningful stabilization, or delayed progression of SMA-associated signs and symptoms
Exclusion Criteria:	• SMA type 4 • Advanced SMA at baseline (complete paralysis of limbs, permanent ventilation support) • Prior treatment with SMA gene therapy (i.e., onasemnogene abeparvovec-xioi) • Will not use in combination with other agents for SMA (e.g., onasemnogene abeparvovec-xioi, risdiplam, etc.)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or provider who is experienced in treatment of spinal muscular atrophy
Coverage Duration:	• Initial approval: 8 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OCRELIZUMAB
Affected Medications: OCREVUS (ocrelizumab), OCREVUS ZUNOVO (ocrelizumab hyaluronidase)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Primary progressive multiple sclerosis (PPMS)
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following:
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)

Required Medical Information:	**RRMS**
	• Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS
	  ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS
	
	CIS
	• Documentation of a monophasic clinical episode, with patient-reported symptoms and corresponding objective clinical evidence as follows: One or more T2-hyperintense lesions that are characteristic of MS in at least two of four MS-typical regions (periventricular, cortical or juxtacortical, infratentorial brain regions, and the spinal cord)
	
	PPMS
	• Documented diagnosis of PPMS, with at least of one year of disease progression (retrospectively or prospectively determined), independent of clinical relapse, AND two of the following:
	  ○ One or more T2- hyperintense lesions characteristic of MS in one or more of the periventricular, cortical or juxtacortical, or infratentorial areas brain regions
	  ○ Two or more T2- hyperintense lesions in the spinal cord
	  ○ Presence of CSF-specific oligoclonal bands
	• Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5
	
	Active SPMS
	• Documented history of RRMS, followed by gradual and persistent worsening in neurologic function over at least 6 months (independent of relapses)
	• Evidence of active SPMS, as shown by ongoing clinical relapses and/or inflammatory activity (i.e., gadolinium enhancing lesions **OR** new or enlarging lesions)
	• Documentation of EDSS score of 3.0 to 6.5

Appropriate Treatment Regimen & Other Criteria:	• **Relapsing Forms of MS**: Coverage of Ocrevus (ocrelizumab) or Ocrevus Zunovo (ocrelizumab hyaluronidase) requires documentation of one of the following:
	  ○ Documentation of inadequate disease response or intolerance to rituximab (preferred products: Truxima, Riabni, Ruxience)
	  ○ Currently receiving treatment with Ocrevus (ocrelizumab) or Ocrevus Zunovo (ocrelizumab hyaluronidase), excluding via samples or manufacturer's patient assistance program
	• No concurrent use of other disease-modifying medications indicated for the treatment of MS
	
	Reauthorization requires documentation of treatment success

Exclusion Criteria:	• Active hepatitis B virus infection
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Initial authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OFEV
Affected Medications: OFEV CAPSULE 100 MG ORAL, OFEV CAPSULE 150 MG ORAL

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Idiopathic pulmonary fibrosis (IPF)
	  ○ Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype
	  ○ Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Required Medical Information:	**<u>Idiopathic Pulmonary Fibrosis (IPF):</u>**
	• Documented diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by **ONE** of the following:
	  ○ Usual interstitial pneumonia (UIP) pattern demonstrated on high-resolution computed tomography (HRCT)
	  ○ UIP pattern demonstrated on surgical lung biopsy
	  ○ Probable UIP pattern demonstrated on **both** HRCT and surgical lung biopsy
	• Documentation confirming known causes of interstitial lung disease have been ruled out (e.g., rheumatic disease, environmental exposure, drug toxicity)
	• Documentation of **both** of the following:
	  ○ Baseline forced vital capacity (FVC) greater than or equal to 50% predicted
	  ○ Baseline diffusing capacity for carbon monoxide (DLCO) greater than or equal to 30 % predicted
	
	<u>Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)</u>
	• Documented diagnosis of SSc-ILD
	• Documentation of greater than or equal to 10% fibrosis on a chest high resolution computed tomography (HRCT) scan conducted within the previous 12 months.
	• Documentation of baseline FVC greater than or equal to 40% of predicted
	• Documentation of predicted DLCO 30-89% of predicted
	
	<u>Chronic Fibrosing Interstitial Lung Disease (ILD) with a Progressive Phenotype</u>
	• Documented diagnosis of chronic fibrosing ILD with a progressive phenotype (aka progressive pulmonary fibrosis), confirmed by at least two of the following:
	  ○ Worsening respiratory symptoms
	  ○ Physiological evidence of disease progression (defined as DLCO reduced by 10% or greater **OR** FVC reduced by 5% or greater)
	  ○ Radiological evidence of disease progression (e.g., increased traction bronchiectasis, new ground-glass opacity or fine reticulation, new/increased honeycombing)
	• Documentation of relevant fibrosis (greater than 10% fibrotic features) on chest HRCT scan
	• Baseline FVC greater than or equal to 45% of predicted
	• Baseline DLCO 30% to less than 80% of predicted

Appropriate Treatment Regimen & Other Criteria:	**<u>IPD</u>** • Documented treatment failure, contraindication, or intolerance to pirfenidone **<u>SSc-ILD:</u>**

	• Documented treatment failure with one of the following: mycophenolate (MMF) or cyclophosphamide **<u>Reauthorization</u>** requires documentation of treatment success
Exclusion Criteria:	• Documentation of airway obstruction (i.e., pre-bronchodilator FEV/FVC less than 0.7) • Combined use with pirfenidone (Esbriet)
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Must be prescribed by, or in consultation with, a pulmonologist or rheumatologist
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OLEZARSEN
Affected Medications: TRYNGOLZA (olezarsen sodium)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Reduce triglycerides as an adjunct to diet in adults with familial chylomicronemia syndrome (FCS)
Required Medical Information:	• Diagnosis of FCS (type 1 hyperlipoproteinemia) confirmed by genetic testing showing a pathogenic gene mutation in LPL, APOC2, APOA5, GPIHBP1 or LMF1 genes • Fasting triglyceride level of at least 880 mg/dL • Will be used as an adjunct to diet
Appropriate Treatment Regimen & Other Criteria:	• Documentation of following a low-fat diet with less than 20 grams of fat per day **Reauthorization** requires documentation of treatment success defined as a decrease in triglycerides since starting therapy
Exclusion Criteria:	• History of acute coronary syndrome
Age Restriction:	• 18 years of age or older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a cardiologist or endocrinologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
OLIPUDASE ALFA
Affected Medications: XENPOZYME

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients

Required Medical Information:	• Documentation of acid sphingomyelinase deficiency as evidenced by one of the following:
	  ○ Enzyme assay showing diminished (less than 10% of controls) or absent acid sphingomyelinase (ASM) activity
	  ○ Gene sequencing showing biallelic pathogenic sphingomyelin phosphodiesterase-1 (SMPD1) mutation
	• Documentation of clinical presentation outside the central nervous system (e.g., hepatosplenomegaly, interstitial lung disease, liver fibrosis, growth restriction of childhood)
	• Documentation of current body mass index (BMI), weight, and height
	• For adults aged 18 years and older, documentation of both of the following:
	  ○ Diffusion capacity of lungs (DLCO) is less than or equal to 70% of the predicted normal value
	  ○ Spleen volume greater than or equal to 6 multiples of normal (MN) measured by magnetic resonance imaging (MRI)
	• For pediatrics aged 18 years and younger, documentation of both of the following:
	  ○ Spleen volume greater than or equal to 5 MN measured by MRI
	  ○ Height Z-score -1 or lower

Appropriate Treatment Regimen & Other Criteria:	**Dosing:** Dosed every two weeks based on FDA label Body mass index (BMI) less than or equal 30, the dosage is based on actual body weight (kg) BMI of greater than 30 is dosed based on adjusted body weight Adjusted body weight= (actual height in m^2) x 30 • Availability: 20 mg single-dose vials • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization**: Documentation of improvement in patient specific disease presentation such as: • Improvement in PFT or DLCO • Improvement in spleen and/or liver volume or function • Improvement/Stability in platelet counts • Improvement in linear growth progression (pediatric)
Exclusion Criteria:	• Exclusive central nervous system manifestations
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a metabolic specialist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OMALIZUMAB
Affected Medications: XOLAIR (omalizumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of moderate to severe allergic asthma in adults and pediatric patients 6 years of age and older
	  ○ Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients
	  ○ Treatment of patients 12 to a maximum age of 20 years with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment
	  ○ Reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adults and pediatric patients aged 1 year and older with IgE-mediated food allergy

Required Medical Information:	**Allergic Asthma**
	• Documentation of moderate to severe allergic asthma defined by all the following:
	  ○ A positive skin test or in vitro reactivity to a perennial aeroallergen (e.g., house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores)
	  ○ A serum total IgE level at baseline of
	  ▪ At least 30 IU/mL and less than 700 IU/mL in patients aged 12 years or older OR
	  ▪ At least 30 IU/mL and less than 1,300 IU/mL in patients aged 6 to 11 years
	  ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal
	
	CRSwNP
	• Documented diagnosis of chronic rhinosinusitis with nasal polyps
	• History of sinus surgery (Functional Endoscopic Sinus Surgery [FESS] or similar)
	• Documentation of both of the following:
	  ○ Presence of bilateral nasal polyps
	  ○ Symptoms of sinonasal obstruction/congestion for over 12 weeks (decreased/absent sense of smell, facial pressure/pain, rhinorrhea/postnasal drip)
	
	CSU
	• Documentation of active CSU where the underlying cause is not considered to be any other allergic condition or other form of urticaria
	• Documentation of presence of recurrent urticaria, angioedema, or both, for a period of six weeks or longer
	• Documented avoidance of triggers (such as nonsteroidal anti-inflammatory drugs [NSAIDs])
	• Documentation of pruritus severe enough to interfere with the ability to grow, develop and participate in school despite treatment with at least 80% adherence
	
	IgE-Mediated Food Allergy
	• Serum total IgE level between 30 and 1850 IU/mL
	• Body weight between 10 and 150 kg
	• Diagnosis of IgE-mediated food anaphylactic allergy to three or more foods with documented positive skin prick test and positive serum IgE

	• Documentation of past IgE-mediated food anaphylactic reactions requiring use of epinephrine despite avoidance of food allergen and modifications to diet • Documentation that avoidance of food allergen alone is not feasible based on the number of allergens, malnutrition due to nutritional restrictions, and impaired quality of life causing food allergy-related anxiety
Appropriate Treatment Regimen & Other Criteria:	**Allergic Asthma** • Documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms AND • Documentation of one of the following: o A documented history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months while on combination inhaled treatment with at least 80% adherence. o Documentation that chronic daily oral corticosteroids are required **CRSwNP** • Documented treatment failure with two intranasal corticosteroids for minimum of 3 months each after sinus surgery **CSU** • Documented treatment failure with up to 4-fold standard dosing (must be scheduled) of one of the following second generation H1- antihistamine products for at least one month: cetirizine, fexofenadine, loratadine, desloratadine, or levocetirizine • Documented treatment failure with scheduled dosing of ALL the following for at least one month each: o Add-on therapy with a leukotriene antagonist (montelukast or zafirlukast) o Add-on therapy with a H2-antagonist (famotidine or cimetidine) o Add-on therapy with a corticosteroid **IgE-Mediated Food Allergy** • Trial and failure of oral immunotherapy (OIT) **Reauthorization** requires documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Use in combination with another monoclonal antibody (e.g., Fasenra, Nucala, Tezspire, Dupixent, Cinqair) • Treatment of CSU in patients 21 years of age and older
Age Restriction:	• **Allergic Asthma**: 6 years of age and older • **CRSwNP**: 18 years of age and older • **CSU**: 12 to 20 years of age • **IgE-Mediated Food Allergy**: 1 year of age and older
Prescriber Restrictions:	• **Allergic Asthma**: Prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist • **CRSwNP**: Prescribed by, or in consultation with, an otolaryngologist • **CSU/IgE-Mediated Food Allergy**: Prescribed by, or in consultation with, an allergist or

	immunologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OMAVELOXOLONE
Affected Medications: SKYCLARYS (omaveloxolone)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older
Required Medical Information:	• Genetically confirmed diagnosis of Friedreich's Ataxia • Documentation of baseline modified Friedreich's Ataxia Rating Scale (mFARS) score under 81 • Documentation that the patient is still ambulatory or retains enough activity to assist in activities with daily living
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success such as a reduction in the rate of decline as determined by prescriber
Exclusion Criteria:	
Age Restriction:	• Must be 16 years of age or older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OMIDUBICEL
Affected Medications: Omisirge

Covered Uses:	• NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better • All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Documented diagnosis of a hematologic malignancy • Clinically stable and eligible for umbilical cord blood transplantation (UCBT) following myeloablative conditioning

Appropriate Treatment Regimen & Other Criteria:	• Must NOT have a matched related donor (MRD), matched unrelated donor (MUD), mismatched unrelated donor (MMUD), or haploidentical donor readily available
	• Documentation that NONE of the following are present:
	  ○ Other active malignancy
	  ○ Active or uncontrolled infection
	  ○ Active central nervous system (CNS) disease
	
	Reauthorization: None- Omisirge will be used as a one-time treatment

Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • HLA (Human leukocyte antigen)-matched donor able to donate • Prior allo- HSCT (Hematopoietic stem cell transplantation) • Pregnancy or lactation
Age Restriction:	• 12 years of age and older
Prescriber/Site of Care Restrictions:	• Must be prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 2 months for 1 time administration, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ONASEMNOGENE ABEPARVOVEC XIOI
Affected Medications: ZOLGENSMA (onasemnogene abeparvovec xioi)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by benefit design ○ Spinal muscular atrophy (SMA)

Required Medical Information:	• Diagnosis of SMA type 1 confirmed by genetic testing of chromosome 5q13.2 demonstrating ONE of the following:
	  ○ Homozygous gene deletion of SMN1 (survival motor neuron 1)
	  ○ Homozygous gene mutation of SMN1
	  ○ Compound heterozygous gene mutation of SMN1
	• Documentation of 2 or fewer copies of the SMN2 (survival motor neuron 2) gene
	• Documentation of previous treatment history
	• Documentation of ventilator use status:
	  ○ Patient is NOT ventilator-dependent (defined as using a ventilator at least 16 hours per day on at least 21 of the last 30 days)
	  ○ This does not apply to patients who require non-invasive ventilator assistance
	• Documentation of anti-adeno-associated virus (AAV) serotype 9 antibody titer less than or equal 1:50
	• Patient weight and planned treatment regimen

Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Prior treatment with SMA gene therapy (i.e., onasemnogene abeparvovec-xioi) • Will not use in combination with other agents for SMA (e.g., nusinersen, risdiplam, etc.) • Advanced SMA at baseline (complete paralysis of limbs, permanent ventilation support)
Age Restriction:	• Children less than 2 years old
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pediatric neurologist or provider who is experienced in treatment of spinal muscular atrophy
Coverage Duration:	• Approved for one dose only per lifetime

POLICY NAME:
ONCOLOGY AGENTS
Affected Medications: ABRAXANE (paclitaxel), ABECMA (idecabtagene vicleucel), ABIRATERONE, ADCETRIS (brentuximab vedotin), ADSTILADRIN (nadofaragene firadenovec-vncg), AKEEGA (niraparib + abiraterone), ALECENSA, ALKERAN, ALIQOPA (copanlisib), ALUNBRIG (brigatinib), ANKTIVA (nogapendekin alfa), ASPARLAS (asparaginase), ARZERRA (ofatumumab), AUCATZYL (obecabtagene autoleucel), AUGTYRO (repotrectinib), AVMAPKI-FAKZYNJA CO-PAK (avutometinib and defactinib), AYVAKIT (avapritinib), AZEDRA (iobenguane I-131), BAVENCIO (avelumab), BALVERSA (erdafitinib), BELEODAQ (belinostat), BELRAPZO (bendamustine), BENDEKA (bendamustine), BESPONSA (inotuzumab ozogamicin), BIZENGRI (zenocutuzumab-zbco), BLENREP (belantamab mafodotin-blmf), BLINCYTO (blinatumomab), BRAFTOVI (encorafenib), BREYANZI (lisocabtagene maraleucel), BRUKINSA (zanubrutinib), CABOMETYX (cabozantinib), CALQUENCE (calabrutinib), CAPRELSA, CARVYKTI (ciltacabtagene autoleucel), COLUMVI (glofitamab-gxbm), COMETRIQ (cabozantinib), COPIKTRA (duvelisib), COSELA (trilaciclib), COTELLIC, CYRAMZA (ramucirumab), DACOGEN (decitabine), DANYELZA (naxitamab), DARZALEX, DARZALEX FASPRO (daratumumab-hyaluronidase), DATROWAY (datopotamab deruxtecan-dlnk), DAURISMO (glasdegib), ELAHERE, ELREXFIO (elranatamab), EMPLICITI, EMRELIS (telisotuzumab vedotin), ENHERTU (fam-trastuzumab deruxtecan), ENSACOVE (ensartinib), EPKINLY (epcoritamab), ERBITUX (cetuximab), ERIVEDGE, ERLEADA (apalutamide), ERLOTINIB, ERWINAZE, EVOMELA, FOTIVDA (tivozanib), FRUZAQLA (fruquintinib), GAVRETO (pralsetinib), GAZYVA, GEFITINIB, GILOTRIF, HERNEXEOS (zongertinib), HEPZATO (melphalan), HYCAMTIN, IBRANCE (palbociclib), IBTROZI (taletrectinib), ICLUSIG, IDHIFA (enasidenib), IMATINIB, IMBRUVICA (ibrutinib), IMDELLTRA (tarlatamab), IMFINZI (durvalumab), IMJUDO (tremelimumab), IMLYGIC (talimogene laherparepvec), INLEXZO (gemcitabine intravesical), INLYTA, INQOVI (decitabine and cedazuridine), INREBIC, ISTODAX (romidepsin), ITOVEBI (inavolisib), IWILFIN (eflornithine), IXEMPRA (ixabepilone), JAKAFI (ruxolitinib), JAYPIRCA (pirtobrutinib), JELMYTO (mitomycin pyelocaliceal), JEMPERLI (dostarlimab), JEVTANA (cabazitaxel), Kadcyla (Ado-trastuzumab), KEYTRUDA (pembrolizumab), KIMMTRAK, KISQALI (ribociclib), KISQALI & FEMARA CO-PACK, KRAZATI (adagrasib), KYMRIAH (tisagenlecleucel), KYPROLIS (carfilzomib), LARTRUVO, lenalidomide, LENVIMA (lenvatinib mesylate), LIBTAYO (cemiplimab-rwlc), LIPOSOMAL DOXORUBICIN, LONSURF, LOQTORZI (toripalimab-tpzi), LORBRENA, LUMAKRAS (sotorasib), LUMOXITI, LUNSUMIO (mosunetuzumab), LUTATHERA, LYNOZYFIC (linvoseltamab), LYNPARZA, LYTGOBI (futibatinib), MARGENZA (margetuximab-cmkb), MARQIBO (liposomal vincristine), MATULANE (procarbazine hydrochloride), MEKINIST (trametinib), MEKTOVI (binmetinib), MODEYSO (dordaviprone), MONJUVI (tafisitamab-cxix), MYLOTARG, NERLYNX (neratinib), SORAFENIB TOSYLATE, NILANDRON, NINLARO (ixazomid), NUBEQA, ODOMZO, OJEMDA (tovorafenib), OJJAARA (momelotinib), ONCASPAR, ONIVYDE (irinotecan), ONUREG (azacitidine), OPDIVO (nivolumab), OPDIVO QVANTIG (nivolumab/ hyaluronidase), OPDUALAG (nivolumab /relatlimab), ORSERDU (elacestrant), PADCEV (enfortumab vedotin), PAZOPANIB, PEMAZYRE (pemigatinib), PEPAXTO (melphalan flufenamide), PERJETA (pertuzumab), PHOTOFRIN (porfimer), PIQRAY (alpelisib), PLUVICTO (lutetium), POLIVY (polatuzumab vedotin-piiq**)**, POMALYST, PORTRAZZA (necitumumab), POTELIGEO, PROLEUKIN (aldesleukin), PROVENGE (sipuleucel-t), QINLOCK (ripretinib), RETEVMO (selpercatinib), REVUFORJ (revumenib), REZLIDHIA (olutasidenib), REZUROCK (belumosudil), ROMVIMZA (vimseltinib), ROZLYTREK, RUBRACA, RYBREVANT (amivantamab), RYDAPT, RYLAZE (asparaginase erwinia chrysanthemi), RYTELO (imetelstat), SARCLISA (isatuximab), STIVARGA (regorafenib), sunitinib, SYNRIBO (omacetaxine), TABRECTA (capmatinib), TAFINLAR (dabrafenib), TAGRISSO, TALVEY (talquetamab-tgvs), TALZENNA (talazopairb), TAZVERIK (tazemetostat), TECARTUS (brexucabtagene autoleucel), TECELRA (afamitresgene), TECENTRIQ (atezolizumab), TECENTRIQ HYBREZA (atezolizumab and hyaluronidase), TECVAYLI, TEPADINA (thiotepa), TEPMETKO (tepotinib), TEVIMBRA (tislelizumab-jsgr), TIBSOVO (ivosidenib), TIVDAK (tisotumab), TORISEL (temsirolimus), TREANDA (bendamustine), TRODELVY (sacituzumab govitecan), TRUQAP (capivasertib), TURALIO (pexidartinib oral capsules), TYKERB, UNITUXIN (dinutuximab), UNLOXCYT (cosibelimab), VANFLYTA (quizartinib), VECTIBIX, VENCLEXTA (venetoclax), VERZENIO (abemaciclib), VIDAZA (Azacitidine), VIVIMUSTA (bendamustine), VIZIMPRO (dacotiminib), VONJO (pacritinib), VORANIGO (Vorasidenib), VYLOY (zolbetuximab), VYXEOS (Daunorubicin and Cytarabine (Liposomal)), XALKORI (crizotinib), XALKORI (crizotinib) pellets, XELODA, XOFIGO (Radium 223), XOSPATA (gilteritinib), XPOVIO (selinexor), XTANDI (enzalutamide), YERVOY (ipilimumab), YESCARTA (axicabtagene ciloleucel), YONDELIS (trabectedin), ZALTRAP (ziv-aflibercept), ZEGFROVY (sunvozertinib), ZEJULA (niraparib), ZELBORAF, ZEPZELCA (lurbinectedin), ZOLINZA, ZYDELIG, ZYKADIA, ZYNLONTA (loncastuximab tesirine), ZYNYZ (retifanlimab-dlwr) injection

PacificSource Community Solutions

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher.
Required Medical Information:	• Documentation of performance status, all prior therapies used, disease staging, and anticipated treatment course • Documentation of use with National Comprehensive Cancer Network (NCCN) 2A or higher level of evidence regimen • Patient weight
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization**: documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OPICAPONE
Affected Medications: ONGENTYS (Opicapone)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's Disease (PD) experiencing "off" episodes
Required Medical Information:	• Diagnosis of PD • Documentation of acute, intermittent, "off" episodes occurring for at least 2 hours per day while awake despite an optimized treatment regimen

Appropriate Treatment Regimen & Other Criteria:	• Established on a stable dose of carbidopa-levodopa with intent to continue
	• Documented treatment failure with concurrent use of levodopa-carbidopa and entacapone
	• Documented treatment failure with concurrent use of levodopa-carbidopa and a second agent from one of the following classes:
	  ○ Monoamine oxidase-B (MAO-B) inhibitors (e.g., selegiline, rasagiline)
	  ○ Dopamine agonists (e.g., pramipexole, ropinirole)
	
	Reauthorization: will require documentation of treatment success defined as a reduction from baseline in "off" episodes associated with Parkinson's disease

Exclusion Criteria:	• Use as monotherapy or first line agent • Concomitant use of non-selective monoamine oxidase (MAO) inhibitors • Pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OPIOID NAÏVE 7 DAY LIMIT
Affected Medications: OPIOIDS

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	• Documentation of previous and current opioid treatment course

Appropriate Treatment Regimen & Other Criteria:	• Documentation that first opioid prescription in current treatment course will not exceed 7 days
	• Exceptions require all of the following:
	  ○ Documentation that a 7 day supply would be inadequate for treatment
	  ○ Follow-up for evaluation within 7 days is not possible

Exclusion Criteria:	• Non-naïve patients (has had a prescription for opioid within the last 180 days) • Pain related to current active cancer • Chronic pain related to sickle cell disease • Pain related to hospice care
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Based on exceptional circumstance, not to exceed 1 month

PacificSource Community Solutions

POLICY NAME:
OPIOID QUANTITY ABOVE 90 MORPHINE MILLIGRAM EQUIVALENTS (MME)
Affected Medications: OPIOIDS

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	Short term use of opioids with an MME per day greater than 90 MME requires one of the following: • Recent surgery • Acute injury Chronic use of opioids with a Morphine Milligram Equivalents (MME) per day greater than 90 MME requires: • A comprehensive individual treatment plan including attestation of a pain management agreement between the prescriber and patient • Continued assessment and documentation of risk of abuse • Documentation that previous tapers have been attempted or documentation of a taper plan or rationale for avoidance of taper initiation
Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Pain related to current active cancer • Chronic pain related to sickle cell disease • Pain related to hospice care • Surgery or documented acute injury – 1 month approval
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OPZELURA
Affected Medications: OPZELURA 1.5% CREAM

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Atopic dermatitis
	  ○ Nonsegmental vitiligo

Required Medical Information:	**<u>All Ages</u>**
	• Documentation of affected body surface area (BSA) and areas of involvement
	
	<u>Age 21 and above</u>
	• Documentation that the skin disease is severe in nature, resulting in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CLDQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living
	  ○ Significant facial involvement preventing normal social interaction
	• Documentation of one or more of the following:
	  ○ BSA of at least 10%
	  ○ Hand, foot, face, or mucous membrane involvement

Appropriate Treatment Regimen & Other Criteria:	**<u>Severe Atopic Dermatitis</u>**
	• Documented treatment failure with a minimum 6-week trial of one topical calcineurin inhibitor
	• Documented treatment failure with a minimum 12-week trial of two of the following: phototherapy, cyclosporine, azathioprine, methotrexate, mycophenolate
	
	• **Reauthorization** requires **BOTH** of the following:
	  ○ Documentation of treatment success and resolution of signs and symptoms within the first 8 weeks of treatment
	  ○ Confirmation that use of Opzelura will be non-continuous (used to treat flares) and will be discontinued each time signs and symptoms resolve
	
	<u>Nonsegmental Vitiligo</u>
	• Documented treatment failure with two topical corticosteroids (at least medium potency) for 4 weeks each, unless intolerant or treatment areas are predominantly limited to the face
	• Documented treatment failure with a minimum 12-week trial with all the following: tacrolimus ointment, pimecrolimus cream, phototherapy
	• **Reauthorization:** Documentation of disease responsiveness to therapy, defined as a decrease in affected BSA from baseline. Please note, the maximum length of treatment for this drug is 24 weeks.

Exclusion Criteria:	• Use in combination with biologics, other JAK inhibitors, or potent immunosuppressants (such as Dupixent, Adbry, Rinvoq, Nemluvio) • Atopic dermatitis or vitiligo not meeting the above criteria is considered a below the line (non-funded) diagnosis per Oregon Health Authority (OHA) for those 21 years of age and older. **Please refer to OHA GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE.**

	<u>Nonsegmental Vitiligo</u> • Previous 24-week treatment course
Age Restriction:	• 2 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
Coverage Duration:	**<u>Severe Atopic Dermatitis</u>** • Authorization: 3 months, unless otherwise specified **<u>Nonsegmental Vitiligo</u>** • Initial Authorization: 8 weeks, unless otherwise specified • Reauthorization: 16 weeks, unless otherwise specified ○ Lifetime Limit: 24 weeks

PacificSource Community Solutions

POLICY NAME:
ORAL-INTRANASAL FENTANYL
Affected Medications: FENTANYL CITRATE LOZENGE ON A HANDLE

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Management of breakthrough pain in cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain

Required Medical Information:	• Documentation of ALL the following:
	  ○ This drug is being prescribed for breakthrough cancer-related pain
	  ○ The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying persistent cancer pain
	  ○ The patient is opioid tolerant, defined as taking one of the following for one week or longer:
	  ▪ At least 60 mg of oral morphine per day
	  ▪ At least 25 mcg of transdermal fentanyl per hour
	  ▪ At least 30 mg of oral oxycodone per day
	  ▪ At least 8 mg of oral hydromorphone per day
	  ▪ At least 25 mg of oral oxymorphone per day
	  ▪ At least 60 mg of oral hydrocodone per day
	  ▪ An equianalgesic dose of another opioid

Appropriate Treatment Regimen & Other Criteria:	• Documentation of ONE of the following:
	  ○ The patient is unable to swallow, or has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting
	  ○ The patient has documented intolerance or allergies to **two** other short-acting narcotics (such as oxycodone, morphine sulfate, hydromorphone, etc.)
	
	Reauthorization requires documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist or specialist in the treatment of cancer-related pain
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
ORENITRAM
Affected Medications: ORENITRAM (treprostinil oral)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO) Group 1

Required Medical Information:	**<u>Pulmonary arterial hypertension (PAH) WHO Group 1</u>**
	• Documentation of PAH confirmed by right-heart catheterization meeting the following criteria:
	  ○ Mean pulmonary artery pressure of at least 20 mm Hg
	  ○ Pulmonary capillary wedge pressure less than or equal to 15 mm Hg AND
	  ○ Pulmonary vascular resistance of at least 2.0 Wood units
	• Etiology of PAH: idiopathic, heritable, or associated with connective tissue disease
	• PAH secondary to one of the following conditions:
	  ○ Connective tissue disease
	  ○ Human immunodeficiency virus (HIV) infection
	  ○ Cirrhosis
	  ○ Anorexigens
	  ○ Congenital left to right shunts
	  ○ Schistosomiasis
	  ○ Drugs and toxins
	  ○ Portal hypertension
	• New York Heart Association (NYHA)/World Health Organization (WHO) Functional Class II or higher symptoms
	• Documentation of acute vasoreactivity testing (positive result requires trial/failure to calcium channel blocker) unless there are contraindications
	  ○ Low systemic blood pressure (systolic blood pressure less than 90), or
	  ○ Low cardiac index OR
	  ○ Presence of severe symptoms (functional class IV)

Appropriate Treatment Regimen & Other Criteria:	• Documentation of failure with Remodulin • The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition • Documentation that treprostinil is used as a single route of administration (Remodulin, Tyvaso, Orenatriam should not be used in combination) • Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out • Not recommended for PAH secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.) **<u>Reauthorization</u>** requires documentation of treatment success defined as one or more of the following: • Improvement in walking distance • Improvement in exercise ability • Improvement in pulmonary function • Improvement or stability in WHO functional class
Exclusion Criteria:	• Severe hepatic impairment (Child Pugh Class C)

PacificSource Community Solutions

Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ORGOVYX
Affected Medications: ORGOVYX (relugolrix)

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher
Required Medical Information:	
Appropriate Treatment Regimen & Other Criteria:	**Prostate Cancer** • Documented treatment failure or intolerable adverse event with leuprolide or degarelix **Reauthorization**: documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ORITAVANCIN
Affected Medications: KIMYRSA

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of adult patients with acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms
	  ▪ Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant isolates)
	  ▪ Streptococcus pyogenes
	  ▪ Streptococcus agalactiae
	  ▪ Streptococcus dysgalactiae
	  ▪ Streptococcus anginosus group (includes S. anginosus, S. intermedius, and S. constellatus)
	  ▪ Enterococcus faecalis (vancomycin-susceptible isolates only)

Required Medical Information:	• Documentation of confirmed or suspected diagnosis • Documentation of treatment history and current treatment regimen • Documentation of planned treatment duration as applicable
Appropriate Treatment Regimen & Other Criteria:	• 1200 mg (1 vial) intravenous (IV) infusion over 1 hour as a single dose • Documented clinical failure with Orbactiv (oritavancin)
Exclusion Criteria:	• Known hypersensitivity to oritavancin products
Age Restriction:	• 18 years or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist
Coverage Duration:	• Initial Authorization: 1 week, unless otherwise specified

POLICY NAME:
OTESECONAZOLE
Affected Medications: VIVJOA (oteseconazole)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are **not** of reproductive potential, alone or in combination with fluconazole
Required Medical Information:	• Diagnosis of RVVC defined as three or more episodes of symptomatic vulvovaginal candidiasis infection within the past 12 months • Documented presence of signs/symptoms of current acute vulvovaginal candidiasis with a positive potassium hydroxide (KOH) test • Documentation confirming that the patient is permanently infertile (e.g. due to tubal ligation, hysterectomy, salpingo-oophorectomy) or postmenopausal
Appropriate Treatment Regimen & Other Criteria:	• Documented disease recurrence following maintenance therapy with fluconazole 150 mg once per week for 6 months • **Not to exceed one treatment course per year** **Reauthorization** requires documentation of treatment success defined as a reduction in symptomatic vulvovaginal candidiasis episodes, and documentation supporting the need for additional treatment
Exclusion Criteria:	• Women of reproductive potential or who are pregnant or breastfeeding
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 3 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OSILODROSTAT
Affected Medications: ISTURISA (osilodrostat)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Cushing's syndrome

Required Medical Information:	• Diagnosis of Cushing's syndrome due to one of the following:
	  ○ Adrenocorticotropic hormone (ACTH)-secreting pituitary adenoma (Cushing's disease)
	  ○ Ectopic ACTH section (EAS) by a non-pituitary tumor
	  ○ Cortisol secretion by an adrenal adenoma
	• Documentation of at least **two** of the following:
	  ○ Mean (at least two measurements) 24-hour urine free cortisol (mUFC) greater than 1.5 times the upper limit of normal (ULN) for the assay
	  ○ Bedtime salivary cortisol (at least two measurements) greater than 145 ng/dL
	  ○ Overnight dexamethasone suppression test (DST) with a serum cortisol greater than 1.8 mcg/dL

Appropriate Treatment Regimen & Other Criteria:	• Documentation confirming surgery is not an option **OR** previous surgery has not been curative **Reauthorization** requires documentation of treatment success defined as mUFC normalization (i.e., less than or equal to the ULN)
Exclusion Criteria:	
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an endocrinologist, neurologist, or adrenal surgeon
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

POLICY NAME:
OXERVATE
Affected Medications: OXERVATE (cenegermin-bkbj)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of neurotrophic keratitis

Required Medical Information:	• Documentation of decreased corneal sensitivity (≤ 4 cm using the Cochet-Bonnet [CB] aesthesiometer) within the area of the recurrent/persistent epithelial defect (PED) or corneal ulcer **AND** outside of the area of the defect in at least one corneal quadrant
	• Documentation of one of the following:
	  ○ Stage 2 neurotrophic keratitis, confirmed by presence of recurrent or persistent corneal epithelial defect
	  ○ Stage 3 neurotrophic keratitis, confirmed by presence of corneal ulceration (with or without stromal melting and perforation)

Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure (e.g., persistent epithelial defects or corneal ulceration) with preservative-free artificial tears/ointments and **TWO** of the following:
	  ○ Therapeutic contact lenses (TCLs) (e.g., corneal or scleral contact lenses, soft bandage contact lenses)
	  ○ Amniotic membrane transplantation
	  ○ Tarsorrhaphy
	  ○ Conjunctival flap surgery
	• Dose may not exceed more than 1 vial per eye per day
	
	Reauthorization requires documentation of treatment response as shown by reduction in corneal staining with fluorescein

Exclusion Criteria:	• Active or suspected ocular or periocular infections
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an ophthalmologist
Coverage Duration:	• Initial Authorization: 8 weeks, unless otherwise specified • Reauthorization: 8 weeks, unless otherwise specified ○ Lifetime Limit: 16 weeks (per affected eye)

POLICY NAME:
OXYBATES
Affected Medications: LUMRYZ (sodium oxybate extended release), sodium oxybate, XYWAV (oxybate salts)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients with narcolepsy
Required Medical Information:	**<u>All Indications</u>** • Polysomnography and multiple sleep latency test results confirming diagnosis • Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) **<u>Narcolepsy with cataplexy</u>** • Diagnosis confirmed by polysomnography and multiple sleep latency test • Documentation of cataplexy episodes defined as more than one episode of sudden loss of muscle tone with retained consciousness **<u>Narcolepsy with EDS</u>** • Diagnosis confirmed by polysomnography and multiple sleep latency test • Current evaluation of symptoms and Epworth Sleepiness Scale (ESS) score of more than 10 despite treatment

Appropriate Treatment Regimen & Other Criteria:	• Authorization for Xywav and Lumryz for current and new utilizers requires documented treatment failure with sodium oxybate
	
	<u>Narcolepsy with cataplexy:</u>
	• Documented treatment failure (inadequately controlled cataplexy) despite treatment with each of the following for at least 1 month unless contraindicated:
	  ○ Venlafaxine, fluoxetine, and a tricyclic antidepressant
	OR
	• Must meet criteria for EDS
	
	<u>Narcolepsy with EDS:</u>
	• Documented treatment failure with at least 3 of the following (1 in each category required) for at least 1 month, unless contraindicated:
	  ○ Modafinil or armodafinil
	  ○ Methylphenidate or dextroamphetamine or lisdexamfetamine
	  ○ Sunosi
	
	<u>Reauthorization</u>:
	• Narcolepsy with cataplexy: clinically significant reduction in cataplexy episodes
	• Narcolepsy with EDS: clinically significant improvement in activities of daily living and in Epworth Sleepiness Scale (ESS) score

Exclusion Criteria:	• Current use of alcohol, sedative/hypnotic drugs, or other central nervous system depressants • Use for other untreated causes of sleepiness

PacificSource Community Solutions

Age Restriction:	• 7 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a sleep specialist or neurologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PALFORZIA
Affected Medications: PALFORZIA (peanut allergen powder)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut

Required Medical Information:	• Documented treatment plan, including dose and frequency
	• Diagnosis of peanut allergy confirmed by one of the following:
	  ○ A positive skin prick test (SPT) response to peanut with a wheal diameter at least 3 mm larger than the control
	  ○ Serum peanut-specific IgE level greater than or equal to 0.35 kUA/L
	• Documented history of an allergic reaction to peanut with all the following:
	  ○ Signs and symptoms of a significant systemic allergic reaction to peanut (e.g., hives, swelling, wheezing, hypotension, gastrointestinal symptoms)
	  ○ The reaction occurred within a short period of time following a known ingestion of peanut or peanut-containing food
	  ○ The reaction was severe enough to warrant a prescription for an epinephrine injection
	• Documentation indicating a significant impact on quality of life due to peanut allergies

Appropriate Treatment Regimen & Other Criteria:	**Dosing:** • Requests for initial dose escalation: must be between 1 and 17 years of age • Requests for up-dosing and maintenance phase: 1 year of age and older **Reauthorization** requires documentation of completion of the appropriate initial dose escalation and up-dosing phases prior to moving on to the maintenance phase AND documentation of treatment success and a clinically significant response to therapy, defined by one or more of the following: • Improvement in quality of life • Reduction in severe allergic reactions • Reduction in epinephrine use • Reduction in physician office visits, ER visits, or hospitalizations due to peanut allergy
Exclusion Criteria:	• Use for the emergency treatment of allergic reactions, including anaphylaxis • Uncontrolled asthma • History of eosinophilic esophagitis (EoE) and other eosinophilic gastrointestinal disease • History of cardiovascular disease, including uncontrolled or inadequately controlled hypertension • History of a mast cell disorder, including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema
Age Restriction:	• 1 year of age and older (see Appropriate Treatment Regimen & Other Criteria for specific age-related dosing requirements)
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an allergist or immunologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified


PacificSource
Community Solutions

PacificSource Community Solutions

POLICY NAME:
PALIPERIDONE PALMITATE INJECTABLES
Affected Medications: INVEGA SUSTENNA (Paliperidone Palmitate Extended-Release Injectable Suspension), INVEGA TRINZA (Paliperidone Palmitate Extended-Release Injectable Suspension), INVEGA HAFYERA (Paliperidone Palmitate Extended-Release Injectable Suspension); ERZOFRI (Paliperidone Palmitate Extended-Release Injectable Suspension)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Schizophrenia (Invega Sustenna, Invega Trinza, and Invega Hafyera, Erzofri)
	  ○ Schizoaffective disorder (Invega Sustenna, Erzofri)

Required Medical Information:	• A documented history of non-compliance, refusal to utilize oral medications, or unable to be stabilized on oral medications

Appropriate Treatment Regimen & Other Criteria:	• Documented anticipated dosing is in accordance with FDA labeling
	
	<u>Invega Sustenna</u>
	• Documented history of receiving at least one of the following:
	  ○ At least three test doses of oral risperidone
	  ○ At least three test doses of oral paliperidone
	  ○ Invega Sustenna
	
	<u>Invega Trinza</u>
	• Adequate treatment has been established with Invega Sustenna for at least 4 months
	• Documented anticipated dose and dosing schedule
	
	<u>Invega Hafyera</u>
	• Adequate treatment has been established with Invega Sustenna for at least 4 months OR with Invega Trinza for at least one three-month injection cycle
	AND
	• Documented anticipated dose and dosing schedule based on maintenance Invega Sustenna or Invega Trinza maintenance dose
	
	<u>Erzofri</u>
	• A documented intolerable adverse event with Invega Sustenna, Invega Trinza or Invega Hafyera, and the adverse event was not an expected adverse event attributed to the active ingredient
	
	<u>Reauthorization</u> will require documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Diagnosis of dementia-related psychosis
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a psychiatrist or a psychiatric practice

PacificSource Community Solutions

Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PALIVIZUMAB
Affected Medications: SYNAGIS (palivizumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Required Medical Information:	**Congenital Heart Disease (CHD)**
	• Documentation of one of the following:
	  ○ Pharmacologically treated acyanotic heart disease that will require surgical intervention
	  ○ Cyanotic heart defects
	  ○ Moderate to severe pulmonary hypertension
	  ○ Receipt of cardiac transplantation during the RSV season
	
	Chronic Lung Disease (CLD) of Prematurity
	• Gestational age less than 32 weeks and 0 days
	• **12 months of age or younger:** Required supplemental oxygen for at least the first 28 days after birth
	• **24 months of age or younger:** Documentation of **both** of the following:
	  ○ Required supplemental oxygen for at least the first 28 days after birth
	  ○ Required continued medical support during the 6-month period prior to RSV season (chronic corticosteroids, diuretics, supplemental oxygen)
	
	Cystic Fibrosis (CF)
	• Documented diagnosis of cystic fibrosis
	• **12 months of age or younger:** Clinical evidence of chronic lung disease and/or nutritional compromise
	• **24 months of age or younger:** Documentation of **ONE** of the following:
	  ○ Manifestations of severe lung disease (prior hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest X-ray or computed tomography that persist when stable)
	  ○ Weight for length less than the 10th percentile
	
	Pulmonary Abnormalities/Neuromuscular Disorders
	• Documentation of congenital anomaly or neuromuscular disease resulting in ineffective cough and impaired ability to clear the upper airway of secretions (excluding cystic fibrosis)
	
	Premature Infants
	• Gestational age less than 29 weeks and 0 days

Appropriate Treatment Regimen & Other Criteria:	**RSV Season** • Not to exceed 5 monthly doses (15 mg/kg per dose) during the RSV season, with first dose administered prior to commencement of the RSV season ○ If hospitalized at the start of RSV season, administer first dose 48-72 hours prior to discharge • Discontinue monthly prophylaxis if hospitalized for breakthrough RSV

	Off Season • Approvable for one 15 mg/kg dose when RSV activity is 10% or greater for the region, per the CDC
Exclusion Criteria:	• Administration of nirsevimab (Beyfortus) during the current RSV season • For use in the treatment of RSV
Age Restriction:	• Less than 2 years of age (at the start of the RSV season)
Prescriber Restrictions:	
Coverage Duration:	• **RSV Season:** 5 months (not to exceed end of RSV season), unless otherwise specified • **Off Season:** 1 month, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PALOVAROTENE
Affected Medications: SOHONOS (palovarotene)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ To reduce the volume of new heterotopic ossification in patients with fibrodysplasia ossificans progressiva (FOP)

Required Medical Information:	• Documentation of genetic testing confirming a diagnosis of FOP with an *activin receptor type 1 (ACVR1)* R206H mutation
	• Radiographic testing has confirmed the presence of both of the following:
	  ○ Heterotopic ossification (HO)
	  ○ Joint malformations (such as hallux valgus deformity, malformed first metatarsal, absent or fused interphalangeal joint)
	• Documentation of at least two flare-ups in the past 12 months requiring prescription strength non-steroidal anti-inflammatory drugs (NSAIDs) and oral glucocorticoids (e.g., prednisone)

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of treatment success defined as a decrease in HO volume or number of flare-ups compared to baseline
Exclusion Criteria:	• Patients weighing less than 10 kg • Pregnancy
Age Restriction:	• Females 8 years of age and older • Males 10 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a physician who specializes in rare connective tissue diseases (e.g., endocrinologist, geneticist, orthopedist, rheumatologist)
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PALYNZIQ
Affected Medications: PALYNZIQ (pegvaliase-pqpz)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Reduce phenylalanine (Phe) blood concentrations in adults with phenylketonuria (PKU) who have uncontrolled blood Phe greater than 600 micromol/L on existing management
Required Medical Information:	• Documentation of a diagnosis of PKU • Documentation of treatment failure with dual therapy of sapropterin and a Phe restricted diet as shown by a blood Phe level greater than 600 micromol/L (10 mg/dL) despite treatment
Appropriate Treatment Regimen & Other Criteria:	• Documentation that Palynziq will not be used in combination with sapropterin **Reauthorization** requires documentation of one of the following: • Reduction in baseline Phe levels by 20 percent • Increase in dietary Phe tolerance • Improvement in clinical symptoms
Exclusion Criteria:	
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist in metabolic disorders or an endocrinologist
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PARATHYROID HORMONE
Affected Medications: YORVIPATH (palopegteriparatide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of hypoparathyroidism

Required Medical Information:	• Documentation of the following lab values while on standard of care calcium and active vitamin D treatment:
	  ○ 25-hydroxyvitamin D levels between 20-80 ng/mL
	  ○ Total serum calcium (albumin-corrected) greater than 7.8 mg/dL

Appropriate Treatment Regimen & Other Criteria:	• Documented failure with at least 12 weeks of a consistent supplementation regimen as follows:
	  ○ Calcium 1000-2000 mg (elemental) daily
	  ○ Vitamin D metabolite (calcitriol) OR vitamin D analog
	
	Reauthorization will require documentation of treatment success defined as total serum calcium (albumin-corrected) within the lower half of the normal range (approximately 8-9 mg/dL)

Exclusion Criteria:	
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist or nephrologist
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PARATHYROID HORMONE ANALOGS
Affected Medications: TERIPARATIDE, TYMLOS (abaloparatide), FORTEO (teriparatide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of osteoporosis in men and postmenopausal women at high risk for fracture (teriparatide, Tymlos, and Forteo)
	  ○ Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture (teriparatide and Forteo only)

Required Medical Information:	• Diagnosis of osteoporosis defined by at least one of the following:
	  ○ T-score –2.5 or lower (current or past) at the lumbar spine, femoral neck, total hip, or 1/3 radius site
	  ○ T-score between –1.0 and –2.5 at the lumbar spine, femoral neck, total hip, or 1/3 radius site **AND** increased risk of fracture as defined by at least one of the following Fracture Risk Assessment Tool (FRAX) scores:
	  ▪ FRAX 10-year probability of major osteoporotic fracture is 20% or greater
	  ▪ FRAX 10-year probability of hip fracture is 3% or greater
	  ○ History of non-traumatic fractures in the absence of other metabolic bone disorders (postmenopausal women with osteoporosis only)
	• For glucocorticoid-induced osteoporosis, in addition to the above, must also provide documentation of the following:
	  ○ Treatment with 5 mg or higher of prednisone (or equivalent) per day for at least 3 months

Appropriate Treatment Regimen & Other Criteria:	Documentation of one of the following:
	• Treatment failure (new fracture or worsening T-score despite adherence to an adequate trial of therapy), contraindication, or intolerance to the following:
	  ○ Oral or Intravenous bisphosphonate (such as alendronate, risedronate, zoledronic acid or ibandronate)
	• High risk of fracture, defined as T-score -3.5 or lower, **OR** T-score -2.5 or lower with a history of fragility fractures
	
	For Forteo requests: documented treatment failure with Tymlos and teriparatide
	
	Total duration of therapy with parathyroid analogues should not exceed 2 years in a lifetime
	• Forteo or teriparatide may be **reauthorized** for up to one additional year beyond two years of parathyroid analogue use (maximum of 3 total years) if meeting the following criteria:
	  ○ Documentation of treatment success with parathyroid hormone use, defined as reduced frequency of fragility fractures or stable T score while on Forteo or teriparatide
	  ○ Documentation that after 24 months of parathyroid hormone use, the patient remains at or has returned to having a high risk for fracture as evidenced by new fragility fracture or decline in T-score

Exclusion Criteria:	• Paget's Disease • Open epiphyses (such as pediatric or young adult patient) • Bone metastases or skeletal malignancies • Hereditary disorders predisposing to osteosarcoma • Prior external beam or implant radiation therapy involving the skeleton • Concurrent use of bisphosphonates, parathyroid hormone analogs, or RANK ligand inhibitors • Pre-existing hypercalcemia • Pregnancy
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 24 months (no reauthorization), unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PAROMOMYCIN
Affected Medications: HUMATIN (paromomycin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Intestinal amebiasis, adjunctive therapy (*Entamoeba histolytica*)
	  ○ Hepatic abscess, adjunctive therapy (*Entamoeba histolytica*)
	• Compendia-supported uses that will be covered (if applicable)
	  ○ Cryptosporidiosis-associated diarrhea in patients with human immunodeficiency virus (HIV)
	  ○ *Dientamoeba fragilis*

Required Medical Information:	• Documentation of current infection confirmed with appropriate lab testing
	  ○ Hepatic abscess: Confirmed by diagnostic imaging (conventional ultrasound, computed tomography scan, or magnetic resonance imaging)
	  ○ *Dientamoeba fragilis*: Identification of *D. fragilis* trophozoites in fecal smears
	  ○ Cryptosporidiosis-associated diarrhea in patients with HIV: Stool specimen microscopic examination (acid-fast staining, direct fluorescent antibody, and/or enzyme immunoassays for detection of *Cryptosporidium* sp. antigens) or molecular methods

Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Intestinal obstruction • Use as monotherapy in *Entamoeba histolytica* infections
Age Restriction:	
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• Approval: 3 months

PacificSource Community Solutions

POLICY NAME:
PCSK9 MONOCLONAL ANTIBODIES
Affected Medications: REPATHA (evolocumab), PRALUENT (alirocumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Prevention of clinical atherosclerotic cardiovascular disease (ASCVD)
	  ○ Primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH])
	  ○ Homozygous familial hypercholesterolemia (HoFH)

Required Medical Information:	**All Indications**
	• Documentation of current complete lipid panel within last 3 months
	• Documentation of baseline (untreated) low-density lipoprotein cholesterol (LDL-C)
	
	Clinical ASCVD
	• For Praluent only: Documentation of established ASCVD, confirmed by at least **ONE** of the following:
	  ○ Acute coronary syndromes (ACS)
	  ○ History of myocardial infarction (MI)
	  ○ Stable or unstable angina
	  ○ Coronary or other arterial revascularization
	  ○ Stroke or transient ischemic attack
	  ○ Peripheral artery disease (PAD) presumed to be of atherosclerotic origin
	
	Primary Hyperlipidemia (non-familial)
	• Documentation of baseline (untreated) LDL-C of at least 160 mg/dl
	
	HeFH
	• Diagnosis confirmed by **ONE** of the following:
	  ○ Minimum baseline LDL-C of 160 mg/dL in adolescents or 190 mg/dL in adults **AND** 1 first-degree relative affected
	  ○ Presence of one abnormal LDL-C-raising gene defect (e.g., LDL receptor [LDLR], apolipoprotein B [apo B], proprotein convertase subtilisin kexin type 9 [PCSK9] gain-of-function mutation, LDL receptor adaptor protein 1 [LDLRAP1])
	  ○ World Health Organization (WHO)/Dutch Lipid Network criteria score of at least 8 points
	  ○ Definite FH diagnosis per the Simon Broome criteria
	
	HoFH
	• Diagnosis confirmed by **ONE** of the following:
	  ○ Baseline LDL-C greater than 560 mg/dL
	  ○ Baseline LDL-C of 400 mg/dL and at least 1 parent with familial hypercholesterolemia
	  ○ Baseline LDL-C of 400 mg/dL with aortic valve disease or xanthomata in ages less than 20 years
	  ○ Presence of two abnormal LDL-C-raising gene defects (excluding double-null LDLR mutations)

Appropriate Treatment	**All Indications** • History of statin intolerance requires documentation of **ONE** of the following:

PacificSource Community Solutions

<table>
<tr>
<td>Regimen & Other Criteria:</td>
<td>

Statin-associated rhabdomyolysis occurred with statin use and was confirmed by a creatinine kinase (CK) level at least 10 times the upper limit of normal
Statin-associated muscle symptoms (e.g., myopathy, myalgia) occurred with statin use and was confirmed by BOTH of the following:

A minimum of three different statin trials, with at least one being a hydrophilic statin (rosuvastatin, pravastatin)
A re-challenge of each statin (muscle symptoms stopped when each was discontinued and restarted upon re-initiation)

OR <u>For Praluent only</u>: Documented intent to take alongside maximally tolerated dose of statin and/or ezetimibe, unless otherwise contraindicated

<u>Clinical ASCVD</u>

Documented treatment failure with minimum 12 weeks of statin/ezetimibe combination therapy at maximally tolerated doses with consistent use, as shown by ONE of the following:

Current LDL-C of at least 70 mg/dL
Current LDL-C of at least 55 mg/dL in patients at very high risk of future ASCVD events, based on history of multiple major ASCVD events OR 1 major ASCVD event + multiple high-risk conditions

<table>
<tr><th>Major ASCVD Events</th><th>High-Risk Conditions</th></tr>
<tr>
<td>
ACS within the past 12 months
History of MI (distinct from ACS event)
Ischemic stroke
Symptomatic PAD
</td>
<td>
Age 65 years and older
HeFH
Prior coronary artery bypass or percutaneous intervention (outside of major ASCVD events)
Diabetes
Hypertension
Chronic kidney disease
Current smoking
History of congestive heart failure
</td>
</tr>
</table>
<u>Primary Hyperlipidemia/HeFH/HoFH</u>

Documented treatment failure, defined as an inability to achieve LDL-C reduction of 50% or greater OR LDL-C less than 100 mg/dL, with minimum 12 weeks of statin/ezetimibe combination therapy at maximally tolerated doses with consistent use

<u>Reauthorization</u>: Documentation of an updated lipid panel showing a clinically significant reduction in LDL-C from baseline AND continued compliance to therapy
</td>
</tr>
<tr>
<td>Exclusion Criteria:</td>
<td>Concurrent use with Leqvio</td>
</tr>
<tr>
<td>Age Restriction:</td>
<td></td>
</tr>
</table>

Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist, endocrinologist, or lipid specialist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
PEDMARK
Affected Medications: PEDMARK (sodium thiosulfate)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.
Required Medical Information:	• Documentation of the following: ○ Treatment plan is a cisplatin-based regimen treating a localized, non-metastatic solid tumor
Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Metastatic disease
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Authorization: 6 months or duration of cisplatin regimen

POLICY NAME:
PEGASYS
Affected Medications: PEGASYS® (peginterferon alfa-2a)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications and compendia-supported not otherwise excluded by plan design
	  ○ Chronic hepatitis B (CHB)
	  ▪ Treatment of adults with HBeAg-positive and HBeAg-negative CHB infection who have compensated liver disease, evidence of viral replication, and liver inflammation
	  ▪ Treatment of HBeAg-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine aminotransferase (ALT)
	  ○ Polycythemia vera
	  ○ Essential thrombocythemia

Required Medical Information:	• Documentation of anticipated treatment course, to include full antiviral regimen, and duration of therapy
	
	<u>CHB – Compensated Cirrhosis</u>
	• Documented of compensated cirrhosis
	• Documented HBV DNA level greater than 2,000 IU/mL
	
	<u>CHB – Non-cirrhotic</u>
	• Documentation of HBeAg-positive non-cirrhotic disease
	• Documented HBV DNA level greater than 20,000 IU/mL
	• Current (within 12 weeks) serum ALT level greater than or equal to 2 times the upper limit of normal
	
	<u>Polycythemia Vera (PV)</u>
	• Diagnosis of polycythemia vera confirmed by all major criteria (1-3) OR the first 2 major criteria (1-2) plus the minor criterion:
	  ○ **Major criteria:**
	  (1) Elevated hemoglobin concentration (greater than 16 g/dL), elevated hematocrit (greater than 48 percent), or increased red blood cell mass (greater than 25 percent above mean normal predicted value)
	  (2) Presence of *JAK2* V617F **or** *JAK2* exon 12 mutation
	  (3) Bone marrow biopsy showing age-adjusted hypercellularity with trilineage proliferation (panmyelosis), including prominent erythroid, granulocytic, and increase in pleomorphic, mature megakaryocytes without atypia. May not be required in patients with sustained absolute erythrocytosis (hemoglobin over 18.5 g/dL and hematocrit over 55.5 percent in men; hemoglobin over 16.5 g/dL and hematocrit over 49.5 percent in women) with presence of a *JAK2* V617F or *JAK2* exon 12 mutation.
	  ○ **Minor criterion:** Subnormal serum erythropoietin level.

PacificSource Community Solutions

	<u>Essential Thrombocythemia (ET)</u>
	• Diagnosis of essential thrombocythemia confirmed by all major criteria (1-4) **OR** the first 3 major criteria (1-3) plus the minor criterion:
	  ○ **Major criteria:**
	  (1) Platelet count greater than or equal to 450,000 cells/mcL.
	  (2) Bone marrow biopsy showing proliferation mainly of the megakaryocytic lineage, with hyperlobulated staghorn-like nuclei, infrequently dense clusters; no significant increase or left shift in neutrophil granulopoiesis or erythropoiesis; no relevant bone marrow fibrosis.
	  (3) Diagnostic criteria for BCR::ABL1-positive chronic myeloid leukemia, polycythemia vera, primary myelofibrosis, or other neoplasms are not met.
	  (4) Presence of *JAK2*, *CALR*, or *MPL* mutation.
	  ○ **Minor criterion:** Presence of another clonal marker (e.g., *ASXL1*, *EZH2*, *TET2*, *IDH1/IDH2*, *SRSF2*, or *SRF3B1* mutation) **OR** no identifiable cause for thrombocytosis (such as iron deficiency, chronic infection, chronic inflammatory disease, prior splenectomy)

Appropriate Treatment Regimen & Other Criteria:	**<u>PV and ET:</u>** • Documented treatment failure, intolerance, or contraindication to hydroxyurea
Exclusion Criteria:	• Autoimmune hepatitis • Hepatic decompensation (Child-Pugh score greater than 6)
Age Restriction:	• CHB with compensated cirrhosis: 18 years of age or older • CHB without cirrhosis: 3 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a gastroenterologist, hematologist, hepatologist, oncologist or infectious disease specialist

Coverage Duration:	• **CHB**: 12 months, unless otherwise specified
	• **PV, ET**:
	  ○ Initial Authorization: 4 months, unless otherwise specified.
	  ○ Reauthorization: 12 months, unless otherwise specified.

PacificSource Community Solutions

POLICY NAME:
PEGLOTICASE
Affected Medications: KRYSTEXXA (pegloticase)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design: ○ Chronic gout in adult patients refractory to conventional therapy

Required Medical Information:	• Baseline serum uric acid (SUA) level greater than 8 mg/dL
	• Documentation of ONE of the following:
	  ○ Two or more gout flares per year that were inadequately controlled by colchicine and/or nonsteroidal anti-inflammatory drugs (NSAIDS) or oral/injectable corticosteroids
	  ○ At least one non-resolving subcutaneous gouty tophus
	  ○ Chronic gouty arthritis (defined clinically or radiographically as joint damage due to gout)

Appropriate Treatment Regimen & Other Criteria:	• Documented contraindication, intolerance or clinical failure (defined as inability to reduce SUA level to less than 6 mg/dL) following a 12-week trial at maximum tolerated dose to BOTH:
	  ○ Xanthine oxidase inhibitor (allopurinol or febuxostat)
	  ○ Combination of a xanthine oxidase inhibitor AND a uricosuric agent (such as probenecid). If xanthine oxidase inhibitor is contraindicated, trial with uricosuric agent required
	• Documentation Krystexxa will be used in combination oral methotrexate 15mg weekly unless contraindicated
	
	<u>Reauthorization</u> will require ALL the following:
	• Documentation of SUA less than 6mg/dL prior to next scheduled Krystexxa dose
	• Documentation of response to treatment such as reduced size of tophi or number of flares or affected joints
	• Rationale to continue treatment after resolution of tophi or reduction in symptoms

Exclusion Criteria:	• Concurrent use with oral urate-lowering therapies
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in combination with, a nephrologist or rheumatologist
Coverage Duration:	• Approval: 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PEMIVIBART
Affected Medications: PEMGARDA (pemivibart)

Covered Uses:	• All Food and Drug Administration (FDA) or compendia supported indications not otherwise excluded by plan design ○ Pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents with moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications/treatments **and** are unlikely to mount an adequate immune response to COVID-19 vaccination

Required Medical Information:	• Documentation of moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments, and are unlikely to mount an adequate response to COVID-19 vaccination, meeting one of the following:
	  ○ Active treatment for solid tumor and hematologic malignancies
	  ○ Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
	  ○ Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
	  ○ Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppressive therapy)
	  ○ Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome)
	  ○ Advanced or untreated human immunodeficiency viruses (HIV) infection (people with HIV and CD4 cell counts less than 200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
	  ○ Active treatment with high-dose corticosteroids (at least 20 mg prednisone or equivalent per day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, and biologic agents that are immunosuppressive or immunomodulatory (such as B-cell depleting agents)
	• Documentation of prophylactic use
	• Weight of 40 kg or more

Appropriate Treatment Regimen & Other Criteria:	• **Dosing** is in accordance with FDA labeling and does not exceed 4500 mg once every 3 months **Reauthorization** requires documentation of continued immune compromise
Exclusion Criteria:	• Positive SARS-CoV-2 antigen test or PCR test within the last 3 months • Received COVID-19 vaccine within the last 2 weeks
Age Restriction:	• 12 years of age and older
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• Authorization: 3 months, unless otherwise specified


PacificSource
Community Solutions

PacificSource Community Solutions

POLICY NAME:
PHENOXYBENZAMINE
Affected Medications: Phenoxybenzamine

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of sweating and hypertension associated with pheochromocytoma

Required Medical Information:	• Documented diagnosis of pheochromocytoma that requires treatment to control episodes of hypertension and sweating
	• This drug will be used for one of the following:
	  ○ Preoperative preparation for a scheduled surgical resection
	  ○ Chronic treatment of pheochromocytoma that is not amenable to surgery

Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure, intolerance, or contraindication to a selective alpha-1 adrenergic receptor blocker (e.g., doxazosin, terazosin, prazosin) **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist or a specialist with experience in the management of pheochromocytoma
Coverage Duration:	• **Preoperative preparation**: 1 month, unless otherwise specified • **Chronic treatment**: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PHENTERMINE/TOPIRAMATE
Affected Medications: phentermine/topiramate

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design

Required Medical Information:	**Pediatric weight loss:**
	• Patient age of 12 to 20 years
	• Severe obesity defined as one of the following:
	  ○ Body mass index (BMI) of greater than or equal to 35kg/m^2
	  ○ Equal to or greater than 120% of the 95th percentile for age and sex

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization:** • Documentation of reduction of weight of at least 5% of baseline BMI since initiation
Exclusion Criteria:	
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a pediatrician or weight loss specialist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PHESGO
Affected Medications: PHESGO (pertuzumab-trastuzumab-hyaluronidase-zzxf)

Covered Uses:	• NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better

Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and prescribed dosing regimen
	• Documentation of HER2 positivity based on
	  ○ 3+ score on immunohistochemistry (IHC) testing
	  OR
	  ○ Positive gene amplification by Fluorescence in situ hybridization (FISH) test

Appropriate Treatment Regimen & Other Criteria:	• Documentation of an intolerable adverse event to **two** of the following preferred products and the adverse event was not an expected adverse event attributed to the active ingredients ○ **Preferred products**: Perjeta in combination with Kanjinti, Perjeta in combination with Ogivri, Perjeta in combination with Trazimera, Perjeta in combination with Herzuma, Perjeta in combination with Ontruzant **Reauthorization** requires documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PHOSPHODIESTERASE-5 (PDE-5) ENZYME INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION
Affected Medications: tadalafil 20 mg tablet, sildenafil 20 mg tablet

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO) Group 1

Required Medical Information:	• Diagnosis of World Health Organization (WHO) Group 1 PAH confirmed by right heart catheterization meeting the following criterias:
	  ○ Mean pulmonary artery pressure of at least 20 mm Hg
	  ○ Pulmonary capillary wedge pressure less than or equal to 15 mm Hg
	  AND
	  ○ Pulmonary vascular resistance of at least 2.0 Wood units
	• New York Heart Association (NYHA)/WHO Functional Class II or higher symptoms
	• Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blockers) unless there are contraindications:
	  ○ Low systemic blood pressure (systolic blood pressure less than 90)
	  ○ Low cardiac index
	  OR
	  ○ Presence of severe symptoms (functional class IV)

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of treatment success defined as one or more of the following: • Improvement in walking distance • Improvement in exercise ability • Improvement in pulmonary function • Improvement or stability in WHO functional class
Exclusion Criteria:	• Concomitant nitrate therapy on a regular or intermittent basis • Concomitant use of a guanylate cyclase stimulator (such as riociguat or vericiguat) • Use for erectile dysfunction
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

POLICY NAME:
PIRFENIDONE
Affected Medications: PIRFENIDONE

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Idiopathic Pulmonary Fibrosis (IPF)

Required Medical Information:	• Documented diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by **ONE** of the following:
	  ○ Usual interstitial pneumonia (UIP) pattern demonstrated on high-resolution computed tomography (HRCT)
	  ○ UIP pattern demonstrated on surgical lung biopsy
	  ○ Probable UIP pattern demonstrated on **both** HRCT and surgical lung biopsy
	• Documentation confirming known causes of interstitial lung disease have been ruled out (e.g., rheumatic disease, environmental exposure, drug toxicity)
	• Documentation of **both** of the following:
	  ○ Baseline forced vital capacity (FVC) greater than or equal to 50 percent predicted
	  ○ Baseline diffusing capacity for carbon monoxide (DLCO) greater than or equal to 30 percent predicted

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of treatment success.
Exclusion Criteria:	• Combined use with nintedanib (Ofev)
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Must be prescribed by, or in consultation with, a pulmonologist
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
POMBILITI AND OPFOLDA
Affected Medications: POMBILITI (cipaglucosidase alfa-atga intravenous injection), OPFOLDA (miglustat oral capsule)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Late-onset Pompe disease for patients weighing 40 kg or more and who are not improving on their current enzyme replacement therapy (ERT)

Required Medical Information:	• Diagnosis of late-onset Pompe disease confirmed by one of the following:
	  ○ Enzyme assay demonstrating a deficiency of acid α-glucosidase (GAA) enzyme activity
	  ○ DNA testing that identifies mutations in the GAA gene
	• One or more clinical signs or symptoms of late-onset Pompe disease:
	  ○ Progressive proximal weakness in a limb-girdle distribution
	  ○ Delayed gross-motor development in childhood
	  ○ Involvement of respiratory muscles causing respiratory difficulty (such as reduced forced vital capacity [FVC] or sleep disordered breathing)
	  ○ Skeletal abnormalities (such as scoliosis or scapula alata)
	  ○ Low/absent reflexes
	• Documentation that patient has a 6-minute walk test (6MWT) of 75 meters or more
	• Documentation has a sitting percent predicted forced vital capacity (FVC) of 30% or more
	• Patient weight

Appropriate Treatment Regimen & Other Criteria:	• Documentation of planned treatment regimen for both Pombiliti and Opfolda which are within FDA-labeling • Documentation that patient is no longer improving after at least one year of current enzyme replacement therapy (ERT) with Lumizyme (alglucosidase alfa) or Nexviazyme (avalglucosidase alfa-ngpt) **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy as evidenced by an improvement, stabilization, or slowing of progression in percent predicted FVC and/or 6MWT
Exclusion Criteria:	• Pregnancy or, if female of reproductive potential, not using effective contraception during treatment • Use of invasive or noninvasive ventilation support for more than 6 hours a day while awake • Diagnosis of infantile-onset Pompe Disease • Concurrent treatment with Lumizyme or Nexviazyme • Pombiliti or Opfolda as monotherapy • Use of Opfolda for Gaucher disease
Age Restriction:	• 18 years or older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a metabolic specialist, endocrinologist, biochemical geneticist, or physician experienced in the management of Pompe disease
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
POSACONAZOLE
Affected Medications: posaconazole suspension, posaconazole delayed release tablets

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of oropharyngeal candidiasis (including infections refractory to itraconazole and/or fluconazole)
	  ○ Treatment of invasive aspergillosis
	  ○ Prophylaxis of invasive *Aspergillus* and *Candida* infections

Required Medical Information:	• Pediatric requests: Current body weight • Documentation of an Oregon Health Authority (OHA) funded condition **Treatment of Oropharyngeal Candidiasis** • Documentation of oropharyngeal candidiasis • Susceptibility cultures confirm posaconazole activity **Invasive Aspergillosis** • Documentation of invasive aspergillosis **Prophylaxis of Invasive Aspergillus and Candida Infections** • Documentation of severely immunocompromised state (such as hematopoietic stem cell transplant [HSCT] with graft-versus-host disease [GVHD], hematologic malignancy with prolonged neutropenia due to chemotherapy)

Appropriate Treatment Regimen & Other Criteria:	**Treatment of Oropharyngeal Candidiasis**
	• Documented treatment failure (defined as no response to therapy) with both of the following:
	  ○ Fluconazole
	  ○ Itraconazole oral solution
	
	Treatment of Invasive Aspergillosis
	• Documented treatment failure or intolerable adverse event with voriconazole
	
	Prophylaxis of Invasive *Aspergillus* and *Candida* Infections
	• Documented treatment failure or intolerable adverse event with at least one systemic agent (e.g., fluconazole for *Candida* infections; voriconazole, amphotericin B, or itraconazole for *Aspergillus* infections)

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist, transplant physician, or oncologist
Coverage Duration:	• Authorization: 6 months, unless otherwise specified.

PacificSource Community Solutions

POLICY NAME:
POTASSIUM REMOVING AGENTS
Affected Medications: LOKELMA, VELTASSA

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Hyperkalemia
Required Medical Information:	• Documentation of recurrent or persistent serum potassium greater than or equal to 5.5 mEq/L
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization:** Requires treatment success and clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• Initial Authorization: 12 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
POZELIMAB
Affected Medications: VEOPOZ (pozelimab-bbfg)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of CD55-deficient protein-losing enteropathy (PLE) or CHAPLE disease
Required Medical Information:	• Diagnosis of CD-55-deficient PLE confirmed by biallelic CD55 loss-of-function mutation using molecular genetic testing • Documentation of hypoalbuminemia (serum albumin of 3.2 g/dL or less) • Clinical signs and features of active PLE including abdominal pain, diarrhea, peripheral edema, or facial edema • Documentation of at least two albumin transfusions or hospitalizations in the past year

Appropriate Treatment Regimen & Other Criteria:	• **Dosing** is in accordance with FDA labeling and does not exceed the following:
	  ○ Loading Dose: 30 mg/kg by intravenous infusion for 1 dose
	  ○ Maintenance Dose: Starting on day 8,
	  10 mg/kg as a subcutaneous injection once weekly
	  May be increased to 12 mg/kg starting week 4
	  ○ Maximum maintenance dosage of 800 mg once weekly
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization requires documentation of positive clinical response with all the following:
	• Improvement or stabilization of clinical symptoms
	• Improvement or normalization of serum albumin concentrations
	• Reduction in albumin transfusion requirements and/or hospitalizations

Exclusion Criteria:	• Receiving concurrent therapy with Soliris (eculizumab) • Unresolved Neisseria meningitidis, Streptococcus pneumoniae, or Haemophilus influenzae type b (Hib) infection
Age Restriction:	• 1 year of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hematologist, gastroenterologist, or provider that specializes in rare genetic hematologic diseases
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PRADEMAGENE ZAMIKERACEL
Affected Medications: ZEVASKYN (prademagene zamikeracel)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Recessive Dystrophic Epidermolysis Bullosa (RDEB)

Required Medical Information:	• Complete description of the site(s) of application
	• Diagnosis of RDEB confirmed by both of the following:
	  ○ Skin biopsy of an induced blister with immunofluorescence mapping (IFM) and/or transmission electron microscopy (TEM)
	  ○ Genetic test results documenting mutations in the COL7A1 gene
	• Presence of partial-thickness RDEB wounds that are open and meet all the following:
	  ○ Area must be at least 20 cm^2
	  ○ Present for at least 6 months
	  ○ Classified as a stage 2 wound, defined as partial thickness loss of dermis presenting as a shallow open ulcer with a pink or red wound bed, without slough or bruising

Appropriate Treatment Regimen & Other Criteria:	• Documentation of receiving standard of care preventative or treatment therapies for wound care, control of infection, nutritional support. • Documented treatment failure with all of the following: Filsuvez, Vyjuvek • Dosing is in accordance with FDA labeling and does not exceed 12 sheets per one-time surgical application
Exclusion Criteria:	• Concurrent use with Vyjuvek (beremagene geperpavec-svdt) or Filsuvez (birch triterpenes) • History of squamous cell carcinoma or active infection in the affected wound(s) • Administered to wound(s) previously treated with Zevaskyn • Administered to wound(s) that are currently healed
Age Restriction:	• 6 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a dermatologist or a specialist experienced in the treatment of epidermolysis bullosa
Coverage Duration:	• Authorization: 1 month, unless otherwise specified (one treatment per wound per lifetime)

POLICY NAME:
PRIMARY BILIARY CHOLANGITIS AGENTS
Affected Medications: OCALIVA (obeticholic acid), IQIRVO (elafibranor), LIVDELZI (seladelpar)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Primary biliary cholangitis (PBC)
Required Medical Information:	• Liver function tests (including alkaline phosphatase and bilirubin) • Child-Pugh score

Appropriate Treatment Regimen & Other Criteria:	• **Documentation that after at least 12 months of adherent therapy with ursodiol or clinical inability to tolerate ursodiol, the patient has ONE of the following:**
	  ○ Alkaline phosphatase level (ALP) at least 1.67 times the upper limit of normal (ULN) of the reference lab
	  ○ Total bilirubin above the ULN of the reference lab
	
	Reauthorization will require documentation of treatment success defined as a significant reduction in Alkaline phosphatase (ALP) and/or bilirubin levels

Exclusion Criteria:	• Complete biliary obstruction • Decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event • For Ocaliva: Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) • Use in combination with another drug on this policy (Ocaliva, Iqirvo, Livdelzi)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hepatologist
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
PROSTAGLANDIN INTRACAMERAL IMPLANTS
Affected Medications: DURYSTA (bimatoprost intracameral implant), iDose TR (travoprost intracameral implant)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT)
Required Medical Information:	• Diagnosis of OAG or OHT with a baseline IOP of at least 22 mmHg • Documentation of clinical justification for inability to manage routine topical therapy (e.g., due to progression of glaucoma, aging, comorbidities, and administration difficulties that cannot be addressed through instruction and technique)
Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure or intolerable adverse event with at least two IOP-lowering agents with different mechanisms of action, (used concurrently), one of which must include a prostaglandin analog such as latanoprost • For iDose TR requests: ○ Documented treatment failure to the preferred product Durysta
Exclusion Criteria:	• Repeat implantation with the same prostaglandin implant • Diagnosis of corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy) • Prior corneal or endothelial cell transplantation (e.g., Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]) • Active or suspected ocular or periocular infections • Absent or ruptured posterior lens capsule (Durysta)
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Must be prescribed by, or in consultation with, an ophthalmologist
Coverage Duration:	• Authorization: 1 month (one implant per impacted eye), unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PROXIMAL COMPLEMENT INHIBITOR
Affected Medications: EMPAVELI (pegcetacoplan), FABHALTA (iptacopan)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH)
	  ○ Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g (Fabhalta)
	  ○ Treatment of complement 3 glomerulopathy (C3G), to reduce proteinuria
	  ○ Treatment of primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria (Empaveli)

Required Medical Information:	• Patients must be administered a meningococcal vaccine at least two weeks prior to initiation of the requested therapy and revaccinated according to current Advisory Committee on Immunization Practices (ACIP) guidelines
	
	PNH
	• Detection of PNH clones of at least 5% by flow cytometry diagnostic testing
	  ○ Presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least 2 different cell lines (e.g., granulocytes, monocytes, erythrocytes)
	• Baseline lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal range
	• One of the following PNH-associated clinical findings:
	  ○ Presence of a thrombotic event
	  ○ Presence of organ damage secondary to chronic hemolysis
	  ○ History of 4 or more blood transfusions required in the previous 12 months
	
	IgAN (Fabhalta)
	• Diagnosis of IgAN confirmed with biopsy
	• Documentation of one of the following (with labs current within 30 days of request):
	  ○ Proteinuria defined as 1 g/day or greater
	  ○ UPCR greater than 1.5 g/g
	
	C3G
	• Biopsy proven diagnosis of C3G
	• UPCR of equal or greater than 1g/g
	• Estimated glomerular rate (eGFR) of 30 mL/min/1.73m^2 or greater
	
	IC-MPGN (Empaveli)
	• Biopsy proven diagnosis of IC-MPGN
	• UPCR of equal or greater than 1g/g
	• Estimated glomerular rate (eGFR) of 30 mL/min/1.73m^2 or greater

Appropriate Treatment Regimen & Other Criteria:	**PNH** • For Empaveli: Documented inadequate response, contraindication, or intolerance to ravulizumab (Ultomiris) • For Fabhalta: Documented inadequate response, contraindication, or intolerance to another complement inhibitor such as ravulizumab (Ultomiris) or Empaveli

	Reauthorization requires documentation of treatment success defined as a decrease in serum LDH, stabilized/improved hemoglobin, decreased transfusion requirement, and reduction in thromboembolic events compared to baseline
	
	IgAN (Fabhalta)
	• Documented treatment failure (defined as proteinuria equal to or greater than 1 g/day OR UPCR greater than 1.5 g/g) with a minimum of 12 weeks of all of the following:
	  ○ Maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB)
	  ○ High dose glucocorticoid therapy such as oral prednisone or methylprednisolone (or an adverse effect to two or more glucocorticoid therapies that is not associated with the corticosteroid class)
	  ○ Filspari (sparsentan) and Vanrafia (atrasentan)
	
	Reauthorization requires documentation of treatment success defined as reduction in UPCR or proteinuria from baseline
	
	C3G
	• Documented inadequate response to all the following:
	  ○ Maximally tolerated renin-angiotensin system (RAS) inhibitor
	  ○ Mycophenolate mofetil or mycophenolate sodium
	  ○ Empaveli
	
	IC-MPGN (Empaveli)
	• Documented inadequate response to all the following:
	  ○ Maximally tolerated renin-angiotensin system (RAS) inhibitor
	  ○ Mycophenolate mofetil or mycophenolate sodium
	
	Reauthorization requires documentation of treatment success defined as reduction in UPCR or proteinuria from baseline

Exclusion Criteria:	• Concurrent use with other biologics for PNH (Soliris, Ultomiris, Empaveli, or Fabhalta) except when cross tapering according to FDA approved dosing • Current meningitis infection or other unresolved serious infection caused by encapsulated bacteria

Age Restriction:	• PNH: 18 years of age and older
	• C3G:
	  ○ Fabhalta: 18 years of age and older
	  ○ Empaveli: 12 years of age and older

Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist or a nephrologist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PYRIMETHAMINE
Affected Medications: PYRIMETHAMINE

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Toxoplasmosis

Required Medical Information:	• Documentation of recent *Toxoplasma* infection
	• Documentation of one of the following:
	  ○ Severe symptoms (pneumonitis, myocarditis, etc) or prolonged symptoms greater than 4 weeks with significant impact on quality of life
	  ○ Immunocompromised status

Appropriate Treatment Regimen & Other Criteria:	• Dosing Regimen (adult):
	  ○ Day 1: Pyrimethamine 100mg, sulfadiazine 2-4gm divided four times daily, leucovorin 5-25mg
	  ○ Day 2: Pyrimethamine 25-50mg, sulfadiazine 2-4gm divided four times daily, leucovorin 5-25mg
	  ○ Day 3 and beyond: Pyrimethamine 25-50mg, sulfadiazine 500mg-1 gm divided four times daily, leucovorin 5-25mg

Exclusion Criteria:	• Treatment regimen does not contain leucovorin and a sulfonamide (or alternative if allergic to sulfa)
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Initial Authorization: Up to 6 weeks, with no reauthorization unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
RAVULIZUMAB-CWVZ
Affected Medications: ULTOMIRIS (ravulizumab-cwvz)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
	  ○ Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy
	  ○ Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive
	  ○ Neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive for adult patients

Required Medical Information:	**PNH**
	• Detection of PNH clones of at least 5% by flow cytometry diagnostic testing
	  ○ Presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least 2 different cell lines (e.g., granulocytes, monocytes, erythrocytes)
	• Baseline lactate dehydrogenase (LDH) levels greater than or equal to 1.5 times the upper limit of normal range
	• One of the following PNH-associated clinical findings:
	  ○ Presence of a thrombotic event
	  ○ Presence of organ damage secondary to chronic hemolysis
	  ○ History of 4 or more blood transfusions required in the previous 12 months
	
	aHUS
	• Clinical presentation of microangiopathic hemolytic anemia, thrombocytopenia, and acute kidney injury
	• Patient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.)
	• ADAMTS13 activity level greater than or equal to 10%
	• Shiga toxin E. coli related hemolytic uremic syndrome (ST-HUS) has been ruled out
	• History of 4 or more blood transfusions required in the previous 12 months
	
	gMG
	• Diagnosis of gMG confirmed by **ONE** of the following:
	  ○ A history of abnormal neuromuscular transmission test
	  ○ A positive edrophonium chloride test
	  ○ Improvement in gMG signs or symptoms with an acetylcholinesterase inhibitor
	• Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
	• Positive serologic test for AChR antibodies
	• Documentation of **ONE** of the following:
	  ○ MG-Activities of Daily Living (MG-ADL) total score of 6 or greater
	  ○ Quantitative Myasthenia Gravis (QMG) total score of 12 or greater
	
	NMOSD
	• Diagnosis of NMOSD with aquaporin-4 immunoglobulin G (AQP4- IgG) antibody positive disease confirmed by all the following:
	  ○ Documentation of positive test for AQP4-IgG antibodies via cell-based assay

PacificSource Community Solutions

<table>
<tr>
<td></td>
<td>

Exclusion of alternative diagnoses (such as multiple sclerosis)
At least one core clinical characteristic:

Acute optic neuritis
Acute myelitis
Area postrema syndrome (episode of otherwise unexplained hiccups or nausea/vomiting)
Acute brainstem syndrome
Symptomatic narcolepsy OR acute diencephalic clinical syndrome with NMSOD-typical diencephalic MRI lesions
Symptomatic cerebral syndrome with NMOSD-typical lesion on magnetic resonance imaging (MRI) [see table below]
Acute cerebral syndrome with NMOSD-typical brain lesion on MRI [see table below]

<table>
<tr><th>Clinical presentation</th><th>Possible MRI findings</th></tr>
<tr><td>Diencephalicsyndrome</td><td>• Periependymal lesion
• Hypothalamic/thalamic lesion</td></tr>
<tr><td>Acute cerebralsyndrome</td><td>• Extensive periependymal lesion
• Long, diffuse, heterogenous, or edematous corpus callosum lesion
• Long corticospinal tract lesion
• Large, confluent subcortical or deep white matter lesion</td></tr>
</table>
</td>
</tr>
<tr>
<td>Appropriate Treatment Regimen & Other Criteria:</td>
<td>
<u>aHUS</u>

Failure to respond to plasma therapy within 10 days

Trial of plasma therapy not required if one of the following is present:

Life-threatening complications of HUS such as seizures, coma, or heart failure
Confirmed presence of a high-risk complement genetic variant (e.g., CFH or CFI)

<u>gMG</u>

Documentation of one of the following:

Treatment failure with an adequate trial (one year or more) of at least 2 immunosuppressive therapies (azathioprine, mycophenolate, tacrolimus, cyclosporine, methotrexate)
Has required three or more courses of rescue therapy (plasmapheresis/plasma exchange and/or intravenous immunoglobulin), while on at least one immunosuppressive therapy, over the last 12 months

Documented inadequate response, contraindication, or intolerance to efgartigimod-alfa (Vyvgart)

<u>NMOSD</u>

Documented inadequate response, contraindication, or intolerance to ALL the following:

Rituximab (preferred products: Riabni, Ruxience, Truxima)

</td>
</tr>
</table>

	○ Satralizumab-mwge (Enspryng) ○ Inebilizumab-cdon (Uplizna) **<u>Reauthorization</u> requires:** • gMG: documentation of treatment success defined as an improvement in MG-ADL or QMG scores from baseline • PNH: documentation of treatment success defined as a decrease in serum LDH, stabilized/improved hemoglobin, decreased transfusion requirement, and reduction in thromboembolic events compared to baseline • aHUS: documentation of treatment success defined as a decrease in serum LDH, stabilized/improved serum creatinine, increased platelet count, and decreased plasma exchange/infusion requirement compared to baseline • NMOSD: documentation of treatment success defined as the stabilization or improvement in neurological symptoms as evidenced by a decrease in acute relapses, Expanded Disability Status Scale (EDSS) score, hospitalizations, or plasma exchange
Exclusion Criteria:	• Current meningitis infection • Concurrent use with other disease-modifying biologics for requested indication, unless indicated by the FDA for combination use with Ultomiris
Age Restriction:	• PNH, aHUS: 1 month of age and older • gMG: 18 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist: ○ PNH: Hematologist ○ aHUS: Hematologist or Nephrologist ○ gMG: Neurologist ○ NMOSD: neurologist or neuro-ophthalmologist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
REMESTEMCEL
Affected Medications: RYONCIL (rememstemcel-L-rknd)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design • Compendia-supported uses that will be covered (if applicable)
Required Medical Information:	• Diagnosis of grade B through D acute graft-versus-host disease; (aGVHD) with symptoms involving skin, liver, and/or GI tract • Steroid resistance defined as consecutive treatment with 2mg/kg/day of methylprednisolone (or equivalent) resulting in: o Progression within 3 days OR o No improvement in 7 days
Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure or intolerance to: o At least one other second-line therapy (such as calcineurin inhibitors, mycophenolate, everolimus, sirolimus, etanercept, infliximab, anti-thymocyte globulin, extracorporeal photopheresis) o Jakafi (if aged 12 or older) **<u>Reauthorization:</u>** o Partial Response (PR) defined as organ improvement of at least 1 stage without worsening of any other organ OR o Mixed Response (MR) defined as improvement in at least 1 evaluable organ stage with worsening in another OR o aGVHD flare defined as grade B through D progression after achieving initial complete response (CR) AND o Documentation showing symptom improvement while on therapy
Exclusion Criteria:	• Grade B acute graft-versus-host disease; (aGVHD) involving skin only
Age Restriction:	• 2 months to 17 years
Prescriber/Site of Care Restrictions:	• Prescribed by (or in consultation with) an oncologist, hematologist, bone marrow transplant specialist, or other qualified prescriber
Coverage Duration:	• Initial Authorization: 4 weeks, unless otherwise specified • Reauthorization: 4 weeks, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
REMODULIN
Affected Medications: REMODULIN INJECTION (treprostinil)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO) Group 1
	  ○ Pulmonary Arterial Hypertension in Patients Requiring Transition from Epoprostenol

Required Medical Information:	• Documentation of planned treatment plan or a projection of initial dosing regimen
	
	<u>Pulmonary arterial hypertension (PAH) WHO Group 1</u>
	• Documentation of PAH confirmed by right-heart catheterization meeting the following criteria:
	  ○ Mean pulmonary artery pressure of at least 20 mm Hg
	  ○ Pulmonary capillary wedge pressure less than or equal to 15 mm Hg AND
	  ○ Pulmonary vascular resistance of at least 2.0 Wood units
	• Etiology of PAH: idiopathic PAH, hereditary PAH, OR
	• PAH secondary to one of the following conditions:
	  ○ Connective tissue disease
	  ○ Human immunodeficiency virus (HIV) infection
	  ○ Cirrhosis
	  ○ Anorexigens
	  ○ Congenital left to right shunts
	  ○ Schistosomiasis
	  ○ Drugs and toxins
	  ○ Portal Hypertension
	• New York Heart Association (NYHA)/World Health Organization (WHO) Functional Class II or higher symptoms
	• Documentation of acute vasoreactivity testing (positive result requires trial/failure to calcium channel blocker) unless contraindications:
	  ○ Low systemic blood pressure (systolic blood pressure less than 90)
	  ○ Low cardiac index OR
	  ○ Presense of severe symptoms (functional class IV)

Appropriate Treatment Regimen & Other Criteria:	• The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition • Documentation that treprostinil is used as a single route of administration (Remodulin, Tyvaso, Orenitram should not be used in combination) • Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered ruled out • Treatment with combination of endothelin receptor antagonist (ERA) and phosphodiesterase 5 inhibitor (PDE5I) has been tried and failed for WHO Functional Class II and III symptoms **<u>Reauthorization</u>** requires documentation of treatment success defined as one or more of the following: • Improvement in walking distance • Improvement in exercise ability • Improvement in pulmonary function • Improvement or stability in WHO functional class
Exclusion Criteria:	• PAH secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g., chronic

	obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• Initial coverage: 6 months, unless otherwise specified • Subsequent coverage: 12 months, unless otherwise specified

POLICY NAME:
RESLIZUMAB
Affected Medications: CINQAIR IV (reslizumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Add-on maintenance treatment of adult patients with severe asthma with an eosinophilic phenotype

Required Medical Information:	• Diagnosis of severe asthma with an eosinophilic phenotype, defined by both of the following:
	  ○ Baseline eosinophil count of at least 400 cells/µL **AND**
	  ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal

Appropriate Treatment Regimen & Other Criteria:	• Documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms
	AND
	• Documentation of one of the following:
	  ○ Documented history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months while on combination inhaler treatment and at least 80% adherence
	  ○ Documentation that chronic daily oral corticosteroids are required
	• Documented treatment failure or intolerable adverse event with all the preferred products (Dupixent, Fasenra, Nucala)
	
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization: documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Use in combination with another monoclonal antibody (e.g., Dupixent, Nucala, Fasenra, Tezspire, Xolair)
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
RESMETIROM
Affected Medications: REZDIFFRA (resmetirom)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), in conjunction with diet and exercise

Required Medical Information:	• Diagnosis of NASH or metabolic dysfunction–associated steatohepatitis (MASH) with moderate to advanced (F2 to F3) liver fibrosis confirmed by **ONE** of the following:
	  ○ Conclusive result from a well-validated non-invasive test such as:
	  ▪ Fibroscan-AST (FAST) score
	  ▪ MAST (score from MRI–proton density fat fraction, Magnetic resonance elastography [MRE], and serum AST)
	  ▪ MEFIB (Fibrosis-4 Index greater than or equal to 1.6 and MRE greater than or equal to 3.3 kPa)
	  ○ Liver biopsy (also required if non-invasive testing is inconclusive or other causes for liver disease have not been ruled out)
	• Other causes for liver steatosis have been ruled out (such as alcohol-associated liver disease, chronic hepatitis C, Wilson disease, drug-induced liver disease)
	• Baseline lab values for AST and ALT

Appropriate Treatment Regimen & Other Criteria:	• Documentation of abstinence from alcohol consumption
	• Documentation of comprehensive comorbidity management being undertaken, including all the following:
	  ○ Use of diet and exercise for weight management
	  ○ Medications to manage associated comorbid conditions, such as thyroid disease (must not have active disease), diabetes, dyslipidemia, hypertension, or cardiovascular conditions
	• Documented treatment failure or intolerable adverse event with Wegovy
	
	Reauthorization: documentation of disease responsiveness to therapy based on improvements or stability in laboratory results, such as ALT and AST, or fibrosis as evaluated by a non-invasive test

Exclusion Criteria:	• History of excessive alcohol use or alcohol-associated liver disease • Current excessive alcohol use • Continued use of medications associated with liver steatosis • Stage 4 liver disease or cirrhosis • Use for other liver disease • Active or untreated thyroid disease
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hepatologist or gastroenterologist
Coverage Duration:	• Authorization: 12 months


PacificSource
Community Solutions

POLICY NAME:
RETHYMIC
Affected Medications: RETHYMIC (allogeneic processed thymus tissue-agdc)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Immune reconstitution in pediatric patients with congenital athymia

Required Medical Information:	• Documentation of congenital athymia associated with one of the following:
	  ○ Complete DiGeorge Syndrome (cDGS)
	  ○ Forkhead Box N1 (FOXN1) deficiency
	  ○ 22q11.2 deletion
	  ○ CHARGE Syndrome (Coloboma, Heart defects, Atresia of the nasal choanae, Retardation of growth and development, Genitourinary anomalies, Ear anomalies)
	  ○ CHD7 mutation
	  ○ 10p13-p14 deletion

Appropriate Treatment Regimen & Other Criteria:	• Congenital athymia confirmed by flow cytometry that demonstrates:
	  ○ Fewer than 50 naïve T cells/mm3 in the peripheral blood
	  OR
	  ○ Less than 5% of total T cells being naïve T cells

Exclusion Criteria:	• Treatment of patients with severe combined immunodeficiency (SCID) • Prior thymus transplant
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pediatric immunologist or prescriber experienced in the treatment of congenital athymia
Coverage Duration:	• Initial Authorization: 1 month (1 treatment only), unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
REVAKINAGENE TARORETCEL-LWEY
Affected Medications: ENCELTO (revakinagene taroretcel-lwey intravitreal implant) - Available on Medical Benefit only

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Idiopathic macular telangiectasia type 2 (MacTel)
Required Medical Information:	• Documented diagnosis of MacTel type 2 with evidence of fluorescein leakage and at least one of these features: ○ Hyperpigmentation outside of a 500 micron radius from the center of the fovea, retinal opacification, crystalline deposits, right-angle vessels • Inner Segment/Outer Segment (IS/OS) photoreceptor (PR) break/loss in ellipsoid zone (EZ) between 0.16 and 2mm^2 measured by Spectral Domain Optical Coherence Tomography (SD-OCT) • Best-corrected visual acuity (BCVA) score of 54 letters or better (20/80 Snellen equivalent)
Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Evidence of neovascular MacTel type 2 • MacTel type 1
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an ophthalmologist or surgeon
Coverage Duration:	• Authorization: 1 month (1 injection per eye per lifetime), unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
RILONACEPT
Affected Medications: ARCALYST (Rilonacept)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) in adults and pediatric patients 12 years and older
	  ○ The maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg
	  ○ Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older

Required Medical Information:	Documentation confirming one of the following:
	• Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS)
	• Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
	  ○ Must include genetic testing results which confirm the presence of homozygous mutations in the interleukin-1 receptor antagonist (IL1RN) gene
	  ○ Disease must currently be in remission
	• Diagnosis of Recurrent Pericarditis with an inflammatory phenotype shown by one of the following:
	  ○ Fever, elevated C-Reactive protein (CRP), elevated white blood cell count, elevated erythrocyte sedimentation rate (ESR), pericardial late gadolinium enhancement (LGE) on cardiac magnetic resonance (CMR), or pericardial contrast enhancement on computed tomography (CT) scan

Appropriate Treatment Regimen & Other Criteria:	**<u>All Indications:</u>**
	• Documented treatment failure or intolerable adverse event with trial of Kineret (anakinra)
	
	<u>Recurrent Pericarditis:</u>
	• Documented treatment failure or intolerable adverse event to triple therapy with all the following:
	  ○ Colchicine
	  ○ Non-steroidal anti-inflammatory (NSAID) or aspirin
	  ○ Glucocorticoid
	
	<u>Dosing for CAPS or Recurrent Pericarditis:</u>
	• Adults: loading dose of 320 mg followed by 160 mg once weekly
	• Pediatric patients (age 12 to 17): loading dose of 4.4 mg/kg (maximum 320 mg) followed by 2.2 mg/kg once weekly (maximum 160 mg)
	<u>Dosing for DIRA:</u>
	• Adults: 320 mg once weekly
	• Pediatric patients (weighing 10 kg or more): 4.4 mg/kg (maximum 320 mg) once weekly
	
	<u>Reauthorization</u> will require:
	• All indications: documentation of treatment success and a clinically significant response to therapy

	• Recurrent pericarditis: documentation that the patient is unable to remain asymptomatic with normal CRP levels upon trial of an appropriate tapering regimen
Exclusion Criteria:	• Active or chronic infection • Concurrent therapy with anakinra, TNF inhibitors, or other biologics
Age Restriction:	• CAPS or Recurrent Pericarditis, 12 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist, immunologist, cardiologist, or dermatologist
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
RIOCIGUAT
Affected Medications: ADEMPAS (riociguat)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1
	  ○ Chronic-Thromboembolic Pulmonary Hypertension (WHO Group 4)

Required Medical Information:	**<u>Chronic thromboembolic pulmonary hypertension (CTEPH)</u>**
	• Documentation of Chronic-Thromboemolic Pulmonary Hypertension (WHO Group 4) meeting the following criteria:
	  ○ Evidence of thromboembolic occlusion of proximal or distal pulmonary vasculature on CT/MRI or V/Q scan
	  ○ Mean pulmonary arterial pressure greater than 20 mmHg
	  ○ PAWP less than 15 mmHg
	  ○ Elevated pulmonary vascular resistance over 2 Wood units
	
	<u>Pulmonary arterial hypertension (PAH)</u>
	• Documentation of PAH confirmed by right-heart catheterization meeting the following criteria:
	  ○ Mean pulmonary artery pressure of at least 20 mm Hg
	  ○ Pulmonary capillary wedge pressure less than or equal to 15 mm Hg
	  ○ Pulmonary vascular resistance of at least 2.0 Wood units
	• Etiology of PAH (idiopathic, heritable, or associated with connective tissue disease)
	• New York Heart Association (NYHA)/World Health Organization (WHO) Functional Class II or higher symptoms
	• Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blocker) unless there are contraindications:
	  ○ Low systemic blood pressure (systolic blood pressure less than 90)
	  ○ Low cardiac index
	  ○ Presence of severe symptoms (functional class IV)

Appropriate Treatment Regimen & Other Criteria:	**<u>CTEPH</u>** • Documentation of failure of or inability to receive pulmonary endarterectomy surgery • Current therapy with anticoagulants **<u>PAH</u>** • Documented failure to the following therapy classes: Phosphodiesterase type 5 (PDE5) inhibitors AND endothelin receptor antagonists **<u>Reauthorization</u>** requires documentation of treatment success defined as one or more of the following: • Improvement in walking distance • Improvement in exercise ability • Improvement in pulmonary function • Improvement or stability in WHO functional class
Exclusion Criteria:	• Concomitant use with nitrates or nitric oxide donors (such as amyl nitrite) • Concomitant use with specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline)
Age Restriction:	

Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
RISANKIZUMAB
Affected Medications: SKYRIZI PREFILLED SYRINGE KIT, SKYRIZI PREFILLED SYRINGE, SKYRIZI AUTO-INJECTOR, SKYRIZI SOLUTION CARTRIDGE, SKYRIZI INTRAVENOUS (IV) SOLUTION

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis (PP)
	  ○ Psoriatic Arthritis (PsA)
	  ○ Crohn's Disease (CD)
	  ○ Ulcerative Colitis (UC)

Required Medical Information:	**<u>Plaque Psoriasis</u>**
	• Documentation of disease that is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) of greater than or equal to 11
	  ○ Children's Dermatology Life Quality Index (CDLQI) greater than or equal to 13
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	• Documentation of one or more of the following:
	  ○ At least 10% body surface area involvement; or
	  ○ Hand, foot, or mucous membrane involvement
	
	<u>Psoriatic Arthritis</u>
	• Documentation of Classification for Psoriatic Arthritis (CASPAR) criteria score of 3 or greater based on chart notes
	  ○ Skin psoriasis: present – two points, **OR** previously present by history – one point, **OR** a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxta-articular bone formation on radiographs (distinct from osteophytes): one point
	
	<u>Crohn's Disease and Ulcerative Colitis</u>
	• Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy
	• Documentation of moderate to severely active disease despite current treatment

Appropriate Treatment Regimen & Other Criteria:	**<u>Plaque Psoriasis</u>**
	• Documented treatment failure with 12 weeks of at least two systemic therapies: methotrexate, cyclosporine, acitretin, phototherapy (UVB, PUVA)
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis)
	  AND
	  ○ One of the following: Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek)

PacificSource Community Solutions

	Psoriatic Arthritis
	• Documented treatment failure of at least 12 weeks with methotrexate
	  ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying anti-rheumatic drug (sulfasalazine, cyclosporine, leflunomide)
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis)
	  AND
	  ○ One of the following: Simponi Aria, Orencia IV, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek)
	
	Crohn's Disease
	• Documented treatment failure with at least one oral treatment for a minimum 12 week trial: azathioprine, 6-mercaptopurine, methotrexate, sulfasalazine, balsalazide
	OR
	• Documentation of previous surgical intervention for Crohn's disease
	OR
	• Documentation of severe, high-risk disease on colonoscopy defined by one of the following:
	  ○ Fistulizing disease
	  ○ Stricture
	  ○ Presence of abscess/phlegmon
	  ○ Deep ulcerations
	  ○ Large burden of disease including ileal, ileocolonic, or proximal gastrointestinal involvement
	  AND
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis)
	  AND
	  ○ Two of the following: Entyvio, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek)
	
	Ulcerative Colitis
	• Documented failure with at least two oral treatments for a minimum of 12 weeks: corticosteroids, sulfasalazine, mesalamine, balsalazide, cyclosporine, azathioprine, 6-mercaptopurine
	OR
	• Documentation of severely active disease despite current treatment defined by greater than or equal to 6 bloody, loose stools per day with severe cramps and evidence of systemic toxicity (fever, tachycardia, anemia, and/or elevated CRP/ESR), or recent hospitalization for ulcerative colitis
	AND
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis) AND
	  ○ Two of the following: Entyvio, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek)

	QL
	• PP/PsA:
	  ○ Induction: 150 mg at week 0 and 4
	  ○ Maintenance: 150 mg per 84 days
	• Crohn's Disease:
	  ○ Induction: 600 mg IV at weeks 0, 4, and 8
	  ○ Maintenance: 360 mg subcutaneously every 8 weeks, beginning week 12
	• Ulcerative Colitis
	  ○ Induction: 1200 mg IV at weeks 0, 4, and 8
	  ○ Maintenance: 360 mg subcutaneously every 8 weeks, beginning week 12
	
	Reauthorization
	• Documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist, dermatologist, or gastroenterologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
RISDIPLAM
Affected Medications: EVRYSDI (Risdiplam)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Spinal muscular atrophy (SMA)

Required Medical Information:	• Diagnosis of SMA type 1, 2, or 3 confirmed by genetic testing of chromosome 5q13.2 demonstrating ONE of the following:
	  ○ Homozygous gene deletion of SMN1 (survival motor neuron 1)
	  ○ Homozygous gene mutation of SMN1
	  ○ Compound heterozygous gene mutation of SMN1
	• Documentation of 4 or fewer copies of the SMN2 (survival motor neuron 2) gene
	• Documentation of one of the following baseline motor assessments appropriate for patient age and motor function:
	  ○ Hammersmith Infant Neurological Examination (HINE-2)
	  ○ Hammersmith Functional Motor Scale (HFSME)
	  ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
	  ○ Upper Limb Module (ULM) test
	  ○ 6-Minute Walk Test (6MWT)
	• Documentation of previous treatment history
	• Documentation of ventilator use status:
	  ○ Patient is NOT ventilator-dependent (defined as using a ventilator at least 16 hours per day on at least 21 of the last 30 days)
	  ○ This does not apply to patients who require non-invasive ventilator assistance
	• Patient weight and planned treatment regimen

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization:** documentation of improvement in baseline motor assessment score, clinically meaningful stabilization, or delayed progression of SMA-associated signs and symptoms
Exclusion Criteria:	• SMA type 4 • Advanced SMA at baseline (complete paralysis of limbs, permanent ventilation support) • Prior treatment with SMA gene therapy (i.e., onasemnogene abeparvovec-xioi) • Will not use in combination with other agents for SMA (e.g., onasemnogene abeparvovec-xioi, nusinersen, etc.)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or provider who is experienced in treatment of spinal muscular atrophy
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
RITUXIMAB
Affected Medications: RITUXAN (rituximab), RITUXAN HYCELA (rituximab & hyaluronidase subcutaneous), TRUXIMA (rituximab-abbs), RUXIENCE (rituximab-pvvr), RIABNI (rituximab-arrx)

Covered Uses:	• All Food and Drug Administration (FDA)-approved and compendia-supported indications not otherwise excluded by plan design
	  ○ Rheumatoid arthritis (RA)
	  ○ Relapsing forms of multiple sclerosis (MS)
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)
	  ○ Neuromyelitis optica spectrum disorder (NMOSD)
	  ○ Microscopic polyangiitis (MPA)
	  ○ Granulomatosis with polyangiitis (GPA)
	  ○ Eosinophilic granulomatosis with polyangiitis (EGPA)
	  ○ Pemphigus vulgaris (PV) and other autoimmune blistering skin diseases
	  ○ Immune thrombocytopenia (ITP), relapsed or refractory
	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2 or higher

Required Medical Information:	• Documentation of disease staging, all prior therapies used, and anticipated treatment course
	
	<u>Rheumatoid Arthritis (RA)</u>
	• Documentation of moderate to severe disease despite current treatment
	• Documented current level of disease activity with one of the following (or equivalent objective scale):
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ Simplified Disease Activity Index (SDAI) greater than 11
	  ○ Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted RAPID3 of at least 2.3
	
	<u>Microscopic Polyangiitis (MPA) or Granulomatosis with Polyangiitis (GPA)</u>
	• Documentation of active MPA or GPA
	
	<u>Eosinophilic Granulomatosis with Polyangiitis (EGPA)</u>
	• Documented diagnosis of active EGPA confirmed by:
	  ○ Eosinophilia at baseline (blood eosinophil level over 10% or absolute count over 1,000 cells/mcL)
	  ○ At least **two** of the following:
	  ▪ Asthma
	  ▪ Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
	  ▪ Peripheral neuropathy (not due to radiculopathy)
	  ▪ Pulmonary infiltrates
	  ▪ Sinonasal abnormality/obstruction
	  ▪ Cardiomyopathy (confirmed on imaging)
	  ▪ Glomerulonephritis
	  ▪ Alveolar hemorrhage

PacificSource Community Solutions

- Palpable purpura
- Antineutrophil cytoplasmic antibody (ANCA) positive (anti-MPO-ANCA or anti-PR3-ANCA)

RRMS

- Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS
  - Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS

CIS

- Documentation of a monophasic clinical episode, with patient-reported symptoms and corresponding objective clinical evidence as follows: One or more T2-hyperintense lesions that are characteristic of MS in at least two of four MS-typical regions (periventricular, cortical or juxtacortical, infratentorial brain regions, and the spinal cord)

Active SPMS

- Documented history of RRMS, followed by gradual and persistent worsening in neurologic function over at least 6 months (independent of relapses)
- Evidence of active SPMS, as shown by ongoing clinical relapses and/or inflammatory activity (i.e., gadolinium enhancing lesions **OR** new or enlarging lesions)
- Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5

NMOSD

- Diagnosis of seropositive aquaporin-4 immunoglobulin G (AQP4-IgG) NMOSD confirmed by all the following:
  - Documentation of AQP4-IgG-specific antibodies on cell-based assay
  - Exclusion of alternative diagnoses (such as multiple sclerosis)
  - At least **one** core clinical characteristic:
    - Acute optic neuritis
    - Acute myelitis
    - Acute area postrema syndrome (episode of otherwise unexplained hiccups or nausea/vomiting)
    - Acute brainstem syndrome
    - Symptomatic narcolepsy **OR** acute diencephalic clinical syndrome with NMOSD-typical diencephalic lesion on magnetic resonance imaging (MRI) [*see table below*]
    - Acute cerebral syndrome with NMOSD-typical brain lesion on MRI [*see table below*]

Clinical presentation	Possible MRI findings
Diencephalic syndrome	• Periependymal lesion • Hypothalamic/thalamic lesion
Acute cerebral syndrome	• Extensive periependymal lesion • Long, diffuse, heterogenous, or edematous corpus callosum lesion • Long corticospinal tract lesion

	• Large, confluent subcortical or deep white matter lesion

Pemphigus Vulgaris (PV) and other autoimmune blistering skin diseases (such as but not limited to pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita, and paraneoplastic pemphigus)

- Diagnosis confirmed by biopsy
- Documented severe or refractory disease with failure to conventional topical and oral systemic therapies

Immune Thrombocytopenia (ITP), Relapsed or Refractory

- Platelet count less than 20,000/microliter **AND**
- One of the following:
  - Documented steroid dependence to maintain platelets/prevent bleeding with ITP equal or greater than 3 months
  - Lack of clinically meaningful response to corticosteroids (defined as inability to increase platelets to at least 50,000/mcl)

Appropriate Treatment Regimen & Other Criteria:

All Uses

- Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
- Coverage of Rituxan or Rituxan Hycela requires documentation of one of the following:
  - A documented intolerable adverse event to the preferred products, Riabni, Truxima and Ruxience, and the adverse event was not an expected adverse event attributed to the active ingredient

Oncology Uses:

- Documentation of ECOG performance status of 1 or 2 OR Karnofsky performance score greater than 50%

RA

- Initial Course: Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred products: Inflectra, Avsola, Renflexis)
- Dose is approved for up to 2 doses of 1,000 mg given every 2 weeks
- Repeat Course: Approve if 16 weeks or more after the first dose of the previous rituximab regimen and the patient has responded (e.g., less joint pain, morning stiffness, or fatigue, or improved mobility, or decreased soft tissue swelling in joints or tendon sheaths) as determined by the prescribing physician

MPA and GPA

- **Initial:** May include one-time induction dose (e.g., 1,000 mg once every 2 weeks for 2 doses **or** 375 mg/m^2 once weekly for 4 doses), to be used in combination with a systemic glucocorticoid
- **Maintenance:** Approvable for up to 1,000 mg annually. Higher doses will require documentation to support (e.g., positive ANCA titers, detection of CD19+ lymphocytes)

EGPA

- **Non-severe disease** (respiratory/sinonasal disease, uncomplicated skin manifestations,

	arthralgias, mild systemic symptoms, etc.): Documented relapsed or refractory disease with systemic glucocorticoids **AND** one immunosuppressive therapy (azathioprine, methotrexate, mycophenolate) • **Severe disease** (glomerulonephritis, cardiomyopathy, gastroenteritis, systemic vasculitis, etc.): Documentation of intent to use in combination with systemic glucocorticoid therapy **Relapsing Forms of MS** • **Initiation**: May include one-time induction dose (e.g., 1,000 mg once every 2 weeks for 2 doses) • **Maintenance**: Approvable up to 2,000 mg annually. Higher doses will require documentation to support **NMOSD** • **Initial**: May include one-time induction dose (e.g., 1,000 mg once every 2 weeks for 2 doses) • **Maintenance**: Approvable up to 2,000 mg annually. Higher doses will require documentation to support (e.g., detection of CD19+ lymphocytes) **PV and other autoimmune blistering skin diseases** • Documentation that rituximab will be administered in combination with a systemic glucocorticoid (if or when appropriate) • Documented treatment failure with 12 weeks of a corticosteroid **AND** • Documented treatment failure with 12 weeks of an immunosuppressant at an adequate dose (e.g., azathioprine, mycophenolate, methotrexate, etc.) or other appropriate corticosteroid-sparing therapy **All other indications** • A Food and Drug Administration (FDA)-approved or compendia supported dose, frequency, and duration of therapy • Documented treatment failure with first line recommended and conventional therapies **Reauthorization:** documentation of disease responsiveness to therapy
Exclusion Criteria:	• MS: Concurrent anti-CD20-directed therapy or other disease-modifying medications indicated for the treatment of MS • Other non-oncology indications: Concurrent use with targeted immune modulators
Age Restriction:	
Prescriber Restrictions:	• **RA:** Prescribed by, or in consultation with, a rheumatologist • **MPA, GPA, EGPA:** Prescribed by, or in consultation with, a specialist (such as a rheumatologist, nephrologist, pulmonologist, or immunologist) • **Oncologic Indications:** Prescribed by, or in consultation with, an oncologist • **MS, NMOSD:** Prescribed by, or in consultation with, a neurologist or MS specialist • **PV:** Prescribed by, or in consultation with, a dermatologist
Coverage Duration:	**Initial Authorization** • MPA, GPA, EGPA, PV: 3 months, unless otherwise specified • Oncology: 4 months, unless otherwise specified • RA, MS, NMOSD: 6 months, unless otherwise specified

	Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
RNA INTERFERENCE DRUGS FOR PRIMARY HYPEROXALURIA 1
Affected Medications: OXLUMO (lumasiran), RIVFLOZA (nedosiran)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Primary hyperoxaluria type 1 (PH1)

Required Medical Information:	• A diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing confirming presence of AGXT gene mutation
	• Metabolic testing demonstrating elevated urinary **oxalate** excretion
	• Presence of clinical manifestations diagnostic of PH1 such as:
	  ○ Metabolic testing demonstrating elevated urinary **glycolate** excretion
	  ○ Normal levels of levels of L-glyceric acid (elevation indicates PH type 2)
	  ○ Normal levels of hydroxy-oxo-glutarate (elevation indicates PH type 3)
	• For Rivfloza: eGFR of 30 or more

Appropriate Treatment Regimen & Other Criteria:	• For Rivfloza: Trial and failure or contraindication with Oxlumo **Reauthorization** will require documentation of the following criteria related to treatment success: • Reduction from baseline in urine or plasma oxalate levels • Improvement, stabilization, or slowed worsening of one more clinical manifestation of PH1 (i.e., nephrocalcinosis, renal stone events, renal impairment, systemic oxalosis)
Exclusion Criteria:	• Diagnosis of primary hyperoxaluria type 2 or type 3 • Secondary hyperoxaluria • Concurrent use of another RNA interference drug for PH1
Age Restriction:	• For Rivfloza: Age in accordance with FDA labeling
Prescriber Restrictions:	• Prescribed by, or in consultation with, a nephrologist, urologist, geneticist, or physician specialized in the treatment of PH1
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ROMIPLOSTIM
Affected Medications: NPLATE (romiplostim)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
	  ○ Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
	  ○ Adult and pediatric patients (including term neonates) with acute exposure to myelosuppressive radiation doses.

Required Medical Information:	**Thrombocytopenia in patients with ITP:**
	• Documentation of **ONE** of the following:
	  ○ Platelet count less than 20,000/microliter
	  ○ Platelet count less than 30,000/microliter AND symptomatic bleeding
	  ○ Platelet count less than 50,000/microliter AND increased risk for bleeding (such as peptic ulcer disease, use of antiplatelets or anticoagulants, history of bleeding at higher platelet count, need for surgery or invasive procedure)
	
	Hematopoietic syndrome of acute radiation syndrome:
	• Suspected or confirmed exposure to radiation levels greater than 2 gray (Gy)

Appropriate Treatment Regimen & Other Criteria:	• Current weight
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Thrombocytopenia in patients with ITP:
	• Documentation of inadequate response, defined as platelets did not increase to at least 50,000/microliter, to the following therapies:
	  ○ **ONE** of the following:
	  ▪ Inadequate response with at least 2 therapies for ITP, including corticosteroids, rituximab, or immunoglobulin
	  ▪ Splenectomy
	  ○ eltrombopag olamine
	
	Reauthorization (ITP only):
	• Response to treatment with platelet count of at least 50,000/microliter (not to exceed 400,000/microliter)
	OR
	• The platelet counts have not increased to a platelet count of at least 50,000/microliter and the patient has NOT been on the maximum dose for at least 4 weeks
	
	Hematopoietic syndrome of acute radiation syndrome
	• Approved for one-time single subcutaneous injection of 10mcg/kg

Exclusion Criteria:	• Treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) • Use in combination with another thrombopoietin receptor agonist, spleen tyrosine kinase inhibitor, or similar treatments (eltrombopag olamine, Doptelet, Tavalisse)

PacificSource Community Solutions

Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	**Thrombocytopenia in patients with ITP:** • Initial Approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified **Hematopoietic syndrome of acute radiation syndrome:** • 1 month, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ROMOSOZUMAB
Affected Medications: EVENITY (romosozumab-aqqg)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of osteoporosis in postmenopausal women at high risk of fracture (defined as history of osteoporotic fracture or multiple risk factors for fracture) or have history of treatment failure or intolerance to other available osteoporosis therapy

Required Medical Information:	• Diagnosis of osteoporosis as defined by at least **one** of the following:
	  ○ T-score less than or equal to –2.5 (current or past) at the lumbar spine, femoral neck, total hip, or 1/3 radius site
	  ○ T-score between –1.0 and –2.5 at the lumbar spine, femoral neck, total hip, or 1/3 radius site **AND** increased risk of fracture as defined by at least **one** of the following Fracture Risk Assessment Tool (FRAX) scores:
	  ▪ FRAX 10-year probability of major osteoporotic fracture is 20% or greater
	  ▪ FRAX 10-year probability of hip fracture is 3% or greater
	  ○ History of non-traumatic fractures in the absence of other metabolic bone disorders

Appropriate Treatment Regimen & Other Criteria:	• Treatment failure, contraindication, or intolerance to all the following:
	  ○ Intravenous bisphosphonate (zoledronic acid or ibandronate)
	  ○ Prolia (denosumab)
	
	<u>Total duration of therapy with Evenity should not exceed 12 months in a lifetime</u>

Exclusion Criteria:	• Heart attack or stroke event within the preceding year • Concurrent use of bisphosphonates, parathyroid hormone analogs or RANK ligand inhibitors • Hypocalcemia that is uncorrected prior to initiating Evenity
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months lifetime maximum

PacificSource Community Solutions

POLICY NAME:
RYPLAZIM
Affected Medications: RYPLAZIM

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Plasminogen Deficiency Type 1

Required Medical Information:	• Diagnosis of symptomatic congenital plasminogen deficiency (C-PLGD) type 1, as evidenced by documentation of all the following:
	  ○ Clinical signs and symptoms of the disease (such as ligneous conjunctivitis, gingivitis, tonsillitis, abnormal wound healing)
	  ○ Presence of (ligneous) pseudomembranous lesions with documentation of size, location, and total number of lesions
	  ○ Baseline plasminogen activity level less than or equal to 45% of laboratory standard

Appropriate Treatment Regimen & Other Criteria:	**Dosing** • Dosing may not exceed 6.6 mg/kg every 2 days • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** requires documentation of disease responsiveness to therapy, defined as the following: • Trough plasminogen activity level (taken 72 hours after dose) increased by 10% or greater above baseline • Improvement (reduction) in lesion number/size from baseline
Exclusion Criteria:	• Prior treatment failure with Ryplazim • Treatment of idiopathic pulmonary fibrosis
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SACROSIDASE
Affected Medications: SUCRAID (Sacrosidase)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Oral replacement therapy for congenital sucrase-isomaltase deficiency (CSID)

Required Medical Information:	• Documentation of confirmed congenital sucrose-isomaltase deficiency, diagnosed by one of the following:
	  ○ Small bowel biopsy
	  ○ Sucrose breath test
	  ○ Genetic test
	• Documentation of current symptoms (e.g., diarrhea, abdominal pain or cramping, bloating, gas, loose stools, nausea, vomiting)
	
	Reauthorization: requires documentation of treatment success and a clinically significant response to therapy (fewer stools, lower number of symptoms)

Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	
Age Restriction:	• 5 months or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a gastroenterologist or metabolic specialist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
SAPROPTERIN
Affected Medications: SAPROPTERIN, JAVYGTOR

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by benefit design ○ Reduce phenylalanine (Phe) levels in those that are one month of age and older with phenylketonuria (PKU)
Required Medical Information:	• Documentation of a diagnosis of PKU • Baseline (pre-treatment) blood Phe level greater than or equal to 360 micromol/L (6 mg/dL) • Documentation of failure to Phe restricted diet as monotherapy
Appropriate Treatment Regimen & Other Criteria:	• Documentation of continuation on a Phe restricted diet **Reauthorization** requires documentation of one of the following: • Reduction in baseline Phe levels by 30 percent or levels maintained between 120 to 360 micromol/L (2 to 6 mg/dL) • Increase in dietary Phe tolerance • Improvement in clinical symptoms
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist in metabolic disorders or endocrinologist
Coverage Duration:	• Initial approval: 2 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SARILUMAB
Affected Medications: KEVZARA AUTO-INJECTOR, KEVZARA PREFILLED SYRINGE

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis (RA)
	  ○ Polymyalgia Rheumatica (PMR)
	  ○ Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Required Medical Information:	**Rheumatoid Arthritis**
	• Documentation of current disease activity with one of the following (or equivalent objective scale)
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) is greater than 3.2
	  ○ Clinical Disease Activity Index (CDAI) is greater than 10
	  ○ Weighted Routine Assessment of Patient Index Data 3 (RAPID3) of at least 2.3
	
	Polymyalgia Rheumatica
	• Age 50 years or older at onset
	• Elevated erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP)
	• Confirmation of PMR according to the American College of Rheumatology/European Union League against Rheumatism (ACR/EULAR) classification criteria (score of 4 or more)
	  ○ Morning stiffness greater than 45 min in duration -2 points
	  ○ Hip pain or limited range of motion - 1 point
	  ○ Absence of rheumatoid factor (RF) or anticitrullinated protein antibody (ACPA) – 2 points
	  ○ Absence of other joint involvement – 1 point
	
	Polyarticular Juvenile Idiopathic Arthritis
	• Documentation of current level of disease activity with physician global assessment (MD global score) or active joint count

Appropriate Treatment Regimen & Other Criteria:	**Rheumatoid Arthritis**
	• Documented failure with at least 12 weeks of treatment with methotrexate
	  ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide)
	• Documentation of treatment failure (or documented intolerable adverse event) for 12 weeks or greater with Infliximab (preferred products Inflectra, Avsola) or tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV)
	
	Polymyalgia Rheumatica
	• Clinical response to low dose glucocorticoids (prednisone 15mg/day or equivalent) within a week of initiation with inability to complete gradual (2- 4 week) taper
	Polyarticular Juvenile Idiopathic Arthritis
	• Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide AND
	• Documented failure with glucocorticoid joint injections or oral corticosteroids
	• Documented treatment failure (or documented intolerable adverse event) with at 12 weeks of two of the following therapies:
	  ○ tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV), Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), and Simponi Aria

	QL RA/PMR/JIA: 200 mg every 2 weeks **Reauthorization:** Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SATRALIZUMAB-MWGE
Affected Medications: ENSPRYNG (satralizumab-mwge)

<table>
<tr><td>Covered Uses:</td><td>

All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design

Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive

</td></tr>
<tr><td>Required Medical Information:</td><td>
<u>NMOSD</u>

Diagnosis of seropositive aquaporin-4 immunoglobulin G (AQP4-IgG) NMOSD confirmed by all the following:

Documentation of AQP4-IgG-specific antibodies on cell-based assay
Exclusion of alternative diagnoses (such as multiple sclerosis)
At least one core clinical characteristic:

Acute optic neuritis
Acute myelitis
Acute area postrema syndrome (episode of otherwise unexplained hiccups or nausea/vomiting)
Acute brainstem syndrome
Symptomatic narcolepsy OR acute diencephalic clinical syndrome with NMOSD-typical diencephalic lesion on magnetic resonance imaging (MRI) [see table below]
Acute cerebral syndrome with NMOSD-typical brain lesion on MRI [see table below]

<table>
<tr><th>Clinical presentation</th><th>Possible MRI findings</th></tr>
<tr><td>Diencephalic syndrome</td><td>• Periependymal lesion
• Hypothalamic/thalamic lesion</td></tr>
<tr><td>Acute cerebral syndrome</td><td>• Extensive periependymal lesion
• Long, diffuse, heterogenous, or edematous corpus callosum lesion
• Long corticospinal tract lesion
• Large, confluent subcortical or deep white matter lesion</td></tr>
</table>

History of at least 1 attack in the past year, or at least 2 attacks in the past 2 years, requiring rescue therapy

</td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>

Documented inadequate response, contraindication, or intolerance to rituximab (preferred agents Truxima, Riabni, and Ruxience)

<u>Reauthorization</u> requires documentation of treatment success
</td></tr>
<tr><td>Exclusion Criteria:</td><td>

Active Hepatitis B Virus (HBV) infection
Active or untreated latent tuberculosis

</td></tr>
</table>

	• Concurrent use with other disease-modifying biologics for requested indication
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or neuro-ophthalmologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
SEBELIPASE ALFA
Affected Medications KANUMA (sebelipase alfa)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Lysosomal Acid Lipase (LAL) deficiency

Required Medical Information:	• Diagnosis of LAL deficiency or Rapidly Progressive LAL deficiency within the first 6 months of life confirmed by one of the following:
	  ○ Absence or deficiency in lysosomal acid lipase activity
	  ○ Mutation in the lipase A, lysosomal acid type (*LIPA*) gene
	• Documentation of patient weight
	• Documentation of prescribed treatment regimen (dose and frequency)
	• Baseline fasting lipid panel including LDL-c prior to initiating therapy (not required for Rapidly Progressive LAL deficiency)

Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **<u>Reauthorization</u>** • Rapidly Progressive LAL deficiency: documentation of improvement in weight-for-age Z-score • LAL deficiency: documentation of improvement in LDL-c
Exclusion Criteria:	
Age Restriction:	• 1 month or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist or metabolic specialist
Coverage Duration:	• Initial Approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
SECUKINUMAB
Affected Medications COSENTYX PREFILLED SYRINGE, COSENTYX SENSOREADY AUTO-INJECTOR, COSENTYX UNOREADY AUTO-INJECTOR, COSENTYX IV SOLUTION

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis (PP)
	  ○ Psoriatic Arthritis (PsA)
	  ○ Ankylosing Spondylitis (AS)
	  ○ Non-radiographic Axial Spondyloarthritis (NR-axSPA)
	  ○ Enthesitis-Related Arthritis (ERA)
	  ○ Juvenile Psoriatic Arthritis (JPsA)
	  ○ Hidradenitis Suppurativa (HS)

Required Medical Information:	**<u>Plaque Psoriasis</u>**
	• Documentation that the skin disease is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	AND
	• Documentation of one or more of the following:
	  ○ At least 10% body surface area involvement despite current treatment
	OR
	  ○ Hand, foot, or mucous membrane involvement
	
	<u>Psoriatic Arthritis</u>
	• Documentation of Classification for Psoriatic Arthritis (CASPAR) criteria score of 3 or greater based on chart notes:
	  ○ Skin psoriasis: present – two points, OR previously present by history – one point, OR a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxta-articular bone formation on radiographs (distinct from osteophytes): one point
	
	<u>Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis</u>
	• Diagnosis of axial spondyloarthritis (SpA) confirmed by sacroiliitis on imaging AND at least 1 spondyloarthritis feature:
	  ○ Inflammatory back pain (4 of 5 features met):
	  ▪ Onset of back discomfort before the age of 40 years
	  ▪ Insidious onset
	  ▪ Improvement with exercise
	  ▪ No improvement with rest
	  ▪ Pain at night (with improvement upon arising)

	○ Arthritis ○ Enthesitis ○ Uveitis ○ Dactylitis (inflammation of entire digit) ○ Psoriasis ○ Crohn's disease/ulcerative colitis ○ Good response to nonsteroidal anti-inflammatory drugs (NSAIDs) ○ Family history of SpA ○ Elevated C-reactive protein (CRP) **OR** ○ HLA-B27 genetic test positive AND at least TWO SpA features • Documentation of active disease defined by Bath ankylosing spondylitis disease activity index (BASDAI) at least 4 or equivalent objective scale **<u>Enthesitis-Related Arthritis or Juvenile Psoriatic Arthritis</u>** • Diagnosis of ERA confirmed by presence of the following: ○ Arthritis persisting at least 6 weeks AND enthesitis present **OR** ○ Arthritis or enthesitis with two of the following features: ▪ Sacroiliac tenderness or inflammatory lumbosacral pain ▪ Positive HLA-B27 ▪ Onset of arthritis in males greater than 6 years of age ▪ Acute symptomatic anterior uveitis ▪ First-degree relative with ERA, sacroilitis associated with inflammatory bowel disease, reactive arthritis, or acute anterior uveitis **OR** • Diagnosis of JPsA confirmed by presence of: ○ Arthritis and psoriasis **OR** ○ Arthritis and at least 2 of the following: ▪ Dactylitis ▪ Nail pitting or onycholysis ▪ Psoriasis in a first-degree relative **<u>Hidradenitis Suppurativa</u>** • Diagnosis of moderate to severe HS as defined by Hurley stage II or stage III disease • Documentation of baseline count of abscesses and inflammatory nodules
Appropriate Treatment Regimen & Other Criteria:	**<u>Plaque Psoriasis</u>** • Documented treatment failure with 12 weeks of at least TWO systemic therapies: methotrexate, cyclosporine, acitretin, phototherapy [UVB, PUVA] • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **<u>Psoriatic Arthritis</u>** • Documented failure with at least 12 weeks of treatment with methotrexate

	○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Simponi Aria, Orencia IV, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) • Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with intravenous formulation (exception made for concomitant plaque psoriasis use) **<u>Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis</u>** • Documented failure with two daily prescription strength nonsteroidal anti-inflammatory drugs (ibuprofen, naproxen, diclofenac, meloxicam, etc.) with minimum 1 month trial each **OR** • For peripheral arthritis: documented treatment failure with locally administered parenteral glucocorticoid • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of: ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Simponi Aria or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) • Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with intravenous formulation (exception made for concomitant plaque psoriasis use) **<u>Enthesitis-Related Arthritis or Juvenile Psoriatic Arthritis</u>** • Documented treatment failure with a nonsteroidal anti-inflammatory drug (ibuprofen, naproxen, celecoxib, meloxicam, etc.) with a minimum trial of 1 month • Documented treatment failure with at least one of the following disease-modifying antirheumatic drugs (DMARDs) with a minimum trial of 12 weeks: methotrexate, sulfasalazine, leflunomide **<u>Hidradenitis Suppurativa</u>** • Documented failure with at least 12-week trial of oral antibiotics for treatment of HS: ○ Doxycycline, tetracycline, minocycline OR ○ Clindamycin plus rifampin • Documented failure with 8 weeks on a systemic retinoid (isotretinoin or acitretin) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of: ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis) **AND** ○ Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) **<u>QL</u>** **Intravenous** • 6 mg/kg at week 0, followed by 1.75 mg/kg every 4 weeks (max of 300mg for maintenance)

	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Subcutaneous
	• Induction
	  ○ Adult PP: 4 two-packs (300 mg) in first 28 days
	  ○ Pediatric PP/JPsA/ERA:
	  ▪ Less than 50 kg: four 75 mg doses in the first 28 days
	  ▪ Greater than or equal to 50 kg: four 150 mg doses in the first 28 days
	  ○ HS: 4 two-packs (300 mg) in first 28 days
	• Maintenance
	  ○ Adult PP: 1 two-pack (300 mg) per 28 days
	  ○ Pediatric PP/JPsA/ERA:
	  ▪ Less than 50 kg: 75 mg per 28 days
	  ▪ Greater than or equal to 50 kg: 150 mg per 28 days
	  ○ PsA without PP/AS/NR-axSPA: 1 injection (150 mg) per 28 days
	  ▪ If a patient continues to have active disease, a dosage of 300 mg may be considered
	  ▪ HS: 1 two-pack (300 mg) per 28 days
	
	<u>Reauthorization</u>
	• Documentation of treatment success and clinically significant response to therapy

Exclusion Criteria:	• Concurrent use with any other biologic therapy or Otezla is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/ dermatologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
SELF-ADMINISTERED DRUGS (SAD)
PA Policy Applicable to: Please refer to package insert for directions on self-administration.

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	
Appropriate Treatment Regimen & Other Criteria:	• In the hospital outpatient setting, the pharmacy benefit will cover pharmaceutical agents that the member can reasonably take or use on their own, while the medical benefit will cover any agents given intravenously (IV) or other forms that the member cannot give to themselves.
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	

PacificSource Community Solutions

POLICY NAME:
SEROSTIM
Affected Medications: SEROSTIM (somatropin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ HIV (human immunodeficiency virus) -associated wasting, cachexia

Required Medical Information:	• Documentation of current body mass index (BMI), actual body weight, and ideal body weight (IBW)
	
	• Serostim is used in combination with antiretroviral therapy to which the patient has documented compliance
	• Alternative causes of wasting (e.g., inadequate nutrition intake, malabsorption, opportunistic infections, hypogonadism) have been ruled out or treated appropriately
	• Prior to somatropin, patient had a suboptimal response to at least 1 other therapy for wasting or cachexia (e.g., megestrol, dronabinol, cyproheptadine, or testosterone therapy if hypogonadal) unless contraindicated or not tolerated
	• Diagnosis of HIV-association wasting syndrome or cachexia confirmed by **one** of the following:
	  ○ Unintentional weight loss greater than or equal to 10% of body weight over prior 12 months
	  ○ Unintentional weight loss greater than or equal to 5% of body weight over prior 6 months
	  ○ BMI less than 20 kg/m^2
	  ○ Weight is less than 90% of IBW

Appropriate Treatment Regimen & Other Criteria:	**<u>Reauthorization:</u>** • Documentation of treatment success and clinically significant response to therapy (e.g., improved or stabilized BMI, increased physical endurance compared to baseline, etc.) • Documentation of continued compliance to antiretroviral regimen
Exclusion Criteria:	• Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental traumas, or acute respiratory failure • Active malignancy • Acute respiratory failure • Active proliferative or severe non-proliferative diabetic retinopathy
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist
Coverage Duration:	• Initial Authorization: 4 months • Reauthorization: 8 months (maximum duration of therapy 48 weeks total)

POLICY NAME:
SIGNIFOR
Affected Medications: SIGNIFOR (pasireotide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Cushing's disease

Required Medical Information:	• Documented diagnosis of Cushing's disease
	• Documentation of at least **TWO** of the following:
	  ○ Mean 24-hour urine free cortisol (mUFC) greater than 1.5 times the upper limit of normal (ULN) for the assay (at least two measurements)
	  ○ Bedtime salivary cortisol greater than 145 ng/dL (at least two measurements)
	  ○ Overnight dexamethasone suppression test (DST) with a serum cortisol greater than 1.8 mcg/dL

Appropriate Treatment Regimen & Other Criteria:	• Documented inadequate response, intolerable adverse event, or contraindication to ketoconazole and cabergoline • Documentation confirming pituitary surgery is not an option **OR** previous surgery has not been curative **Reauthorization** requires documentation of treatment success defined as mUFC normalization (i.e., less than or equal to the ULN)
Exclusion Criteria:	• Severe hepatic impairment (Child Pugh C)
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SIGNIFOR LAR
Affected Medications: SIGNIFOR LAR (pasireotide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Acromegaly
	  ○ Cushing's disease

Required Medical Information:	**Acromegaly**
	• Documentation confirming clinical manifestations of disease
	• Diagnosis of acromegaly confirmed by **ONE** of the following:
	  ○ Elevated pre-treatment serum insulin-like growth factor-1 (IGF-1) level for age/gender
	  ○ Serum growth hormone (GH) level of 1 microgram/mL or greater after an oral glucose tolerance test (OGTT)
	
	Cushing's Disease
	• Documented diagnosis of Cushing's disease
	• Documentation of at least **TWO** of the following:
	  ○ Mean 24-hour urine free cortisol (mUFC) greater than 1.5 times the upper limit of normal (ULN) for the assay (at least two measurements)
	  ○ Bedtime salivary cortisol greater than 145 ng/dL (at least two measurements)
	  ○ Overnight dexamethasone suppression test (DST) with a serum cortisol greater than 1.8 mcg/dL

Appropriate Treatment Regimen & Other Criteria:	**Acromegaly**
	• Documented treatment failure or intolerance to lanreotide (Somatuline Depot) **OR** octreotide
	• Documentation confirming **ONE** of the following:
	  ○ Inadequate response to surgery or radiotherapy
	  ○ Not a candidate for surgical management or radiotherapy (e.g., medically unstable, high risk for complications under anesthesia, major systemic complications of acromegaly, severe hypertension, uncontrolled diabetes, etc.)
	• **Dosing:** Not to exceed 60 mg every 4 weeks (after 3 months of 40 mg)
	• **Reauthorization** requires documentation of treatment success shown by decreased/normalized IGF-1 or GH levels
	
	Cushing's Disease
	• Documentation confirming pituitary surgery is not an option **OR** previous surgery has not been curative
	• Documented treatment failure or intolerance to ketoconazole and cabergoline
	• **Dosing:** Not to exceed 40 mg every 4 weeks (after 4 months of 10 mg)
	• **Reauthorization** requires documentation of treatment success defined as UFC normalization (i.e., less than or equal to the ULN)

Exclusion Criteria:	• Severe hepatic impairment (Child Pugh C)
Age Restriction:	• 18 years of age and older

Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
SILTUXIMAB
Affected Medications: SYLVANT (siltuximab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • The diagnosis was confirmed by biopsy of lymph gland • Documented negative tests for HIV and HHV-8 • Patient weight
Appropriate Treatment Regimen & Other Criteria:	**Dosing** • **MCD:** 11 mg/kg intravenous (IV) infusion once every 3 weeks until treatment failure • **Cytokine release syndrome (CRS):** 11 mg/kg IV infusion one time only • Availability: 100 mg and 400 mg vials • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** requires documentation of disease responsiveness to therapy
Exclusion Criteria:	
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist

Coverage Duration:	• MCD:
	  ○ Initial Authorization: 4 months, unless otherwise specified
	  ○ Reauthorization: 12 months, unless otherwise specified
	• CRS: 1 month (1 dose only), unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SIROLIMUS GEL
Affected Medications: HYFTOR (sirolimus gel)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ For the treatment of facial angiofibroma (FA) associated with tuberous sclerosis complex (TSC)

Required Medical Information:	• Documented diagnosis of FA associated with TSC which are:
	  ○ Rapidly changing in size and/or number
	  ○ Causing functional interference, pain or bleeding
	  ○ Inhibiting social interactions
	• Current and baseline description of FA including lesion count, associated symptoms and complications, and overall severity

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with laser therapy and/or surgery (such as shave excision, cryotherapy, radiofrequency ablation, or dermabrasion), unless contraindicated **Reauthorization** requires documentation of a positive clinical response to therapy (decrease in size and/or redness of facial angiofibromas)
Exclusion Criteria:	• Concurrent use of systemic mammalian target of rapamycin (mTOR) inhibitors • Treatment of non-facial angiofibroma
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a dermatologist, oncologist, or neurologist.
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified. • Reauthorization: 12 months, unless otherwise specified.

PacificSource Community Solutions

POLICY NAME:
SODIUM PHENYLBUTYRATE
Affected Medications: sodium phenylbutyrate

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Adjunctive therapy in the chronic management of patients with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS)
	  ○ Neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life)
	  ○ Late-onset disease (partial enzymatic deficiency, presenting after the first month of life) with history of hyperammonemic encephalopathy

Required Medical Information:	• Diagnosis confirmed by blood, enzymatic, biochemical, or genetic testing
Appropriate Treatment Regimen & Other Criteria:	• Oral tablets require documented inability to use sodium phenylbutyrate powder • Documented treatment failure with dietary protein restriction and/or amino acid supplementation alone • Must be used in combination with dietary protein restriction **Reauthorization** will require **BOTH** of the following: • Documentation of treatment success defined as ammonia levels maintained within normal limits • That this drug continues to be used in combination with dietary protein restriction
Exclusion Criteria:	• Use for management of acute hyperammonemia
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic diseases
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SOMATOSTATIN ANALOGS
Affected Medications: OCTREOTIDE, LANREOTIDE (Somatuline Depot)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design **Octreotide:** • Acromegaly • Symptomatic treatment of metastatic carcinoid tumors (carcinoid syndrome) • Symptomatic treatment of vasoactive intestinal peptide tumors (VIPomas) **Lanreotide (Somatuline Depot):** • Acromegaly • Carcinoid syndrome (to reduce the frequency of short-acting somatostatin analog rescue therapy) • Unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or higher

Required Medical Information:	**Acromegaly**
	• Documentation confirming clinical manifestations of disease
	• Diagnosis of acromegaly confirmed by **ONE** of the following:
	  ○ Elevated pre-treatment serum insulin-like growth factor-1 (IGF-1) level for age/gender
	  ○ Serum growth hormone (GH) level of 1 microgram/mL or greater after an oral glucose tolerance test (OGTT)
	
	All other indications
	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course

Appropriate Treatment Regimen & Other Criteria:	**Acromegaly**
	• Documentation confirming **ONE** of the following:
	  ○ Inadequate response to surgery or radiotherapy
	  ○ Not a candidate for surgical management or radiotherapy (e.g., medically unstable, high risk for complications under anesthesia, major systemic complications of acromegaly, severe hypertension, uncontrolled diabetes, etc.)
	
	Lanreotide (Somatuline Depot)
	• GEP-NETs must use 120 mg injection
	
	Reauthorization:
	• **Acromegaly:** requires documentation of treatment success shown by decreased/normalized IGF-1 or GH levels
	• **All other indications:** requires documentation of disease responsiveness to therapy

PacificSource Community Solutions

Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist, endocrinologist, or gastroenterologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SOTATERCEPT-CSRK
Affected Medications: WINREVAIR (sotatercept-csrk)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO) Group 1

Required Medical Information:	• Documentation of PAH confirmed by right-heart catheterization meeting the following criteria:
	  ○ Mean pulmonary artery pressure of at least 20 mm Hg
	  ○ Pulmonary capillary wedge pressure less than or equal to 15 mm Hg
	  ○ Pulmonary vascular resistance of at least 5 Wood units
	• Etiology of PAH: idiopathic PAH, hereditary PAH
	OR
	• PAH secondary to one of the following conditions:
	  ○ Connective tissue disease
	  ○ Simple, congenital systemic to pulmonary shunts at least 1 year following repair
	  ○ Drugs and toxins
	• New York Heart Association (NYHA)/World Health Organization (WHO) Functional Class II or III symptoms
	• Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blockers) unless there are contraindications:
	  ○ Low systemic blood pressure (systolic blood pressure less than 90)
	  ○ Low cardiac index (cardiac index less than 2 L/min/m^2)
	  OR
	  ○ Presence of severe symptoms (functional class IV)
	• Baseline 6-minute walk test (6MWD)

Appropriate Treatment Regimen & Other Criteria:	• Documentation that drug will be used as an add-on treatment with all of the following (one from each category) at optimized doses for at least 90 days:
	  ○ Phosphodiesterase-5 (PDE-5) inhibitor: sildenafil, tadalafil
	  ○ Endothelin Receptor Antagonist: ambrisentan, bosentan
	  ○ Prostacyclin: treprostinil, epoprostenol, Ventavis
	• Documentation of inadequate response or intolerance to oral calcium channel blocking agents (nifedipine, diltiazem) if positive Acute Vasoreactivity Test
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization requires documentation of treatment success defined as one or more of the following:
	• Improvement in walking distance (6MWD)
	• Improvement or stability in WHO functional class

Exclusion Criteria:	• Human immunodeficiency virus (HIV)-associated PAH • PAH associated with portal hypertension • Schistosomiasis-associated PAH • Pulmonary veno-occlusive disease • Platelet count less than 50,000/mm^3 (50 x 10^9/L) • Hemoglobin (Hgb) at screening above gender-specific upper limit of normal (ULN)
Age Restriction:	• 18 years of age and older

Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SPESOLIMAB
Affected Medications: SPEVIGO (spesolimab-SBZO injection)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Generalized pustular psoriasis flares (GPP, also called von Zumbusch psoriasis)

Required Medical Information:	• Diagnosis of generalized pustular psoriasis as confirmed by the following:
	  ○ The presence of widespread sterile pustules arising on erythematous skin
	  ○ Pustulation is not restricted to psoriatic plaques
	• Signs and symptoms of an acute GPP flare of moderate-to-severe intensity as follows:
	  ○ A Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of greater than or equal to 3
	  ○ A GPPGA pustulation score of greater than or equal to 2 (moderate to very high-density pustules)
	  ○ Greater than or equal to 5% body surface area (BSA) covered with erythema and the presence of pustules

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure of acute disease flare (or documented intolerable adverse event) with:
	  ○ A 1-week trial of cyclosporine
	  AND
	  ○ Infliximab (preferred biosimilars Inflectra, Avsola)
	• Treatment for each flare is limited to two 900mg infusions of Spevigo separated by 1 week

Exclusion Criteria:	• Previous use of Spevigo • Erythrodermic plaque psoriasis without pustules or with pustules restricted to psoriatic plaques • Synovitis-acne-pustulosis-hyperostosis-osteitis syndrome • Drug-induced acute generalized exanthematous pustulosis
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a dermatologist
Coverage Duration:	• Authorization: One month with no reauthorization, unless otherwise specified

POLICY NAME:
SPHINGOSINE 1-PHOSPHATE (S1P) RECEPTOR MODULATORS
Affected Medications: MAYZENT (siponimod), PONVORY (ponesimod), VELSIPITY (etrasimod), ZEPOSIA (ozanimod)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following (Mayzent, Ponvory, Zeposia):
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)
	  ○ Ulcerative colitis (UC) (Velsipity, Zeposia)

Required Medical Information:	**MS** • Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS **UC** • Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy • Documentation of moderate to severely active disease despite current treatment

Appropriate Treatment Regimen & Other Criteria:	**Relapsing Forms of MS**
	• **Mayzent, Ponvory, Zeposia:** Documentation of treatment failure with (or intolerance to) **TWO** of the following: dimethyl fumarate, fingolimod, teriflunomide
	
	UC
	• Documentation of one of the following:
	  ○ Treatment failure with at least two oral treatments for a minimum of 12 weeks: corticosteroids, sulfasalazine, mesalamine, balsalazide, cyclosporine, azathioprine, 6-mercaptopurine
	  OR
	  ○ Severely active disease despite current treatment, defined by greater than 5 bloody, loose stools per day with severe cramps and evidence of systemic toxicity (fever, tachycardia, anemia, and/or elevated CRP/ESR), **OR** recent hospitalization for UC
	• Documentation of treatment failure with (or intolerance to) at least 12 weeks of ALL the following: infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis), Adalimumab (preferred biosimilar products: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), Xeljanz, Entyvio
	• **Zeposia:** Documentation of one of the following:
	  ○ Treatment failure with (or intolerance to) Velsipity
	  ○ Currently receiving treatment with Zeposia, excluding via samples or manufacturer's patient assistance program
	
	Reauthorization: provider attestation of treatment success

Exclusion Criteria:	• Mayzent: CYP2C9*3/*3 genotype • Concurrent use of other disease modifying medications indicated for the treatment of MS • Concurrent use with a JAK inhibitor or biologic medication for the treatment of UC
Age Restriction:	
Prescriber Restrictions:	• MS: Prescribed by, or in consultation with, a neurologist or MS specialist • UC: Prescribed by, or in consultation with, a gastroenterologist

Coverage Duration:	• Initial Authorization:
	  ○ UC: 6 months, unless otherwise specified
	  ○ MS: 24 months, unless otherwise specified
	• Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SPRAVATO
Affected Medications: SPRAVATO (esketamine nasal spray)

<table>
<tr><td>Covered Uses:</td><td>

All Food and Drug Administration (FDA)-approved indications not otherwise excluded

Indicated for the treatment of treatment resistant depression (TRD) in adults and depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant

</td></tr>
<tr><td>Required Medical Information:</td><td>
<u>Diagnosis of treatment-resistant depression:</u>

Assessment of patient’s risk for abuse or misuse
Patient Health Questionnaire-9 (PHQ-9) score at baseline (or other standard rating scale)
Inventory of Depressive Symptomatology-Clinician (IDS-C30) score of 34 or greater, PHQ-9 score of 15 or greater (or other standard rating scale) indicating moderate to severe depression

<u>Diagnosis of MDD with acute suicidal ideation or behavior:</u>

Assessment of patient’s risk for abuse or misuse
Montgomery-Asberg Depression Rating Scale (MADRS) total score greater than 28, PHQ-9 score of 15 or greater or other standard rating scale indicating severe depression

</td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>
<u>Treatment – Resistant Depression:</u>

Failure to clinically respond to three trials of antidepressant drugs at highest tolerated doses for at least 6 weeks from two or more different classes during the current depressive episode as defined by less than 50% reduction in symptom severity using a standard rating scale that reliably measures depressive symptoms (such as PHQ-9) and at least one trial must have used an augmentation strategy (aripiprazole, lithium, olanzapine, quetiapine, risperidone, thyroid hormone)
Failure to respond to evidence based psychotherapy such as Cognitive Behavioral Therapy (CBT) and/or Interpersonal Therapy as documented by an objective scale such as a PHQ-9 or similar rating scale for depressive symptoms
Dose: Approve #8 dose packs in first 28 days, then limit of #4 per 28 days (maximum). Per table below

<table>
<tr><th colspan="3">Recommended Dosage for SPRAVATO</th></tr>
<tr><td colspan="2"></td><td>Adults</td></tr>
<tr><td>Induction Phase</td><td><u>Weeks 1 to 4:</u></td><td></td></tr>
<tr><td></td><td>Administer twice per week</td><td>56 mg or 84 mg</td></tr>
<tr><td>Maintenance Phase</td><td><u>Weeks 5 to 8:</u></td><td></td></tr>
<tr><td></td><td>Administer once weekly</td><td>56 mg or 84 mg</td></tr>
<tr><td></td><td><u>Week 9 and after:</u></td><td></td></tr>
</table>
</td></tr>
</table>

PacificSource Community Solutions

	<table><tr><td></td><td>Administer every 2 weeks or once weekly*</td><td>56 mg or 84 mg</td></tr></table> *Dosing frequency should be individualized to the least frequent dosing to maintain remission/response **Reauthorization (for TRD indication only)** requires: • Documentation of treatment success defined as at least a 50% reduction in symptoms of depression compared to baseline using a standard rating scale that measures depressive symptoms **MDD with acute suicidal ideation or behavior:** • Documentation of current inpatient psychiatric hospitalization OR documentation of why patient is not currently at inpatient level of care • Will use Spravato in addition to oral antidepressant therapy (at a therapeutic dose) • Dosing: 84 mg twice weekly for 4 weeks maximum (No reauthorization unless requirements for TRD met)
Exclusion Criteria:	• Concomitant psychotic disorder • Bipolar or related disorders • History of substance use disorder • Use as an anesthetic agent • Pregnancy • Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation • History of intracerebral hemorrhage • Hypersensitivity to esketamine, ketamine, or any of the excipients
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• REMS Program certified (others will be unable to order drug) • Behavioral health specialist
Coverage Duration:	**Initial authorization** • Major depressive disorder (MDD) with acute suicidal ideation or behavior: 1 month (limit #24 nasal spray devices in 28 days of treatment only), unless otherwise specified • TRD: 2 months (Induction phase – maximum of 23 nasal spray devices in first 28 days followed by once weekly maintenance phase), unless otherwise specified **Reauthorization** (TRD indication only): 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
STIRIPENTOL
Affected Medications: Diacomit (stiripentol) capsules

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of seizures associated with Dravet syndrome (DS)
Required Medical Information:	• Current weight • Documentation that therapy is being used as adjunct to clobazam for seizures • Documentation of at least 4 generalized clonic or tonic-clonic seizures in the last month while on stable antiepileptic drug therapy

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment and inadequate control of seizures with at least four guideline directed therapies including:
	  ○ Valproate and
	  ○ Clobazam and
	  ○ Topiramate and
	  ○ Clonazepam, levetiracetam, or zonisamide
	
	Reauthorization will require documentation of treatment success and a reduction in seizure severity, frequency, or duration

Exclusion Criteria:	
Age Restriction:	• 6 months of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
STRENSIQ
Affected Medications: STRENSIQ (asfotase alfa)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. ○ Perinatal/infantile or Juvenile onset hypophosphatasia (HPP)

Required Medical Information:	**<u>Diagnosis of Perinatal/infantile or Juvenile onset hypophosphatasia (HPP) with ALL of the following:</u>**
	• Age of onset less than 18 years
	• One of the following:
	  ○ Clinical manifestations consistent with hypophospatasia at onset prior to age 18 such as: vitamin B6 dependent seizures, respiratory insufficiency, failure to thrive, non-traumatic fracture, dental abnormalities, low score on 6 minute walk test, low bone density score
	  ○ Skeletal abnormalities confirmed with radiographic imaging (such as flared and frayed metaphyses, widened growth plate, bowed arms or legs, rachitic chest deformity, craniosynostosis)
	• Genetic test confirming mutation of tissue-non-specific alkaline phosphatase (TNSALP) gene
	• Low level of serum alkaline phosphatase (ALP) evidenced by lab result below reference range for patient's age and gender
	• Elevated levels of one of the following:
	  ○ Urine or serum concentration of phosphoethanolamine (PEA)
	  ○ Serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test
	  ○ Urinary inorganic pyrophosphate (PPi)

Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	  ○ Please note: the 80mg/0.8ml vial is for patients weighing greater than 40 kilograms only
	
	<u>Reauthorization</u> requires documentation of:
	• Laboratory results confirming a decrease in urine concentration of urine or serum phosphoethanolamine (PEA), serum concentration of pyridoxal 5'-phosphate (PLP), or urinary inorganic pyrophosphate (PPi)
	• Improvement or stabilization in the clinical signs and symptoms of hypophosphatasia, such as:
	  ○ Radiographic evidence of improvement in skeletal deformities or growth
	  ○ Improvement in 6-minute walk test
	  ○ Improved bone density
	  ○ Reduction in fractures
	  ○ Respiratory function/breathing
	  ○ Improvement in developmental milestones

Exclusion Criteria:	• Other types of osteomalacia or hypophosphatasia, including adult onset hypophosphatasia
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist OR specialist experienced in the treatment of metabolic bone disorders

Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SUBCUTANEOUS IMMUNE GLOBULIN
Affected Medications: Cuvitru, Cutaquig, Gamunex-C, Hizentra, Hyqvia, Xembify

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Primary immunodeficiency (PID)/Wiskott-Aldrich syndrome
	  ▪ Such as: x-linked agammaglobulinemia, common variable immunodeficiency (CVID), transient hypogammaglobulinemia of infancy, immunoglobulin G (IgG) subclass deficiency with or without immunoglobulin A (IgA) deficiency, antibody deficiency with near normal immunoglobulin levels) and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) [list not all inclusive]

Required Medical Information:	• Monthly intravenous immune globulin (IVIG) dose for those transitioning
	• Patient weight
	
	<u>Primary Immunodeficiency (PID)</u>
	• Type of immunodeficiency
	• Documentation of one of the following:
	  ○ Recent IgG level less than 200
	  ○ Low IgG levels (below the laboratory reference range lower limit of normal) AND a history of multiple hard to treat infections as indicated by at least one of the following:
	  ▪ Four or more ear infections within 1 year
	  ▪ Two or more serious sinus infections within 1 year
	  ▪ Two or more months of antibiotics with little effect
	  ▪ Two or more pneumonias within 1 year
	  ▪ Recurrent or deep skin abscesses
	  ▪ Need for intravenous antibiotics to clear infections
	  ▪ Two or more deep-seated infections including septicemia
	• Documentation showing a deficiency in producing antibodies in response to vaccination including all the following:
	  ○ Titers that were drawn before challenging with vaccination
	  ○ Titers that were drawn between 4 and 8 weeks after vaccination

Appropriate Treatment Regimen & Other Criteria:	• Meets all criteria for IVIG approval • Exceptions may be given for patients without prior intravenous (IV) or subcutaneous (SC) immune globulin use • Documentation of at least 3 months of IVIG therapy **<u>Renewal Criteria</u>** • Renewal requires documented disease response defined as a decrease in the frequency or severity of infections
Exclusion Criteria:	• IgA deficiency with antibodies to IgA • History of hypersensitivity to immune globulin or product components • Hyperprolinemia type I or II
Age Restriction:	• PID: 2 years of age and older

Prescriber/Site of Care Restrictions:	• PID: prescribed by, or in consultation with, an immunologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SUTIMLIMAB
Affected Medications: ENJAYMO (sutimlimab-jome)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of hemolysis in adults with cold agglutinin disease (CAD)

Required Medical Information:	**Cold Agglutinin Disease (CAD)**
	• Documentation of current weight
	• Diagnosis of CAD as confirmed by all the following:
	  ○ Chronic hemolysis as confirmed by hemoglobin level of 10 g/dL or less AND elevated indirect bilirubin level
	  ○ Positive monospecific direct antiglobulin test (DAT) or Coombs test for C3d
	  ○ A positive DAT or Coombs test for IgG of 1+ or less
	  ○ Cold agglutinin titer of greater than or equal to 64 at 4°C

Appropriate Treatment Regimen & Other Criteria:	**Cold Agglutinin Disease (CAD)**
	• Dosing:
	  ○ 39 kg to less than 75 kg: 6,500 mg/dose
	  ○ 75 kg or greater: 7,500 mg/dose
	  ○ Administered weekly for the first two weeks, then every two weeks thereafter.
	
	Reauthorization: documentation of disease responsiveness to therapy (e.g., increased hemoglobin, normalized markers of hemolysis [bilirubin, lactate dehydrogenase, reticulocyte count], reduced blood transfusion requirements)

Exclusion Criteria:	• Disease secondary to infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy • Concomitant use of rituximab with or without cytotoxic agents
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SUZETRIGINE
Affected Medications: JOURNAVX (suzetrigine)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of moderate to severe acute pain in adults
Required Medical Information:	**Documentation of all the following:** • Use for a new episode of moderate to severe acute pain (such as a recent surgery or acute injury). • One of the following: A) In a non-surgical setting, member has tried and failed two prescription medications (such as NSAIDs like ibuprofen or opioids such as hydrocodone/acetaminophen) for the current pain episode, OR B) Following surgery: a) Member has received suzetrigine in the perioperative setting, OR b) Member has a history of or is at high risk for substance use disorder. • Suzetrigine will not be used in combination with opioids. **Dosing**: In accordance with FDA-approved labeling, not to exceed a 14-day treatment course for any one acute pain episode.
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization**: No reauthorization is allowed for extended (or repeat) treatment courses for the same acute pain episode. New requests should include the new cause and/or new location of pain.
Exclusion Criteria:	• Use for chronic pain • Use for neuropathy
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• Authorization: 1 month, unless otherwise specified

POLICY NAME:
TAGRAXOFUSP-ERZS
Affected Medications: ELZONRIS (tagraxofusp-erzs)

Covered Uses:	• Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients at least 2 years of age • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better

Required Medical Information:	• Diagnosis of BPDCN is confirmed by **ALL** the following:
	  ○ A biopsy showing the morphology of plasmacytoid dendritic blast cells
	  ○ At least 3 of the following plasmacytoid dendritic cell (pDC) markers are expressed by immunohistochemistry (IHC) or flow cytometry:
	  ▪ CD123
	  ▪ CD4
	  ▪ CD56
	  ▪ TCF4
	  ▪ TCL1
	  ▪ CD303
	  ▪ CD304
	  ○ The following pDC markers are negative: CD3, CD14, CD19, CD34, lysozyme, myeloperoxidase
	  ○ Diagnosis is made by a board-certified hematopathologist or dermatopathologist
	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization:** documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Pregnancy
Age Restriction:	• 2 years of age and older
Prescriber Restrictions:	• Must be prescribed by, or in consultation with, a prescriber experienced in the treatment of BPDCN
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TARPEYO
Affected Medications: BUDESONIDE DELAYED RELEASE CAPSULE 4MG

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression
Required Medical Information:	• Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed with biopsy • Documentation of proteinuria greater than or equal to 1 g/day (with labs taken within 30 days of request) • Documented estimated glomerular filtration rate (eGFR) equal to or greater than 35 mL/min/1.73m^2

Appropriate Treatment Regimen & Other Criteria:	• Persistent proteinuria (greater than or equal to 1 g/day) despite a minimum 12-week trial with **each** of the following:
	  ○ Maximally tolerated angiotensin-converting enzyme (ACE) inhibitor **OR** angiotensin receptor II blocker (ARB)
	  ○ Alternative glucocorticoid therapy, such as prednisone or methylprednisolone (or adverse effect with two or more glucocorticoid therapies, which is not associated with the corticosteroid class)
	  ○ Filspari
	
	No reauthorization – Recommended duration of therapy is 9 months followed by a 2-week dose taper prior to discontinuation

Exclusion Criteria:	• Treatment of other glomerulopathies or nephrotic syndrome
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a nephrologist
Coverage Duration:	• Authorization: 10 months unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TEDIZOLID
Affected Medications: SIVEXTRO injection, SIVEXTRO tablets

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms:
	  ▪ *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates)
	  ▪ *Streptococcus pyogenes*
	  ▪ *Streptococcus agalactiae*
	  ▪ *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*)
	  ▪ *Enterococcus faecalis*

Required Medical Information:	• Documentation of confirmed or suspected diagnosis • Documentation of treatment history and current treatment regimen • Documentation of culture and sensitivity data • Documentation of planned treatment duration

Appropriate Treatment Regimen & Other Criteria:	• Dosing is in accordance with FDA labeling
	
	Requests for the intravenous formulation will require both of the following:
	• Documentation of treatment failure, contraindication, or intolerable adverse event with intravenous linezolid **AND**
	• Documentation of treatment failure, contraindication, or intolerable adverse event with at least 2 of the following drugs/drug classes:
	  ○ Vancomycin
	  ▪ Avoidance of vancomycin due to nephrotoxicity will require documentation of multiple (at least 2 consecutive) increased serum creatinine concentrations (increase of 0.5 mg/dL [44 mcmol/L] or at least 50 percent increase from baseline, whichever is greater), without an alternative explanation
	  ○ Daptomycin
	  ○ Cephalosporin (cefazolin)
	
	Requests for the oral tablet formulation will require both of the following:
	• Documentation of treatment failure, contraindication, or intolerable adverse event with oral linezolid **AND**
	• Documentation of treatment failure, contraindication, or intolerable adverse event with at least 2 of the following drugs/drug classes:
	  ○ Trimethoprim-sulfamethoxazole
	  ○ Tetracycline (doxycycline, minocycline)
	  ○ Clindamycin

Exclusion Criteria:	
Age Restriction:	

Prescriber Restrictions:	
Coverage Duration:	• 1 month, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TEDUGLUTIDE
Affected Medications: GATTEX KIT (teduglutide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Short Bowel Syndrome (SBS)
Required Medical Information:	• Documentation of confirmed SBS diagnosis • Dependence on parenteral nutrition (PN) and/or intravenous (IV) fluids at least 12 consecutive months continuously • Receiving three or more days per week of parenteral nutrition (PN) support such as fluids, electrolytes, and/or nutrients

Appropriate Treatment Regimen & Other Criteria:	• Documentation of unable to be weaned from PN despite use of the following conventional measures:
	  ○ Dietary manipulations, oral rehydration solutions
	  ○ Antidiarrheal/motility agents: loperamide or diphenoxylate
	  ○ Antisecretory agents: H2 receptor antagonists or proton pump inhibitors
	OR
	• Developed significant complications or severe impairment in quality of life related to parenteral nutrition use (such as loss of vascular access sites, recurrent catheter-related bloodstream infections, and liver disease)
	
	• Dose does not exceed 0.05 mg/kg daily
	
	Reauthorization: requires documentation of clinically significant benefit defined by parenteral support reduction of 1 day or greater a week

Exclusion Criteria:	• Weight of less than 10 kg • Onset or worsening of gallbladder/biliary disease • Onset or worsening of pancreatic disease • Presence of any gastrointestinal malignancy • Presence of intestinal or stomal obstruction
Age Restriction:	• 1 year of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a gastroenterologist or SBS specialist
Coverage Duration:	• Approval: 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TENOFOVIR ALAFENAMIDE
Affected Medications: Vemlidy tablet

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ For the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 6 years of age and older with compensated liver disease
Required Medical Information:	• Diagnosis of chronic hepatitis B infection • Documentation of compensated liver disease (Child-Pugh A) within 12 weeks prior to anticipated start of therapy

Appropriate Treatment Regimen & Other Criteria:	• Documentation of one or more of the following:
	  ○ Inadequate virologic response or intolerable adverse event to tenofovir disoproxil fumarate
	  ○ CrCl less than or equal to 80 mL/min within 12 weeks prior to anticipated start date OR high risk for acute renal injury (i.e., nephrotoxic medications)
	  ○ Diagnosis of osteoporosis or osteopenia OR high risk (i.e., chronic use of steroids or other drugs that worsen bone density, poor nutrition, early menopause)
	
	Reauthorization: documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Decompensated hepatic impairment (Child-Pugh B or C)
Age Restriction:	• 6 years of age or older
Prescriber Restrictions:	• Must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration:	• Approval duration: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TEPROTUMUMAB-TRBW
Affected Medications: TEPEZZA (teprotumumab-trbw)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Thyroid Eye Disease (TED) regardless of TED activity or duration

Required Medical Information:	• Documentation that baseline disease is under control prior to starting therapy, as defined by one of the following:
	  ○ Patient is euthyroid (thyroid function tests are within normal limits)
	  ○ Patient has recent and mild hypo- or hyperthyroidism (thyroid function tests show free thyroxine (T4) and free triiodothyronine (T3) levels less than 50% above or below normal limits) and will undergo treatment to maintain euthyroid state
	• TED has an appreciable impact on daily life, defined as:
	  ○ Proptosis greater than or equal to 3-mm increase from baseline (prior to diagnosis of TED) and/or proptosis greater than or equal to 3 mm above normal for race and gender
	  OR
	  ○ Current moderate-to-severe active TED with a Clinical Activity Score (CAS) greater than or equal to 4 (on the 7-item scale) for the most severely affected eye and symptoms such as: lid retraction greater than or equal to 3 mm, moderate or severe soft tissue involvement, diplopia, and/or proptosis greater than or equal to 3 mm above normal for race and gender

Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced • Evidence of stable, well-controlled disease if comorbid inflammatory bowel disease (IBD) or diabetes • Documented failure to intravenous or oral steroid at appropriate dose over 12 weeks
Exclusion Criteria:	• Use of more than one course of Tepezza treatment • Prior orbital irradiation, orbital decompression, or strabismus surgery • Decreasing visual acuity, new defect in visual field, color vision defect from optic nerve involvement within the previous 6 months • Corneal decompensation that is unresponsive to medical management
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an ophthalmologist
Coverage Duration:	• Authorization: 7 months, maximum approval (total of 8 doses) with no reauthorization, unless otherwise specified

POLICY NAME:
TEPLIZUMAB-MZWV
Affected Medications: TZIELD (teplizumab-mzwv)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Type 1 diabetes mellitus, to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients with Stage 2 type 1 diabetes

Required Medical Information:	• Diagnosis of Stage 2 type 1 diabetes, confirmed by both of the following:
	  ○ Positive for two or more of the following pancreatic islet cell autoantibodies within the past 6 months:
	  ▪ Glutamic acid decarboxylase 65 (GAD) autoantibodies
	  ▪ Insulin autoantibody (IAA)
	  ▪ Insulinoma-associated antigen 2 autoantibody (IA-2A)
	  ▪ Zinc transporter 8 autoantibody (ZnT8A)
	  ▪ Islet cell autoantibody (ICA)
	  ○ Dysglycemia on oral glucose tolerance testing (OGTT) within the past 6 months, as shown by one of the following:
	  ▪ Fasting blood glucose between 110 mg/dL and 125 mg/dL
	  ▪ 2 hour glucose greater than or equal to 140 mg/dL and less than 200 mg/dL
	  ▪ 30, 60, or 90 minute value on OGTT greater than or equal to 200 mg/dL on two separate occasions
	• Documentation that the patient has a first-degree or second-degree relative with type 1 diabetes and one of the following:
	  ○ If first-degree relative (brother, sister, parent, offspring), patient must be between 8 and 45 years of age
	  ○ If second-degree relative (niece, nephew, aunt, uncle, grandchild, cousin), patient must be between 8 and 20 years of age
	• Documentation of the patient's current body surface area (BSA) or height and weight to calculate BSA
	• Treatment plan, including planned dose and frequency

Appropriate Treatment Regimen & Other Criteria:	**Approved for one-time 14-day infusion only, based on the following dosing schedule:** Treatment Day: Dose Day 1: 65 mcg/m^2 Day 2: 125 mcg/m^2 Day 3: 250 mcg/m^2 Day 4: 500 mcg/m^2 Days 5 - 14: 1,030 mcg/m^2 • Availability: 2 mg/2 mL (1 mg/mL) single-dose vials • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
Exclusion Criteria:	• Prior treatment with Tzield • Diagnosis of Stage 3 type 1 diabetes (clinical type 1 diabetes) • Diagnosis of Type 2 diabetes • Current active serious infection or chronic infection

	• Pregnant or lactating
Age Restriction:	• 8 to 45 years of age • See Required Medical Information for age requirements based on first-degree or second-degree relative
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist
Coverage Duration:	• Authorization: 3 months, unless otherwise specified (one 14-day infusion only)

PacificSource Community Solutions

POLICY NAME:
TESTOSTERONE
Affected Medications: Testopel (testosterone pellets), Testosterone gel, Jatenzo capsules (testosterone undecanoate capsules), Tlando (testosterone undecanoate capsules), Azmiro (testosterone cypionate pre-filled syringe)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism or hypogonadotropic hypogonadism • Gender dysphoria

Required Medical Information:	**<u>All Indications:</u>**
	• If 65 years of age and older, must provide documentation of a yearly evaluation that includes ALL the following:
	  ○ The need for continued hormone replacement therapy
	  ○ Education on the risks of hormone replacement therapy (heart attack, stroke)
	  ○ Discussion about the limited efficacy and safety for hormone replacement therapy in patients experiencing an age-related decrease in testosterone levels
	
	<u>Hypogonadism in Adults</u>
	• Confirmed low testosterone level (total testosterone less than 300 ng/dl or morning free or bioavailable testosterone less than 5 ng/dL) or absence of endogenous testosterone
	
	<u>Gender Dysphoria</u>
	• Documented diagnosis of gender dysphoria
	• If under 18 years of age, documentation of all the following:
	  ○ Current Tanner stage 2 or greater OR baseline and current estradiol and testosterone levels to confirm onset of puberty
	  ○ Confirmed diagnosis of gender dysphoria that is persistent
	  ○ The patient has the capacity to make a fully informed decision and to give consent for treatment
	  ○ Any significant medical or mental health concerns are reasonably well controlled
	  ○ A comprehensive mental health evaluation has been completed by a licensed mental health professional (LMHP) and provided in accordance with the most current version of the World Professional Association for Transgender Health (WPATH) Standards of Care
	  ○ Note: For requests following pubertal suppression therapy, an updated or new comprehensive mental health evaluation must be provided prior to initiation of hormone supplementation

Appropriate Treatment Regimen & Other Criteria:	**STEP 1 MEDICATIONS:** Testosterone injections
	
	STEP 2 MEDICATIONS: Transdermal testosterone, Tlando, and Jatenzo capsules
	• Approval requires documented failure, intolerance, or clinical rationale for avoidance of the testosterone injections
	
	STEP 3 MEDICATIONS: Testopel, Azmiro
	• Approval requires documented treatment failure with each of the following:
	  ○ testosterone injection
	  ○ generic transdermal testosterone
	  ○ oral testosterone (e.g. Tlando, Jatenzo)
	• Testopel dosage (in milligrams) or number of pellets to be administered and frequency

	○ Maximum of 450 mg per treatment **<u>Reauthorization:</u>** • Hypogonadism in Adults: Documentation of a recent testosterone level within normal limits • Gender Dysphoria: Documentation of treatment success
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Gender dysphoria: Diagnosis made and prescribed by, or in consultation with, a specialist in the treatment of gender dysphoria
Coverage Duration:	**<u>Gender Dysphoria:</u>** • Testopel: Maximum of 4 treatments in 12 months, unless otherwise specified • All other formulations: 5 years, unless otherwise specified **<u>All Other indications:</u>** • Testopel: Maximum of 4 treatments in 12 months, unless otherwise specified • All other formulations: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TEZEPELUMAB-EKKO
Affected Medications: TEZSPIRE (tezepelumab-ekko)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Add-on maintenance treatment of patients aged 12 years and older with severe asthma

Required Medical Information:	• Diagnosis of severe asthma defined by the following:
	  ○ For adults: FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal
	  ○ For adolescents aged 12 to 17: FEV1 less than 90% at baseline or FEV1/FVC reduced by at least 5% from normal

Appropriate Treatment Regimen & Other Criteria:	• Documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms AND • A documented history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months while on combination inhaled treatment with at least 80% adherence **Reauthorization:** documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Use in combination with another monoclonal antibody (e.g., Fasenra, Nucala, Xolair, Dupixent, Cinqair)
Age Restriction:	• 12 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
THALIDOMIDE
Affected Medications: THALOMID (thalidomide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved OR compendia-supported indications not otherwise excluded by plan design
	  ○ Multiple Myeloma (MM)
	  ○ Erythema Nodosum Leprosum (ENL)
	  ○ Systemic light chain amyloidosis
	  ○ AIDS-related aphthous stomatitis
	  ○ Waldenström macroglobulinemia
	  ○ Graft-versus-host disease, chronic (refractory)
	• NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or higher

Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course
Appropriate Treatment Regimen & Other Criteria:	**Multiple Myeloma** • NCCN (National Comprehensive Cancer Network) regimen with evidence level of 2A or higher **Systemic light chain amyloidosis** • NCCN (National Comprehensive Cancer Network) regimen with evidence level of 2A or higher **Waldenström Macroglobulinemia** • NCCN (National Comprehensive Cancer Network) regimen with evidence level of 2A or higher **AIDS-related or Severe recurrent aphthous stomatitis** • Documented trial and failure with BOTH topical and systemic corticosteroids **Erythema Nodosum Leprosum (ENL)** • Acute treatment of the cutaneous manifestations of moderate to severe ENL (Type 2 reaction) • Maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence **Reauthorization:** Documentation of disease responsiveness to therapy
Exclusion Criteria:	• Pregnancy • Karnofsky Performance Status less than or equal to 50% or ECOG performance score greater than or equal to 3
Age Restriction:	• 12 years of age or older

Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist or infectious disease specialist
Coverage Duration:	• Initial authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
THICK-IT
Affected Medications: THICK-IT ORIGINAL POWDER, THICK-IT #2, THICK-IT LIQUID

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Dysphagia
	  ○ Swallowing disorder

Required Medical Information:	• Documentation of esophageal or throat dysfunction that compromises ability to safely consume food or liquids **OR** • Documentation of high risk for aspiration pneumonia
Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Maintained on enteral or parenteral nutrition
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

POLICY NAME:
TILDRAKIZUMAB
Affected Medications: ILUMYA PREFILLED SYRINGE

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Plaque Psoriasis (PP)

Required Medical Information:	**Plaque Psoriasis**
	• Documentation that the skin disease is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) 11 or greater
	  ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	AND
	• Documentation of one or more of the following:
	  ○ At least 10% body surface area involvement despite current treatment
	OR
	  ○ Hand, foot, or mucous membrane involvement

Appropriate Treatment Regimen & Other Criteria:	**Plaque Psoriasis**
	• Documented treatment failure with 12 weeks of at least TWO systemic therapies: methotrexate, cyclosporine, acitretin, phototherapy [UVB, PUVA]
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis)
	  AND
	  ○ One of the following: Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek)
	
	QL
	• PP: 100 mg at week 0 and 4, followed by every 12 weeks
	
	Reauthorization
	• Documentation of treatment success and clinically significant response to therapy

Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a dermatologist
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

POLICY NAME:
TOBRAMYCIN INHALATION
Affected Medications: TOBI PODHALER (tobramycin inhalation powder), tobramycin nebulized solution, KITABIS PAK (tobramycin), BETHKIS (tobramycin), Tobi (tobramycin)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
Required Medical Information:	• Diagnosis of Cystic Fibrosis (CF) (phenotyping not required). • Culture and sensitivity report confirming presence of pseudomonas aeruginosa in the lungs • For Tobi Podhaler: Baseline forced expiratory volume in 1 second (FEV1) equal to or greater than 25% but equal to or less than 80% • For Bethkis: Baseline FEV1 equal to or greater than 40% but equal to or less than 80% • For Kitabis Pak: Baseline FEV1 equal to or greater than 25% but equal to or less than 75%
Appropriate Treatment Regimen & Other Criteria:	• For Tobi Podhaler, Kitabis Pak, Bethkis, and Tobi: Documentation of failure with nebulized tobramycin or clinical rationale for avoidance • Use is limited to 28 days on and 28 days off regimen • **Reauthorization** requires documentation of improved respiratory symptoms and need for long-term use
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pulmonologist or provider who specializes in CF
Coverage Duration:	• 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TOCILIZUMAB
Affected Medications: ACTEMRA INTRAVENOUS (IV), ACTEMRA ACTPEN AUTO-INJECTOR, ACTEMRA PREFILLED SYRINGE, TOFIDENCE (IV), TYENNE (IV), TYENNE PREFILLED SYRINGE, TYENNE AUTO-INJECTOR

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis (RA)
	  ○ Giant Cell Arteritis (GCA)
	  ○ Polyarticular Juvenile Idiopathic Arthritis (PJIA)
	  ○ Systemic Juvenile Idiopathic Arthritis (SJIA)
	  ○ Cytokine Release Syndrome (CRS)
	  ○ Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Required Medical Information:	**Rheumatoid Arthritis**
	• Documentation of current disease activity with one of the following (or equivalent objective scale)
	  ○ Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted Routine Assessment of Patient Index Data 3 (RAPID3) of at least 2.3
	
	Giant Cell Arteritis
	• Confirmed diagnosis of GCA based on:
	  ○ Temporal artery biopsy
	  ○ Color doppler ultrasound
	OR
	• Confirmed diagnosis of large vessel GCA based on:
	  ○ Vascular tree imaging computed tomography (CT), magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), positron emission tomography (PET) or PET with CT
	
	Cytokine Release Syndrome
	• Documentation of previous chimeric antigen receptor (CAR) T cell therapy treatment plan
	• Documentation of active cytokine release syndrome
	
	Polyarticular Juvenile Idiopathic Arthritis
	• Documentation of current level of disease activity with physician global assessment (MD global score) or active joint count
	
	Systemic Sclerosis-Associated Interstitial Lung Disease
	• Documentation of diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease from the American College of Rheumatology / European League Against Rheumatism classification criteria with the following:
	  ○ Documentation of onset of disease (first non-Raynaud symptom) of less than 7 years
	  ○ SSc-ILD confirmed by a chest high resolution computed tomography (HRCT) scan conducted within the previous 12 months.
	  ○ Documentation of baseline observed forced vital capacity (FVC) and percent predicted forced vital capacity (ppFVC)

Appropriate Treatment	**All Indications** • Coverage of Actemra IV requires documentation of the following:

PacificSource Community Solutions

Regimen & Other Criteria:	○ A documented intolerable adverse event to the preferred products, Tyenne IV, Tofidence IV and the adverse event was not an expected adverse event attributed to the active ingredient **Rheumatoid Arthritis** • Documented failure with at least 12 weeks of treatment with methotrexate ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide) • Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with tocilizumab intravenous formulation **Giant Cell Arteritis and Cytokine Release Syndrome** • Documentation of disease refractory to glucocorticoid treatment • Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with tocilizumab intravenous formulation **Polyarticular Juvenile Idiopathic Arthritis** • Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide • Documented failure with glucocorticoid joint injections or oral corticosteroids • Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with tocilizumab intravenous formulation **Systemic Sclerosis-Associated Interstitial Lung Disease** • Documented treatment failure or intolerable adverse event with mycophenolate and cyclophosphamide **QL** • **Intravenous** ○ RA: 4 mg/kg every 4 weeks; may increase to 8 mg/kg every 4 weeks based on clinical response (maximum 800 mg/dose) ○ GCA: 6 mg/kg every 4 weeks ○ CRS: ▪ <30 kg: 12 mg/kg once, may repeat every 8 hours (maximum 4 doses) ▪ ≥30 kg: 8 mg/kg once (maximum 800 mg/dose), may repeat every 8 hours (maximum 4 doses) ○ PJIA: ▪ <30 kg: 10 mg/kg every 4 weeks ▪ ≥30 kg: 8 mg/kg every 4 weeks (maximum 800 mg/dose) ○ SJIA: ▪ <30 kg: 12 mg/kg every 2 weeks ▪ ≥30 kg: 8 mg/kg every 2 weeks (maximum 800 mg/dose) ○ Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced • **Subcutaneous** ○ RA: ▪ <100 kg: 162 mg every other week; may increase to 162 mg weekly based on clinical response ▪ ≥100 kg: 162 mg weekly

	○ GCA: 162 mg weekly ○ PJIA ▪ <30 kg: 162 mg every 3 weeks ▪ ≥30 kg: 162 mg every 2 weeks ○ SJIA ▪ <30 kg: 162 mg every 2 weeks ▪ ≥30 kg: 162 mg weekly ○ SSc-ILD: 162 mg weekly **Reauthorization** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/oncologist/pulmonologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TOFACITINIB
Affected Medications: XELJANZ, XELJANZ XR, XELJANZ SOLUTION

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis
	  ○ Psoriatic Arthritis
	  ○ Ulcerative Colitis
	  ○ Polyarticular Juvenile Idiopathic Arthritis (JIA)
	  ○ Ankylosing Spondylitis

Required Medical Information:	**<u>Rheumatoid Arthritis</u>**
	• Documentation of current disease activity with one of the following (or equivalent objective scale)
	  ○ The Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2
	  ○ The Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted RAPID3 of at least 2.3
	
	<u>Psoriatic Arthritis</u>
	• Documentation of CASPAR criteria score of 3 or greater based on chart notes:
	  ○ Skin psoriasis: present – two points, OR previously present by history – one point, OR a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point o Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxtaarticular bone formation on radiographs (distinct from osteophytes): one point
	
	<u>Ulcerative Colitis</u>
	• Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy
	
	<u>Polyarticular Juvenile Idiopathic Arthritis (JIA)</u>
	• Documentation of current level of disease activity with physician global assessment (MD global score) or active joint count
	
	<u>Ankylosing Spondylitis (AS)</u>
	• Diagnosis of axial spondyloarthritis (SpA) confirmed by Sacroiliitis on imaging AND at least 1 Spondyloarthritis (SpA) feature:
	  ○ Inflammatory back pain (4 of 5 features met):
	  ▪ Onset of back discomfort before the age of 40 years
	  ▪ Insidious onset
	  ▪ Improvement with exercise
	  ▪ No improvement with rest
	  ▪ Pain at night (with improvement upon arising)
	  ○ Arthritis
	  ○ Enthesitis
	  ○ Uveitis
	  ○ Dactylitis (inflammation of entire digit)
	  ○ Psoriasis
	  ○ Crohn’s disease/ulcerative colitis

	○ Good response to NSAIDs ○ Family history of SpA ○ Elevated CRP • Documentation of active disease defined by Bath ankylosing spondylitis disease activity index (BASDAI) at least 4 or equivalent objective scale
Appropriate Treatment Regimen & Other Criteria:	**<u>Rheumatoid Arthritis</u>** • Documented failure with at least 12 weeks of treatment with methotrexate ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, hydroxychloroquine, leflunomide) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ One of following: Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis), tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV) **AND** ○ Two of the following: Olumiant, Kevzara, Simponi Aria, Actemra SQ, Kineret, rituximab (preferred biosimilar products Truxima, Riabni, and Ruxience), Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) **<u>Psoriatic Arthritis</u>** • Documented failure with at least 12 weeks of treatment with methotrexate • If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide) • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Simponi Aria, Orencia IV, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **<u>Ulcerative Colitis</u>** • Documented failure with at least two oral treatments for a minimum of 12 weeks: corticosteroids, sulfasalazine, mesalamine, balsalazide, cyclosporine, azathioprine, 6-mercaptopurine **OR** • Documentation of severely active disease despite current treatment defined by greater than or equal to 6 bloody, loose stools per day with severe cramps and evidence of systemic toxicity (fever, tachycardia, anemia, and/or elevated CRP/ESR), or recent hospitalization for ulcerative colitis **AND** • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy: ○ Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis) **AND** ○ One of the following: Entyvio, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) or Ustekinumab (preferred biosimilars: Selarsdi, Yesintek) **<u>Polyarticular Juvenile Idiopathic Arthritis (JIA)</u>** • Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide **AND**

	• Documented failure with glucocorticoid joint injections or oral corticosteroids
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of tocilizumab (preferred biosimilars: Tyenne IV, Tofidence IV) and Simponi Aria
	
	<u>Ankylosing Spondylitis (AS)</u>
	• Documented failure with two daily prescription strength nonsteroidal anti-inflammatory drugs (ibuprofen, naproxen, diclofenac, meloxicam, etc.) with minimum 1 month trial each
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis)
	AND
	  ○ One of the following: Simponi Aria, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz)
	
	<u>QL:</u>
	• Xeljanz tablets (5mg, 10mg): One tablet twice daily
	• Xeljanz XR tablets (11mg, 22mg): One tablet daily
	• Xeljanz Solution: 240 mL/30 days
	
	<u>Reauthorization</u>
	• Documentation of treatment success and clinically significant response to therapy

Exclusion Criteria:	• Concurrent use with any other biologic therapy or Otezla is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/gastroenterologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TOFERSEN
Affected Medications: QALSODY (tofersen)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Amyotrophic lateral sclerosis (ALS) associated with a mutation in the superoxide dismutase 1 (*SOD1*) gene (SOD1-ALS)
Required Medical Information:	• Documentation of "definite" or "probable" ALS diagnosis based on revised El Escorial (Airlie House) or Awaji criteria • Documentation of a confirmed SOD1 genetic mutation • Forced vital capacity (FVC) greater than or equal to 50% as adjusted for age, sex, and height (from a sitting position) • Baseline plasma neurofilament light chain (NfL) value • Patient currently retains most activities of daily living defined as at least 2 points on all 12 items of the ALS functional rating scale-revised (ALSFRS-R)

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success and a clinically significant response to therapy, defined as both of the following:
	  ○ Reduction in plasma NfL from baseline
	  ○ The patient's baseline functional status has been maintained at or above baseline level or not declined more than expected given the natural disease progression
	  ○ Patient is not dependent on invasive mechanical ventilation (e.g., intubation, tracheostomy)

Exclusion Criteria:	
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist, neuromuscular specialist, or specialist with experience in the treatment of ALS
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TOLVAPTAN
Affected Medications: tolvaptan (15 mg, 30 mg)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium less than 125 mEq/L OR less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)
	  ○ To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

Required Medical Information:	**Hyponatremia** • Serum sodium less than 125 mEq/L at baseline **OR** • Serum sodium less than 135 mEq/L at baseline and symptomatic (nausea, vomiting, headache, lethargy, confusion) **ADPKD** • Diagnosis of typical ADPKD confirmed by family history, imaging, and if applicable, genetic testing • Estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73m^2 • High risk for rapid progression determined by Mayo imaging class 1C, 1D, or 1E
Appropriate Treatment Regimen & Other Criteria:	**Hyponatremia** • Treatment is initiated or re-initiated in a hospital setting prior to discharge **ADPKD** • Documentation of intensive blood pressure control with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), unless contraindicated **Reauthorization:** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Patients requiring intervention to raise serum sodium urgently to prevent or treat serious neurological symptoms • Patients who are unable to sense or respond to thirst • Hypovolemic hyponatremia • Anuria • Uncorrected urinary outflow obstruction
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a nephrologist
Coverage Duration:	**Hyponatremia** • Authorization: 1 month (no reauthorization), unless otherwise specified

	ADPKD • Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TOPICAL AGENTS FOR CUTANEOUS T-CELL LYMPHOMA (including Mycosis fungoides and Sézary syndrome)
Affected Medications: VALCHLOR (mechlorethamine topical gel), TARGRETIN (bexarotene gel)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or higher
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Documentation of cutaneous T-cell lymphoma (CTCL), stage and type confirmed by biopsy. • Extent of skin involvement (limited/localized or generalized)

Appropriate Treatment Regimen & Other Criteria:	**Limited/localized skin involvement** (topical bexarotene and mechlorethamine)
	• Documented clinical failure to ALL the following:
	  ○ Topical corticosteroids (high or super-high potency) such as clobetasol, betamethasone, fluocinonide, halobetasol
	  ○ Topical imiquimod
	  ○ Phototherapy
	
	Generalized skin involvement (Topical mechlorethamine only)
	• Documentation of failure or contraindication to at least 1 skin-directed therapy
	
	Reauthorization: documentation of disease responsiveness to therapy

Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Pregnancy
Age Restriction:	• 18 years of age or older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TOPICAL AGENTS FOR SEVERE INFLAMMATORY SKIN DISEASE
Affected Medications: TACROLIMUS OINTMENT (0.1%, 0.03%), PIMECROLIMUS CREAM (1%), CALCIPOTRIENE CREAM (0.005%), VTAMA CREAM (1%), ZORYVE CREAM (0.3%), ZORYVE CREAM (0.15%)

Covered Uses:	• All Food and Drug Administration (FDA)-approved and compendia supported indications not otherwise excluded by plan design
	  ○ Atopic dermatitis (AD)
	  ○ Plaque psoriasis (PP)
	  ○ Vitiligo

Required Medical Information:	**<u>All Ages</u>**
	• Documentation of affected body surface area (BSA) and areas of involvement
	
	<u>Age 21 and above</u>
	• Documentation that the skin disease is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) 11 or greater
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living
	  ○ Significant facial involvement preventing normal social interaction
	• Documentation of one or more of the following:
	  ○ BSA of at least 10%
	  ○ Hand, foot, face, or mucous membrane involvement

Appropriate Treatment Regimen & Other Criteria:	**<u>All Indications</u>**
	• **Tacrolimus ointment, pimecrolimus cream:** Documented treatment failure with emollients and prescription strength topical corticosteroids **OR** facial involvement
	
	<u>Atopic Dermatitis</u>
	• **Zoryve 0.15% cream:** Documented treatment failure with ALL the following:
	  ○ A high or super-high potency topical corticosteroid
	  ○ Minimum 6-week trial with **one** topical calcineurin inhibitor
	  ○ Minimum 12-week trial with **one** systemic therapy: phototherapy, cyclosporine, methotrexate, azathioprine, mycophenolate
	• **Vtama**: Documented treatment failure with ALL the following:
	  ○ A high or super-high potency topical corticosteroid
	  ○ Minimum 6-week trial with **one** topical calcineurin inhibitor
	  ○ Minimum 12-week trial with **one** systemic therapy: phototherapy, cyclosporine, methotrexate, azathioprine, mycophenolate
	  ○ Minimum 4-week trial with Zoryve 0.15% cream
	
	<u>Plaque Psoriasis</u>
	• **Calcipotriene cream:** Documented treatment failure with emollients and prescription strength topical corticosteroids **OR** facial involvement
	• **Zoryve 0.3% cream/foam:** Documented treatment failure with ALL the following:
	  ○ A high or super-high potency topical corticosteroid
	  ○ Calcipotriene cream
	  ○ Minimum 12-week trial with **one** systemic therapy: phototherapy, cyclosporine,

	methotrexate, acitretin
	• **Vtama:** Documented treatment failure with ALL the following:
	  o A high or super-high potency topical corticosteroid
	  o Calcipotriene cream
	  o Minimum 12-week trial with **one** systemic therapy: phototherapy, cyclosporine, methotrexate, acitretin
	  o Minimum 8-week trial with Zoryve 0.3% cream
	
	Reauthorization: Documentation of disease responsiveness to therapy, defined as a decrease in affected BSA from baseline

Exclusion Criteria:	• Atopic dermatitis, plaque psoriasis, or vitiligo not meeting the above criteria is considered a below the line (non-funded) diagnosis per Oregon Health Authority (OHA) for those 21 years of age and older**. Please refer to OHA GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE.**

Age Restriction:	• Tacrolimus ointment 0.03%: 2 years of age and older
	• Tacrolimus ointment 0.1%: 16 years of age and older
	• Vtama: 18 years of age and older (plaque psoriasis)
	• Vtama: 2 years of age and older (atopic dermatitis)
	• Zoryve cream: 6 years of age and older
	• Zoryve foam:
	  o 9 years of age and older (seborrheic dermatitis)
	  o 12 years of age and older (plaque psoriasis)

Prescriber Restrictions:	• Prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
Coverage Duration:	• Initial Authorization: 12 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

POLICY NAME:
TRALOKINUMAB
Affected Medications: ADBRY (tralokinumab)

1. Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #2
2. Is the request to treat a diagnosis according to one of the Food and Drug Administration (FDA)-approved indications? • Treatment of moderate to severe atopic dermatitis in adults	Yes – Go to appropriate section below	No – Criteria not met
Moderate to Severe Atopic Dermatitis		
1. Is there documentation of severe inflammatory skin disease defined as functional impairment as defined by one of the following: ○ Dermatology Life Quality Index (DQLI) 11 or greater ○ Children's Dermatology Life Quality Index (CDLQI) 13 or greater ○ Severe disease on other validated tools ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction	Yes – Document and go to #2	No – Criteria not met
2. Is there a documented body surface area (BSA) effected of at least 10% OR hand, foot or mucous membrane involvement?	Yes – Document and go to #3	No – Criteria not met
3. Is there documented failure of a 4-week trial of a combination of topical moderate to high potency topical steroids and a topical non-steroidal agent?	Yes – Document and go to #5	No – Go to #4
4. Is there documented treatment failure with one of the following for at least 12 weeks: Phototherapy, cyclosporine, azathioprine, methotrexate, mycophenolate?	Yes – Document and go to #5	No – Criteria not met
5. Is the drug prescribed by, or in consultation with, a specialist in the treatment of atopic dermatitis (Such as a dermatologist)?	Yes – Approve up to 6 months	No – Criteria not met
Renewal Criteria		

1. Is there documentation of treatment success and a clinically significant response to therapy as assessed by the prescribing provider?	Yes – Go to #2	No – Criteria not met
2. Is the requested dose within the Food and Drug Administration (FDA)-approved label and PacificSource quantity limitations?	Yes – Approve up to 12 months	No – Criteria not met

Quantity Limitations

- **Adbry**
  - Availability: 150mg/ml prefilled syringes, 300 mg/2mL autoinjectors
  - Dosing:
    - Adults 18 years and older: 600 mg as single dose, then 300 mg every 2 weeks
- If less than 100kg and clear/almost clear is achieved, dosing may be reduced to 300mg every 4 weeks
    - Pediatric patients 12 to 17 years old: 300 mg as a single dose, then 150 mg every 2 weeks

POLICY NAME:
TRASTUZUMAB
Affected Medications: HERCEPTIN IV (trastuzumab), HERCEPTIN HYLECTA SQ (Trastuzumab and hyaluronidase), OGIVRI (trastuzumab-dkst), KANJINTI (trastuzumab-anns), TRAZIMERA (trastuzumab-qyyp), HERZUMA (trastuzumab-pkrb), ONTRUZANT (trastuzumab-dttb), HERCESSI (trastuzumab-strf)

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher

Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and prescribed dosing regimen
	• Documentation of HER2 positivity based on:
	  ○ 3+ score on immunohistochemistry (IHC) testing
	OR
	  ○ Positive gene amplification by Fluorescence in situ hybridization (FISH) test

Appropriate Treatment Regimen & Other Criteria:	• Maximum duration for adjuvant breast cancer therapy is 12 months **<u>All Indications</u>** • Coverage for a non-preferred product (Herceptin or Herceptin Hylecta) requires documentation of the following: ○ A documented intolerable adverse event to **two** preferred products (Kanjinti, Trazimera, Herzuma, Ontruzant, Hercessi, and Ogivri), and the adverse event was not an expected adverse event attributed to the active ingredient **<u>Reauthorization</u>** will require documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist

Coverage Duration:	• For new starts to adjuvant breast cancer therapy – approve 12 months with no reauthorization
	• For all other clinical scenarios:
	  ○ Initial approval: 4 months, unless otherwise specified
	  ○ Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TRIPTORELIN
Affected Medications: TRELSTAR, TRIPTODUR (triptorelin)

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher
	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Prostate Cancer (Trelstar)
	  ○ Central Precocious Puberty (Triptodur)
	• Compendia-supported uses that will be covered
	  ○ Gender Dysphoria

Required Medical Information:	**<u>Central Precocious Puberty (CPP)</u>**
	• Documentation of CPP confirmed by one of the following labs:
	  ○ Elevated basal luteinizing hormone (LH) level greater than 0.2 - 0.3 mIU/L
	  ○ Elevated leuprolide-stimulated LH level greater than 3.3 - 5 IU/L (dependent on type of assay used)
	• Bone age greater than 2 standard deviations (SD) beyond chronological age
	
	<u>Gender Dysphoria</u>
	• Documentation of all the following:
	  ○ Current Tanner stage 2 or greater OR baseline and current estradiol and testosterone levels to confirm onset of puberty
	  ○ Confirmed diagnosis of gender dysphoria that is persistent
	  ○ The patient has the capacity to make a fully informed decision and to give consent for treatment
	  ○ Any significant medical or mental health concerns are reasonably well controlled
	  ○ A comprehensive mental health evaluation has been completed by a licensed mental health professional (LMHP) and provided in accordance with the most current version of the World Professional Association for Transgender Health (WPATH) Standards of Care

Appropriate Treatment Regimen & Other Criteria:	• For all Triptodur requests: ○ Documentation of treatment failure to Lupron (leuprolide) **<u>Reauthorization</u>** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Use as neoadjuvant ADT for radical prostatectomy
Age Restriction:	3. CPP: Age 11 or younger (females), age 12 or younger (males)
Prescriber Restrictions:	• Oncology: prescribed by, or in consultation with, an oncologist • CPP: prescribed by, or in consultation with, a pediatric endocrinologist

Coverage Duration:	• (Oncology) Initial approval: 4 months, unless otherwise specified • CPP Approval/Oncology reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TROFINETIDE
Affected Medications: DAYBUE

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of Rett syndrome (RTT)

Required Medical Information:	• Documented diagnosis of typical RTT (per the revised diagnostic criteria for Rett Syndrome) AND a period of regression followed by recovery or stabilization
	• Documented presence of mutation in the *MECP2* gene
	• Documentation of all the following:
	  ○ Partial or complete loss of acquired purposeful hand skills
	  ○ Partial or complete loss of acquired spoken language
	  ○ Gait abnormalities: Impaired (dyspraxic) or absence of ability
	  ○ Stereotypic hand movements such as hand wringing/squeezing, clapping/tapping, mouthing, and washing/rubbing automatisms
	• Current weight (within past 30 days)
	  ○ Must weigh minimum of 9 kilograms

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of treatment success determined by treating provider
Exclusion Criteria:	• Brain injury secondary to trauma or severe infection • Grossly abnormal psychomotor development in first 6 months of life
Age Restriction:	• 2 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist or provider experienced in the management of Rett syndrome
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TROGARZO
Affected Medications: TROGARZO (ibalizumab-uiyk/IV infusion)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of human immunodeficiency virus type 1 (HIV-1) infection, in combination with other antiretrovirals, in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen

Required Medical Information:	• Documentation of all prior therapies used
	• Documentation of active antiretroviral therapy for at least 6 months
	• Documented resistance to at least one antiretroviral agent from three different classes:
	  ○ Nucleoside reverse-transcriptase inhibitors (NRTIs)
	  ○ Non-nucleoside reverse-transcriptase inhibitors (NNRTIs)
	  ○ Integrase strand transfer inhibitors (INSTIs)
	  ○ Protease inhibitors (PIs)
	• Documentation of current (within the past 30 days) HIV-1 RNA viral load of at least 200 copies/mL

Appropriate Treatment Regimen & Other Criteria:	• Prescribed in combination with an optimized background antiretroviral regimen
	
	<u>Reauthorization</u>:
	• Treatment plan includes continued use of optimized background antiretroviral regimen
	• Documentation of treatment success as evidenced by one of the following:
	  ○ Reduction in viral load from baseline or maintenance of undetectable viral load
	  ○ Absence of postbaseline emergence of ibalizumab resistance-associated mutations confirmed by resistance testing

Exclusion Criteria:	
Age Restriction:	• 18 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease or HIV specialist
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TRYVIO
Affected Medications: TRYVIO (aprocitentan)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of hypertension in combination with other antihypertensive drugs
Required Medical Information:	• Diagnosis of resistant hypertension • Blood pressure remains above target goal (as determined by treating provider) despite adherence to antihypertensive therapies • Documentation of intent to use as an adjunct to current antihypertensive therapies

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with concurrent use of at least four antihypertensive drugs (from different drug classes) at maximum tolerated doses, for a minimum of 12 weeks:
	  ○ Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin II receptor blocker (ARB)
	  ○ Calcium channel blocker (e.g. amlodipine, nifedipine, diltiazem, verapamil)
	  ○ Diuretic (e.g. hydrochlorothiazide, chlorthalidone)
	  ○ Beta-blocker (e.g. atenolol, carvedilol)
	  ○ Mineralocorticoid receptor antagonist (e.g. spironolactone, eplerenone)
	
	Reauthorization requires documentation of treatment success and continued use of at least three background blood pressure therapies

Exclusion Criteria:	• Pregnancy • Concurrent use with an endothelin receptor antagonist (e.g. ambrisentan, bosentan, Opsumit, Filspari)
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a cardiologist, nephrologist, or endocrinologist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TTR STABILIZERS
Affected Medications: VYNDAQEL (tafamidis meglumine 20 mg), VYNDAMAX (tafamidis 61 mg), ATTRUBY (acoramidis hydrochloride)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of wild type or hereditary transthyretin amyloid cardiomyopathy (ATTR-CM) to reduce cardiovascular mortality and cardiovascular-related hospitalizations in adults
Required Medical Information:	• Diagnosis of ATTR-CM supported by **ONE** of the following (a, b, or c): d. Cardiac tissue biopsy confirms presence of ATTR amyloid deposits by immunohistochemistry (IHC) or mass spectrometry e. Documentation of **BOTH** of the following (i and ii): i. Noncardiac tissue biopsy confirms presence of ATTR amyloid deposits by IHC or mass spectrometry ii. Imaging consistent with cardiac amyloidosis (echocardiogram [ECG], cardiac magnetic resonance [CMR], or positron emission tomography [PET]) f. Documentation of **ALL** the following (i, ii, and iii): i. Grade 2 to 3 uptake on cardiac scintigraphy (utilizing Tc-PYP, Tc-DPD, or Tc-HMDP radiotracers) ii. Normal serum kappa/lambda free light chain (sFLC) ratio, serum protein immunofixation, **AND** urine protein immunofixation iii. Imaging consistent with cardiac amyloidosis (ECG, CMR, or PET) • Documentation of New York Heart Association (NYHA) Functional Class I to III
Appropriate Treatment Regimen & Other Criteria:	Coverage for Vyndaqel or Vyndamax is provided when the following is met: • Documented treatment failure with Attruby (acoramidis) **Reauthorization** requires documentation of disease responsiveness (improvement in symptoms, quality of life, or 6-Minute Walk Test; slowing or stabilization of disease progression; reduced cardiovascular-related hospitalizations, etc.)
Exclusion Criteria:	• NYHA Functional Class IV heart failure • Presence of light-chain (primary) amyloidosis • Prior liver or heart transplant • Implanted cardiac mechanical assist device • Combined use with another TTR stabilizer or TTR silencer (such as eplontersen, patisiran, vultrisiran)
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or specialist experienced in the treatment of amyloidosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TUCATINIB
Affected Medications: Tukysa (tucatinib)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Documentation of RAS wild-type, HER2 (human epidermal growth factor receptor-2) - positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan based chemotherapy **OR** • Advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer, with prior treatment of 1 or more anti-HER2-based regimens in the metastatic setting.
Appropriate Treatment Regimen & Other Criteria:	**Colorectal cancer** • Documented intolerable adverse event to both preferred products Lapatinib and Pertuzumab **Reauthorization:** documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Colorectal cancer ONLY: previous treatment with a HER2 inhibitor
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TYVASO
Affected Medications: TYVASO (treprostinil), TYVASO REFILL, TYVASO STARTER, TYVASO DPI

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO) Group 1
	  ○ Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO) Group 3

Required Medical Information:	**<u>Pulmonary arterial hypertension (PAH) WHO Group 1</u>**
	• Documentation of PAH confirmed by right-heart catheterization meeting the following criteria:
	  ○ Mean pulmonary artery pressure of at least 20 mm Hg
	  ○ Pulmonary capillary wedge pressure less than or equal to 15 mm Hg
	  ○ Pulmonary vascular resistance of at least 2.0 Wood units
	• Etiology of PAH: idiopathic PAH, hereditary PAH, OR
	• PAH secondary to one of the following conditions:
	  ○ Connective tissue disease
	  ○ Human immunodeficiency virus (HIV) infection
	  ○ Drugs
	  ○ Congenital left to right shunts
	  ○ Schistosomiasis
	  ○ Portal hypertension
	• New York Heart Association (NYHA)/World Health Organization (WHO) Functional Class III or higher symptoms
	• Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blockers) unless there are contraindications:
	  ○ Low systemic blood pressure (systolic blood pressure less than 90)
	  ○ Low cardiac index OR
	  ○ Presence of severe symptoms (functional class IV)
	
	<u>Pulmonary Hypertension Associated with Interstitial Lung Disease WHO GROUP 3</u>
	• Documentation of diagnosis of idiopathic pulmonary fibrosis confirmed by presence of usual interstitial pneumonia (UIP) or high-resolution computed tomography (HRCT), and/or surgical lung biopsy **OR**
	• Pulmonary fibrosis and emphysema **OR**
	• Connective tissue disorder

Appropriate Treatment Regimen & Other Criteria:	• The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition
	• Documentation that treprostinil is used as a single route of administration (Remodulin, Tyvaso, Orenitram should not be used in combination)
	
	<u>WHO Group 1 only:</u>
	• Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out
	• Treatment with combination of endothelin receptor antagonist (ERA) and phosphodiesterase 5 (PDE-5) inhibitor has been tried and failed for WHO Functional Class II and III
	  ○ Ambrisentan and tadalafil
	  ○ Bosentan and riociguat
	  ○ Macitentan and sildenafil

	<u>Reauthorization</u> requires documentation of treatment success defined as one or more of the following: • Improvement in walking distance • Improvement in exercise ability • Improvement in pulmonary function • Improvement or stability in WHO functional class
Exclusion Criteria:	• PAH secondary to pulmonary venous hypertension such as (left sided atrial or ventricular disease, left sided valvular heart disease, etc) or disorders of the respiratory system such as (chronic obstructive pulmonary disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• Initial coverage: 6 months unless otherwise specified • Subsequent coverage: 12 months unless otherwise specified

POLICY NAME:
UBLITUXIMAB-XIIY
Affected Medications: BRIUMVI (Ublituximab-xiiy)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
	  ○ Treatment of relapsing forms of multiple sclerosis (MS), including the following:
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive multiple sclerosis (SPMS)

Required Medical Information:	**RRMS** • Diagnosis confirmed with magnetic resonance imaging (MRI), per revised McDonald diagnostic criteria for MS ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS **CIS** • Documentation of a monophasic clinical episode, with patient-reported symptoms and corresponding objective clinical evidence as follows: One or more T2-hyperintense lesions that are characteristic of MS in at least two of four MS-typical regions (periventricular, cortical or juxtacortical, infratentorial brain regions, and the spinal cord) **Active SPMS** • Documented history of RRMS, followed by gradual and persistent worsening in neurologic function over at least 6 months (independent of relapses) • Evidence of active SPMS, as shown by ongoing clinical relapses and/or inflammatory activity (i.e., gadolinium enhancing lesions OR new or enlarging lesions) • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5

Appropriate Treatment Regimen & Other Criteria:	• Coverage of Briumvi requires documentation of one of the following:
	  ○ Documented disease progression or intolerance to rituximab (preferred products: Truxima, Riabni, Ruxience)
	  ○ Currently receiving treatment with Briumvi, excluding via samples or manufacturer's patient assistance programs
	• No concurrent use of disease-modifying medications indicated for the treatment of MS
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization requires documentation of treatment success

Exclusion Criteria:	• Active hepatitis B infection
Prescriber/Site of Care Restrictions	• Prescribed by, or in consultation with, a neurologist or an MS specialist
Coverage Duration	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
USTEKINUMAB
Affected Medications: SELARSDI IV, YESINTEK IV, PYZCHIVA IV, STEQEYMA IV, WEZLANA IV, OTULFI IV, IMULDOSA IV, STELARA IV, SELARSDI, YESINTEK

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis (PP)
	  ○ Psoriatic Arthritis (PsA)
	  ○ Crohn's Disease (CD)
	  ○ Ulcerative Colitis (UC)

Required Medical Information:	**<u>Plaque Psoriasis</u>**
	• Documentation that the skin disease is severe in nature, which has resulted in functional impairment as defined by one of the following:
	  ○ Dermatology Life Quality Index (DLQI) of greater than or equal to 11
	  ○ Children's Dermatology Life Quality Index (CDLQI) greater than or equal to 13
	  ○ Severe disease on other validated tools
	  ○ Inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction
	• Documentation of one or more of the following:
	  ○ At least 10% body surface area involvement; or
	  ○ Hand, foot, or mucous membrane involvement
	
	<u>Crohn's Disease and Ulcerative Colitis</u>
	• Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy
	• Documentation of moderate to severely active disease despite current treatment
	
	<u>Psoriatic Arthritis</u>
	• Documentation of Classification for Psoriatic Arthritis (CASPAR) criteria score of 3 or greater based on chart notes
	  ○ Skin psoriasis: present – two points, **OR** previously present by history – one point, **OR** a family history of psoriasis, if the patient is not affected – one point
	  ○ Nail lesions (onycholysis, pitting): one point
	  ○ Dactylitis (present or past, documented by a rheumatologist): one point
	  ○ Negative rheumatoid factor (RF): one point
	  ○ Juxta-articular bone formation on radiographs (distinct from osteophytes): one point

Appropriate Treatment Regimen & Other Criteria:	**<u>All Indications:</u>** • Coverage for the non-preferred products, Pyzchiva IV, Steqeyma IV, Wezlana IV, Otulfi IV, Stelara IV, Imuldosa IV is provided when the member meets the following criteria: ○ Documented treatment failure or intolerable adverse event to Selarsdi IV, Yesintek IV **<u>Plaque psoriasis</u>** • Documented treatment failure with 12 weeks of at least TWO systemic therapies: methotrexate, cyclosporine, acitretin, phototherapy (UVB, PUVA)

PacificSource Community Solutions

	AND
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis)
	
	<u>Psoriatic Arthritis (PsA)</u>
	• Documented failure with at least 12 weeks of treatment with methotrexate
	  ○ If unable to tolerate methotrexate or contraindications apply, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide)
	AND
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis)
	
	<u>Crohn's Disease</u>
	• Documented treatment failure with at least one oral treatment for a minimum 12-week trial: azathioprine, 6-mercaptopurine, methotrexate, sulfasalazine, balsalazide
	OR
	• Documentation of previous surgical intervention for Crohn's disease
	OR
	• Documentation of severe, high-risk disease on colonoscopy defined by:
	  ○ Fistulizing disease
	  ○ Stricture
	  ○ Presence of abscess/phlegmon
	  ○ Deep ulcerations
	  ○ Large burden of disease including ileal, ileocolonic, or proximal GI involvement
	AND
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis)
	
	<u>Ulcerative Colitis</u>
	• Documented failure with at least two oral treatments for a minimum of 12 weeks: corticosteroids, sulfasalazine, azathioprine, mesalamine, balsalazide, cyclosporine, azathioprine, 6-mercaptopurine
	OR
	• Documentation of severely active disease despite current treatment defined by greater than or equal to 6 bloody, loose stools per day with severe cramps and evidence of systemic toxicity (fever, tachycardia, anemia, and/or elevated CRP/ESR), or recent hospitalization for ulcerative colitis
	AND
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Avsola, Renflexis)
	
	<u>QL</u>
	• **Induction**
	  ○ PP:
	  ▪ <60 kg: 0.75 mg/kg at week 0 and 4
	  ▪ 60-100 kg: 45 mg at week 0 and 4

	▪ >100 kg: 90 mg at week 0 and 4 ○ PsA: 45 mg at week 0 and 4 ▪ <60 kg: 0.75 mg/kg at week 0 and 4 ▪ ≥60 kg: 45 mg at week 0 and 4 ○ PsA with coexistent moderate to severe PP and weight >100 kg: 90 mg at week 0 and 4 ○ CD/UC: A single IV infusion per below: ▪ ≤55 kg: 260 mg ▪ >55-85 kg: 390 mg ▪ > 85 kg: 520 mg • **Maintenance** ○ PP: ▪ <60 kg: 0.75 mg/kg every 12 weeks ▪ 60-100 kg: 45 mg every 12 weeks ▪ >100 kg: 90 mg every 12 weeks ○ PsA: ▪ <60 kg: 0.75 mg/kg every 12 weeks ▪ ≥60 kg: 45 mg every 12 weeks ○ PsA with coexistent moderate to severe PP and weight >100 kg: 90 mg every 12 weeks ○ CD/UC: 90 mg every 8 weeks **<u>Reauthorization</u>** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/dermatologist/gastroenterologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months initiation, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
VAGINAL PROGESTERONE
Affected Medications: FIRST-PROGESTERONE VGS 100 MG, FIRST-PROGESTERONE VGS 200 MG

Covered Uses:	• Prevention of preterm birth in pregnancy

Required Medical Information:	• Documentation of a current pregnancy with one or more risk factor(s) for preterm birth, including but not limited to:
	  ○ Ethnicity (e.g., African American, American Indian/Alaska Native)
	  ○ Lifestyle factors (e.g., smoking, drinking alcohol, using illegal drugs)
	  ○ Being underweight or obese before pregnancy
	  ○ Prior preterm delivery
	  ○ Having multiple gestations (e.g., twins, triplets)
	  ○ Short time period between pregnancies (less than 6 months between a birth and the beginning of the next pregnancy)
	• Documentation of a short cervix (defined as cervical length less than or equal to 25 mm) confirmed by ultrasound
	• Current week of gestation and estimated delivery date

Appropriate Treatment Regimen & Other Criteria:	• May continue until completion of 36 weeks gestation
Exclusion Criteria:	• Treatment of infertility
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a gynecologist or obstetrician
Coverage Duration:	• Up to 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
VALOCTOCOGENE ROXAPARVOVEC-RVOX
Affected Medications: ROCTAVIAN (Medical Benefit only)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Hemophilia A (Factor VIII deficiency)

Required Medical Information:	• Documentation of diagnosis of Hemophilia A
	• Documentation of current testing with negative results for active factor VIII inhibitors on 2 consecutive occasions (at least one week apart within the past 12 months) and is not receiving a bypassing agent (e.g., Feiba)
	• Documentation of baseline circulating level of factor with Factor VIII activity level equal to or less than 1 IU/dL or 1% endogenous factor VIII
	• Evidence of any bleeding disorder NOT related to hemophilia A has been ruled out
	• No detectable antibodies to AAV5 as determined by an FDA-approved / CLIA-compliant test
	• Has received stable dosing of prophylactic Factor VIII replacement therapy on a regular basis for at least 1 year
	• Baseline lab values (must be less than 2 times upper limit of normal):
	  ○ ALT
	  ○ AST
	  ○ Total bilirubin
	  ○ Alkaline phosphatase (ALP)

Appropriate Treatment Regimen & Other Criteria:	**Dosing** 6×10^{13} vector genomes/kg (which is 3 mL/kg) as a single one-time dose
Exclusion Criteria:	• History of or current presence of Factor VIII inhibitors • Prior gene therapy administration • Active Hepatitis B or C infection or other active acute or uncontrolled chronic infection • Cirrhosis • Female gender at birth • Allergy to mannitol
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a hematologist or specialist with experience in the treatment of hemophilia
Coverage Duration:	• Initial Authorization: 2 months (one time infusion)

POLICY NAME:
VARIZIG
Affected Medications: VARIZIG (varicella zoster immune globulin (human) IM injection)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded from benefit design. ○ For postexposure prophylaxis of varicella in high-risk individuals
Required Medical Information:	**Documentation of immunocompromised patient, defined as:** • Newborns of mothers with signs and symptoms of varicella shortly before or after delivery (five days before to two days after delivery) • Hospitalized premature infants born at at least 28 weeks of gestation who are exposed during their hospitalization and whose mothers do not have evidence of immunity • Hospitalized premature infants less than 28 weeks of gestation or who weigh 1000 grams or less at birth and were exposed to varicella during hospitalization, regardless of mother's immunity status to varicella • Immunocompromised children and adults who lack evidence of immunity to varicella • Pregnant women who lack evidence of immunity to varicella ○ Lack evidence of immunity to varicella is defined as: those who are seronegative for varicella zoster antibodies OR those with unknown history of varicella
Appropriate Treatment Regimen & Other Criteria:	• If repeat dose is necessary due to re-exposure, use more than 3 weeks after initial administration
Exclusion Criteria:	• Coagulation disorders
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
VEDOLIZUMAB
Affected Medication: ENTYVIO IV (Vedolizumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Crohn's Disease (CD)
	  ○ Ulcerative Colitis (UC)

Required documentation:	**<u>All Indications:</u>** • Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy • Documentation of moderate to severe disease despite current treatment

Appropriate Treatment Regimen:	**<u>Crohn's Disease</u>**
	• Documentation of **ONE** of the following:
	  ○ Documented treatment failure with at least one oral treatment for a minimum 12 week trial: azathioprine, 6-mercaptopurine, methotrexate, sulfasalazine, balsalazide Documentation of previous surgical intervention for Crohn's disease
	  ○ Documentation of severe, high-risk disease on colonoscopy defined by one of the following:
	  ▪ Fistulizing disease
	  ▪ Stricture
	  ▪ Presence of abscess/phlegmon
	  ▪ Deep ulcerations
	  ▪ Large burden of disease including ileal, ileocolonic, or proximal gastrointestinal involvement
	• Documented treatment failure (or documented intolerable adverse event) with 12 weeks of Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis)
	
	<u>Ulcerative Colitis</u>
	• Documentation of **ONE** of the following:
	  ○ Documented failure with at least two oral treatments for a minimum of 12 weeks: corticosteroids, sulfasalazine, mesalamine, balsalazide, cyclosporine, azathioprine, 6-mercaptopurine
	  ○ Documentation of severely active disease despite current treatment defined by greater than or equal to 6 bloody, loose stools per day with severe cramps and evidence of systemic toxicity (fever, tachycardia, anemia, and/or elevated CRP/ESR), or recent hospitalization for ulcerative colitis
	• Documented treatment failure (or documented intolerable adverse event) with 12 weeks of Infliximab (preferred biosimilar products Inflectra, Avsola, Renflexis)
	
	<u>QL</u>
	• **Initial:** 300 mg IV at weeks 0, 2, and 6
	• **Maintenance:**
	  ○ **IV:** 300 mg every 8 weeks
	• **Dose escalation:** 300 mg IV every 4 weeks
	  ○ Requires documented loss of response after a minimum 6-month trial of 300 mg IV every 8 weeks
	
	<u>Loss of Response</u>
	• Defined as an initial response to therapy (improvement in signs/symptoms of disease) with a subsequent loss of response, which can be shown by any of the following:

	○ Moderate to severe disease evident by mucosal appearance (e.g., per endoscopy, colonoscopy, sigmoidoscopy) ○ Validated clinical indices (e.g., Crohn's Disease Activity Index [CDAI] 220 or greater, Partial Mayo Clinic Score for UC of 5 or greater) ○ New increase in disease activity accompanied by C-reactive protein (CRP) level of 10 mg/mL or greater and/or fecal calprotectin level over 150 mcg/g ○ New increase in disease activity requiring additional therapy (e.g., conventional synthetic disease modifying therapy or systemic corticosteroid) **Reauthorization** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other targeted immune modulator is considered experimental and is not a covered benefit
Age Restriction:	
Provider Restriction:	• Prescribed by, or in consultation with, a gastroenterologist
Approval Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 24 months, unless otherwise specified

POLICY NAME:
VELMANASE ALFA-TYCV
Affected Medications: LAMZEDE

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ The treatment of non-central nervous system manifestations of alpha-mannosidosis
Required Medical Information:	• Diagnosis of alpha-mannosidosis (AM) confirmed by enzyme assay demonstrating alpha-mannosidase activity less than 10% of normal activity • Documentation of symptoms consistent with AM such as hearing impairment, difficulty walking, skeletal abnormalities, or intellectual disabilities
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success such as improvement in motor function, forced viral capacity (FVC), or reduction in frequency of infections
Exclusion Criteria:	• Patients with only central nervous system manifestations and no other symptoms
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, specialist familiar with the treatment of lysosomal storage disorders
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
VERTEPORFIN INJECTION
Affected Medications: VISUDYNE (verteporfin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Treatment of predominantly classic subfoveal choroidal neovascularization (CNV) due to one of the following:
	  ▪ Age-related macular degeneration (AMD)
	  ▪ Pathologic myopia
	  ▪ Presumed ocular histoplasmosis

Required Medical Information:	• Documented diagnosis of subfoveal CNV due to one of the following:
	  ○ Neovascular AMD
	  ○ Pathologic myopia
	  ○ Presumed ocular histoplasmosis
	• Documentation of current body surface area (BSA)

Appropriate Treatment Regimen & Other Criteria:	**<u>Neovascular AMD and Pathologic Myopia</u>** • Documented treatment failure or intolerance following a minimum 3-month trial with Avastin and ranibizumab (preferred products: Byooviz and Lucentis) **Dosing** • 6 mg/m^2 BSA ○ Every 3 month dosing is permitted with evidence of choroidal neovascular leakage (see reauthorization criteria) • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** requires documentation of the following: • Positive response to therapy (e.g., improved or stable visual acuity, reduced central macular thickness) • Evidence of recurrent or persistent leakage on fluorescein angiogram or optical coherence tomography (OCT), performed at least 3 months after the last treatment
Exclusion Criteria:	• Concurrent therapy with vascular endothelial growth factor (VEGF) inhibitors • Treatment of non-neovascular (dry) AMD
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an ophthalmologist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
VIGABATRIN
Affected Medications: SABRIL (vigabatrin), VIGADRONE (vigabatrin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Refractory Complex Partial Seizures (focal seizures with impaired awareness)
	  ○ Infantile spasms

Required Medical Information:	**Infantile Spasms** • Used as monotherapy for pediatric patients (1 month to 2 years of age) **Refractory Complex Partial Seizures (focal seizures with impaired awareness)** • Used as adjunctive therapy only
Appropriate Treatment Regimen & Other Criteria:	**Refractory Complex Partial Seizures (focal seizures with impaired awareness)** • Documentation the patient has tried at least 2 alternative therapies: carbamazepine, phenytoin, levetiracetam, topiramate, oxcarbazepine, or lamotrigine **Reauthorization** will require documentation of treatment success and a reduction in seizure severity, frequency, and/or duration
Exclusion Criteria:	• Use as a first line agent for Complex Partial Seizures (focal seizures with impaired awareness)
Age Restriction:	**Infantile Spasms:** 1 month to 2 years of age **Refractory Complex Partial Seizures (focal seizures with impaired awareness):** greater than 2 years of age
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	**Infantile Spasms** • Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months (or up to 2 years of age), unless otherwise specified **Refractory Complex Partial Seizures (focal seizures with impaired awareness)** • Approval: 12 months, unless otherwise specified

POLICY NAME:
VIJOICE
Affected Medications: VIJOICE (alpelisib)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of severe manifestations of PIK3CA-related overgrowth spectrum (PROS) in patients who require systemic therapy

Required Medical Information:	• Documented diagnosis of PROS, to include any of the following:
	  ○ CLAPOS syndrome
	  ○ CLOVES syndrome
	  ○ Diffuse capillary malformation with overgrowth (DCMO)
	  ○ Dysplastic megalencephaly (DMEG)
	  ○ Facial infiltrating lipomatosis (FIL)
	  ○ Fibroadipose hyperplasia (FAH)/fibroadipose overgrowth (FAO)/ hemihyperplasia multiple lipomatosis (HHML) syndrome
	  ○ Fibroadipose vascular anomaly (FAVA)
	  ○ Hemimegalencephaly (HMEG)
	  ○ Klippel-Trenaunay syndrome (KTS)
	  ○ Lipomatosis of nerve (LON)
	  ○ Megalencephaly-capillary malformation (MCAP) syndrome
	  ○ Muscular hemihyperplasia (HH)
	• Documentation of PIK3CA gene mutation
	• Documentation of clinical manifestations that were assessed by the treating provider as severe or life-threatening and necessitating systemic treatment
	• Documentation that clinical manifestations are a direct result of a lesion that is both of the following:
	  ○ Inoperable, as defined by the treating provider
	  ○ Causing functional impairment
	• Documentation of one or more target lesion(s) identified on imaging within 6 months prior to request, including location(s) and volume of lesion(s)

Appropriate Treatment Regimen & Other Criteria:	• Treatment failure (or intolerable adverse event) with sirolimus for at least 6 months at a dose of at least 2 mg daily in patients with lymphatic, venous, or combined manifestations of disease
	
	• Reauthorization will require documentation of both of the following:
	  ○ Radiological response, defined as greater than or equal to a 20% reduction from baseline in the sum of measurable target lesion volume, confirmed by at least one subsequent imaging assessment
	  ○ Absence of greater than or equal to a 20% increase from baseline in any target lesion, progression of non-target lesions, or appearance of a new lesion

Exclusion Criteria:	• Treatment of PIK3CA-mutated conditions other than PROS
Age Restriction:	• Must be 2 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist with experience in the treatment of PROS

Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
VISTOGARD
Affected Medications: VISTOGARD (uridine triacetate)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ For the emergency treatment of adult and pediatric patients:
	  ▪ Following a fluorouracil or capecitabine overdose regardless of the presence of symptoms, **OR**
	  ▪ Who exhibit early-onset, severe, or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration

Required Medical Information:	• Documentation of fluorouracil or capecitabine administration • Documentation of overdose **OR** early-onset, severe adverse reaction, or life-threatening toxicity
Appropriate Treatment Regimen & Other Criteria:	• Dosing is in accordance with FDA labeling
Exclusion Criteria:	• Non-emergent treatment of adverse events associated with fluorouracil or capecitabine • Use more than 96 hours following the end of fluorouracil or capecitabine administration
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Approval: 7 days, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
VMAT2 INHIBITORS
Affected Medications: tetrabenazine, AUSTEDO (deutetrabenazine), AUSTEDO XR (deutetrabenazine), INGREZZA (valbenazine), INGREZZA SPRINKLE (valbenazine)

Covered Uses:	• All Food and Drug Administration (FDA)-approved and compendia supported indications not otherwise excluded by plan design
	  ○ Chorea associated with Huntington's disease
	  ○ Tardive dyskinesia

Required Medical Information:	**Chorea related to Huntington's Disease**
	• Diagnosis of Huntington's Disease with Chorea requiring treatment
	
	Tardive Dyskinesia
	• Diagnosis of moderate to severe tardive dyskinesia including all of the following:
	  ○ A history of at least one month of ongoing or previous dopamine receptor-blocking agent exposure
	  ○ Presence of dyskinetic or dystonic involuntary movements that developed either while exposed to a dopamine receptor-blocking agent, or within 4 weeks of discontinuation from an oral agent (8 weeks from a depot formulation)
	  ○ Other causes of abnormal movements have been excluded
	• Baseline evaluation of the condition using one of the following:
	  ○ Abnormal Involuntary Movement Scale (AIMS)
	  ○ Extrapyramidal Symptom Rating Scale (ESRS)

Appropriate Treatment Regimen & Other Criteria:	For new start requests for Austedo and Austedo XR: • Documented treatment failure with at least 12 weeks of Ingrezza or Ingrezza Sprinkle (valbenazine) **Tardive Dyskinesia** • Persistent dyskinesia despite dose reduction or discontinuation of the offending agent **OR** • Documented clinical inability to reduce dose or discontinue the offending agent **Reauthorization:** requires documentation of treatment success and a clinically significant response to therapy ○ Tardive Dyskinesia: must include an improvement in AIMS or ESRS score from baseline
Exclusion Criteria:	• Use for Huntington's comorbid with untreated or inadequately treated depression or suicidal ideation • Concomitant use with another VMAT2 inhibitor or reserpine • Hepatic impairment
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist or psychiatrist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
VOCLOSPORIN
Affected Medications: LUPKYNIS CAPSULE 7.9 MG ORAL

1. Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #2
1. Is the request to treat a diagnosis according to the Food and Drug Administration (FDA)-approved indication? a. For use in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis	Yes – Go to appropriate section below	No – Criteria not met
Lupus Nephritis (LN)		
1. Is there documented International Society of Nephrology/Renal Pathology Society (ISN/RPS) biopsy-proven active class III, IV and/or V disease?	Yes – Document and go to #2	No – Criteria not met
2. Are there documented current baseline values (within the last 3 months) for all of the following? a. Estimated glomerular filtration rate (eGFR) b. Urine protein to creatinine ratio (uPCR) c. Blood pressure	Yes – Document and go to #3	No – Criteria not met
3. Is there documented treatment failure with at least 12 weeks of standard therapy with both mycophenolate mofetil (MMF) AND cyclophosphamide?	Yes – Document and go to #4	No – Criteria not met
4. Is there documented treatment failure with at least 12 weeks of IV or subcutaneous Benlysta?	Yes – Document and go to #5	No – Criteria not met
5. Will Lupkynis be used in combination with MMF and corticosteroids or other background immunosuppressive therapy, other than cyclophosphamide?	Yes – Document and go to #6	No – Criteria not met
6. Is the drug prescribed by, or in consultation with, a rheumatologist, immunologist, nephrologist, or kidney specialist?	Yes – Go to #10	No – Criteria not met
7. Is the requested dose within the Food and Drug Administration (FDA)-approved label and PacificSource quantity limitations?	Yes – Approve up to 12 months	No – Criteria not met
Renewal Criteria		

• Is there documentation of treatment success defined as an increase in eGFR, decrease in uPCR, or decrease in flares and corticosteroid use?	Yes – Go to #2	No – Criteria not met
• Is the requested dose within the Food and Drug Administration (FDA)-approved label and PacificSource quantity limitations?	Yes – Approve up to 6 months (lifetime maximum 12 months of therapy)	No – Criteria not met
Quantity Limitations		

• **Lupkynis**
  ○ Starting dose: 23.7 mg twice daily (BID)
  ○ Starting dose must be reduced in the below situations as follows:
  ▪ eGFR 45 mL/min/1.73 m^2 or less at initiation: 15.8mg BID
  ▪ Mild-to-moderate hepatic impairment (Child-Pugh A or B): 15.8mg BID
  ▪ Concomitant use with moderate CYP3A4 inhibitors: 15.8mg in morning and 7.9mg in afternoon.		

PacificSource Community Solutions

POLICY NAME:
VORETIGENE NEPARVOVEC
Affected Medications: LUXTURNA (voretigene neparvovec-rzyl intraocular suspension for subretinal injection)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. ○ Inherited Retinal Dystrophies (IRD) caused by mutations in the retinal pigment epithelium-specific protein 65kDa (RPE65) gene.
Required Medical Information:	• Diagnosis of a confirmed biallelic RPE65 mutation-associated retinal dystrophy (e.g. Leber's congenital amaurosis [LCA], Retinitis pigmentosa [RP], Early Onset Severe Retinal Dystrophy [EOSRD], etc.); **AND** • Genetic testing documenting biallelic mutations of the RPE65 gene; **AND** • Visual acuity of at least 20/800 OR have remaining light perception in the eye(s) receiving treatment **AND** • Visual acuity of less than 20/60 OR a visual field of less than 20 degrees **AND** • Presence of neural retina and a retinal thickness greater than 100 microns within the posterior pole as assessed by optical coherence tomography with AND have sufficient viable retinal cells as assessed by the treating physician
Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Patient has been previously enrolled in clinical trials of gene therapy for retinal dystrophy RPE65 mutations or has previously been treated with gene therapy for retinal dystrophy in the eye(s) receiving treatment • Patient has other pre-existing eye conditions or complicating systemic diseases that would eventually lead to irreversible vision loss and prevent the patient from receiving full benefit from treatment (e.g. severe diabetic retinopathy)
Age Restriction:	• 12 months of age and older
Prescriber Restrictions:	• Ophthalmologist or retinal surgeon with experience providing sub-retinal injections
Coverage Duration:	• Approval: 1 month - 1 injection per eye, per lifetime

PacificSource Community Solutions

POLICY NAME:
VORICONAZOLE
Affected Medications: Voriconazole tablet, Voriconazole Intravenous (IV)

Covered Uses:	• All Food and Drug Administration (FDA)-approved or compendia supported indications not otherwise excluded from benefit design
	  ○ Invasive aspergillosis
	  ○ Candidemia in non-neutropenic patients with the following Candida infections: disseminated skin infections and infections in the abdomen, kidney, bladder wall and wounds
	  ○ Esophageal candidiasis
	  ○ Invasive candidiasis
	  ○ Serious mycosis infections due to Scedosporium apiospermum and Fusarium species
	  ○ Empiric therapy in high-risk patients with febrile neutropenia despite receiving broad-spectrum antibiotic therapy
	  ○ Continuation of therapy for patients started/stabilized on IV or oral voriconazole for a systemic infection
	  ○ Blastomycosis
	  ○ Candida endophthalmitis
	  ○ Infection caused by Talaromyces marneffei in patients with HIV
	  ○ Chronic pulmonary aspergillosis – cavitary or necrotizing

Required Medical Information:	• **All indications:**
	  ○ Susceptibility cultures matching voriconazole activity
	  ▪ Exceptions made for empiric therapy as long as treatment is adjusted when susceptibility cultures are available, and for esophageal candidiasis
	  ○ Documentation of an Oregon Health Authority (OHA) funded condition
	• **Esophageal candidiasis**
	  ○ Documented treatment failure with one other systemic agent (such as fluconazole, IV amphotericin B, itraconazole oral solution)

Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	
Age Restriction:	• 2 years of age or older
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 12 month, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
VOSORITIDE
Affected Medications: VOXZOGO (vosoritide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ To increase linear growth in pediatric patients with achondroplasia with open epiphyses
Required Medical Information:	• Diagnosis of achondroplasia confirmed by molecular genetic testing showing a mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene • Baseline height, growth velocity, and patient weight

Appropriate Treatment Regimen & Other Criteria:	• Documentation of all the following:
	  ○ Evaluation of epiphyses (growth plates) documenting they are open
	  ○ Growth velocity greater than or equal to 1.5 cm/yr
	
	• **<u>Reauthorization:</u>**
	  ○ Evaluation of epiphyses (growth plates) documenting they remain open
	  ○ Growth velocity greater than or equal to 1.5 cm/yr

Exclusion Criteria:	• Hypochondroplasia • Other short stature condition other than achondroplasia • Evidence of growth plate closure
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a pediatric orthopedist, endocrinologist, or a provider with experience in treating skeletal dysplasias
Coverage Duration:	• Initial Authorization: 12 months • Reauthorization: 12 months

PacificSource Community Solutions

POLICY NAME:
VOXELOTOR
Affected Medications: Oxbryta (voxelotor)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. • Oxbryta is indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older.
Required Medical Information:	• Two or more sickle cell-related crises in the past 12 months (defined as acute painful crisis or acute chest syndrome for which there are no explanation other than vaso-occlusive crisis). • Therapeutic failure of 6 month trial on maximum tolerated dose of hydroxyurea or intolerable adverse event to hydroxyurea. • Baseline hemoglobin (Hb) greater than or equal to 5.5 or less than or equal to 10.5 g/dL • Current weight
Appropriate Treatment Regimen & Other Criteria:	• Tablets for oral suspension, must be unable to swallow tablets **Reauthorization** requires documentation of treatment success defined by an increase in hemoglobin of more than 1 gm/dL from baseline or a decrease in the number of sickle cell-related crises.
Exclusion Criteria:	• Receiving regular red-cell transfusion therapy or have received a transfusion in the past 60 days • Have been hospitalized for vaso-occlusive crisis within 14 days of request • Combined use with anti-P selectin monoclonal antibody (crizanlizumab)
Age Restriction:	• Patients aged 4 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Intial approval: 6 months • Reauthorization: 12 months

PacificSource Community Solutions

POLICY NAME:
XEOMIN, DYSPORT, MYOBLOC, and DAXXIFY
Affected Medications: XEOMIN (incobotulinumtoxinA), DYSPORT (AbobotulinumtoxinA), MYOBLOC (RimabotulinumtoxinB), DAXXIFY (daxibotulinumtoxinA-lanm)

Covered Uses:	• All Food and Drug Administration (FDA)-approved and compendia-supported indications not otherwise excluded by plan design
	  ○ Dysport
	  ▪ Focal dystonia (cervical dystonia, blepharospasm, laryngeal spasm, oromandibular dystonia, severe writer's cramp)
	  ▪ Upper/lower limb spasticity
	  ○ Xeomin
	  ▪ Cervical dystonia
	  ▪ Blepharospasm
	  ▪ Upper limb spasticity
	  ○ Myobloc, Daxxify
	  ▪ Cervical dystonia

Required Medical Information:	• Pertinent medical records and diagnostic testing • Complete description of the site(s) of injection • Strength and dosage of botulinum toxin used
Appropriate Treatment Regimen & Other Criteria:	**Dysport** • Approved first-line for focal dystonia, drug-induced orofacial dyskinesia, upper or lower limb spasticity **Xeomin** • **Cervical dystonia and upper limb spasticity:** Documentation of treatment failure with Botox and Dysport • **Blepharospasm:** Documentation of treatment failure with Botox **Myobloc** • **Cervical dystonia:** Documentation of treatment failure with Botox and Dysport **Daxxify** • **Cervical dystonia:** Documentation of treatment failure with Botox, Dysport, and Xeomin **Quantity limitations** • Maximum of 4 treatments per 12 months **Reauthorization** requires documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Headaches/migraines • Hemifacial spasm, sialorrhea, cosmetic procedures: not above the line on the prioritized list
Age Restriction:	• Myobloc, Daxxify: 18 years of age and older
Prescriber Restrictions:	• **Blepharospasm:** Prescribed by, or in consult with, a neurologist, ophthalmologist, or optometrist **Other indications:** Prescribed by, or in consultation with, a neurologist

PacificSource Community Solutions

Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
XGEVA
Affected Medications: XGEVA (denosumab), WYOST (denosumab-bbdz), OSENVELT (denosumab-bmwo), BOMNYTRA (denosumab-bnht)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Giant cell tumor
	  ○ Bone metastases from solid tumors
	  ○ Hypercalcemia of malignancy
	  ○ Multiple myeloma
	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher

Required Medical Information:	• **Giant cell tumor**
	  ○ Unresectable disease or surgical resection would likely result in severe morbidity
	• **Bone metastases from solid tumors**
	• **Hypercalcemia of malignancy**
	  ○ Refractory to bisphosphonate therapy or contraindication
	• **Multiple myeloma**
	  ○ Requires failure of zoledronic acid or pamidronate OR creatinine clearance less than 30mL/min

Appropriate Treatment Regimen:	**Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	• **Giant cell tumor**: Adults and adolescents at least 12 years of age and skeletally mature weighing at least 45 kg • **All other indications**: 18 years of age or older
Provider Restriction:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Approval: 12 months

POLICY NAME:
XIAFLEX
Affected Medications: XIAFLEX (collagenase clostridium histolyticum)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Dupuytren's contracture with a palpable cord
Required Medical Information:	
Appropriate Treatment Regimen:	**Dupuytren's** • Authorization will be limited per joint as follows: One injection per month for a maximum of three injections per cord **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	
Age Restriction:	
Provider Restriction:	
Coverage Duration:	• Dupuytren's: 12 weeks, unless otherwise specified (separate approval is required for each hand)

POLICY NAME:
XIFAXAN
Affected Medications: XIFAXAN (rifaximin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Prevention of hepatic encephalopathy (HE)
	• Compendia-supported uses that will be covered (if applicable)
	  ○ Treatment of HE

Required Medical Information:	• Documentation of complete & current treatment course required. • Previous antibiotic history and documented allergies/hypersensitivity
Appropriate Treatment Regimen & Other Criteria:	**HE:** • Documented treatment failure with at least 1 month of lactulose therapy defined as continued altered mental status or elevated ammonium levels despite adequate upward titration **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	**HE:** • Xifaxan exceeding the recommended dose of two 550 mg tablets daily or 400 mg 3 times daily for the treatment or prevention of hepatic encephalopathy
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	**HE:** • Authorization: 12 months, unless otherwise specified

POLICY NAME:
XURIDEN
Affected Medications: XURIDEN (uridine triacetate)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Hereditary orotic aciduria

Required Medical Information:	• Diagnosis of hereditary orotic aciduria confirmed by **ONE** of the following:
	  ○ Molecular genetic testing confirming biallelic pathogenic mutation in the UMPS gene
	  ○ Urinary orotic acid level above the normal reference range
	  ○ Clinical manifestations consistent with disease such as:
	  ▪ Megaloblastic anemia
	  ▪ Leukopenia
	  ▪ Developmental delays
	  ▪ Failure to thrive

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of treatment success based on **ONE** of the following: • Improvement of hematologic abnormalities such as megaloblastic anemia and leukopenia • Reduction of urinary orotic acid levels
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a metabolic specialist or geneticist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
YONSA
Affected Medications: YONSA (abiraterone)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course
Appropriate Treatment Regimen & Other Criteria:	• A documented inadequate response or intolerable adverse event with the preferred product abiraterone acetate **Reauthorization** will require documentation of disease responsiveness to therapy
Exclusion Criteria:	• Child-Pugh Class C • Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Subsequent approval: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ZANIDATAMAB
Affected Medications: ZIIHERA (zanidatamab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Documentation that Ziihera will be administered as monotherapy • Documentation of previously treated unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive biliary tract cancer (BTC) that has progressed following at least 1 prior systemic therapy • Documentation of HER2 positivity with a score of 3+ on immunohistochemistry (IHC) testing
Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure or intolerable adverse event with Enhertu (fam-trastuzumab deruxtecan) **Reauthorization:** documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ZILUCOPLAN
Affected Medications: ZILBRYSQ (zilucoplan)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

Required Medical Information:	• Diagnosis of generalized Myasthenia Gravis (gMG) confirmed by one of the following:
	  ○ A history of abnormal neuromuscular transmission test
	  ○ A positive edrophonium chloride test
	  ○ Improvement in gMG signs or symptoms with an acetylcholinesterase inhibitor
	• Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
	• Positive serologic test for AChR antibodies
	• MG-Activities of Daily Living (MG-ADL) total score of 6 or greater **OR**
	• Quantitative Myasthenia Gravis (QMG) total score of 12 or greater

Appropriate Treatment Regimen & Other Criteria:	• Currently on a stable dose of at least one gMG therapy (acetylcholinesterase inhibitor, corticosteroid, or non-steroidal immunosuppressive therapy (NSIST)) that will be continued during initial treatment with Zilbrysq.
	
	• Documentation of one of the following:
	  ○ Treatment failure with an adequate trial (one year or more) of at least two immunosuppressive therapies (azathioprine, mycophenolate, tacrolimus, cyclosporine, methotrexate)
	  ○ Has required three or more courses of rescue therapy (plasmapheresis/plasma exchange and/or intravenous immunoglobulin), while on at least one immunosuppressive therapy, over the last 12 months
	
	<u>Reauthorization</u> requires:
	• Documentation of treatment success and clinically significant response to therapy defined as:
	  ○ A minimum 2-point reduction in MG-ADL score from baseline AND
	  ○ Absent or reduced need for rescue therapy compared to baseline
	• That the patient requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity

Exclusion Criteria:	• Current or recent systemic infection within 2 weeks • Concurrent use with other biologics (rituximab, eculizumab, IVIG, etc)
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
ZOPAPOGENE IMADENOVEC-DRBA
Affected Medications: Papzimeos (zopaopgene imadenovec-drba)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ The treatment of adults with recurrent respiratory papillomatosis (RRP)
Required Medical Information:	• Histologically confirmed diagnosis from a CLIA-certified (or comparable) laboratory report • More than or equal to 3 surgeries in the previous 12 months to remove papillomas • Documentation of laryngotracheal papillomas • Documentation of human papillomavirus (HPV) vaccination
Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with bevacizumab or cidofovir
Exclusion Criteria:	• Prior use of Papzimeos (zopapogene imadenovec-drba)
Age Restriction:	
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• Initial Authorization: 12 weeks • Reauthorization: None

PacificSource Community Solutions

POLICY NAME:
ZUSDURI
Affected Medications: ZUSDURI (mitomycin thermal hydrogel)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design • NCCN (National Comprehensive Cancer Network) indications with evidence level of 2A or better
Required Medical Information:	• Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course • Recurrent low-grade intermediate-risk non–muscle-invasive bladder cancer (LG-IR-NMIBC) confirmed by cystoscopy and pathology.
Appropriate Treatment Regimen & Other Criteria:	• Documented recurrence after prior transurethral resection of bladder tumor (TURBT) AND • Clinical justification for TURBT ineligibility (e.g. high anesthesia risk, complex anatomy or prior complications with resection)
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Use in low-risk or high-grade non–muscle-invasive bladder cancer (NMBIC)
Age Restriction:	• 18 years and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an oncologist or urologist
Coverage Duration:	• Initial authorization: 4 months, unless otherwise specified • Reauthorization: None


PacificSource
Community Solutions