PacificSource
Community Solutions

2023 Prior Authorization Criteria

Last Modified: 09/15/2023

PacificSource Community Solutions

2023 Medicaid Preapproval Criteria

POLICY NAME:
ABATACEPT
Affected Medications: ORENCIA, ORENCIA 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 Diseasae (GVHD) Prophylaxis

Required Medical Information:	**Rheumatoid Arthritis**
	• 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
	
	Psoriatic Arthritis
	• 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
	
	Juvenile Idiopathic Arthritis (JIA)
	• 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 treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy:
	  ○ Methotrexate plus sulfasalazine
	  ○ Methotrexate plus hydroxychloroquine
	  ○ Sulfasalazine plus hydroxychloroquine
	  ○ Leflunomide plus sulfasalazine

	○ Leflunomide plus hydroxychloroquine • One of the following: Infliximab (preferred biosimilar products Inflectra, Renflexis, Avsola), Actemra 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, Renflexis, Avsola) • Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with intravenous formulation **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 • Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of two of the following therapies: ○ Actemra 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: Availability: 250 mg single-use vials • RA/PsA: <60kg: 500mg, 60-100kg: 750mg, >100mg: 1000mg at 0, 2, and 4 weeks followed by every 4 weeks thereafter • JIA: 6 years and older and <75kg: 10 mg/kg; 75-100kg: 750mg; >100kg: 1000mg (max dose) at 0, 2, and 4 weeks followed by every 4 weeks thereafter • 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: Availability: 50mg/0.4mL; 87.5mg/0.7mL; 125mg/mL prefilled syringe; 125mg/mL clickjet autoinjector • RA: with or without IV loading dose, followed by 125mg once weekly • PsA: (no IV loading dose) 125mg once weekly • JIA: (no IV loading dose) 10-25kg: 50mg once weekly, 25-50kg: 87.5mg once weekly, 50kg or more: 125mg once weekly
Exclusion Criteria:	• Concurrent use with any other biologic therapy or Otezla 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: 12 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%

Covered Uses:	• 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)

Required Medical Information:	**Severe Acne** For age 21 and above: • Documentation of persistent or recurrent inflammatory nodules and cysts AND ongoing scarring • For Acne Conglobata: Documentation of recurrent abscesses or communicating sinuses **Hidradenitis suppurativa** 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:	**Acne:** **Step 1 agents:** • Clindamycin phosphate solution 1%, clindamycin phosphate gel 1%, clindamycin phosphate lotion 1%, clindamycin phosphate swab 1%, erythromycin solution 2%, erythromycin 2% gel, sulfacetamide lotion 10%, oral antibiotics for treatment of acne (e.g., doxycycline, minocycline) **Step 2 agents:** • Approval requires documented trial and failure with two Step 1 agents • Adapalene gel 0.1%, adapalene gel 0.3%, adapalene-benzoyl peroxide gel 0.1-2.5%, benzoyl peroxide-erythromycin gel 5-3%, dapsone gel 5%, dapsone gel 7.5%, tretinoin cream 0.025%, tretinoin cream 0.05%, tretinoin cream 0.1%, tretinoin gel 0.01%, tretinoin gel 0.025%, tretinoin gel 0.05% **Hidradenitis suppurativa** • 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

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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
	  ○ Rheumatoid Arthritis
	  ○ Psoriatic Arthritis
	  ○ Ankylosing Spondylitis
	  ○ Non-radigraphic axial spondyloarthritis
	  ○ Crohn's Disease
	  ○ Uveitis
	  ○ Juvenile Idiopathic Arthritis
	  ○ Ulcerative Colitis
	  ○ Hidradenitis Suppurativa

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 **Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (NR-axSPA)** • 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 **Ulcerative Colitis** • Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy **Crohn's disease** • Documentation of moderate to severely active disease despite current treatment **Juvenile Idiopathic Arthritis (JIA)** • Documented of current level of disease activity with physician global assessment (MD global score) or active joint count **Uveitis** • Documented diagnosis of noninfectious intermediate, posterior, or panuveitis uveitis **Hidradenitis Suppurativa (HS)** • 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

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Appropriate Treatment Regimen & Other Criteria:	**Rheumatoid Arthritis**
	• Documented treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy:
	  ○ Methotrexate plus sulfasalazine
	  ○ Methotrexate plus hydroxychloroquine
	  ○ Sulfasalazine plus hydroxychloroquine
	  ○ Leflunomide plus sulfasalazine
	  ○ Leflunomide plus hydroxychloroquine
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ One of following: Infliximab (preferred biosimilar products Inflectra, Renflexis, Avsola), Actemra IV
	
	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, Renflexis, Avsola)
	
	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, Renflexis, Avsola)
	
	Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (NR-axSPA),
	• 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, Renflexis, Avsola)
	
	Crohn's disease
	• Documented treatment failure with at least two oral treatments for minimum of 12 weeks trial: corticosteroids, 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, Renflexis, Avsola)
	
	Juvenile Idiopathic Arthritis (JIA)
	• Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide
	AND
	• Documented failure with glucocorticoid joint injections or oral corticosteroids
	
	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, Renflexis, and Avsola)
	
	Hidradenitis Suppurativa (HS)
	• Documented failure with at least 12 weeks 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 acetretin)
	• Documented failure with (or documented intolerable adverse event) with 12 weeks of infliximab (preferred biosimilar products Inflectra, Renflexis, and Avsola)
	
	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 Infliximab (preferred biosimilar products: Inflectra, Renflexis, Avsola)
	QL:
	• Induction

	○ Plaque Psoriasis/Uveitis: 160mg in first 28 days ○ Crohn's/Ulcerative Colitis/HS: 160mg day 1, then 80mg day 15 • Maintenance ○ RA/Psoriasis/Psoriatic Arthritis/Crohn's/UC/AS/Uveitis/JIA: 40mg every 14 days ○ HS: 40mg every week OR 80mg every 14 days **Reauthorization** • 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: 12 months, unless otherwise specified

POLICY NAME:
ADCIRCA
Affected Medications: ADCIRCA (tadalafil)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• Pulmonary arterial hypertension (PAH) (World Health Organization (WHO) Group 1) confirmed by right heart catheterization • Etiology of PAH (idiopathic, heritable, or associated with connective tissue disease) • New York Heart Association (NYHA)/WHO Functional Class II or III symptoms • Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blocker)
Appropriate Treatment Regimen & Other Criteria:	• Inadequate response or intolerance to sildenafil citrate tablets (Revatio) • Subsequent approvals require documentation of treatment success such as improved walking distance or improvements in functional class **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Concomitant nitrate therapy on a regular or intermittent basis • Concomitant use of Guanylate Cyclase Stimulators (eg. riociguat)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by or in consultation with, a cardiologist or pulmonologist as appropriate for diagnosis
Coverage Duration:	• 12 months, unless otherwise specified

POLICY NAME:
ADENOSINE DEAMINASE (ADA) REPLACEMENT
Affected Medications: ADAGEN (pegademase bovine), 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:	• A confirmed diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID)
	  ○ 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 AND • For Revcovi requests- documentation that treatment with Adagen was unsuccessful • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
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 prescriber experienced in SCID
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 6 months, unless otherwise specified

POLICY NAME:
ADUCANUMAB-AVWA
Affected Medications: ADUHELM (aducanumab-avwa)

<table>
<tr><td>Covered Uses:</td><td>• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
o 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:
o Clinical Dementia Rating (CDR) global score of 0.5
o Evidence of cognitive impairment at baseline using validated objective scales
o Mini-Mental Status Exam (MMSE) score from 24 to 30
o 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: 170mg/1.7mL vial and 300mg/3mL 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 4 weeks)</th><th>Dose</th><th>Monitoring</th></tr>
<tr><td>Infusion 1 and 2</td><td>1 mg/kg</td><td>Baseline MRI prior to Infusion 1</td></tr>
<tr><td>Infusion 3 and 4</td><td>3 mg/kg</td><td></td></tr>
<tr><td>Infusion 5 and 6</td><td>6 mg/kg</td><td>MRI between Infusion 6 and 7</td></tr>
<tr><td>Infusion 7 to 11</td><td>10 mg/kg</td><td>MRI between Infusion 11 and 12</td></tr>
<tr><td>Infusion 12 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:
o Cognitive or functional improvement
o Disease stabilization
o 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</td></tr>
</table>

	• Non-Alzheimer's dementia • Concurrent anticoagulant use
Age Restriction:	• 50 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Initial Authorization: 7 months • Reauthorization: 12 months

POLICY NAME:
AFAMELANOTIDE
Affected Medications: Scenesse (Afamelanotide Injection)

• Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #2
• Is the request to treat a diagnosis according to one of the Food and Drug Administration (FDA)-approved indications? ○ Treatment of patients with Erythropoetic protoporphyria (EPP) with phototoxic reactions	Yes – Go to appropriate section below	No – Criteria not met
Erythropoetic protoporphyria (EPP)		
• Is there documentation of a diagnosis of Erythropoetic protoporphyria confirmed with mutation in the Ferrochelatase (FECH) gene OR mutation of the ALAS2 gene?	Yes – Document and go to #2	No – Criteria not met
• Is there documentation of an increase in total erythrocyte protoporphyrin with at least 85% metal-free protoporphyrin?	Yes – Document and go to #3	No – Criteria not met
• Is there documented symptoms of erythropoietic protoporphyria phototoxicity that causes dysfunction significantly impacting activities of daily living?	Yes – Document and go to # 4	No – Criteria not met
• Is there documented associated neuropathic pain that has not responded to analgesics after a minimum of 12 weeks?	Yes – Document and go to # 5	No – Criteria not met
• Is the drug prescribed and managed by a specialist at a recognized Porphyria Center?	Yes – Approve up to 6 months	No – Criteria not met
Renewal Criteria		

• Is there documentation of treatment success and a clinically significant response to therapy (e.g., decreased severity and number of phototoxic reactions, increased duration of sun exposure, increased quality of life, etc) as assessed by the prescribing provider?	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 12 months	No – Criteria not met
Quantity Limitations		
• **Scenesse** ○ Availability: 16 mg implant. ○ Dosing: 16 mg under the skin every 2 months (60 days)		

POLICY NAME:
AFINITOR
Affected Medications: AFINITOR

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, and prescribed treatment regimen • Documentation of use with NCCN 2A or higher level of evidence regimen
Appropriate Treatment Regimen & Other Criteria:	• Documentation of medication review and / or avoidance with strong CYP3A4 inhibitors, CYP3A4 inducers, PgP inhibitors • **Reauthorization** requires documentation of disease responsiveness to therapy
Exclusion Criteria:	• Hypersensitivity to rapamycin derivatives • 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: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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POLICY NAME:
AFINITOR DISPERZ
Affected Medications: AFINITOR DISPERZ

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher • Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	**SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) INDICATION:** • Diagnosis of SEGA **TUBEROUS SCLEROSIS COMPLEX (TSC)-ASSOICATED PARTIAL-ONSET SEIZURES** • Documentation of monotherapy failure for seizure control with 2 different Anti-Epileptic regimens AND • Documentation of treatment failure with epidiolex (cannabidiol solution) adjunct therapy • Documentation that this is being used as adjunct therapy for seizures
Appropriate Treatment Regimen & Other Criteria:	**SEGA INDICATION:** • Patient has SEGA associated with a tuberous sclerosis complex (TSC) that requires therapeutic intervention but is not a candidate for curative surgical resection. • Documentation of medication review and / or avoidance with strong CYP3A4 inhibitors, CYP3A4 inducers, PgP inhibitors • **Reauthorization** requires documentation of disease responsiveness to therapy
Exclusion Criteria:	
Age Restriction:	• Greater than or equal to 1 year
Prescriber Restrictions:	**SEGA INDICATION:** • Must be prescribed by, or in consultation with, an oncologist **TSC-ASSOICATED PARTIAL-ONSET SEIZURES:** • Prescribed by, or in consultation with, a neurologist or specialist in the treatment of TSC
Coverage Duration:	• Initial Authorization: 3 months, 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 disease (SPMS)

Required Medical Information:	• 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 <u>Secondary-Progressive MS</u> • Documentation of prior history of RRMS with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e., new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5
Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure (or documented intolerable adverse event) to rituximab (preferred biosimilar products Truxima, Riabni, and Ruxience) OR Ocrevus (ocrelizumab) if previously established on treatment • No concurrent use of other disease-modifying medications indicated for the treatment of MS Dosing: • Initial dosing: 12mg intravenously (IV) daily on 5 consecutive days. • Subsequent treatment(s): 12 mg IV daily on 3 consecutive days, one year after any previous dosing. • Subsequent courses (12 mg IV daily on 3 consecutive days) may be administered, as needed, at least 12 months after the last dose of any prior treatment course <u>Reauthorization</u> requires provider attestation of treatment success
Exclusion Criteria:	• Patients with current Human Immunodeficiency Virus (HIV)
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

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:	
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. ○ Indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin deficiency)

Required Medical Information:	• Documentation of severe alpha1-antitrypsin (AAT) deficiency with emphysema or Chronic Obstructive Pulmonary Disease (COPD) that includes ALL of the following:
	  ○ Baseline (pretreatment) alpha1-antitrypsin serum concentration less than 11 micromol/L, OR less than 57 mg/dL by nephelometry, OR less than 80 mg/dL by radial immunodiffusion
	  ○ Forced Expiratory Volume in one second (FEV1) between 30-64% of predicted, OR FEV1 that is between 65-80% of predicted, but has declined by at least 100 mL per 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 • Coverage of Aralast NP, Glassia, or Zemaira will require a documented intolerable adverse event to Prolastin-C • Dosing: 60 mg/kg intravenously once weekly **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 lung or 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

POLICY NAME:
AMBRISENTAN
Affected Medications: LETAIRIS (ambrisentan)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Pulmonary arterial hypertension (PAH)
Required Medical Information:	PAH World Health Organization (WHO) Group 1 • Documentation of PAH confirmed by right-heart catheterization • Etiology of PAH (idiopathic, heritable, or associated with connective tissue disease) • New York Heart Association (NYHA)/WHO Functional Class II, III, or IV symptoms • Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blocker) unless there are contraindications such as 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, unless the patient has cardiopulmonary comorbidities (defined as risk factors for heart failure with preserved ejection fraction [HFpEF], such as obesity, diabetes, coronary heart disease, hypertension, and/or a low diffusing capacity for carbon monoxide [DLCO]) **Reauthorization** requires documentation of treatment success such as improved walking distance or improvements in functional class
Exclusion Criteria:	• Pregnancy • Idiopathic Pulmonary Fibrosis (IPF), including IPF patients with PAH (WHO Group 3)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• 12 months, unless otherwise specified

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

Required Medical Information:	<u>Lambert-Eaton myasthenic syndrome to reduce symptoms</u>
	• Documentation of diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by all of the following:
	  ○ Records of electrodiagnostic studies, including repetitive nerve stimulation (RNS)
	  ○ Anti-P/Q-type voltage-gated calcium channel (VGCC) antibody testing
	  ○ Reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise.
	• Documented clinical failure to at least 12 weeks of each of the following:
	  ○ Pyridostigmine
	  ○ Immunosuppressive agents such as Corticosteroids (dosed at 1mg/kg/day), Azathioprine and Mycophenolate
	  ○ Intravenous Immune Globulin (IVIG)

Appropriate Treatment Regimen & Other Criteria:	<u>Lambert-Eaton myasthenic syndrome to reduce symptoms</u> **Adults (any weight) and pediatric patients weighing 45 kg or more:** • 15 to 30 mg/day in 3 to 4 divided doses; May increase based on response and tolerability in 5 mg increments every 3 to 4 days. Maximum 80 mg/day. **Pediatric patients weighing less than 45 kg:** • 5 to 15 mg/day in 3 to 4 divided doses; May increase based on response and tolerability in 2.5 mg increments every 3 to 4 days. Maximum 40 mg/day. <u>Reauthorization requires documentation of treatment success</u> Electromyography records
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
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
AMVUTTRA
Affected Medications: AMVUTTRA (vutrisiran)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

Required Medical Information:	• Documented pathogenic mutation in transthyretin (TTR) confirmed by genetic testing
	• Diagnosis of hereditary transthyretin (hATTR) amyloidosis with polyneuropathy
	• Presence of clinical signs and symptoms of disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction)
	• Documented failure with diflunisal
	• Documentation of one of the following:
	  ○ Baseline polyneuropathy disability (PND) score of less than or equal to IIIb
	  ○ Baseline neuropathy impairment (NIS) score between 10 and 130
	  ○ Baseline FAP stage 1 or 2

Appropriate Treatment Regimen & Other Criteria:	**<u>Reauthorization:</u>** • Documentation of a positive clinical response to vutrisiran (e.g., improved neurologic impairment, motor function, cardiac function, quality of life assessment, serum TTR levels, etc.)
Exclusion Criteria:	• Prior or planned liver transplantation • New York Heart Association (NYHA) class III or IV • Diagnosis of other (non-hATTR) forms of amyloidosis or leptomeningeal amyloidosis • Combined use with TTR-lowering therapy, including inotersen or patisiran • Combined use with TTR-stabilizing therapy, including diflunisal, tafamidis, or tafamidis meglumine
Age Restriction:	• Adults aged 18 to 85 years old
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or provider experience in management of amyloidosis

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

POLICY NAME:
ANAKINRA
Affected Medications: KINERET (Anakinra)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Juvenile idiopathic arthritis (JIA), Juvenile rheumatoid arthritis (JRA), polyarticular course (regardless of type of onset)
	  ○ Systemic onset JIA
	  ○ Still's disease (SD)
	  ○ Neonatal-onset multisystem inflammatory disease (NOMID)
	  ○ Chronic infantile neurological cutaneous and articular (CINCA) syndrome
	  ○ Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Required Medical Information:	• Indication must be documented in chart notes within the last 6 months • Documentation of complete and current treatment course • Documented latent TB screening with either a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB) with a negative result. Must be receiving or have completed treatment for latent TB prior to initiation. • Recent CrCl or SCr, height, and weight. Dose every other day with CrCl < 30mL/min. • Rheumatoid Arthritis: laboratory test confirming diagnosis of RA (anti-CCP, RF)

Appropriate Treatment Regimen & Other Criteria:	**<u>Rheumatoid Arthritis</u>**
	• Documented treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy:
	  ○ Methotrexate plus sulfasalazine
	  ○ Methotrexate plus hydroxychloroquine
	  ○ Sulfasalazine plus hydroxychloroquine
	  ○ Leflunomide plus sulfasalazine
	  ○ Leflunomide plus hydroxychloroquine
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ One of following: Infliximab (preferred biosimilar products Inflectra, Renflexis, Avsola), Actemra IV
	• QL – 18.76 ml per 28-day supply
	
	<u>JIA/JRA (regardless of onset)</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:
	  ○ Actemra IV, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), and Simponi Aria

	• QL – 18.76 ml per 28-day supply **DIRA** • Documentation of genetically confirmed DIRA • Maximum dose of 8 mg/kg daily. **Reauthorization** requires documentation of treatment success
Exclusion Criteria:	• Concurrent use with biologic DMARDs: Enbrel, adalimumab, Infliximab, Cimzia, Simponi, Orencia, Rituxan, Actemra, Xeljanz • Sepsis syndrome or graft versus host disease • Use in the management of symptomatic osteoarthritis, lupus arthritis, or type 2 diabetes mellitus.
Age Restriction:	• Rheumatoid arthritis: less than or equal to 18 years of age • Polyarticular JIA or systemic JIA: less than or equal to 18 years of age
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 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
Required Medical Information:	• Documentation of systemic lupus erythematosus with moderate to severe disease (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 standard 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 intravenous Benlysta **Dosing**: • 300 mg every 4 weeks **Reauthorization**: • Documentation of treatment success or a clinically significant improvement such as a decrease in flares or corticosteroid use
Exclusion Criteria:	• Saphnelo is not approved to be used in combination with other biologic therapies • Saphnelo is not approved to be used in severe active lupus nephritis or severe active central nervous system lupus
Age Restriction:	• Must be 18 years 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:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
ANTIEMETICS
Affected Medications: Akynzeo (fosnetupitant 235mcg and palonosetron 0.25mg), Varubi (rolapitant 90 mg), Sustol (granisetron 1 mg)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	• Varubi (rolapitant)
	  ○ Prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy
	• Akynzeo (fosnetupitant and palonosetron)
	  ○ Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.
	  ○ Akynzeo injection is not approved for use in anthracycline or cyclophosphamide-based chemotherapy or chemotherapy not considered highly emetogenic
	• 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
	  ○ Prophylaxis of radiation therapy-associated emesis

Required Medical Information:	• For chemotherapy induced nausea and vomiting (CINV) - documentation of planned chemotherapy regimen • Highly emetogenic chemotherapy (HEC): Carboplatin, carmustine, cisplatin, cyclophosphamide, dacarbazine, doxorubicin, epirubicin, ifosfamide, mechlorethamine, melphalan, streptozocin, FOLFOX regimen • The following can be considered HEC in certain patients: Dactinomycin, daunorubicin, irinotecan, methotrexate (250 mg/m2 or greater), oxaliplatin, trabectedin

Appropriate Treatment Regimen & Other Criteria:	Prevention of Chemotherapy induced Nausea and vomiting (CINV) in adults
	• Akynzeo & Varubi
	  ○ require a highly emetogenic chemotherapy (HEC) regimen
	  ○ failure with another generically available 5-HT3 receptor antagonist (e.g., ondansetron, granisetron or palonosetron) and NK1 receptor antagonist (e.g., aprepitant, fosaprepitant or rolapitant) while receiving the current chemotherapy regimen
	• Akynzeo is NOT covered for: Breakthrough emesis or repeat dosing in multi-day emetogenic chemotherapy regimens
	• Sustol
	  ○ Require a moderate or highly emetogenic chemotherapy regimen
	  ○ Failure of all of the following, while receiving the current chemotherapy regimen:
	  ▪ Granisetron oral tablet
	  ▪ Granisetron intravenous solution

	• Maximum 1 injection per 7 days **Prevention of Chemotherapy induced Nausea and vomiting (CINV) in Pediatric Patients (1 month to less than 17 years old)** • Documentation of emetogenic chemotherapy • Varubi - Not being used for acute nausea and vomiting Maximum 1 vial per 7 days for Akynzeo; 1 vial per 14 days for Varubi **Reauthorization** requires documentation of treatment success and initial criteria to be met.
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist (For CINV)
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 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,
	  ○ 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 Vonvendi for routine prophylaxis; documentation of severe Type 3 VWD
	
	<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

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 **Hemophilia B (factor IX deficiency)** • For Benefix, Idelvion and Rebinyn: documentation of failure or contraindication to Rixubis • For Alprolix: documentation of contraindication to Rixubis in perioperative management **Von Willebrand disease (VWD)** • For Vonvendi: documentation of failure or contraindication to Humate P AND Alphanate
Exclusion Criteria:	• History of anaphylaxis or severe hypersensitivity to any component of the chosen agent • 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 and Adynovate: 12 years and older • Vonvendi: 18 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified • Perioperative management: 1 month, unless otherwise specified

POLICY NAME:
ANTITHROMBIN
Affected Medications: ATRYN (antithrombin alfa)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• Diagnosed hereditary antithrombin deficiency via reduced plasma antithrombin level (not in midst of acute illness or surgery that could give falsely low antithrombin levels) • Can be given for prophylaxis if negative personal/family history of thromboembolic events in high risk-settings as in surgery and pregnancy. • Patient weight • Documentation of intended dose based on reasonable projections and current dose utilization and product labeling.
Appropriate Treatment Regimen & Other Criteria:	• Confirmed diagnosis of Hereditary Antithrombin deficiency **<u>Peri-partum thromboembolic prophylaxis</u>** • If positive personal/family history of VTE, ATryn recommended prior to and at the time of delivery when anticoagulation cannot be administered, and used until anticoagulation can be resumed • If negative personal history of VTE, patient may need single dose of ATryn • ATryn use is limited to third trimester • If positive personal/family history of VTE, ATryn recommended • Can be concomitantly given with LMWH or heparin **<u>Peri-operative thromboembolic event prophylaxis</u>** • Used during warfarin interruption leading up to surgical procedure (with or without heparin) • Utilized until patient can resume warfarin therapy
Exclusion Criteria:	• Hypersensitivity to goats and goat milk protein • Administration within first two trimesters of pregnancy • Active thromboembolic event
Age Restriction:	• 18 – 65 years of age
Prescriber Restrictions:	• Prescribed by, or in consultation with, an OB-GYN, MD
Coverage Duration:	• Approval: 1 month, unless otherwise specified

POLICY NAME:
ANTITHYMOCYTE
Affected Medications: ATGAM (Antithymocyte globulin)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design • Management of allograft rejection in renal transplant patients • Treatment of moderate to severe aplastic anemia in patients unsuitable for bone marrow transplantation • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better • Myelodysplastic Syndromes (MDS)
Required Medical Information:	• For myelodysplastic syndromes: Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course

Appropriate Treatment Regimen & Other Criteria:	• Dosing
	  ○ Aplastic anemia: 10 to 20 mg/kg once daily for 8 to 14 days, then if needed, may administer every other day for 7 more doses for a total of 21 doses in 28 days OR 40 mg/kg daily for 4 days
	  ○ MDS: 40 mg/kg once daily for 4 days
	  ○ Renal transplant rejection: 10 to 15 mg/kg once daily for 14 days. Additional alternate-day therapy up to a total of 21 doses may be given.
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced

Exclusion Criteria:	• All uses not listed in covered uses are considered experimental and are excluded from coverage • Oncology: Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • 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
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist in oncology, hematology or transplant medicine
Coverage Duration:	• Approval: Maximum 4 weeks per dosing above

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

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	• Diagnosis of advanced Parkinson's Disease (PD) • Documentation of at least one well defined acute intermittent hypomobility or "off" episode for 2 hours or more during the waking day, despite optimized therapy with other agents

Appropriate Treatment Regimen & Other Criteria:	• Concurrent therapy with levodopa/carbidopa at the maximum tolerated dose and a second agent from one of the following alternate anti-Parkinson's drug classes:
	  ○ Monoamine oxidase-B (MAO-B) inhibitors (ex: selegiline, rasagiline)
	  ○ Dopamine agonists (ex: amantadine, pramipexole, ropinirole)
	  ○ Catechol-O-methyltransferase (COMT) inhibitors (ex: entacapone)
	• Apokyn requires documentation of failure or contraindication to Kynmobi
	
	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

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POLICY NAME:
APREMILAST
Affected Medications: OTEZLA, OTEZLA KIT

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Psoriatic Arthritis
	  ○ Psoriasis
	  ○ 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 (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
	
	Psoriatic Arthritis
	• Documentation of ClASsifcation 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 Bechet'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:	**<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 Infliximab (preferred biosimilar products: Inflectra, Renflexis, 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, Renflexis, Avsola) **<u>Oral Ulcers Associated with Bechet's Disease</u>** • Documented clinical failure of at least 1 oral medication for Behcet's disease after at least 12 weeks (colchicine, prednisone, azathioprine) **<u>QL:</u>** • Induction (All indications): Titration pack • Maintenance (All indications): 60 tablets per 30 days **<u>Reauthorization</u>** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with any other biologic therapy 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: 12 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. • For initial authorization only: documented plan for ensuring oral adherence during first 21 days of initial Aristada is required • Documentation of anticipated dosing based on oral aripiprazole maintenance dose. • 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 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 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.
Required Medical Information:	• Diagnosis of Mycobacterium avium complex (MAC) lung disease confirmed by a MAC-positive sputum culture • 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:	• Arikayce must be used as part of a multi-drug regimen and will not be approved for use as a single agent treatment • To be used with Lamira Nebulizer system only **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 recertification approval (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:	
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 or BCR::ABL1-positive chronic myeloid leukemia (CML) in chronic phase
Appropriate Treatment Regimen & Other Criteria:	• Previous treatment with imatinib AND one or more additional tyrosine kinase inhibitor (TKI) ○ Second line TKIs are bosutinib, dasatinib, or nilotinib. (Note BCR::ABL1 kinase domain mutation status for contraindications) **OR** • Documented T315I positive mutation **AND** • Documented clinical failure with ponatinib **Quantity Limit in Philadelphia-positive CML with T315I mutation**: • 40 mg tablets #300 per 30 days **Quantity Limit in Philadelphia-positive CML previously treated with imatinib and 1 or more additional TKIs**: • 40 mg tablets #60 per 30 days • 20 mg tablets #60 per 30 days **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 or P465S 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:
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
	• Appropriate medical support is readily available when medication is administered in the event of anaphylaxis, severe allergic reaction, or acute cardiorespiratory failure.
	• Patients weighing less than 30 kilograms will require documented treatment failure or intolerable adverse event to Lumizyme.
	• 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 treatment with Lumizyme
Age Restriction:	• 1 year of age and older
Prescriber Restrictions:	• Metabolic specialist, endocrinologist, or physician experienced in the management of Pompe disease.
Coverage Duration:	• Approval: 12 months, unless otherwise specified.

POLICY NAME:
AVATROMBOPAG
Affected Medications: DOPTELET (avatrombopag)

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 adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment

Required Medical Information:	**Thrombocytopenia in patients with CLD undergoing a procedure:**
	• Documentation of planned procedure including date
	• Documentation of baseline platelet count of less than 50,000/microliter
	
	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 CLD undergoing a procedure**
	• Approved for one time 5-day dosing regimen
	
	Thrombocytopenia in patients with chronic ITP
	• 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
	• Documented inability to respond adequately to Promacta
	
	Reauthorization (chronic ITP only):
	• 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:	
Age Restriction:	• 18 years of age or 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 (5 days of treatment maximum), 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:
AVONEX
Affected Medications: AVONEX (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 disease (SPMS)

Required Medical Information:	• 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 **<u>Clinically Isolated Syndrome</u>** • Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event **<u>Secondary-Progressive MS</u>** • Documentation of prior history of RRMS with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e. new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5
Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure (or documented intolerable adverse event) with glatiramer • No concurrent use of other disease-modifying medications indicated for the treatment of MS QL: • Avonex Initial dosing: 7.5 mcg week 1, then increase dose in increments of 7.5 mcg once weekly (weeks 2 to 4) up to recommended dose • Titrate weekly to recommended dose of 30 mcg **<u>Reauthorization</u>** requires provider attestation of treatment success

Exclusion Criteria:	
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:
BARICITINIB
Affected Medications: OLUMIANT (baricitinib)

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

Required Medical Information:	• 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

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy
	  ○ Methotrexate plus sulfasalazine
	  ○ Methotrexate plus hydroxychloroquine
	  ○ Sulfasalazine plus hydroxychloroquine
	  ○ Leflunomide plus sulfasalazine
	  ○ Leflunomide plus hydroxychloroquine
	• Documentation of treatment failure (or documented intolerable adverse event) for 12 weeks or greater with Infliximab (preferred products Inflectra, Renflexis, Avsola) or Actemra IV
	• **QL:**
	  ○ 1mg or 2mg tablets once daily
	
	Reauthorization
	• 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 • 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:12 months, unless otherwise specified

POLICY NAME:
BEDAQUILINE
Affected Medications: SIRTURO (bedaquiline fumarate)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. • Pulmonary multi-drug resistant tuberculosis (MDR-TB).
Required Medical Information:	Patient has failed, is resistant, or is allergic to quad therapy of any combination of the following: • Isoniazid • Rifampin • Ethambutol • Pyrazinamide • Fluoroquinolones • Capreomycin (Kanamycin, Amikacin, Streptomycin) • Ethionamide/Prothinamide • Cycloserine/Terizidone • Aminosalicylic acid (acidic salt)
Appropriate Treatment Regimen & Other Criteria:	• Documentation of being administered by directly observed therapy (DOT) • Baseline electrocardiogram (ECG) • Basic Metabolic Panel (BMP) (including K, Ca, Mg documentation of correction if needed) • Liver Function Tests (LFTs)
Exclusion Criteria:	• Drug-sensitive TB (DS-TB) • Latent infection due to mycobacterium TB • Extrapulmonary TB (e.g., central nervous system) • QTc greater than 500 milliseconds
Age Restriction:	• 5 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist
Coverage Duration:	• 24 weeks, unless otherwise specified

POLICY NAME:
BELINOSTAT
Affected Medications: BELEODAQ (belinostat)

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level 2A or higher.
Required Medical Information:	• Documentation of staging, all prior therapies used, performance status and anticipated treatment course • Complete blood count (CBC) with differential, creatinine clearance (CrCl), liver function tests • Documentation of UGT1A1*28 allele status
Appropriate Treatment Regimen & Other Criteria:	• Appropriate dose reduction based on absolute neutrophil count (ANC) OR homozygous UGT1a1*28 allele • 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:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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
	  ○ Lupus Nephritis

Required Medical Information:	**Systemic Lupus Erythematosus**: • Documentation of systemic lupus erythematosus with moderate classification (significant but non-organ threatening disease including constitutional, cutaneous, musculoskeletal, or hematologic involvement) • Documentation of patient's current weight **Lupus Nephritis:** • Documentation of lupus nephritis disease stage III, IV, or V • Documentation of patient's current weight AND • Documentation of blood pressure and lipid control or appropriate therapy management, if indicated
Appropriate Treatment Regimen & Other Criteria:	**Systemic Lupus Erythematosus:** • 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 a clinically significant improvement in SLE Responder Index-4 (SRI-4) or decrease in flares/corticosteroid use. **Lupus Nephritis:** • Failure of at least 12 weeks of standard therapy with mycophenolate mofetil AND cyclophosphamide • **Reauthorization**: Documentation of treatment success defined as an improvement in eGFR, reduction in urinary protein:creatinine ratio, or decrease in flares/corticosteroid use **Dosing:** • Loading dose - 400 mg subcutaneous once weekly for 4 doses (LN only) • Maintenance - 200 mg subcutaneous once weekly • Loading dose - 10 mg/kg intravenous every 2 weeks for 3 doses • Maintenance - 10 mg/kg intravenous every 4 weeks
Exclusion Criteria:	• Benlysta is not approved to be used in combination with other biologic therapies • Benlysta is not approved to be used in severe active central nervous system lupus
Age Restriction:	• Intravenous formulation: 5 years of age and older

	• Subcutaneous formulation: 18 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:
	  ○ Systemic Lupus Erythematosus - 12 months, unless otherwise specified
	  ○ Lupus Nephritis
	  ▪ Initial: 6 months, unless otherwise specified
	  ▪ Reauthorization: 12 months, unless otherwise specified

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:	• Documentation of Von Hippel-Lindau (VHL) disease as defined by VHL germline mutation and presence of at least one measurable solid tumor located in the kidney, brain/spine, or pancreas • 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 • Metastatic 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)**

• Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #2
• Is the request for use in combination with another monoclonal antibody (e.g., Dupixent, Nucala, Xolair, Cinqair)?	Yes – Criteria not met; combination use is experimental	No – Go to #3
• Is the request to treat a diagnosis according to one of the Food and Drug Administration (FDA)-approved indications? ○ Add-on maintenance treatment of patients with severe asthma aged 12 years and older with an eosinophilic phenotype	Yes – Go to appropriate section below	No –
Severe Eosinophilic Asthma		
• Is there documentation of severe eosinophilic asthma defined by the following: ○ Baseline eosinophil count at least 300 cells/µL AND ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal	Yes – Document and go to #2	No – Criteria not met
• Is there documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms?	Yes – Document and go to #3	No – Criteria not met
• Is there a 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?	Yes – Go to #5	No – Go to #4
• Is there documentation that chronic daily oral corticosteroids are required?	Yes – Go to #5	No – Criteria not met

• Is the drug prescribed by, or in consultation with, an Allergist, Immunologist, or Pulmonologist?	Yes – Approve up to 6 months	No – Criteria not met
Renewal Criteria		
○ 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
○ Is the request for use in combination with another monoclonal antibody (e.g., Dupixent, Nucala, Xolair, Cinqair)?	Yes – Criteria not met; combination use is experimental	No – Go to #3
○ 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		
• **Fasenra** ○ Availability: 30 mg/mL pre-filled syringe or auto-injector ○ Dosing: 30 mg every 4 weeks for the first 3 doses, then 30 mg every 8 weeks thereafter *Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced for all medical infusion drugs		

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 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
	• 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
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

POLICY NAME:
BETAINE
Affected Medications: CYSTADANE (betaine), Betaine

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

Required Medical Information:	• Documentation of one of the following:
	  ○ Cystathionine beta-synthase (CBS) deficiency
	  ○ 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency
	  ○ Cobalamin cofactor metabolism (cbl) defect
	• Vitamin B12 and folic acid serum levels

Appropriate Treatment Regimen & Other Criteria:	• Vitamin B6, B12, and folate supplementation **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Uncorrected vitamin B12 or folic acid levels
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified.

POLICY NAME:
BETASERON
Affected Medications: BETASERON (interferon beta-1b)

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 disease (SPMS)

Required Medical Information:	• 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 inadequate response or intolerance to at least one preferred product (Avonex, dimethyl fumarate, Extavia, fingolimod, glatiramer, Glatopa) • No concurrent use of other disease-modifying medications indicated for the treatment of MS • **Reauthorization:** provider attestation of treatment success
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
BEVACIZUMAB
Affected Medications: AVASTIN (bevacizumab), MVASI (bevacizumab-awwb), ZIRABEV (bevacizumab-bvzr), ALYMSYS, VEGZELMA

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:	**Non-Small Cell Lung Cancer (NSCLC)**
	• Approval will be limited to NCCN category 1 recommended therapies for first line treatment of advanced NSCLC
	
	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) 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
	  ○ Currently receiving treatment with a non-preferred product, excluding via samples or manufacturer's patient assistance programs
	
	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


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POLICY NAME:
BEXAROTENE
Affected Medications: BEXAROTENE

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better

Required Medical Information:	**Bexarotene Gel:**
	• Documentation of cutaneous T-cell lymphoma (CTCL) stage IA or IB
	• Diagnosis confirmed by biopsy (exclusion of other T cell lymphomas with cutaneous involvement)
	• Documented clinical failure to ALL of the following:
	  ○ Topical corticosteroids (high or super-high potency) such as clobetasol, betamethasone, fluocinonide, halobetasol
	  ○ Topical imiquimod
	  ○ Phototherapy

Appropriate Treatment Regimen & Other Criteria:	• Patient has been instructed on the importance and proper utilization of appropriate contraceptive methods. **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Pregnancy.
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist or dermatologist as appropriate for diagnosis.
Coverage Duration:	• Initial approval: 4 months (2 weeks partial fill), unless otherwise specified • Subsequent approval: 12 months, unless otherwise specified.

POLICY NAME:
BEZLOTOXUMAB
Affected Medications: ZINPLAVA (bezlotoxumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ In conjunction with antibacterial drug treatment for Clostridium difficile infection (CDI)

Required Medical Information:	• Stool test results showing one of the following:
	  ○ Glutamate dehydrogenase (GDH) antigen AND Toxin A & B positive
	OR
	  ○ PCR (polymerase chain reaction) positive
	• Diagnosis of CDI confirmed by at least 3 unformed stools in 24 hours
	• Stool test positive for toxigenic Clostridium difficile collected no more than 7 days prior to infusion
	• Patient must be receiving concurrent treatment for Clostridium difficile

Appropriate Treatment Regimen & Other Criteria:	• Patients at high risk for CDI recurrence (must have at least one risk factor): age >65, one or more episodes of *Clostridium Difficile* infection (CDI) in previous 6 months, immunocompromised status, clinically severe CDI (as defined by Zar score ≥2). • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
Exclusion Criteria:	• Heart Failure
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	
Coverage Duration:	• Approval: One treatment may be given while patient is receiving antibiotic therapy for treatment of C. difficile (usually 14 days)

POLICY NAME:
BIMATOPROST IMPLANT
Affected Medications: DURYSTA (Bimatoprost Intracameral Implant)

1. 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, experimental/investigational
Open-Angle Glaucoma (OAG) or Ocular Hypertension (OHT)		
1. Is there a documented diagnosis of Open-Angle Glaucoma (OAG) or Ocular Hypertension (OHT) with a baseline intraocular pressure (IOP) at least 22 mmHg?	Yes – Document and go to #2	No – Criteria not met
2. Is there a documented history of positive response to prostaglandin drops (e.g., latanoprost, bimatoprost)?	Yes – Document and go to #3	No – Criteria not met
3. Is there documented medical justification supporting inability to manage regular glaucoma eye drop use (e.g., due to age or comorbidities including visual impairment)?	Yes – Document and go to #4	No – Criteria not met
4. Is there a diagnosis of corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy)?	Yes – Criteria not met; contraindication	No – Go to #5
5. Is there a history of corneal transplantation or endothelial cell transplant (e.g., Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK))?	Yes – Criteria not met; contraindication	No – Go to #6
6. Is the drug being prescribed by, or in consultation with, an ophthalmologist?	Yes – Go to #7	No – Criteria not met
7. Is the request for repeat implantation?	Yes – Criteria not met; repeat implantation currently considered experimental	No – Approve up to 2 months (1 implant per impacted eye) without renewal

Quantity Limitations
• **Durysta**   ○ A single intracameral bimatoprost implant per eye. Should not be readministered to an eye that received a prior Durysta

POLICY NAME:
BLINATUMOMAB
Affected Medications: BLINCYTO (blinatumomab)

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher
Required Medical Information:	• Documentation of disease staging, all prior therapies used, performance status and anticipated treatment course AND • Philadelphia chromosome status AND • Documentation of ECOG performance status of 1 or 2 OR Karnofsky performance score greater than 50%
Appropriate Treatment Regimen & Other Criteria:	• Blincyto should permanently be discontinued for the following adverse reactions: grade 4 cytokine release syndrome, grade 4 neurological toxicity, or two Blincyto induced seizures • Maximum approval: 9 cycles for Relapsed or Refractory Acute Lymphoblastic Leukemia (ALL), 4 cycles for ALL in 1st or 2nd remission with Minimal Residual Disease (MRD)
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 30 weeks for Relapsed or Refractory ALL; 24 weeks for ALL in 1st or 2nd remission with MRD • Reauthorization: 48 weeks for Relapsed or Refractory ALL (4 cycles of continued therapy x 12 weeks each, to complete a maximum of 9 cycles total); NO reauthorization for ALL in 1st or 2nd remission with MRD, unless otherwise specified

POLICY NAME:
BONJESTA & DICLEGIS
Affected Medications: BONJESTA (doxylamine succinnate and pyridoxine hydrochloride extended-release oral tablets), DICLEGIS (doxylamine-pyridoxine Tab 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.) <u>Documented failure, intolerance or clinical rationale for avoidance to ALL of the following:</u> • OTC pyridoxine with OTC doxylamine **AND** • Dopamine antagonist (prochlorperazine, metoclopramide, etc.) **OR** • H1 antagonist (promethazine, meclizine, dimenhydrinate, diphenhydramine, etc.) **OR** • Ondansetron
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 weeks, unless otherwise specified

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POLICY NAME:
BOSENTAN
Affected Medications: TRACLEER (Bosentan)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	**Pulmonary arterial hypertension (PAH) WHO Group 1** • Documentation of PAH confirmed by right-heart catheterization • Etiology of PAH (idiopathic, heritable, associated with connective tissue disease, or associated with congenital heart disease with left-to-right shunts) • New York Heart Association (NYHA)/World Health Organization (WHO) Functional Classification II, III or IV • Liver Function Tests within normal limits prior to initiation • Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blocker) unless contraindications exist such as 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 of trial with at least 1 PDE5 inhibitor (unless contraindicated) **OR** patient at high risk necessitating endothelin receptor antagonist. • Not recommended for patients with PAH secondary to heart failure with severe systolic dysfunction • Not recommended for patients with moderate to severe liver impairment **Reauthorization** requires documentation of treatment success such as improved walking distance or improvements in functional class
Exclusion Criteria:	• Pregnancy • Concomitant use with glyburide and cyclosporine
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or a pulmonologist
Coverage Duration:	• 12 months, unless otherwise specified

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

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
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, drug-induced orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm or dysphonia, upper and lower limb spasticity or other conditions of central focal spasticity 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
	
	Idiopathic or neurogenic detrusor over-activity (Overactive Bladder (OAB))/Urinary incontinence associated with neurologic condition:
	• Inadequate response to, or intolerance to, 2 or more urinary incontinence antimuscarinic or beta-3 adrenergic therapies (oxybutynin, solifenacin, tolterodine, mirabegron, vibegron, etc.)
	
	Laryngeal stenosis or dysphonia:
	• Must be associated with recurrent aspiration pneumonia or airway obstruction **OR** for children under 18 years of age with dysphagia persisting for at least 12 months
	
	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 AND documented failure with an adequate trial (at least 8 weeks) of an oral migraine preventive therapy (beta-blocker, calcium channel blocker, anticonvulsant or tricyclic antidepressant) as follows:
	  ○ Propranolol 40 mg daily, Metoprolol 100 mg daily
	  ○ Amitriptyline 25 mg daily,
	  ○ Topiramate 50 mg daily, Valproic acid, Divalproex sodium
	
	Achalasia (Cardiospasm):
	• Must meet 1 of the following:
	  ○ Failure or intolerance to peroral endoscopic myotomy (POEM) or laparoscopic Heller myotomy AND failure or intolerance to pneumatic dilation
	  ○ Not a candidate for POEM, surgical myotomy, or pneumatic dilation due to high risk of complications

	<u>Number of treatments must not exceed the following:</u> • Idiopathic or neurogenic detrusor over-activity (OAB) / Urinary incontinence associated with neurologic condition: 2 treatments/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/12 months unless otherwise specified **<u>Reauthorization:</u>** • **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: documented current/recent urinary tract infection or urinary retention
	• Hemifacial spasm: no longer above the line on the prioritized list
	• 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
	  ○ Use of combination of any previously mentioned products without overuse of any one agent if no causative pattern can be established
	• Combined use with Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists (Ajovy, Aimovig or Emgality) for the prevention of migraine

Age Restriction:	
Prescriber Restrictions:	• Blepharospasm, strabismus: ophthalmologist or neurologist • Chronic migraine: treatment is administered in consultation with a neurologist or headache specialist. • OAB or urinary incontinence due to neurologic condition: urologist or neurologist • Documentation of consultation with any of the above specialists mentioned
Coverage Duration:	**Chronic migraine:** • Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified **Idiopathic or neurogenic detrusor over-activity (OAB) / Urinary incontinence associated with neurologic condition:** • Initial approval: 3 months, unless otherwise specified

	• Reauthorization: 12 months, unless otherwise specified **All other indications:** • Approval 12 months, unless otherwise specified

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:	• Documentation of major depressive episode as diagnosed by DSM-5 Criteria
	  ○ Five or more of the following symptoms present during the same two week period and represent a change from previous function. Must include either (1) depressed mood or (2) lack of interest or pleasure
	  ▪ Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad, empty, hopeless) or observations made by others (e.g., appears tearful). (NOTE: In children and adolescents, can be irritable mood.)
	  ▪ 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)
	  ▪ Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month) or decrease or increase in appetite nearly every day. (NOTE: In children, consider failure to make expected weight gain.)
	  ▪ Insomnia or hypersomnia nearly every day
	  ▪ Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
	  ▪ Fatigue or loss of energy nearly every day
	  ▪ Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
	  ▪ Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by their subjective account or as observed by others)
	  ▪ 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
	AND
	  ○ Symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning **AND**
	  ○ 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

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

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
	  ○ The treatment of X-linked hypophosphatemia (XLH)
	  ○ The treatment of FGF23-related hypophosphatemia in tumor induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized

Required Medical Information:	**<u>All indications:</u>**
	• Documentation of diagnosis by:
	  ○ A blood test demonstrating:
	  ▪ Decreased phosphate AND
	  ▪ Increased FGF-23 AND
	  ▪ Decreased 1,25-(OH)2D AND
	  ▪ Normal parathyroid hormone (PTH) AND
	  ○ 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 AND
	• Alternative renal phosphate-wasting disorders have been ruled out

Appropriate Treatment Regimen & Other Criteria:	**<u>For all diagnoses:</u>** • Documentation of treatment failure or intolerable adverse event with oral phosphate and calcitriol supplementation in combination for at least 12 months, or contraindication to therapy • 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 AND improvement in radiographic imaging of skeletal abnormalities.
Exclusion Criteria:	
Age Restriction:	• X-Linked Hypophosphatemia: Patient is at least 6 months of age • Tumor-Induced Osteomalacia: Patient is at least 2 years of age

Prescriber Restrictions:	• Prescribed by, or in consultation with, a nephrologist or 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

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 AND documentation of all the following prior to treatment initiation:
	  ○ Stage 3 or 4 CKD (baseline eGFR of 15 – 59 mL/min)
	  ○ 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:
	  ○ Vitamin D3 (cholecalciferol)
	  ○ Vitamin D2 (ergocalciferol)
	  ○ 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:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a nephrologist or endocrinologist.
Coverage Duration:	• Approval: 12 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
	
	Lennox-Gastaut syndrome (LGS)
	  ○ Documentation of at least 8 drop seizures per month while on stable antiepileptic drug therapy
	  ○ Documented treatment and inadequate seizure control with at least three guideline directed therapies including:
	  ▪ Valproate **and**
	  ▪ Lamotrigine **and**
	  ▪ Rufinamide, topiramate, felbamate, **or** clobazam
	
	Dravet Syndrome (DS)
	  ○ Documentation of at least 4 convulsive seizures in the last month while on stable antiepileptic drug therapy
	  ○ Documented treatment and inadequate seizure control with at least four guideline directed therapies including:
	  ▪ Valproate **and**
	  ▪ Clobazam **and**
	  ▪ Topiramate **and**
	  ▪ Clonazepam, levetiracetam, **or** zonisamide
	
	Tuberous Sclerosis Complex
	• Documentation of monotherapy failure for seizure control with two antiepileptic regimens AND
	• Documentation of failure with at least one adjunctive therapy for seizure control

Appropriate Treatment Regimen & Other Criteria:	**Dosing**: • Lennox-Gastaut Syndrome or Dravet Syndrome: Not to exceed 20 mg/kg per day • Tuberous Sclerosis Complex: 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:	• Greater than or equal to 1 year
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:
CAPLACIZUMAB
Affected Medications: CABLIVI (caplacizumab)

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 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
	  ○ Testing for ADAMTS13 activity levels has been completed or is in progress
	• Cablivi used as initial treatment will require 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
	• Cablivi will be used in combination with standard-of-care treatment for aTTP (plasma exchange and glucocorticoid).

Appropriate Treatment Regimen & Other Criteria:	• Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange Dosing: • First day of treatment: Intravenous (IV) followed by subcutaneous (SubQ): 11 mg IV at least 15 minutes prior to plasma exchange, followed by 11 mg SubQ after completion of plasma exchange on day 1. • Subsequent treatment days (during daily plasma exchange): SubQ: 11 mg once daily following plasma exchange. • Treatment after plasma exchange period: SubQ: 11 mg once daily, continuing for 30 days following the last daily plasma exchange; if sign(s) of persistent underlying disease remain present (e.g., suppressed ADAMTS13 activity levels) after initial treatment course, treatment may be extended up to a maximum of 28 days. • Discontinuation: Discontinue caplacizumab if more than 2 recurrences of aTTP occur during treatment. **Reauthorization** requires documented signs of ongoing disease (e.g., 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:	

Age Restriction:	• 18 years and older
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:
CARGLUMIC ACID
Affected Medications: carglumic acid

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

Required Medical Information:	• 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

Appropriate Treatment Regimen & Other Criteria:	**Acute hyperammonemia** • Ammonia level greater than 100 micromol/L • 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) **Chronic hyperammonemia due to N-Acetylglutamate Synthase (NAGS) deficiency** • Ammonia level greater than or equal to 50 micromol/L • NAGS deficiency confirmed by enzymatic, biochemical, or genetic testing • Prescribed in combination with a protein-restricted diet **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
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
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a metabolic disease specialist
Coverage Duration:	• Initial approval: 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, Vimpat, zonisamide, phenytoin, valproic acid, gabapentin, pregabalin)
Appropriate Treatment Regimen & Other Criteria:	**Dosing**: max 400 mg/day **Reauthorization** will require documentation of treatment success and a reduction in seizure severity, frequency, and/or duration.
Exclusion Criteria:	• Familial short QT syndrome
Age Restriction:	• 18 years of age or older
Prescriber 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:
CERLIPONASE ALFA
Affected Medications: BRINEURA (cerliponase alfa)

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

Required Medical Information:	• Confirmed diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) with one of the following:
	  ○ Documented deficient tripeptidyl peptidase-1 (TPP1) activity in leukocytes
	  ○ Pathogenic variants/mutations in each allele of TPP1/CLN2 gene AND baseline motor, speech and vision function documented by the physician
	• Documentation of mild to moderate functional impairment at baseline using the CLN2 Clinical Rating Scale, defined as:
	  ○ A combined motor and language domain score of 3 to 6 AND
	  ○ A score of at least 1 in each of these two domains
	• Planned treatment regimen including doses, frequency
	• Planned monitoring parameters for infections and side effects

Appropriate Treatment Regimen & Other Criteria:	• Dosing: 300 mg administered once every other week by intraventricular infusion **<u>Reauthorization:</u>** • Documentation of continuing meeting initial review criteria AND • Documentation of clinical responsiveness to therapy with disease stability/improvement defined as a score of 1 or higher in the motor domain of the CLN2 Clinical Rating Scale.
Exclusion Criteria:	• Patients with acute intraventricular access device-related complications (e.g., leakage, device failure or signs of device-related infection such as swelling, erythema of the scalp, extravasation of fluid, or bulging of the scalp around or above the intraventricular access device) • Other form of neuronal ceroid lipofuscinosis • Patients with ventriculoperitoneal shunts
Age Restriction:	• Between 3 years of age to 16 years of age
Prescriber Restrictions:	• Must be prescribed by a neurologist, or in consultation with, a neurologist with expertise in the diagnosis of CLN2 • Must be administered by, or under the direction of a physician knowledgeable in intraventricular administration
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization: 6 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
CERTOLIZUMAB
Affected Medications: CIMZIA (certolizumab)

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

Required Medical Information:	**Rheumatoid Arthritis**
	• 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
	
	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 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), and Psoriatic Arthritis with Axial Involvement</u>
	• Diagnosis of axial spondyloarthritis (SpA) confirmed by Sacroiliitis on imaging AND at least one 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>Crohn's disease</u>
	• Documentation of moderate to severely active disease despite current treatment

Appropriate Treatment Regimen & Other Criteria:	**<u>All indications</u>**
	• Exception for pregnancy requires documentation of actively attempting to conceive
	
	<u>Rheumatoid Arthritis</u>
	• Documented treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy:
	  ○ Methotrexate plus sulfasalazine
	  ○ Methotrexate plus hydroxychloroquine
	  ○ Sulfasalazine plus hydroxychloroquine
	  ○ Leflunomide plus sulfasalazine
	  ○ Leflunomide plus hydroxychloroquine
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	  ○ One of following: Infliximab (preferred biosimilar products Inflectra, Renflexis, Avsola), Actemra 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>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, Renflexis, Avsola) **AND** ○ One of the following: Otezla, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), or Ilumya **<u>Psoriatic Arthritis</u>** • 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, Renflexis, Avsola) **AND** ○ One of the following: Otezla, Simponi Aria, Orencia, or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) **<u>Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (NR-axSPA), 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, Renflexis, Avsola) **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 two oral treatments for minimum of 12 weeks trial: corticosteroids, 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, Renflexis, Avsola)
	  AND
	  ○ One of the following: Entyvio or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz)
	
	<u>Quantity Limitations (QL):</u>
	• Induction
	  ○ CD/RA/PsA/AS/Plaque Psoriasis: 400 mg (2 injections) at week 0, 2 and 4
	• Maintenance
	  ○ CD/RA/PsA/AS/ Plaque Psoriasis (90 kg or less): 400 mg (2 injections) per 28 days
	
	<u>Reauthorization</u>
	• Documentation of treatment success and a 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:	• 18 years of age or older
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: 12 months, unless otherwise specified

POLICY NAME:
CGRP INHIBITORS
PA policy applicable to:
Preferred drugs: Aimovig, Ajovy, Emgality
Medical infusion drugs: Vyepti

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 for combined use with Botox or another calcitonin gene-related peptide (CGRP) inhibitor for the prevention of chronic migraine?	Yes – Criteria not met, considered experimental	No – Go to #3
3. Is the request to treat a diagnosis according to one of the Food and Drug Administration (FDA)-approved indications (not otherwise excluded by plan design) at the approved dosing?	Yes – Go to appropriate section below	No – Criteria not met
Chronic or Episodic Migraine in adults **Preferred Drug – Emgality, Ajovy, Aimovig** **Medical Infusion Drugs – Vyepti**		
1. Is there a 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?	Yes – Document and go to #3	No – Go to #2
2. Is there a diagnosis of episodic migraine with at least 8 migraine days per month at baseline?	Yes – Document and go to #3	No – Criteria not met
3. Is the request for treatment of possible medication overuse headache? Headaches occurring 15 or more days each month in a patient with pre-existing headache-causing condition possibly due to o Use of ergotamines, triptans, opioids, or combination analgesics at least 10 days per month for at least three months	Yes – Criteria not met	No – Go to #4

○ 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		
4. Is there documented treatment failure with an adequate trial (at least 8 weeks) of an oral migraine preventive therapy as follows: ○ Propranolol 40 mg daily, metoprolol 100 mg daily ○ Amitriptyline 25 mg daily ○ Topiramate 50 mg daily, valproic acid, divalproex sodium	Yes – Document and go to #5	No – Criteria not met
5. Is the request for treatment with Vyepti?	Yes – Document and go to #7	No – Go to #6
6. Is there documented treatment failure with 6 months (two treatments) with Botox therapy? (Required only for chronic migraine).	Yes – Approve up to 6 months	No – Criteria not met
7. Is there documented treatment failure or intolerable adverse event to one of the preferred drugs (Emgality, Ajovy, Aimovig) AND Botox?	Yes – Approve up to 6 months	No – Criteria not met
Episodic Cluster Headaches - Emgality		
1. Is there a history of episodic cluster headaches with at least two cluster periods lasting from 7 days to 1 year (when untreated) that were separated by pain-free remission periods of at least one month?	Yes – Go to #2	No – Criteria not met
2. Is there 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)?	Yes – Approve up to 6 months (Maximum 6 fills per year)	No –Criteria not met
Renewal Criteria		

○ Is there documentation of treatment success defined as a 50% reduction in monthly headache frequency since starting treatment?	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 12 months	No – Criteria not met

Quantity Limitations

- **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
- **Ajovy**
  - Availability: 225 mg/1.5 mL syringe
  - Dosing: 225 mg every 30 days or 675 mg (3x 225 mg injection) every 90 days
- **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

PacificSource Community Solutions

POLICY NAME:
CHELATING AGENTS

PA policy applicable to: **Preferred drugs:** deferasirox soluble tablet, deferasirox tablet **Non -Preferred drugs:** Ferriprox (deferiprone), deferiprone, Jadenu (deferasirox)		
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 **Preferred Drugs –** deferasirox soluble tablet, deferasirox tablet **Non -Preferred drugs:** Ferriprox (deferiprone), Jadenu (deferasirox)		
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 generic formulation of deferasirox (oral or soluble tablet)?	Yes – Go to #6	No- Go to #5
5. Is there documented failure to deferasirox and deferoxamine (Desferal)?	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 **Preferred Drugs –** deferasirox soluble tablet, deferasirox tablet		

Non -Preferred drugs: Ferriprox (deferiprone), deferiprone, Jadenu (deferasirox)		
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 generic formulation of deferasirox (oral or soluble tablet)?	Yes – Document and go to #4	No – Go to #3
3. Is there documented failure to deferasirox and deferoxamine (Desferal)?	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
Indication: Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndromes **Preferred Drugs –** deferasirox soluble tablet, deferasirox tablet, Jadenu (deferasirox tablet)		
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:
CHOLBAM
Affected Medications: CHOLBAM (cholic acid) 50 & 250mg capsules

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
Required Medical Information:	• Patient weight, dose and frequency • Baseline liver function tests (AST, ALT, GGT, ALP, total bilirubin, INR) • Diagnosis confirmed by assessment of serum or urinary bile acid levels using mass spectrometry (Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis)
Appropriate Treatment Regimen & Other Criteria:	• Dose: 10 to 15 mg/kg orally once daily, or in two divided doses • Dose if concomitant familial hypertriglyceridemia: 11 to 17 mg/kg orally once daily, or in two divided doses • **Reauthorization** requires documentation of clinically significant improvement in liver function as determined by meeting TWO of the following criteria: ALT or AST values reduced to less than 50 U/L, or baseline levels reduced by 80%; total bilirubin values reduced to less than or equal to 1 mg/dL; no evidence of cholestasis on liver biopsy; body weight increased by 10% or stable at greater than the 50th percentile • Treatment should be discontinued if liver function does not improve after 3 months of start of treatment
Exclusion Criteria:	• Treatment of extrahepatic manifestations (such as neurologic symptoms) of bile acid synthesis disorders due to single enzyme defects or peroxisomal disorders including Zellweger spectrum disorders
Age Restriction:	• 3 weeks and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hepatologist or gastroenterologist
Coverage Duration:	• Initial: 3 months • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
CLADRIBINE
Affected Medications: MAVENCLAD (cladribine)

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

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 isolating syndrome (CIS)
Relapsing-remitting multiple sclerosis (RRMS)
Active secondary progressive disease (SPMS)

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

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

Documentation of previous treatment with a disease-modifying therapy (DMT)

<u>Clinically Isolated Syndrome</u>

Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event

<u>Secondary-Progressive MS</u>

Documentation of prior history of RRMS with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses
Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e., new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years
Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5

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

No concurrent use of other disease-modifying medications indicated for the treatment of MS
Documented failure with at least two other disease-modifying therapies (DMTs) for multiple sclerosis (MS) for at least 3 months

Reauthorization <u>(1 time only)</u>:

Documentation of clinical treatment success
Administer second course starting at least 43 weeks after the last dose of the first course
Dosing according to the approved label:

<table>
<tr><th colspan="2">Dose of MAVENCLAD per Cycle by Patient Weight in Each Treatment Course</th></tr>
<tr><th>Weight Range</th><th>Dose in mg (number of 10 mg tablets) per cycle</th></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><th>Kg</th><th>First Cycle</th><th>Second Cycle</th></tr>
<tr><td>40* to less than 50</td><td>40 mg (4 tablets)</td><td>40 mg (4 tablets)</td></tr>
<tr><td>50 to less than 60</td><td>50 mg (5 tablets)</td><td>50 mg (5 tablets)</td></tr>
<tr><td>60 to less than 70</td><td>60 mg (6 tablets)</td><td>60 mg (6 tablets)</td></tr>
<tr><td>70 to less than 80</td><td>70 mg (7 tablets)</td><td>70 mg (7 tablets)</td></tr>
<tr><td>80 to less than 90</td><td>80 mg (8 tablets)</td><td>70 mg (7 tablets)</td></tr>
<tr><td>90 to less than 100</td><td>90 mg (9 tablets)</td><td>80 mg (8 tablets)</td></tr>
<tr><td>100 to less than 110</td><td>100 mg (10 tablets)</td><td>90 mg (9 tablets)</td></tr>
<tr><td>110 and above</td><td>100 mg (10 tablets)</td><td>100 mg (10 tablets)</td></tr>
</table>
*The use of MAVENCLAD in patients weighing less than 40 kg has not been investigated
</td></tr>
<tr><td>Exclusion Criteria:</td><td>• Patients with current malignancy
• Patients with current Human Immunodeficiency Virus (HIV)
• Treatment beyond 2 years</td></tr>
<tr><td>Age Restriction:</td><td></td></tr>
<tr><td>Prescriber Restrictions:</td><td>• Prescribed by, or in consultation with, a neurologist or a MS Specialist</td></tr>
<tr><td>Coverage Duration:</td><td>• Initial Authorization: 2 months, unless otherwise specified
• Reauthorization: 2 months – at least 43 weeks after last dose, unless otherwise specified</td></tr>
</table>

PacificSource Community Solutions

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

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

Required Medical Information:	• Documentation of dose based on reasonable projections and current dose utilization and product labeling, diagnosis, baseline factor level, circulating factor activity (% of normal or units/dL) and rationale for use
	• Patient weight
	• Documentation with one of the following diagnostic categories:
	  ○ On-demand treatment and control of bleeding episodes
	  ○ Perioperative management of bleeding in patients with mild, moderate, and severe hereditary Factor X deficiency
	  ○ Routine prophylaxis to reduce the frequency of bleeding episodes
	
	Reauthorization (Routine Prophylaxis only) requires documentation of planned treatment dose, number of acute bleeds since last approval with severity, and cause of bleed

Appropriate Treatment Regimen & Other Criteria:	• Food and Drug Administration (FDA)-approved dosing
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified • Perioperative management: 1 month, unless otherwise specified

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

POLICY NAME:
CONTINUOUS GLUCOSE MONITORS
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

Required Medical Information:	• Diagnosis of Type 1 diabetes currently on an insulin pump
	• Diagnosis of Type 1 diabetes not currently using an insulin pump with one of the following:
	  ○ Baseline HbA1c Level 8.0% or higher
	  ○ Frequent or severe hypoglycemia
	  ○ Impaired awareness of hypoglycemia
	• Pregnant women or actively attempting to conceive and have a diagnosis of Type 1 diabetes
	• Children and adolescents under 21 with a diagnosis of Type 1 diabetes
	Reauthorization requires documentation of improved glycemic control

Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Type 2 diabetes
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 2 years, 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

Required Medical Information:	• Diagnosis of Wilson's disease confirmed by one of the following:
	  ○ Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals)
	  OR
	  ○ Documentation of at least two of the following:
	  ▪ Presence of Kayser-Fleischer rings
	  ▪ Serum ceruloplasmin level less than 20 mg/dL
	  ▪ Liver biopsy findings consistent with Wilson's disease
	  ▪ 24-hour urinary copper excretion greater than 40 mcg

Appropriate Treatment Regimen & Other Criteria:	• For trientine hydrochloride, must have a documented treatment failure (or intolerable adverse event) with a minimum 6-month trial of penicillamine
	• 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
	
	Reauthorization: Documentation of treatment success and a clinically significant response to therapy as shown by 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

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

POLICY NAME:
CORLANOR
Affected Medications: CORLANOR (ivabradine)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
	  ○ Heart failure with reduced ejection fraction (adjunctive agent)
	  ○ Heart failure, dilated cardiomyopathy in pediatric patients 6 months and older.
	• Compendia-supported uses that will be covered: Inappropriate sinus tachycardia

Required Medical Information:	**Chronic heart failure** • 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) **Heart failure, dilated cardiomyopathy in pediatric patients** • Sinus rhythm with an elevated heart rate **Inappropriate sinus tachycardia** • Heart rate of at least 100 beats per minute, with average mean heart rate of at least 90 beats per minute over 24 hours not due to appropriate physiologic response or primary abnormality (hyperthyroidism or anemia) • Symptomatic (palpitations, shortness of breath, dizziness, and/or decreased exercise capacity) • Documentation for absence of identifiable causes of sinus tachycardia and exclusion of atrial tachycardia
Appropriate Treatment Regimen & Other Criteria:	• Effective contraception is recommended in women of child-bearing age **Chronic heart failure** • Documentation of tried or currently receiving one beta blocker (metoprolol succinate extended release, carvedilol, or carvedilol extended release) at the maximally tolerated dose for heart failure treatment OR • Documentation of medical reason for avoidance of beta-blockers **Heart failure, dilated cardiomyopathy in pediatric patients** • Trial with beta blocker or digoxin therapy or contraindication or intolerance to beta blocker or digoxin use. **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-Paugh class C) • Heart rate maintained exclusively by pacemaker
Age Restriction:	• Heart failure-dilated cardiomyopathy: infants ≥6 months, Children, and Adolescents <18 years
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist
Coverage Duration:	• 12 months

POLICY NAME:
CORTICOTROPIN INJECTION GEL
Affected Medications: ACTHAR HP (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 HP ONLY**: Diagnosis of infantile spasms and the patient is currently receiving treatment with HP Acthar gel and has shown substantial clinical benefit from therapy, OR the patient has not received previous treatment with HP 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 HP 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 HP 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

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:	• 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 sickle cell-related crises
Exclusion Criteria:	• Long-term red blood cell transfusion therapy • Hemoglobin is <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 hemoglobin oxygen affinity modulator (voxelotor)
Age Restriction:	• Pediatric patients under 15 years of age
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist.
Coverage Duration:	• Initial approval: 6 months • Reauthorization: 12 months

POLICY NAME:
CYSTEAMINE
Affected Medications: CYSTAGON (cysteamine bitartrate), PROCYSBI (cysteamine)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• Diagnosis of nephropathic cystinosis • The diagnosis was confirmed by the presence of increased cysteine concentration in leukocytes (generally 3-23 nmol half-cystine/mg protein) or by DNA testing (mutations in the CTNS gene) or by demonstration of cysteine corneal crystals by the slit lamp examination
Appropriate Treatment Regimen & Other Criteria:	For Procysbi request: • Documented treatment failure, intolerance, or clinical rationale for avoidance of Cystagon.
Exclusion Criteria:	• Documented history of hypersensitivity to cysteamine or penicillamine
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months unless otherwise specified

POLICY NAME:
DALFAMPRIDINE
Affected Medications: dalfampridine

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded from plan design.
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
Appropriate Treatment Regimen & Other Criteria:	• Reauthorization requires documentation of treatment success defined as a stabilization or improvement from baseline in timed walking speed (timed 25 foot walk).
Exclusion Criteria:	• History of seizures
Age Restriction:	
Prescriber Restrictions:	• Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
DAPTOMYCIN
Affected Medications: DAPTOMYCIN

Covered Uses:	• Empiric treatment of an infection caused by an undefined pathogen on an outpatient basis
	• 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 and MRSA
	  ▪ Streptococcus pyogenes
	  ▪ Streptococcus agalactiae
	  ▪ Streptococcus dysgalactiae subsp. equisimilis
	  ▪ Enterococcus faecalis
	  ○ MRSA infections
	• Compendia-supported uses that will be covered
	  ○ Vancomycin resistant enterococci (VRE) or vancomycin resistant staph aureus (VRSA) infections where linezolid is not a therapeutic option
	  ○ Bacteremia associated with intravascular line
	  ○ Osteomyelitis
	  ○ Septic arthritis
	  ○ Febrile neutropenia

Required Medical Information:	• Documentation of confirmed or suspected diagnosis • 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 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 treatment of an infection caused by an undefined pathogen on an outpatient basis for up to 7 days **Bacteremia, including right-sided infective endocarditis**

	• Documentation of pathogen resistance to vancomycin or contraindication to therapy
	• Adult dosing:
	  ○ 6 to 10mg/kg once daily for 2 to 6 weeks
	  ○ CrCl less than 30 mL/min: 6 mg/kg once every 48 hours for 2 to 6 weeks
	• 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: up to 6 weeks
	cSSSI
	• For infections caused by MRSA: Documentation of pathogen resistance to sulfamethoxazole/trimethoprim, rifampin, clindamycin, doxycycline, vancomycin and linezolid or contraindication to therapy with each
	• Adult dosing:
	  ○ 4mg/kg once daily for 7 to 14 days
	  ○ CrCl less than 30 mL/min: 4 mg/kg once every 48 hours for 7 to 14 days
	• 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: up to 14 days
	MRSA infections
	• Documentation of pathogen resistance to vancomycin and linezolid or contraindication to therapy with both
	Bacteremia associated with intravascular line
	• Documentation indicating infection is caused by ampicillin- and VRE, OR
	• For infections caused by MRSA, coagulase-negative staphylococci, or ampicillin-resistant, vancomycin-susceptible Enterococcus faecalis/faecium: Documentation of pathogen resistance to vancomycin or contraindication to therapy
	• Adult dosing
	  ○ MRSA: 6 to 8mg/kg once daily
	  ○ Other: 6mg/kg once daily
	Osteomyelitis
	• Documentation indicating infection is caused by VRSA
	• For infections caused by MRSA: documentation of pathogen resistance to vancomycin and linezolid or contraindication to therapy with both
	• Adult dosing: 6 to 8mg/kg
	• Pediatric dosing: 6 to 10mg/kg once daily

	Septic arthritis • For infections caused by MRSA and other bacteria where these agents are a therapeutic option: Documentation of pathogen resistance to vancomycin, linezolid, sulfamethoxazole/trimethoprim, and linezolid or contraindication to therapy with each • Adult dosing: 6mg/kg once daily for 3 to 4 weeks • Pediatric dosing: 6 to 10mg/kg once daily
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:
DASATINIB
Affected Medications: SPRYCEL (dasatinib)

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, all prior therapies used, and prescribed treatment regimen • Documentation of Philadelphia chromosome-positive mutation status
Appropriate Treatment Regimen & Other Criteria:	• For patients with Chronic myeloid leukemia (CML) and low risk score, documented clinical failure with Imatinib • For patients with acute lymphoblastic leukemia (ALL), documented clinical failure with imatinib. **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 Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial authorization: 4 months (2 week initial partial fill), unless otherwise specified • Reauthorization:12 months, unless otherwise specified

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:	• Administer for a minimum of 21 days. If after 21 days signs and symptoms of hepatic VOD have not resolved, continue until resolution of VOD or up to a maximum of 60 days
Exclusion Criteria:	• Concomitant administration with systemic anticoagulant or fibrinolytic therapy
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 2 months with no reauthorization, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
DIABETIC TEST STRIPS
Affected Medications: DIABETIC TEST STRIPS

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Diabetes Mellitus (DM)
Required Medical Information:	• Documentation of complete & current treatment course

Appropriate Treatment Regimen & Other Criteria:	Preferred products must be prescribed *(If a patient requires a new meter, please call 541-330-4999)*:
	  ○ Freestyle
	  ○ Freestyle Lite
	  ○ Freestyle InsuLinx
	  ○ Freestyle Precision Neo
	
	Standard Quantity Limits:
	• Insulin dependent DM: #100 test strips per 25 days (4x/day)
	• Non-insulin dependent DM: #100 test strips per 25 days (4x/day)
	
	Quantity Limit exceptions:
	• Uncontrolled (HbA1c >10), insulin administration 4 times daily or greater, new onset, or gestational: #150 test strips per 25 days (6x/day)
	• New onset Pediatric DM or Insulin Pump Start: #250 test strips per 25 days (10x/day)

Exclusion Criteria:	• Patients actively utilizing continuous glucose monitors (CGM) will not be approved for greater than 4 times daily testing (#100/25 days).
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months

POLICY NAME:
DINUTUXIMAB
Affected Medications: UNITUXIN (dinutuximab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded from 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 prescribed dosing regimen • Documentation of Neuroblastoma, High risk, with at least a partial response to prior first-line multi-agent, multimodality therapy
Appropriate Treatment Regimen & Other Criteria:	• Maximum duration: 5 cycles • Must be used in combination with granulocyte-macrophage colony-stimulating factor, interleukin-2, and 13-cis-retinoic acid **Reauthorization** will require documentation of treatment success and a clinically significant response 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:	• Approval: 5 months, unless otherwise specified

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

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 (eg 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:	• Known hypersensitivity to dornase alfa, Chinese Hamster Ovary cell products, or any component of the product.
Age Restriction:	• 1 month or older
Prescriber Restrictions:	
Coverage Duration:	• Approval: 24 months, unless otherwise specified.

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.
Required Medical Information:	• Diagnosis of idiopathic Parkinson's Disease (PD) based on presence of bradykinesia and at least one other cardinal PD feature (tremor, rigidity, postural instability) AND • Levodopa responsive with clearly defined "On" periods AND • Persistent motor complications with disabling "Off" periods for a minimum of 3 hours/day, despite optimal medical therapy with oral levodopa-carbidopa, and at least two other classes of anti-PD therapy (i.e. COMT, MAO-B inhibitor, or dopamine agonist)
Appropriate Treatment Regimen & Other Criteria:	• Duopa is delivered as a 16-hour infusion through either a naso-jejunal tube for SHORT-term administration or through a PEG-J for LONG-term administration **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)

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 for use in combination with another monoclonal antibody (e.g., Fasenra, Nucala, Xolair, Cinqair)?	Yes – Criteria not met; combination use is experimental	No – Go to #3
3. Is the request to treat a diagnosis according to one of the Food and Drug Administration (FDA)-approved indications? ○ Add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma ○ Treatment of patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable ○ Treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE)	Yes – Go to appropriate section below	No – Criteria not met
Moderate-to-Severe Eosinophilic Asthma		
1. Is there documentation of severe eosinophilic asthma defined by the following: ○ Baseline eosinophil count at least 300 cells/µL AND ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal	Yes – Document and go to #2	No – Criteria not met
2. Is there documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms?	Yes – Document and go to #3	No – Criteria not met

3. Is there 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 and at least 80% adherence?	Yes – Go to #5	No – Go to #4
4. Is there documentation that chronic daily oral corticosteroids are required?	Yes – Go to #5	No – Criteria not met
5. Is the drug prescribed by, or in consultation with, an Allergist, Immunologist, or Pulmonologist?	Yes – Approve up to 6 months	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 – 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 steroids and a topical non-steroidal agent (e.g., tacrolimus ointment, pimecrolimus cream)?	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
Indication: Chronic Rhinosinusitis with nasal polyposis (CRSwNP)		
1. Is there documentation of chronic sinusitis after total ethmoidectomy with a need for revision endoscopic sinus surgery due to continued symptoms of nasal congestion/obstruction from recurrent bilateral sinus obstruction due to nasal polyps?	Yes – Document and go to #2	No – Criteria not met
2. Is there documented failure with at least 1 intranasal corticosteroid (such as fluticasone) after ethmoidectomy?	Yes – Document and go to #3	No – Criteria not met
3. Is the drug prescribed by a specialist in the treatment of nasal polyps (otolaryngologist)?	Yes – Approve up to 6 months	No – Criteria not met
Indication: Eosinophilic Esophagitis (EoE)		
1. Is there a confirmed diagnosis of EOE by endoscopic biopsy?	Yes – Document and go to #2	No – Criteria not met
2. Is the age 12 years or older and body weight above or equal to 40 kg?	Yes – Document and go to #3	No – Criteria not met
3. Is there a history of TWO or more dysphagia episodes per week despite current treatment?	Yes – Go to # 4	No – Criteria not met
4. Is there documented treatment failure (minimum of at least 12 week trial) to both of the following: a. High dose (twice daily dosing) Proton Pump Inhibitor (PPI) b. Swallowed inhaled respiratory corticosteroid therapy (such as fluticasone or budesonide)	Yes – Go to #5	No – Criteria not met
5. Is the drug prescribed by, or in consultation with, a specialist in the treatment of EoE such as gastroenterologist or allergy/immunology specialist?	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 request for use in combination with another monoclonal antibody (e.g., Fasenra, Nucala, Xolair, Cinqair)?	Yes – Criteria not met; combination use is experimental	No – Go to #3
3. 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

- **Dupixent**
  - Availability: 300 mg/2 mL pre-filled syringe or pre-filled pen, or 200 mg/1.14 mL pre-filled syringe or prefilled pen, 100 mg/0.67 mL prefilled syringe
  - Dosing:
    - Eosinophilic Esophagitis;
      - Adults and children (12 years of age and older):
        - 40kg or greater: 300mg every week
    - Atopic Dermatitis:
      - Children greater than or equal to 6 months up to 5 years of age (no initial loading dose is recommended):
        - 5 to less than 15 kg: 200mg every 4 weeks
        - 15 to less than 30 kg: 300mg every 4 weeks
      - Children 6 to 17 years of age:
        - 15 to less than 30kg: Initial dose of 600 mg (two 300 mg injections) followed by 300 mg every 4 weeks
        - 30 to less than 60 kg: Initial dose of 400 mg (two 200 mg injections) followed by 200 mg every other week
        - Greater than 60kg: Initial dose of 600 mg (two 300 mg injections) followed by 300 mg every other week
      - Adults 18 years or greater:
        - Initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week
  - Asthma:
    - Children 6 to 11 years old: NO LOADING DOSE RECOMMENDED
      - 15 kg to less than 30 kg: 100 mg every other week OR 300 mg every 4 weeks

- 30 kg or greater: 200 mg every other week

- Adults and adolescents 12 years of age and older: Initial dose of 400 mg (two 200 mg injections) followed by 200 mg given every other week or initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week
- CRSwNP: 300 mg every other week

*Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced for all medical infusion drugs

POLICY NAME:
ECULIZUMAB
Affected Medications: SOLIRIS (eculizumab)

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) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive

Required Medical Information:	• Patients must be administered a meningococcal vaccine at least two weeks prior to initiation of Soliris therapy and revaccinated according to current Advisory Committee on Immunization Practices (ACIP) guidelines
	
	<u>Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis:</u>
	• 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
	
	<u>Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-medicated thrombotic microangiopathy:</u>
	• 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

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	Generalized Myasthenia Gravis (gMG)
	• Diagnosis of generalized Myasthenia Gravis (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 anti-acetylcholine receptor (AchR) antibodies
	• MG-Activities of Daily Living (MG-ADL) total score of greater than or equal to 6
	• Documentation of baseline Quantitative Myasthenia Gravis (QMG) score
	
	Neuromyelitis Optica Spectrum Disorder (NMOSD)
	• Diagnosis of NMOSD with aquaporin-4 immunoglobulin G (AQP4-IgG) antibody positive disease confirmed by all the following:
	  ○ At least one core clinical characteristic:
	  ▪ Optic neuritis
	  ▪ Acute myelitis
	  ▪ Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting
	  ▪ Acute brainstem syndrome
	  ▪ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMSOD-typical diencephalic MRI lesions
	  ▪ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
	  ○ Documentation of positive test for AQP4-IgG antibodies via cell-based assay
	  ○ Exclusion of alternative diagnoses (such as multiple sclerosis)

Appropriate Treatment Regimen & Other Criteria:	**Paroxysmal nocturnal hemoglobinuria to reduce hemolysis:**
	• Documented inadequate response, contraindication, or intolerance to ravulizumab (Ultomiris)
	
	Atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy:
	• 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 (Ultomiris)

	<u>Generalized Myasthenia Gravis</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)
	  ○ Need for ongoing rescue therapy (at least 3 courses in the past 12 months) with plasmapheresis, plasma exchange or intravenous immunoglobulin (IVIG) while consistently taking an immunosuppressive therapy (azathioprine, mycophenolate, tacrolimus, cyclosporine, methotrexate)
	• Documented inadequate response, contraindication, or intolerance to efgartigimod-alfa (Vyvgart)
	• Documented inadequate response, contraindication, or intolerance to ravulizumab (Ultomiris)
	
	<u>Neuromyelitis Optica Spectrum Disorder (NMOSD)</u>
	• Documented inadequate response, contraindication, or intolerance to rituximab (preferred agents Truxima, Riabni, and Ruxience)
	• Documented inadequate response, contraindication, or intolerance to satralizumab (Enspryng)
	• Documented inadequate response, contraindication, or intolerance to inebilizumab (Uplizna)
	
	*****Dose Adjustment in Case of Plasmapheresis, Plasma Exchange, or Fresh Frozen Plasma Infusion**
	• For adult and pediatric patients with aHUS, and adult patients with gMG or NMOSD, supplemental dosing of Soliris is required in the setting of concomitant plasmapheresis or plasma exchange, or fresh frozen plasma infusion
	
	<u>Reauthorization requires:</u>
	• 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 biologics (rituximab, inebilizumab, tocilizumab, ravulizumab, pegcetacoplan, etc.) • Current meningitis infection

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Age Restriction:	• PNH, gMG, and NMOSD: 18 years of age or 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

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:	• Definite or probable Amyotrophic lateral sclerosis (ALS) based on El Escorial revised (Airlie House) 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 defined as at least 2 points on all 12 items of the ALS functional rating scale-revised (ALSFRS-R)
Appropriate Treatment Regimen & Other Criteria:	Documentation of one of the following: • Member is stable on riluzole • Prescriber has indicated clinical inappropriateness of riluzole 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**: Treatment success as determined by prescriber including retaining most activities of daily living
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

POLICY NAME:
ELAGOLIX

PA policy applicable to: Orilissa (elagolix 150 mg & 200 mg tablets) and Oriahnn (elagolix 300 mg/estradiol 1 mg/ norethindrone acetate 0.5 mg capsules)		
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
Uterine Fibroids – Oriahnn		
1. Is there attestation of premenopausal status?	Yes –Go to #2	No – Criteria not met
2. Is there attestation that the member does not have a history of osteoporosis?	Yes – Go to #3	No – Criteria not met
3. Is there attestation from the provider that the member is not pregnant and does not have plans to become pregnant?	Yes – Go to #4	No – Go to
4. Is there documentation of a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas?	Yes – Approve up to 6 months	No – Criteria not met
Pain due to endometriosis – Orilissa		
1. Is there attestation of premenopausal status?	Yes – Go to #2	No – Criteria not met
2. Is there attestation that the member does not have a history of osteoporosis?	Yes – Go to #3	No – Criteria not met
3. Is there attestation from the provider that the member is not pregnant and does not have plans to become pregnant?	Yes – Go to #4	No – Criteria not met

4. Is there documentation of a diagnosis of moderate to severe pain associated with endometriosis?	Yes – go to #5	No – Criteria not met
5. Is there documentation of a trial and inadequate relief after at least three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and continuous (no placebo pills) hormonal contraceptives?	Yes – Document and 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 18 months for: 1. Oriahnn 2. Orilissa 150 mg once daily*	No – Criteria not met
Quantity Limitations		

• **Oriahnn**
  ○ 56 tablets per 28 days
• **Orilissa**
  ○ 150 mg: 30 tablets per 30 days
  ○ 200 mg: 60 tablets per 30 days
***Maximum treatment duration for 200 mg twice daily, or 150 mg once daily with moderate hepatic impairment (Child-Pugh Class B) is 6 months. Reauthorization not allowed		

POLICY NAME:
ELAPRASE
Affected Medications: ELAPRASE (idursulfase)

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

Required Medical Information:	• Diagnosis of Mucopolysaccharidosis type II confirmed by enzyme assay demonstrating a deficiency of iduronate 2-sulfatase enzyme activity or by DNA testing that shows pathologic iduronate 2-sulfatase gene mutation
	• Documented clinical signs and symptoms of Hunters syndrome such as abnormal facial appearance, liver or spleen enlargement, cardiovascular disorders, neurocognitive decline, presence of pearly popular skin lesions
	• Baseline values for one or more of the following:
	  ○ 6 minute walk test (6-MWT)
	  ○ Forced vital capacity (FVC)
	  ○ Liver and/or spleen volume
	  ○ Urinary glycosaminoglycan (GAG) level

Appropriate Treatment Regimen & Other Criteria:	Dose does not exceed 0.5 mg/kg/week • 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 6-MWT • Improvement or stability in FVC • Reduction in liver and/or spleen volume • Reduction in urinary GAG level
Exclusion Criteria:	
Age Restriction:	• 16 months of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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POLICY NAME:
ELIGLUSTAT
Affected Medications: CERDELGA (eliglustat)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Gaucher disease type 1 (GD1)
Required Medical Information:	• Diagnosis must be documented in the members chart notes within the past 6 months • Diagnosis confirmed by enzyme assay • Documentation of cytochrome P450 2D6 (CYP2D6) Genotype by a FDA approved test indicating CYP2D6 extensive metabolizers, intermediated metabolizers, or poor metabolizers • Documentation of complete and current treatment course • Documentation of baseline tests such as hemoglobin level, platelet count, liver function tests, renal function tests.
Appropriate Treatment Regimen & Other Criteria:	• Documentation of failure, intolerance, or clinical rationale for the avoidance of combination therapy with Cerezyme, and failure with Cerezyme monotherapy **Extensive or Immediate 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 **Reauthorization:** will require documentation of treatment success and a clinically significant response to therapy.
Exclusion Criteria:	• UMs • Moderate or severe hepatic impairment • Pre-existing cardiac disease (congestive heart failure, myocardial infarction, bradycardia, heart block, arrhythmias, and long QT syndrome) • Treatment with Class 1A (e.g., quinidine, procainaminde) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications • Presence of moderate to severe renal impairment or end stage renal disease
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a metabolic disease specialist
Coverage Duration:	• Approval: 3 months, unless otherwise specified • Reapproval: 12 months, unless otherwise specified

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)

POLICY NAME:
ELOSULFASE ALFA
Affected Medications: VIMIZIM (elosulfase alfa)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Mucopolysaccharidosis type IVA (MPS IVA; Morquio A Syndrome)
Required Medical Information:	• Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) confirmed by an enzyme assay or detection of biallelic pathogenic mutations in the GALNS gene by molecular genetic testing • Documented clinical signs and symptoms of Morquio A syndrome such as knee deformity, hip deformity, protuberant sternum, kyphoscoliosis, and abnormal gait • Baseline six minute walk test (6-MWT) or three minute stair climb test (3-MSCT)
Appropriate Treatment Regimen & Other Criteria:	• Dose does not exceed 2 mg/kg/week • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced for all medical infusion drugs **Reauthorization** requires documentation of treatment success defined as improvement in six minute walk test (6-MWT) or three minute stair climb test (3-MSCT)
Exclusion Criteria:	
Age Restriction:	• 5 years of age and older
Prescriber Restrictions:	
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
ELTROMBOPAG
Affected Medications: PROMACTA (eltrombopag), PROMACTA PACKET

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
	  ○ Thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
	  ○ In combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia
	  ○ Patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy

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 **AND**
	• 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:	• Oral suspension formulation requires documented medical inability to use Promacta tablets **<u>Thrombocytopenia in patients with 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 Promacta 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 Promacta 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:	
Age Restriction:	**<u>Thrombocytopenia in patients with ITP</u>** • 1 year of age and older **<u>Thrombocytopenia in patients with chronic hepatitis C and patients with severe aplastic anemia</u>** • 18 years of age and older

	Severe Aplastic Anemia (initial therapy) • 2 years of age and older
Prescriber Restrictions:	• Prescribed by, or consultation with, a hematologist or gastroenterology/liver specialist
Coverage Duration:	**Thrombocytopenia in patients with ITP** • Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified **Thrombocytopenia in patients with chronic hepatitis C** • Initial Authorization: 2 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified **Severe aplastic anemia** • Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified **Severe aplastic anemia in combination with cyclosporine and Atgam** • Approval: 6 months, no reauthorization, unless otherwise specified

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 adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

Required Medical Information:	<u>Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)</u>
	• Medical records (e.g., chart notes, laboratory values) confirming the following:
	  ○ Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D); **AND**
	  ○ Confirmation that 5 of the following clinical characteristics are present:
	  ▪ Fever 101.3°F or higher
	  ▪ Splenomegaly
	  ▪ **Two** of the following cytopenias in the peripheral blood:
	  • Hemoglobin less than 9 g/dL; or
	  • Platelet count less than 100 x 109/L; or
	  • Neutrophils less than 1 x 109/L
	  ▪ **One** of the following:
	  • Hypertriglyceridemia defined as fasting triglycerides 3 mmol/L or higher or 265 mg/dL or higher; or
	  • Hypofibrinogenemia defined as fibrinogen 1.5 g/L or lower
	  ▪ Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy
	  ▪ Low or absent natural killer cell activity (according to local laboratory reference)
	  ▪ Ferritin 500 mg/L or higher
	  ▪ Soluble CD25 (i.e., soluble IL-2 receptor) 2,400 U/ml or higher
	<u>AND</u>
	• Patient has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (i.e., etoposide + dexamethasone); **and**
	• Emapalumab will be administered with dexamethasone; **and**
	• Patient is a candidate for stem cell transplant; **and**

	• Emapalumab is being used as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant; **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Approval is for no more than 6 months
Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
Exclusion Criteria:	• Emapalumab for the treatment of secondary HLH
Age Restriction:	
Prescriber Restrictions:	• Must be prescribed by, or in consultation with, a prescriber experienced in the treatment of HLH
Coverage Duration:	• Initial Authorization: 2 months, unless otherwise specified • Reauthorization: 4 months, unless otherwise specified (not to exceed 6 months total of treatment)

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:	Nutritional Deficiency identified by one of the following:
	• 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)
	OR
	• 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)
	OR
	• 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
	
	Oral nutritional supplements may be approved when the following criteria has been met:
	
	<u>Clients age 6 and above:</u>
	• Must have a nutritional deficiency identified by one of the following:
	  ○ Recent low serum protein levels OR
	  ○ Recent registered dietician assessment shows sufficient caloric/protein intake is not obtainable through regular, liquefied or pureed foods OR
	  ○ Must meet all of the following:
	  ▪ Prolonged history (i.e. years) of malnutrition, and diagnosis or symptoms of cachexia
	  ▪ Client residence in home, nursing facility, or chronic home care facility
	  ▪ Where the above conditions be futile and invasive
	AND
	• Must have a recent unplanned weight loss of at least 10%, PLUS one of the following:
	  ○ Increased metabolic need resulting from severe trauma OR
	  ○ Malabsorption difficulties (e.g., short-gut syndrome, fistula, cystic fibrosis, renal dialysis) OR
	  ○ Ongoing cancer treatment, advanced Acquired Immune Deficiency Syndrome (AIDS) or pulmonary insufficiency.
	<u>*Note:*</u> Weight loss criteria may be waived if body weight is being maintained by supplements due to patient's medical condition (e.g., renal failure, AIDS)
	
	<u>Clients under age 6:</u>
	• Diagnosis of failure to thrive AND

	• Must meet same criteria as above, with the exception of % of weight loss.
Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by a practitioner licensed to prescribe medications
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ENZYME REPLACEMENT THERAPY (ERT) FOR FABRY DISEASE
Affected Medications: ELFABRIO (pegunigalsidase alfa), FABRAZYME (agalsidase beta)

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 alpha-galactosidase enzyme activity (less than 3 percent)
	  ○ Males: Deficiency of alpha-galactosidase enzyme activity (less than 35 percent) and molecular genetic testing showing a mutation in the GLA gene
	  ○ Females: Molecular genetic testing showing a mutation in the GLA gene
	• Clinical signs and symptoms of Fabry disease including severe neuropathic pain, dermatologic manifestations (telangiectasias and angiokeratomas), corneal opacities, kidney manifestations (proteinuria, polyuria, polydipsia), cardiac involvement (left ventricular hypertrophy, myocardial fibrosis, heart failure), or cerebrovascular involvement (transient ischemic attacks, ischemic strokes)

Appropriate Treatment Regimen & Other Criteria:	• Documented clinical failure (at least 12 weeks) or intolerable adverse event to Fabrazyme prior to Elfabrio approval • Dose does not exceed 1 mg/kg every 2 weeks • 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 ERT or Galafold
Age Restriction:	• 2 years of age and older for Fabrazyme • 18 years of age and older for Elfabrio
Prescriber Restrictions:	• Prescribed by, or in consultation with, a geneticist or a specialist experienced in the treatment of Fabry disease
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
EPOPROSTENOL
Affected Medications: Epoprostenol, Veletri, Flolan

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	**Pulmonary arterial hypertension (PAH) WHO Group 1** • Documentation of PAH confirmed by right-heart catheterization • Documentation of acute vasoreactivity testing testing (positive result requires trial/failure to calcium channel blocker) unless contraindications such as low systemic blood pressure (systolic blood pressure less than 90), low cardiac index, or presence of severe symptoms (functional class IV) • Patient weight, planned dose and frequency
Appropriate Treatment Regimen & Other Criteria:	• PAH: for initiation of therapy patient must have mean pulmonary artery pressure at least 20 mm Hg, pulmonary capillary wedge pressure less than or equal to 15 mm Hg, and pulmonary vascular resistance at least 3 Wood units **AND** • Failure of the following therapy classes: PDE5 inhibitors **AND** • Endothelin receptor antagonists (exception for severe disease, WHO class IV) • Subsequent approval requires documentation of treatment success: exercise endurance, echocardiographic testing, hemodynamic testing, BNP, functional class **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Flolan: Heart failure caused by reduced left ventricular ejection fraction • Veletri: Long-term use in patients with heart failure due to severe left ventricular systolic dysfunction; long-term use patients who develop pulmonary edema during dose initiation
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• Initial coverage: 3 months, unless otherwise specified • Subsequent coverage: 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 migraines described as being moderate-severe
	• Documentation of inadequate response or contraindication to all of the following:
	  ○ Minimum of two prescription strength NSAIDs or combination analgesics (e.g., ibuprofen, naproxen, or acetaminophen plus aspirin plus caffeine)
	  ○ Minimum of 1 oral 5-hydroxytryptamine-1 (5HT1) receptor agonists (e.g., sumatriptan, naratriptan, rizatriptan, or zolmitriptan)
	  ○ Minimum of 1 NON-oral 5HT1 agonist (e.g., sumatriptan, zolmitriptan)

Appropriate Treatment Regimen & Other Criteria:	• Injection doses should not exceed 3 mg in a 24 hour period, and 6 mg in one week
	  ○ QL 12mL/30 days
	• Nasal solutions should not exceed 2 mg per day, no additional benefit shown
	  ○ QL 2mL/30 days (or 8mg/30 days)
	
	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:	• Patients 18 years 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: o Anemia associated with chronic renal failure o Anemia secondary to chemotherapy with a minimum of two additional months of planned chemotherapy o Anemia secondary to zidovudine-treated Human Immunodeficiency Virus (HIV) patients o Anemia in patients scheduled to undergo elective, non-cardiac, nonvascular surgery o Symptomatic anemia in Myelodysplastic syndrome o Allogenic bone marrow transplantation o Anemia associated with Hepatitis C (HCV) treatment o 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

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-readigraphic axial spondyloarthritis
	  ○ Plaque Psoriasis

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 • The Clinical Disease Activity Index (CDAI) greater than 10 • Weighted RAPID3 of at least 2.3 **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 (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 **Psoriatic Arthritis** • 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 • Juxta-articular bone formation on radiographs (distinct from osteophytes): one point **Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (NR-axSPA)**

	• 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>Polyarticular Juvenile Idiopathic Arthritis</u>
	• Documented 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 treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy:
	  ○ Methotrexate plus sulfasalazine
	  ○ Methotrexate plus hydroxychloroquine
	  ○ Sulfasalazine plus hydroxychloroquine
	  ○ Leflunomide plus sulfasalazine
	  ○ Leflunomide plus hydroxychloroquine
	• Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of each therapy:
	• One of following: Infliximab (preferred biosimilar products: Inflectra, Renflexis, Avsola), Actemra 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>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, Renflexis, Avsola)
	  AND
	  ○ One of the following: Otezla, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), or Ilumya
	
	<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, Renflexis, Avsola)
	  AND
	  ○ One of the following: Otezla, Simponi Aria, Orencia, or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz)
	
	<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, Renflexis, Avsola)
	  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:
	  ○ Actemra IV, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), and Simponi Aria
	
	<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: 12 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 treatment failure or intolerable adverse event to ALL the following, unless contraindicated:
	  ○ Calcitriol oral (capsule or solution) and injection
	  ○ Paricalcitol oral and injection
	  ○ Doxercalciferol oral and injection
	  ○ 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

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:	**Dosing** • 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 ○ As an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies (LLTs) for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH)

Required Medical Information:	• Diagnosis of HoFH confirmed by at least 1 of the following:
	  ○ Genetic testing showing multiple mutant alleles across the following gene loci: low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1).
	  ○ Untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND one of the following: (1) history of cutaneous or tendinous xanthoma prior to age 10 years or (2) documentation of untreated LDL-C greater than 190 mg/dL consistent with heterozygous familial hypercholesterolemia in both parents
	• Documentation of baseline untreated LDL-C

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure defined as an LDL-C greater than 100mg/dL despite at least six months of adherent therapy with all of the following, unless contraindicated or not tolerated:
	  ○ High intensity statin therapy (atorvastatin, rosuvastatin)
	  ○ Ezetimibe
	  ○ PCSK9 inhibitor (Praluent, Repatha) unless double-null or LDLR activity 15% or less
	• **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
	• Dosing: 15mg/kg IV once every 4 weeks

Exclusion Criteria:	
Age Restriction:	• 12 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

POLICY NAME:
EXTAVIA
Affected Medications: **Extavia** (interferon beta-1b)

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 isolating syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive disease (SPMS)

Required Medical Information:	• 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 **Clinically Isolated Syndrome** • Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event **Secondary-Progressive MS** • Documentation of prior history RRMS with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e. new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5
Appropriate Treatment Regimen & Other Criteria:	• No concurrent use of other disease-modifying medications indicated for the treatment of MS **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 neurologist or an MS specialist.

Coverage Duration:	• Authorization will be for 12 months, unless otherwise specified.

POLICY NAME:
FDA APPROVED DRUG – Below the Medicaid Line of Coverage

Covered Uses:	• Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	• Medications used to treat a condition that is below the Oregon Health Authority (OHA)-funded line of the Prioritized List of Health Services are not covered by PacificSource Community Solutions. • 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
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

POLICY NAME:
FDA APPROVED DRUG – Drug or Indication Not Yet Reviewed By Plan for Formulary Placement
Affected Medications: New Medications or Indications of Existing Drugs Not Yet Reviewed 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:	• Prescriber restrictions based on package insert requirements
Coverage Duration:	• Case by case based on member need

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:	• Previous treatment with each of the following in the setting of CDI recurrence:
	  ○ Vancomycin **OR** fidaxomicin (Dificid)
	  ○ Zinplava **OR** fecal microbiota transplant (FMT)
	• For Vowst requests: Documented treatment failure with all the above agents AND 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

POLICY NAME:
FENFLURAMINE
Affected Medications: **FINTEPLA (fenfluramine)**

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
Required Medical Information:	• Documented diagnosis of Dravet syndrome (DS) or Lennox-Gastaut Syndrome (LGS) • Patient 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 • Documentation of baseline cardiac function testing **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, or topiramate
	
	Lennox-Gastaut Syndrome (LGS)
	• Documented treatment and inadequate control of seizures with Epidolex **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 as determined by treating provider

Exclusion Criteria:	• Concomitant use of, or within 14 days of the administration of monoamine oxidase inhibitors.
Age Restriction:	• 2 years of age and older
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

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, defined as:
	  ○ Prescence of *C. difficile* toxin A or B in the stool AND
	  ○ 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
	  ○ 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:
FILSPARI
Affected Medications: FILSPARI (sparsentan)

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 rapid disease progression
Required Medical Information:	• Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed with biopsy • Proteinuria defined as equal to or greater than 1 g/day (labs current within 30 days of request) **OR** • Urine protein-to-creatinine ratio (UPCR) greater than 1.5 g/g
Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with a minimum of 12 weeks of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blockers (ARB) • Documented treatment failure with a minimum of 12 weeks of glucocorticoid therapy such as oral prednisone or methylprednisolone (treatment failure defined as proteinuria equal to or greater than 1 g/day or an adverse effect to two or more glucocorticoid therapies that is not associated with the corticosteroid class) **No reauthorization** – Recommended duration of therapy is 9 months
Exclusion Criteria:	• Hepatic impairment (Child-Pugh class A-C)
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a nephrologist that is REMS certified
Coverage Duration:	• Authorization: 9 months, unless otherwise specified

POLICY NAME:
FLUCYTOSINE
Affected Medications: FLUCYTOSINE

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Candidal endocarditis
	  ○ Candidiasis
	  ○ Candidiasis of urogenital site
	  ○ Cryptococcosis
	• Compendia-supported uses that will be covered (if applicable)
	  ○ Candida endophthalmitis
	  ○ Central nervous system candidiasis
	  ○ Cryptococcal meningitis – HIV infection
	  ○ HIV infection – Pulmonary cryptococcosis

Required Medical Information:	• Susceptibility cultures matching flucytosine activity
Appropriate Treatment Regimen & Other Criteria:	• Dosing: maximum 150 mg/kg/day
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an Infectious Disease specialist
Coverage Duration:	• Approval: 8 weeks, or lesser requested duration

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 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
	• Documented inability to respond adequately to Promacta
	
	Reauthorization requires response to treatment with platelet count of at least 50,000/microliter or above (not to exceed 400,000 microliter)

Exclusion Criteria:	
Age Restriction:	• 18 years of age and 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

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.
Required Medical Information:	**Iluvien** • Diagnosis of clinically significant diabetic macular edema AND • Documentation of past treatment with corticosteroids without a clinically significant rise in intraocular pressure AND • Documentation of insufficient response to initial therapy with intravitreal bevacizumab (or another anti-VEGF therapy) AND • Documentation of insufficient response to laser photocoagulation **Retisert and Yutiq** • Diagnosis of recurrent non-infectious uveitis with documentation of slit-lamp examination and dilated fundus examination • Authorization for Retisert requires documented clinical failure with Yutiq

Appropriate Treatment Regimen & Other Criteria:	**Iluvien**
	• One intravitreal implant per 36 months as monotherapy
	• If the physician determines that adjunctive therapy with anti-VEGF is necessary (e.g. worsening visual acuity, retinal volume, or fluorescein leakage with Iluvien monotherapy), the request will be reviewed and determination will be made based on medical necessity. Adjunctive therapy with Avastin (bevacizumab) will be the preferred option.
	
	Retisert and Yutiq
	• One intravitreal implant per 30 months (Retisert) or 36 months (Yutiq)
	• Documented failure with
	  ○ A 12-week trial with a systemic corticosteroid (such as prednisone) **AND**
	  ○ At least one immunosuppressive agent: methotrexate, azathioprine, mycophenolate AND
	  ○ At least one calcineurin inhibitor (cyclosporine, tacrolimus) **AND**
	  ○ At least two of the following ocular steroids: Ozurdex, Triesence, Trivaris **AND**
	  ○ Authorization for Retisert requires documented clinical failure with Yutiq

Exclusion Criteria:	• Active or suspected ocular or periocular infections • Glaucoma or documentation of past treatment with corticosteroids with a clinically significant rise in intraocular pressure • Concurrent use of intravitreal implants and injections: Ozurdex (dexamethasone), Triesence (triamcinolone), Trivaris (triamcinolone)
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: Dimethyl fumarate, 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 disease (SPMS)

Required Medical Information:	• 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 **Clinically Isolated Syndrome** • Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event **Secondary-Progressive MS** • Documentation of prior history of RRMS with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e., new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5
Appropriate Treatment Regimen & Other Criteria:	• **Bafiertam**: Documentation of treatment failure or intolerable adverse event to dimethyl fumarate. • **Vumerity:** Documentation of treatment failure or intolerable adverse event to dimethyl fumarate and Bafiertam • No concurrent use of other disease-modifying medications indicated for the treatment of MS Reauthorization: provider attestation of treatment success
Exclusion Criteria:	
Age Restriction:	

Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

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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:
GALAFOLD
Affected Medications: GALAFOLD (migalastat)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• Diagnosis of Fabry disease confirmed by: ○ Enzyme assay demonstrating a deficiency of alpha-galactosidase enzyme activity **AND** ○ Genetic testing confirming the presence of at least one amenable galactosidase alpha (GLA) variant. • The patient has clinical signs and symptoms of Fabry disease.
Appropriate Treatment Regimen & Other Criteria:	• **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Concurrent use with Fabrazyme
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a prescriber experienced in the treatment of Fabry disease
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Subsequent approval: 12 months, unless otherwise specified

POLICY NAME:
GALSULFASE
Affected Medications: NAGLAZYME (galsulfase)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by benefit design ○ Mucopolysaccharidosis type VI (MPS VI, Maroteaux-Lamy syndrome)
Required Medical Information:	• Diagnosis of Mucopolysaccharidosis type VI (MPS VI, Maroteaux-Lamy syndrome) confirmed by an enzyme assay or detection of pathogenic mutations in the Arylsulfatase B (ARSB) gene by molecular genetic testing • Documented clinical signs and symptoms of Maroteaux-Lamy syndrome such as coarse facial features, severe skeletal disease, joint abnormalities, respiratory disease, and cardiac abnormalities • Baseline six minute walk test (6-MWT) or three minute stair climb test (3-MSCT)
Appropriate Treatment Regimen & Other Criteria:	• Dose does not exceed 1 mg/kg/week **Reauthorization** requires documentation of treatment success defined as improvement in six minute walk test (6-MWT) or three minute stair climb test (3-MSCT) • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced for all medical infusion drugs
Exclusion Criteria:	
Age Restriction:	• 5 years of age and older
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
GANAXOLONE
Affected Medications: ZTALMY

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older
Required Medical Information:	• Documentation of CDKL5 mutation confirmed by genetic testing • Documentation of inadequately controlled seizures despite current treatment
Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with at least two therapies for seizure management **Reauthorization** will require documentation of treatment success defined as a reduction in seizure frequency when compared to baseline
Exclusion Criteria:	• West syndrome • Seizures of a predominantly infantile spasm type
Age Restriction:	• 2 years of age or older
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

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 and elimination of exacerbating factors including medications, smoking, drinking, and infections • Documentation of baseline liver function tests

Appropriate Treatment Regimen & Other Criteria:	• Documentation of active acute disease defined as at least 2 documented porphyria attacks within the last six months requiring Hemin administration that are not attributable to a specific exacerbating factor
	• For women:
	  ○ Documented 12-week trial and failure of gonadotropin releasing hormone analogue (ex. Leuprolide) OR
	  ○ Documentation that attacks are not related to the luteal phase of the menstrual cycle
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization will require documentation of greater than 50% reduction in baseline acute attack frequency

Exclusion Criteria:	• Active HIV, Hepatitis C, or Hepatitis B infection(s) • History of Pancreatitis • Concomitant use with prophylactic hemin
Age Restriction:	• Greater than or equal to 12 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 • Reauthorization: 12 months

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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 disease (SPMS)

Required Medical Information:	• 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 <u>Clinically Isolated Syndrome</u> • Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event <u>Secondary-Progressive MS</u> • Documentation of prior history of RRMS with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e. new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5
Appropriate Treatment Regimen & Other Criteria:	• Documentation of dose and frequency as the 20 mg/mL and 40 mg/mL formulations are not interchangeable • No concurrent use of other disease-modifying medications indicated for the treatment of MS **<u>Reauthorization:</u>** requires provider attestation of treatment success
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or an MS specialist.

Coverage Duration:	• Authorization: 12 months unless otherwise specified

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POLICY NAME:
GLUCAGON-LIKE PEPTIDE-1 AGONISTS
Affected Medications: BYETTA Subcutaneous (Exenatide), BYDUREON Subcutaneous (Exenatide), BYDUREON BCise Subcutaneous (Exenatide), OZEMPIC (semaglutide), VICTOZA Subcutaneous (Liraglutide), 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
Required Medical Information:	• The patient is diagnosed as having type-2 diabetes with a blood glucose A1C level greater than 7. • The patient demonstrated an inadequate treatment response, intolerance or contraindication to an adequate trial of: metformin AND an additional antidiabetic agent
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization:** • Documentation of treatment success and a clinically significant response to therapy.
Exclusion Criteria:	• Weight Loss
Age Restriction:	• Byetta, Bydureon, Victoza 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

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POLICY NAME:
GOLIMUMAB
Affected Medications: SIMPONI ARIA

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

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
	  ○ The Clinical Disease Activity Index (CDAI) greater than 10
	  ○ Weighted RAPID3 of at least 2.3
	Psoriatic Arthritis
	• 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
	Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (NR-axSPA)
	• 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 • Documented of active disease defined by Bath ankylosing spondylitis disease activity index (BASDAI) at least 4 or equivalent objective scale **Juvenile Idiopathic Arthritis (JIA)** • 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 treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy: ○ Methotrexate plus sulfasalazine ○ Methotrexate plus hydroxychloroquine ○ Sulfasalazine plus hydroxychloroquine ○ leflunomide plus sulfasalazine ○ leflunomide plus hydroxychloroquine **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, Renflexis, Avsola) **Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (NR-axSPA)** • 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, Renflexis, Avsola) **Juvenile Idiopathic Arthritis (JIA)** • Documented failure with at least 12 weeks of treatment with methotrexate or leflunomide AND • Documented failure with glucocorticoid joint injections or oral corticosteroids **QL:** • RA/PsA/AS; 2mg/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 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
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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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 • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better
Required Medical Information:	**Prostate/Breast Cancer** • Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course
Appropriate Treatment Regimen & Other Criteria:	• For endometriosis: documentation of a trial and inadequate relief after at least three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and continuous (no placebo pills) hormonal contraceptives • Reauthorization for oncologic uses requires documentation of disease responsiveness to therapy **Dosing** • Breast Cancer: 3.6 mg every 28 days • Endometrial thinning: 3.6 mg for 1 or 2 doses with each depot is given 28 days apart. (When 1 depot is given, endometrial ablation surgery should be performed at 4 weeks. If 2 depots are given, surgery should be performed within 2-4 weeks following the second depot dosage) • Endometriosis: 3.6 mg every 28 days for 6 months • Prostate Cancer: 3.6 mg depot 8 weeks before radiotherapy, followed in 28 days by the Zoladex 10.8 mg depot, can be administered. Alternatively, four injections of 3.6 mg depot can be administered at 28-day intervals, two depots preceding and two during radiotherapy.
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • For gynecologic uses, prior use of Zoladex for a 6-month period
Age Restriction:	• 18 years and up for endometriosis and endometrial thinning
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	Oncologic uses • Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified Endometriosis • 6 months with no reauthorization, unless otherwise specified

POLICY NAME:
GROWTH HORMONES (somatropin) Injectables
Affected Medications: GENOTROPIN®, HUMATROPE®, NORDITROPIN FLEXPRO®, NORDITROPIN NORDIFLEX®, NUTROPIN AQ, NUSPIN®, NUTROPIN AQ®, OMNITROPE®, SAIZEN®, TEV-TROPIN®, ZOMACTON, SKYTROFA, SOGROYA

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 dosage requesting
	
	<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-I, and IGFBP-3 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

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	• No secondary factor present that would explain observed growth delays
	
	Noonan's syndrome
	• 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
	Short stature homeobox-containing gene (SHOX) deficiency
	• For initial approval, documentation of the following is required:
	  ○ Diagnosis of SHOX deficiency done through genetic testing
	  ▪ 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
	Growth failure secondary to chronic kidney disease stage 3 and greater OR kidney transplant
	• For initial approval, documentation of the following is required:
	  ○ Diagnosis of chronic kidney disease stage 3 or higher (CrCl less than 60mL/min)
	  ○ Height velocity (SDS) less than -1.88 for bone age.
	Prader-Willi syndrome
	• For initial approval, documentation of the following is required:
	  ○ Diagnosis of Prader-Willi syndrome through genetic testing AND
	  ○ Height velocity impaired
	Small for gestational age
	• For initial approval, documentation of the following is required:
	  ○ Documentation of weight and/or length of at least 2 standard deviations (SD) from the mean for gestational age and sex at birth
	  ○ At least two years old
	  ○ Height standard deviation score of at least -2.5 at the start of therapy
	  ○ Documentation of lab work ruling out other physiological and genetic conditions that cause short stature including:
	  ▪ IGF-I 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
	Adult Growth Hormone
	• For initial approval, documentation of the following is required:
	  ○ Growth hormone deficiency defined as IGF-I outside of reference range for patients' sex and age
	  ○ Failure of a growth hormone stimulation test (insulin tolerance test ITT or glucagon stimulation test)

	Reauthorization: • 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: Documented IGF-I within normal reference range for age and sex as well as documentation of clinical improvement
Appropriate Treatment Regimen & Other Criteria:	• Documentation of clinical failure with an adequate trial (at least 12 weeks) of all formulary growth hormone options prior to Skytrofa approval • Documented clinical failure with an adequate trial (at least 12 weeks each) of Norditropin AND one additional growth hormone agent prior to Sogroya approval • 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

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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 <u>all</u> the following pre-treatment testing been documented: ○ Genotype testing in past 3 years is required if the patient has decompensated cirrhosis, <u>prior</u> <u>treatment experience</u> 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

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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.

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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

	<u>Reauthorization</u> 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
	
	<u>Prophylaxis</u>
	• 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.
	  ○ Requires documented treatment failure (or documented intolerable adverse event) to Haegarda AND Takhzyro
	OR
	  ○ 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
	  ○ 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.
	  ○ Requires documented treatment failure (or documented intolerable adverse event) to Haegarda AND Takhzyro
	OR
	  ○ 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
	  ○ 2 years of age to less than 6: 150 mg SC every 4 weeks
	  ○ 6 years of age to less than 12: 150 mg SC every 2 weeks
	  ○ 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:
HEREDITARY TYROSINEMIA (HT-1)
Affected Medications: NITISINONE, ORFADIN

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• Diagnosis of hereditary tyrosinemia type 1 confirmed by biochemical testing (e.g. detection of succinylacetone in urine) and appropriate clinical picture of the patient or by DNA testing • Current patient weight

Appropriate Treatment Regimen & Other Criteria:	• Use as an adjunct to dietary restriction of tyrosine and phenylalanine
	• Dosing: Initial- 0.5 mg/kg twice daily
	  ○ Maximum: 2 mg/kg/day
	  ○ Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	• Orfadin requires documented failure with or contraindication to nitisinone
	• **Reauthorization:** documentation of treatment success confirmed by urine or plasma succinylacetone reduction since starting therapy and documented adherence to medical/nutritional therapy

Exclusion Criteria:	
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: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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

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

Required Medical Information:	**Central Precocious puberty**
	• Documentation of central precocious puberty (CPP) confirmed by basal luteinizing hormone (LH), follicle-stimulating hormone (FSH), and either estradiol or testosterone concentrations
	Gender Dysphoria
	• Documentation of current Tanner stage 2 or greater or documentation of baseline and current estradiol and testosterone levels to confirm onset of puberty
	• Documentation from a licensed mental health professional (LMHP) confirming diagnosis and addressing the patient's general identifying characteristics.
	  ○ The initial and evolving gender and any associated mental health concerns, and other psychiatric diagnoses.
	  ○ The duration of the referring licensed mental health professional's relationship with the client, including the type of evaluation and psychotherapy to date.
	  ○ The clinical rationale for supporting the client's request for hormone therapy and statement that the client meets eligibility criteria AND
	  ○ Permission to contact the licensed mental health professional for coordination of care

Appropriate Treatment Regimen & Other Criteria:	**All Indications** • Approval of Supprelin requires rationale for avoidance of Lupron formulations • QL: 50 mg implant every 12 months **Gender dysphoria** • Comprehensive mental health evaluation should be provided in accordance with most current version of the World Professional Association for Transgender Health (WPATH) Standards of Care **Reauthorization** 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, estropipate, 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 current Tanner stage 2 or greater OR documentation of baseline and current estradiol and testosterone levels to confirm onset of puberty
	• Documentation from a licensed mental health professional (LMHP) confirming diagnosis and addressing the patient's general identifying characteristics;
	  ○ The initial and evolving gender and any associated mental health concerns, and other psychiatric diagnoses;
	  ○ The duration of the referring licensed mental health professional's relationship with the client, including the type of evaluation and psychotherapy to date;
	  ○ The clinical rationale for supporting the client's request for cross-hormone therapy and statement that the client meets eligibility criteria;
	  ○ Informed consent required from both patient and guardian documented by prescribing provider
	  ○ Permission to contact the licensed mental health professional for coordination of care
	• Comprehensive mental health evaluation should be provided in accordance with 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: 12 months, unless otherwise specified


PacificSource
Community Solutions

POLICY NAME:
HYALURONIC ACID DERIVATIVES
Affected Medications: EUFLEXXA, GENVISC, GEL-ONE, GEL-SYN, HYALGAN, HYMOVIS, MONOVISC, ORTHOVISC, SUPARTZ, SYNVISC, SYNVISC-ONE, TRI-VISC

Covered Uses:	• Coverage of Hyaluronic Acids is excluded based Oregon Health Authority: **Viscosupplementation of the knee (CPT 20610) is not covered for treatment of 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-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 • Current glucocorticoid replacement therapy regimen, if applicable

Appropriate Treatment Regimen & Other Criteria:	• Total daily dose of replacement therapy regimen must be the equivalent of 10 mg or less of hydrocortisone
	  ○ For doses of greater than 10 mg daily, coverage will not be granted
	• Documented treatment failure with 6 months of compounded hydrocortisone oral capsules or oral solution
	• Starting dose: 8-10 mg/m2/day in 3 divided doses
	  ○ Exception: infants with Congenital Adrenal Hyperplasia may start at a dose of 10-15mg/m2/day in 3 divided doses
	• When switching patients from other oral hydrocortisone replacement therapy regimens, total daily dose should be equal
	• Response to therapy should be evaluated monthly in the first three months after starting, every three months in older infants, every six months thereafter while still growing and yearly in those who have achieved adult height
	• Dose should be reduced if there is evidence of excessive glucocorticoid replacement (excessive weight gain with decreased height velocity, facial plethora, or other symptoms or signs of Cushing syndrome)
	<u>Reauthorization:</u>
	• All initial criteria must be met
	• 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

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:	• <u>Diagnosis of RVVC:</u> ○ Documented 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 KOH test • Documentation confirming that the patient is not pregnant and is on contraceptive for length of planned treatment

Appropriate Treatment Regimen & Other Criteria:	• Treatment failure with vaginally administered treatment (such as clotrimazole cream, miconazole cream, terconazole cream or suppository)
	• Treatment failure with fluconazole defined as:
	  ○ For RVVC - Documented recurrence following 10 to 14 days of induction therapy with oral fluconazole, followed by fluconazole 150 mg once per week for 12 weeks.
	  ○ For VVC – Failure to 7-day course of fluconazole taken orally every third day for a total of 3 doses (days 1, 4, and 7) for the current episode
	• <u>Reauthorization</u> 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

POLICY NAME:
ICOSAPENT ETHYL CAPSULES
Affected Medications: VASCEPA (icosapent ethyl capsules)

• Is the request for continuation of therapy currently approved by PacificSource?	Yes – Go to renewal criteria	No – Go to #2
• Is the diagnosis being treated according to one of the covered indications below?	Yes – Go to appropriate section below	No – Criteria not met
Pure Hypertriglyceridemia		
• Is there documentation of a current triglyceride level of at least 500 mg/dL?	Yes – Document and go to #2	No – Criteria not met
• Is there a documented failure with at least 12 weeks of each fenofibrate and Omega-3-acid ethyl esters (generic Lovaza)?	Yes – Document and go to #3	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 12 months	No – Criteria not met
Cardiovascular Disease		
• Is there documentation of established cardiovascular disease (coronary artery disease, cerebrovascular or carotid disease, or peripheral artery disease) OR diabetes mellitus with at least one additional risk factor for cardiovascular disease (Hypertension, tobacco use, decreased kidney function, retinopathy, micro- or macroalbuminuria)?	Yes – Document and go to #2	No – Criteria not met
• Is there documented consistent use of highest-tolerated statin dose for at least 3 months prior to starting Vascepa?	Yes – Document and go to #3	No – Criteria not met
• Is there documentation that the statin will be continued during therapy with Vascepa?	Yes – Go to #4	No – Criteria not met
• Is the requested dose within the Food and Drug Administration (FDA)-approved label and PacificSource	Yes – Approve up to 12 months	No – Criteria not met

quantity limitations?		
Renewal Criteria		
• 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
• 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		
• Vascepa (icosapent ethyl capsules) ○ 1 gram capsule or 500 mg capsule: #120 capsules per 30 days		

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.
Required documentation:	**<u>Pulmonary arterial hypertension (PAH) WHO Group 1</u>** • Documentation of PAH confirmed by right-heart catheterization • 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 • Shistosomiasis • Portal hypertension • Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blocker) unless contraindications exist such as low systemic blood pressure (systolic blood pressure less than 90), low cardiac index, or presence of severe symptoms (functional class IV) • NYHA/WHO Functional Class III to IV symptoms
Appropriate Treatment Regimen:	• For initiation of therapy patient must have mean pulmonary artery pressure at least 25 mmHg at rest or at least 30 mmHg with exertion **AND** the pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition **<u>Reauthorization</u>** requires documentation of treatment success such as improved walking distance or improvements in 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:	• 18 years or older
Provider Restriction:	• Prescribed by, or in consultation with, a cardiologist or a pulmonologist
Approval Duration:	• 12 months, unless otherwise specified

PacificSource Community Solutions

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), Familial Mediterranean Fever (FMF), Adult-Onset Still's Disease (AOSD), Systemic Juvenile Idiopathic Arthritis (SJIA), Cryopyrin-Associated Periodic Syndromes (CAPS).
Required Medical Information:	• Patient weight Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) • Confirmed diagnosis of TRAPS with frequent and/or severe recurrent disease AND documented genetic defect of TNFRSF1A gene Hyperimmunoglobulin D syndrome (HIDS) • Confirmed diagnosis including presence of heterozygous or homozygous mutation in the mevalonate kinase (MVK) gene • Documented frequent and severe attacks with substantive quality-of-life detriment 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 • Documentation of active joint count 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)
Appropriate Treatment Regimen & Other Criteria:	**Tumor Necrosis Factor Receptor Associated Periodic Syndrome (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. **Hyperimmunoglobulin D syndrome (HIDS)** • Documented treatment failure to episodic treatment with nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and anakinra. **Familial Mediterranean Fever (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
	
	<u>Still's Disease</u>
	• Documentation of frequent and/or severe recurrence disease despite adequate treatment with minimum of 12 weeks trial each:
	  ○ NSAIDS or Glucocorticoids AND
	  ○ Methotrexate or leflunomide AND
	  ○ Anakinra AND
	  ○ Actemra
	
	<u>Cryopyrin-Associated Periodic Syndromes (CAPS)</u>
	• Documentation of failure with at least 12 week trial with anakinra or contraindication to use.
	
	• After up to 8 weeks of therapy if the patient has had a response to therapy as determined by prescribing physician an additional **<u>6</u>** months authorization is allowed
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	• **Reauthorization: documentation of treatment success**

Exclusion Criteria:	• Treatment of neonatal onset multisystem inflammatory disorder (NOMID) or chronic infantile neurological cutaneous and articular syndrome (CINCA), gout, 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:	• Ages 2 years and older for FMF, HIDS, juvenile idiopathic arthritis, TRAPS • Ages 4 year and older for CAPS
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:
IMIGLUCERASE
Affected Medications: CEREZYME (imiglucerase)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Gaucher disease, Type 1

Required Medical Information:	• Diagnosis of Type 1 Gaucher disease confirmed by enzyme assay.
	
	Must include current symptoms characteristic of bone involvement such as:
	  ○ Low platelet count
	  ○ Low hemoglobin and hematocrit levels
	  ○ Radiologic bone disease, T-score less than -2.5 or bone pain
	  ○ Delayed growth in children
	• Documented patient weight, dose and frequency

Appropriate Treatment Regimen & Other Criteria:	• Documented adult patients with symptomatic disease: platelet count less than 60,000/microL, liver greater than 2.5 times normal size, spleen greater 15 times normal size, radiologic evidence of skeletal disease, etc. • Documented symptomatic children: includes those with malnutrition, growth retardation, impaired psychomotor development, and/or fatigue (early presentation is associated with more severe disease) • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **Reauthorization** will require documentation of treatment efficacy based on improved labs or patient symptoms
Exclusion Criteria:	• Gaucher disease (Type 2 or Type 3) • Combination treatment with more than one targeted therapy for Gaucher disease
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a provider experienced in the treatment of Gaucher disease
Coverage Duration:	• Initial approval: 3 months • Reauthorization: 12 months, unless otherwise specified

IMMUNE GLOBULIN

Affected Medications: ASCENIV, BIVIGAM, CARIMUNE-NF, FLEBOGAMMA, GAMMAGARD LIQUID/S-D, GAMMAPLEX, GAMUNEX-C, GAMASTAN, OCTAGAM, PRIVIGEN, PANZYGA,

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) ○ Guillain-Barre Syndrome (Acute inflammatory polyneuropathy) ○ HIV infected children: 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 ○ 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: o Titers that were drawn before challenging with vaccination; AND o Titers that were drawn between 4 and 8 weeks after vaccination **Idiopathic thrombocytopenia purpura (ITP)** • For acute disease state: • Documented use to manage acute bleeding due to severe thrombocytopenia (platelet counts less than 30); OR • To increase platelet counts prior to invasive surgical procedures, such as splenectomy. (Platelets less than 100); OR • Documented severe thrombocytopenia (platelet counts less than 20) and is considered to be at risk for intracerebral hemorrhage. • Authorization is valid for 1 month only • Chronic Immune Thrombocytopenia (CIT): o Documentation of increased risk for bleeding as indicated by a platelet count less than 30; AND o History of failure, contraindication, or intolerance with corticosteroids; AND o Duration of illness more than 6 months; AND o 10 years of age or older **Guillain-Barre Syndrome (Acute inflammatory polyneuropathy)** • Documentation that the disease is severe (aid required to walk); AND • Onset of symptoms are recent (less than 1 month); AND • Approval will be granted for a maximum of 2 rounds of therapy within 6 weeks of onset; 2 months maximum **HIV infected children: Bacterial control or prevention** • Approved for those 13 years of age and younger **Myasthenia Gravis** • Documented myasthenic crisis (impending respiratory or bulbar compromise); AND • 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) • Approval for one course (1 month) **Dermatomyositis/Polymyositis** • Documented severe active disease state on physical exam; AND • Proximal weakness in all upper and/or lower limbs; AND

	• CPK greater than 1,000 (with documentation of previously normal CPK); AND
	• Documented failure with a trial of corticosteroids (such as prednisone); AND
	• Documented failure with a trial of immunosuppressants (Methotrexate, azathioprine)
	• Initial approval will be valid for 3 months;
	• Renewals will require current CPK lab and physical exam
	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 BMT was allogeneic; AND
	• Transplant was less than 100 days ago
	• Authorization is valid for 3 months
	Kawasaki's Disease (Pediatric)
	• Approved for age 13 years or under for 1 course of treatment (1 month)
	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
	• Approved for 1 course of treatment (1 month)
	Auto-immune Mucocutaneous Blistering Diseases
	• Diagnosis confirmed by biopsy of one of the following:
	  ○ Pemphigus vulgaris
	  ○ Pemphigus foliaceus
	  ○ Bullous Pemphigoid
	  ○ Mucous Membrane Pemphigoid (also known as Cicatricial Pemphigoid)
	  ○ Epidermolysis bullosa aquisita
	  ○ Pemphigus gestationis (Herpes gestationis)
	  ○ Linear IgA dermatosis; AND
	• Documented severe disease that is extensive and debilitating; AND
	• Disease is progressive; AND

	• Refractory to a trial of conventional combination therapy with corticosteroids and immunosuppressive treatment (azathioprine, cyclophosphamide, mycophenolate mofetil)
	Chronic lymphocytic leukemia with associated hypogammaglobulinemia
	• Documentation of an IgG level less than 500
	AND
	• A documented history of recurrent or chronic infections that have required intravenous antibiotics or hospitalization
	Toxic Shock Syndrome
	• Approved for a single course of therapy (1 month)
	Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infections (PANDAS)
	• Documentation of active autoimmune process (neuro-inflammation or post-infectious autoimmunity) confirmed by appropriate indicators such as:
	  ○ Elevated erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP)
	  ○ Exacerbation of autoimmune disease (eg, thyroiditis, spondyloarthritis, rheumatoid arthritis, etc.)
	• Abrupt and severe onset of the following symptoms between 3 years of age and the onset of puberty:
	  ○ Obsessive-compulsive disorder (OCD) or severely restricted food intake AND
	  ○ Acute onset of at least two concurrent severe neuropsychiatric symptoms (eg, anxiety, depression, emotional lability, etc)
	  ○ Documentation that symptoms cause significant interference with daily activities and overall functioning
	• Documentation of comprehensive psychiatric evaluation
	• Documentation of lab work and other studies excluding alternate diagnoses
	• Trial and failure of all of the following treatments in combination for at least 6 weeks:
	  ○ Behavioral pharmacologic therapy (eg. Fluoxetine, fluvoxamine, sertraline) AND behavior therapies for neuropsychiatric symptoms
	  ○ NSAIDs (eg. Naproxen, Diclofenac, Ibuprofen)
	  ○ Oral and IV corticosteroids (eg. Prednisone, methylprednisolone)
	• Approved for a single course of therapy (1 month)

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** • 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 **Multifocal Motor Neuropathy** • Renewals will require documentation that there has been a demonstrated 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) **HIV infected children: Bacterial control or prevention** • Age 13 years or less **Dermatomyositis/Polymyositis** • Renewal will require documentation that CPK (Creatine phosphokinase) levels are lower upon renewal request; AND • Documentation of clinically significant improvement above baseline per physical exam • Approved for up to 6 months **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 • Renewals will be approved for up to 6 months **Chronic lymphocytic leukemia (CLL) with associated hypogammaglobulinemia** • Renewal requires disease response as evidenced by a decrease in the frequency and/or severity of infections • Renewals will be approved for up to 6 months **Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorder Associated With Streptococcal Infections (PANDAS)** • Renewal requires documentation of symptomatic improvement within 4 weeks after initial dose with evident recurrence of symptoms after initial course

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<table>
<tr><td>Dosing:</td><td>Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>PID</td><td>Up to 800 mg/kg every 21 days</td></tr>
<tr><td>ITP</td><td>2 g/kg divided over 5 days in a 28 day cycle</td></tr>
<tr><td>FAIT</td><td>1 g/kg/week until delivery</td></tr>
<tr><td>Kawasaki’s Disease (pediatric patients)</td><td>2 g/kg x 1 single dose</td></tr>
<tr><td>CLL</td><td>400 mg/kg every 3 weeks</td></tr>
<tr><td>Pediatric HIV</td><td>400 mg/kg every 28 days</td></tr>
<tr><td>Guillain-Barre</td><td>2 g/kg divided over 5 days x 1 cycle</td></tr>
<tr><td>Myasthenia Gravis</td><td>1 g/kg x 1 dose (acute attacks)</td></tr>
<tr><td>Auto-immune blistering diseases</td><td>2 g/kg divided over 5 days in a 28 day cycle</td></tr>
<tr><td>Dermatomyositis/Polymyositis</td><td>2 g/kg divided over 5 days in a 28 day cycle</td></tr>
<tr><td>Bone Marrow or Stem Cell Transplant</td><td>500 mg/kg/week x 90 days, then 500 mg/kg/month up to one year post-transplant</td></tr>
<tr><td>Complications of transplanted solid organ: (kidney, liver, lung, heart, pancreas) transplant</td><td>2 g/kg divided over 5 days in a 28 day cycle</td></tr>
<tr><td>Toxic shock syndrome</td><td>2 g/kg divided over 5 days x 1 cycle</td></tr>
<tr><td>Hemolytic disease of the newborn</td><td>1 g/kg x 1 dose, may be repeated once if needed</td></tr>
<tr><td>PANS/PANDAS</td><td>Initial dose: 1.5-2 g/kg divided over 2-5 days
Subsequent: monthly doses (up to 6 total doses): 1-2 g/kg divided over 2-5 days</td></tr>
</table></td></tr>
<tr><td>Prescriber/Site of Care Restrictions:</td><td>• Must be prescribed by a specialist for the condition being treated (e.g., neurologist, rheumatologist, immunologist, hematologist)</td></tr>
<tr><td>Coverage Duration:</td><td>Initial Authorization: Up to 3 months, unless otherwise specified
Reauthorization: Up to 12 months, unless otherwise specified</td></tr>
</table>

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

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. ○ Adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C)

Required Medical Information:	**Heterozygous Familial Hypercholesterolemia (HeFH):**
	• Diagnosis of HeFH confirmed by:
	  ○ Genetic testing OR
	  ○ Documented history of untreated LDL-C of greater than 190 mg/dL AND a first degree relative with confirmed HeFH, LDL-C of greater than 190 mg/dL, or with known premature coronary heart disease (less than 55 years for men; less than 60 years for women).
	• Treated baseline LDL-C of 100 mg/dL or greater
	• Documentation of current rosuvastatin 20-40 mg or atorvastatin 40-80 mg and/or ezetimibe if no contraindication.
	
	Clinical Atherosclerotic Cardiovascular Disease (ASCVD):
	• History of Clinical ASCVD or a cardiovascular event, defined as:
	  ○ Acute coronary syndromes, myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization procedure (e.g., CABG, PTCA), stroke of presumed atherosclerotic origin, transient ischemic attack (TIA), peripheral arterial disease of presumed atherosclerotic origin, findings from CT angiogram or catheterization consistent with clinical ASCVD
	• Treated baseline LDL-C of 50 mg/dL or greater
	• Documentation of failure of 6 months of combination therapy with maximally tolerated high-intensity statin (rosuvastatin 20-40 mg or atorvastatin 40-80 mg) plus ezetimibe therapy as seen by inadequate reduction of LDL to target level

Appropriate Treatment Regimen & Other Criteria:	**All indications (must meet all of the following):** • Documentation of treatment failure (or intolerable adverse event) to a minimum 12-week trials of Repatha OR Praluent • Must take along with maximally tolerated doses of statin and ezetimibe if no contraindication **Reauthorization:**

	• Reauthorization will require updated lipid panel (once since starting therapy and then yearly thereafter) showing a clinically significant reduction in LDL-C. **Dosing:** 284 mg as a single injection at 0 and 3 months, then every 6 months thereafter
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Initial Authorization: 12 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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

Required Medical Information:	• Diagnosis of NMOSD with aquaporin-4 immunoglobulin G (AQP4-IgG) antibody positive disease confirmed by all the following:
	  ○ At least one core clinical characteristic:
	  ▪ Optic neuritis
	  ▪ Acute myelitis
	  ▪ Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
	  ▪ Acute brainstem syndrome
	  ▪ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMSOD-typical diencephalic MRI lesions
	  ▪ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
	  ○ Documentation of positive test for AQP4-IgG antibodies via cell-based assay
	  ○ Exclusion of alternative diagnoses (such as multiple sclerosis)
	• History of at least 1 attack in the past year, or at least 2 attacks in the past 2 years, requiring rescue therapy
	• Expanded Disability Status Scale (EDSS) score of 8 or less

Appropriate Treatment Regimen & Other Criteria:	• Documented inadequate response, contraindication, or intolerance to rituximab (preferred agents Truxima, Riabni, and Ruxience) • Documented inadequate response, contraindication, or intolerance to satralizumab (Enspryng) **Reauthorization** requires documentation of treatment success
Exclusion Criteria:	• Active Hepatitis B Virus (HBV) infection • Active or untreated latent tuberculosis • Concurrent use with other biologics (rituximab, eculizumab, tocilizumab, satralizumab, etc.)
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:
INFLIXIMAB
Affected Medications: INFLECTRA, RENFLEXIS, AVSOLA, REMICADE, INFLIXIMAB (J1745)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Plaque Psoriasis ○ Rheumatoid Arthritis ○ Psoriatic Arthritis ○ Ankylosing Spondylitis ○ Non-radiographic axial spondyloarthritis ○ Crohn's Disease ○ Uveitis ○ Ulcerative Colitis ○ Hidradenitis Suppurativa ○ Generalized Pustualar Psoriasis Flare
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 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

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Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (NR-axSPA)

- 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

Ulcerative Colitis

- Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy

Crohn's disease

- Documentation of moderate to severely active disease despite current treatment

Uveitis

- Documented diagnosis of noninfectious intermediate, posterios, or panuveitis uveitis

Hidradenitis Suppurativa (HS)

- 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 (GPP)

- 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:	**<u>All Indications</u>** • Approval of Remicade or Infliximab-(J1745) requires documentation of adverse event not attributed to the active ingredient to a biosimilar product **<u>Rheumatoid Arthritis</u>** • Documented treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy: ○ Methotrexate plus sulfasalazine ○ Methotrexate plus hydroxychloroquine ○ Sulfasalazine plus hydroxychloroquine ○ Leflunomide plus sulfasalazine ○ Leflunomide plus hydroxychloroquine **<u>Plaque Psoriasis</u>** • Documented treatment failure with 12 weeks of at least TWO systemic therapies: Methotrexate, Cyclosporine, Acitretin, Phototherapy [UVB, PUVA] **<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) **<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 **<u>Crohn's disease</u>** • Documented treatment failure with at least two oral treatments for minimum of 12 weeks trial: corticosteroids, 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 **<u>Uveitis</u>**

	• 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 **<u>Hidradenitis Suppurativa (HS)</u>** • Documented failure with at least 12 weeks 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 acetretin) **<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 **<u>Generalized Pustular Psoriasis Flare (GPP)</u>** • Documented 1 week treatment failure of acute disease flare (or documented intolerable adverse event) with: ○ Cyclosporine **<u>Dosing:</u>** • Availability: 100 mg single-dose vials • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced • Crohn's/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 • Psoriatic Arthritis/Plaque Psoriasis/Generalized Pustular Psoriasis Flare: 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 biologic therapy or Otezla is considered experimental and is not a covered benefit

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Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a rheumatologist/ dermatologist/ophthamologist/gastroenterologist as appropriate for diagnosis
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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POLICY NAME:
INOTERSEN
Affected Medications: TEGSEDI (inotersen sodium)

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

Required Medical Information:	• Documented pathogenic mutation in transthyretin (TTR) confirmed by genetic testing
	• Diagnosis of hereditary transthyretin (hATTR) amyloidosis with polyneuropathy
	• Documented amyloid deposits determined on biopsy
	• Presence of clinical signs and symptoms of disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, and renal dysfunction)
	• Documentation with one of the following (or equivalent objective scale):
	  ○ Baseline polyneuropathy disability (PND) score of less than or equal to IIIb
	  ○ Baseline neuropathy impairment (NIS) score between 10 and 130
	  ○ Baseline FAP stage 1 or 2

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of a positive clinical response to inotersen (e.g., improved neurologic impairment, motor function, cardiac function, quality of life assessment, serum TTR levels, etc.)
Exclusion Criteria:	• Platelet count less than 100 x 10^9/L prior to start of Tegsedi • Urinary protein to creatinine ratio (UPCR) is 1000 mg/g or higher • Prior or planned liver transplantation • NYHA class III or IV • Combined use with TTR-lowering therapy including inotersen or patisiran • Combined use with TTR-stabilizing therapy including diflunisal, tafamidis, or tafamidis meglumine
Age Restriction:	• Adults 18 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or provider with experience in the management of amyloidosis
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
INSOMNIA AGENTS
Affected Medications: zolpidem tablets, zolpidem extended release, eszopiclone tablets, zaleplon capsules

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
	  ○ Insomnia with obstructive sleep apnea
	  ○ Insomnia with co-morbid depression, anxiety/panic disorder, or bipolar disorder

Required Medical Information:	• Documentation of full treatment history including drugs, dosages, and frequencies **Obstructive Sleep Apnea** • Documentation of diagnosis of obstructive sleep apnea by a sleep specialist **AND** • Documentation of CPAP utilization **Mental Health disorder** • Documentation of a mental health disorder
Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	• Treatment of uncomplicated insomnia
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified

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POLICY NAME:
INTRAVITREAL ANTI-VEGF THERAPY
Affected Medications: Lucentis (ranibizumab), Eylea (aflibercept), Eylea PF Syringe, Beovu (brolucizumab), Susvimo (ranibizumab ocular implant), Vabysmo (faricimab), Byooviz (ranibizumab-nuna), CIMERLI (ranibizumab-eqrn)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
	  ○ Neovascular (Wet) Age-Related Macular Degeneration (AMD)
	  ▪ Eylea, Lucentis, Susvimo, Beovu, Vabysmo, Byooviz, Cimerli
	  ○ Macular Edema Following Retinal Vein Occlusion (RVO)
	  ▪ Eylea, Lucentis, Byooviz, Cimerli
	  ○ Diabetic Macular Edema (DME)
	  ▪ Eylea, Lucentis, Vabysmo, Beovu, Cimerli
	  ○ Diabetic Retinopathy (DR) in patients with Diabetes Mellitus
	  ▪ Eylea, Lucentis, Cimerli
	  ○ Myopic Choroidal Neovascularization (mCNV)
	  ▪ Lucentis, Byooviz, Cimerli
	  ○ 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 Dosing</u>
	• Approval requires documentation of one of the following:
	  ○ Treatment failure or intolerable adverse event with at least 3 months of ranibizumab (preferred biosimilar products: Byooviz, Cimerli)
	  ○ Documentation of treatment-naïve retinopathy of prematurity (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>Lucentis Dosing</u>
	• Approval requires documentation of adverse event not attributed to the active ingredient to a biosimilar product (preferred biosimilar products: Byooviz, Cimerli)
	• **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>Byooviz Dosing</u>
	• **AMD and RVO -** maximum 0.5mg every 4 weeks
	• **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 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 biosimilar products: Byooviz, Cimerli) injections with response to treatment for a minimum of 6 months at standard dosing (0.5mg every 4 weeks)
	• AMD– 2mg administered continuously via ocular implant with refills every 24 weeks.
	
	<u>Vabysmo Dosing</u>
	• Approval requires documented treatment failure or intolerable adverse event with at least 3 months of ranibizumab (preferred biosimilar products: Byooviz, Cimerli)
	• **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 Cimerli Dosing • **AMD and RVO** – maximum 0.5 mg 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 minimum of 28-day intervals **Reauthorization** 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:	**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

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POLICY NAME:
INTRAVITREAL COMPLEMENT INHIBITORS
Affected Medications: SYFOVRE

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:	• Best-corrected visual acuity (BCVA) using Early Treatment Diabetic Retinopathy Study (ETDRS) charts. ○ Must be 24 letters or better (approximately 20/320 Snellen equivalent)

Appropriate Treatment Regimen & Other Criteria:	• Dosing: 15 mg (0.1 mL) to each affected eye once every 25 to 60 days
	• **Reauthorization**:
	  ○ Documentation of treatment success as determined by treating provider
	  ○ BCVA remains 24 letters or better
	  ○ Absence of choroidal neovascularization (CNV) in the affected eye(s)

Exclusion Criteria:	• Presence of choroidal neovascularization in the affected eye(s) at baseline
Age Restriction:	• 60 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, an ophthalmologist
Coverage Duration:	• 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:
INVEGA 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)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Schizophrenia (Invega Sustenna, Invega Trinza, and Invega Hafyera)
	  ○ Schizoaffective disorder (Invega Sustenna only)

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:	**Invega Sustenna**
	• Documented history of one of the following:
	  ○ A minimum of at least three test doses of oral risperidone
	  ○ A minimum of at least three test doses of oral paliperidone
	  ○ Previous use of Invega Sustenna.
	• Once a month dosing
	
	Invega Trinza
	• Adequate treatment has been established with Invega Sustenna for at least 4 months
	AND
	• Documented anticipated dose and dosing schedule based on maintenance Invega Sustenna maintenance dose
	• Once every 3 months dosing
	
	Invega Hafyera
	• 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
	• Once every 6 months dosing
	
	Reauthorization will require documentation of treatment success and a clinically significant response to therapy

Exclusion Criteria:	• Diagnosis of dementia-related psychosis

	• Prior hypersensitivity (anaphylactic reactions and/or angioedema) to paliperidone or risperidone
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a psychiatrist or a psychiatric practice
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
IOBENGUANE I-131
Affected Medications: AZEDRA (IOBENGUANE I-131)

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:	• Documented diagnosis of metastatic or unresectable pheochromocytoma or paraganglioma **AND** • Positive adrenal/abdominal MRI or CT scan **AND** • Prior positive meta-iodobenzylguanidine (MIBG) scan with dosimetry **Reauthorization**: Reauthorization will require documentation of disease responsiveness to therapy
Appropriate Treatment Regimen & Other Criteria:	Dosimetric Dose • Patients weighing greater than 50 kg: 185 to 222 MBq (5 or 6 mCi) intravenous • Patients weighing 50 kg or less: 3.7 MBq/kg (0.1 mCi/kg) intravenous Therapeutic Dosage: administer 2 therapeutic doses intravenously a minimum of 90 days apart • Patients weighing greater than 62.5 kg: 18,500 MBq (500 mCi) • Patients weighing 62.5 kg or less: 296 MBq/kg (8 mCi/kg)
Exclusion Criteria:	
Age Restriction:	• Must be at least 12 years old
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 4 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.
	  ○ Invasive aspergillosis
	  ○ Invasive mucormycosis

Required Medical Information:	**Aspergillosis:**
	• Documented clinical failure, contraindication, or intolerable adverse event to at least 6 weeks of both of the following:
	  ○ Voriconazole
	  ○ Posaconazole
	
	Mucormycosis:
	• Documented clinical failure, contraindication, or intolerable adverse event to at least 6 weeks of one of the following:
	  ○ Amphotericin B (if request is for initial therapy)
	  ○ Posaconazole (if request is for oral step-down therapy after initial therapy)

Appropriate Treatment Regimen & Other Criteria:	All Indications: • Susceptibility cultures matching isavuconazonium activity • Exceptions made for empiric therapy as long as treatment is adjusted when susceptibility cultures are available **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:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 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:	**For all indications** • Current Weight **Severe Acne** For age 21 and above: • Documentation of persistent or recurrent inflammatory nodules and cysts AND ongoing scarring • For Acne Conglobata: documentation of recurrent abscesses or communicating sinuses **Hidradenitis Suppurativa (HS)** 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:	**Severe Acne** • Documented trial and failure of at least 12 weeks of oral antibiotic (such as doxycycline or minocyline) in combination with topical retinoid treatment (such as tretinoin or Adapalene) with at least 80% adherence to treatment. **Hidradenitis Suppurativa** • Documented trial and failure of at least 12 weeks of oral antibiotics (such as doxycycline, minocycline, or clindamycin plus rifampin) **Reauthorization** 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

POLICY NAME:
ITRACONAZOLE
Affected Medications: ITRACONAZOLE

Covered Uses:	• All Food and Drug Administration (FDA) approved OR compendia supported indications not otherwise excluded by benefit design.
Required Medical Information:	• Documented diagnosis of onychomycosis or any other susceptible unresolved fungal infection (tinea pedis, tinea corporis, tinea cruris, and tinea capitis) **AND** • The member has a secondary risk factor that is considered a covered condition per Oregon Health Authority (e.g. diabetes mellitus, peripheral vascular disease, immunocompromised) **AND** • If the indication is onychomycosis, the diagnosis must be confirmed with a fungal diagnostic test (KOH preparation, fungal culture, or nail biopsy)
Appropriate Treatment Regimen & Other Criteria:	• For tinea pedis, tinea corporis, tinea cruris, and tinea capitis, the member has had an adequate trial on a topical antifungal agent and either oral griseofulvin or ketoconazole
Exclusion Criteria:	• Concomitant use of CYP3A4 substrates
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: All but onychomycosis and other tinea infections – 6 months, unless otherwise specified • Approval: Onychomycosis – fingernails 6 weeks (allows two fills), toenails 12 weeks (allows three fills), unless otherwise specified • Approval: Other tinea infections – 1 month, unless otherwise specified

POLICY NAME:
IVACAFTOR
Affected Medications KALYDECO (ivacaftor)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Cystic Fibrosis (CF)
Required Medical Information:	• Documentation of cystic fibrosis (CF) diagnosis • Documentation confirming FDA approved mutation by appropriate genetic or diagnostic testing (FDA approved CF mutation test) • Documentation of diagnostic testing report and/or Cystic Fibrosis Foundation Patient Registry Report • Liver Function Test prior to Kalydeco initiation, every 3 months during first year of treatment, and annually thereafter
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Homozygous F508del mutation
Age Restriction:	• Ivacaftor oral granules are approved in patients one month of age and older • Ivacaftor oral tablets are approved in patients 6 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pulmonologist or provider who specializes in CF
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 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 disease (SPMS)

Required Medical Information:	• 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 **<u>Clinically Isolated Syndrome</u>** • Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event **<u>Secondary-Progressive MS</u>** • Documentation of prior history of RRMS with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e., new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • 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
	• No concurrent use of other disease-modifying medications indicated for the treatment of MS
	
	QL:
	• Initial: 20 mg once weekly for 3 doses (weeks 0, 1, and 2)
	• Maintenance: 20 mg once monthly starting at week 4.
	
	<u>Reauthorization</u> requires provider attestation of treatment success

Exclusion Criteria:	

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Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

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POLICY NAME:
KUVAN
Affected Medications: KUVAN (sapropterin)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by benefit design.
Required Medical Information:	• Documentation of anticipated treatment course, including target phenylalanine (Phe) level set by specialist • Documentation of failure to Phe restricted diet as monotherapy • Current patient weight • Baseline (pre-treatment) blood Phe levels Baseline Phe concentration must be consistent with the following: • Age less than or equal to 12 years: Phe level must be greater than 6mg/dL (360 microM) • Age greater than or equal to 12 years: Phe level must be greater than 10mg/dL (600 microM) • During pregnancy: Phe level must be greater than 6mg/dL (360 microM) **Reauthorization** after initial approval requires documentation of updated Phe labs decreased by 30% or greater from baseline • Treatment with Kuvan should be discontinued in patients whose blood Phe has not decreased by at least 30 percent from baseline **Reauthorization** for continued long-term approval (12 months) requires updated Phe labs meeting one of the following criteria: • Phe level less than 30 percent of baseline OR • Phe level lower than baseline and meets specialist's target level
Appropriate Treatment Regimen & Other Criteria:	If patient has failed monotherapy with Phe restricted diet and treatment with Kuvan is warranted, treatment must be consistent with the following: • Phe restricted diet must be maintained during Kuvan treatment **AND** • Initial dose must be 10mg/kg/day x 1 month ○ If blood Phe does not decrease from baseline after 1 month, dose can be increased to 20mg/kg/day x 1 month
Exclusion Criteria:	• Prior intolerance or allergic reaction to requested medication • Doses greater than 20mg/kg/day
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

POLICY NAME:
LARONIDASE
Affected Medications: ALDURAZYME (laronidase)

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

Required Medical Information:	• Diagnosis of one the following type I mucopolysaccharidosis:
	  ○ Hurler Mucopolysacchardiosis I (MPS I H)
	  ○ Herler-Scheie Mucopolysaccharidosis I (MPS I H/S)
	  ○ Scheie form of Mucopolysacchardiosis (MPS I S) with moderate to severe symptoms
	• Diagnosis confirmed by an enzyme assay showing deficiency of alpha-L-iduronidase enzyme activity or by detection of biallelic pathogenic mutations in the IDUA gene by molecular genetic testing
	• Documented clinical signs and symptoms of MPS I such as skeletal abnormalities, significant joint stiffness, liver or spleen enlargement, corneal clouding, umbilical or inguinal hernia, cord compression, recurrent sinopulmonary infections.
	• Baseline values for one or more of the following:
	  ○ 6 minute walk test (6-MWT)
	  ○ Forced vital capacity (FVC)
	  ○ Liver and/or spleen volume
	  ○ Urinary glycosaminoglycan (GAG) level

Appropriate Treatment Regimen & Other Criteria:	• Dose does not exceed 0.58 mg/kg/week • 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 6 minute walk test (6MWT) • Improvement or stability in pulmonary function tests (FVC) • Reduction in liver and/or spleen volume • Reduction in urinary GAG level • Improvement in sleep apnea and shoulder flexion
Exclusion Criteria:	• Treatment of central nervous system manifestation of the disorder
Age Restriction:	• 6 months of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
LAROTRECTINIB
Affected Medications: VITRAKVI CAPSULE 100 MG ORAL, VITRAKVI CAPSULE 25 MG ORAL, VITRAKVI SOLUTION 20 MG/ML ORAL

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 NTRK gene-fusion, as determined by an FDA approved test.
Appropriate Treatment Regimen & Other Criteria:	• Requires previous treatment with Rozlytrek • 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: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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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

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

Prior stroke or brain hemorrhage

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

	• Evidence of moderate to severe Alzheimer's disease • Non-Alzheimer's dementia • Concurrent anticoagulant use
Age Restriction:	• 50 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	Initial Authorization: 6 months, unless otherwise specified Reauthorization: 12 months, unless otherwise specified

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: o Nucleoside reverse-transcriptase inhibitors (NRTIs) o Non-nucleoside reverse-transcriptase inhibitors (NNRTIs) o Protease inhibitors (PIs) o Integrase strand transfer inhibitors (INSTIs) • Documentation of current (within the past 30 days) HIV-1 RNA viral load of greater than or equal to 400 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 • **Reauthorization:** o Treatment plan includes continued use of optimized background antiretroviral regimen o Documentation of treatment success, as evidenced by the following: ▪ Reduction in viral load from baseline, OR ▪ If viral load has not declined, resistance testing confirms absence of postbaseline emergence of lenacapavir resistance-associated mutations
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

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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

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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 adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic cell transplant
	  ○ Prophylaxis of CMV disease in high-risk adult patients undergoing kidney transplant

Required Medical Information:	• Has received an allogeneic hematopoietic stem cell transplant (HSCT) • Is cytomegalovirus (CMV) seropositive **OR** • Has received a kidney transplant and is at high risk (Donor CMV-seropositive/Recipient CMV seronegative [D+/R-] of CMV infection
Appropriate Treatment Regimen & Other Criteria:	• Documented trial and failure (or intolerable adverse event) with an adequate trial (at least 14 days) of at least one of the following: ganciclovir, valganciclovir, Foscarnet (HSCT only) • **HSCT Dosing:** 480 mg (or 240 mg) once daily beginning between Day 0 and Day 28 post-transplantation and continued through Day 100 post-transplantation. • **Kidney transplant Dosing:** 480mg once daily beginning between Day 0 and Day 7 post kidney transplant for high-risk recipients (donor CMV seropositive/recipient CMV seronegative) and continue through day 200 post transplantation
Exclusion Criteria:	
Age Restriction:	• 18 years of age and older
Prescriber/Site of Care Restrictions:	• Prescribed by an infectious disease provider or a specialist with experience in the prevention and treatment of CMV infection
Coverage Duration:	• HSCT: 4 months, unless otherwise specified • Kidney transplant: 7 months, unless otherwise specified

POLICY NAME:
LEUPROLIDE

Affected Medications: Lupron Depot 3.75 and 11.25mg AND Lupron Depot-Ped 11.25mg; Lupron Depot 7.5, 22.5, 30, and 45mg AND Lupron Depot-Ped 15mg AND Eligard; Leuprolide Acetate or injection solution; Fensolvi (leuprolide acetate kit), Camcevi 45mg; Lutrate Depot Kit 22.5 mg

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

Required Medical Information:	**Endometriosis**
	• Documentation of moderate to severe pain due to endometriosis
	• Documentation of a trial and inadequate relief (or contraindication) after at least three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and continuous (no placebo pills) hormonal contraceptives
	Preoperative anemia due to uterine leiomyomata
	• Documentation of leiomyoma-related surgery in 6 or less months
	• Documentation of planned use in combination with iron supplements
	Gender dysphoria
	• Documentation of current Tanner stage 2 or greater OR Documentation of baseline and current estradiol and testosterone levels to confirm onset of puberty
	• Documentation from a licensed mental health professional (LMHP) confirming diagnosis and addressing the patient's general identifying characteristics
	  ○ The initial and evolving gender and any associated mental health concerns, and other psychiatric diagnoses
	  ○ The duration of the referring licensed mental health professional's relationship with the client, including the type of evaluation and psychotherapy to date
	  ○ The clinical rationale for supporting the client's request for hormone therapy and statement that the client meets eligibility criteria
	  AND
	  ○ Permission to contact the licensed mental health professional for coordination of care
	• Comprehensive mental health evaluation should be provided in accordance with most current version of the World Professional Association for Transgender Health (WPATH) Standards of Care
	
	Central precocious puberty
	• Documentation of central precocious puberty (CPP) confirmed by basal luteinizing hormone (LH), follicle-stimulating hormone (FSH), and either estradiol or testosterone concentrations

Appropriate Treatment	• Women of childbirth age should have pregnancy ruled out and a plan to use a non-hormonal based contraceptive during therapy **Endometriosis** • Lupron Depot 3.75 and 11.25mg

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Regimen & Other Criteria:	**<u>Preoperative anemia due to uterine leiomyomata</u>** • Lupron Depot 3.75 and 11.25mg • Planned treatment of 6 months or less • Must be given in conjunction with iron supplementation **<u>Central precocious puberty</u>** • Leuprolide Acetate, Lupron Depot-Ped 11.25 and 15mg, Fensolvi 45mg • Approval of Fensolvi requires rationale for avoidance of Lupron and Supprelin LA **<u>Gender dysphoria</u>** • Comprehensive mental health evaluation should be provided in accordance with most current version of the World Professional Association for Transgender Health (WPATH) Standards of Care
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:	• Prescribed by, or in consultation with, oncologist, endocrinologist, or gynecologist for endometriosis • Gender Dysphoria: Diagnosis made and prescribed by, or in consultation with, a specialist in the treatment of gender dysphoria
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:
	  ○ Corticotropin (ACTH)-producing pituitary tumor (Cushing's disease)
	  ○ Ectopic ACTH secretion by a non-pituitary tumor
	  ○ Cortisol secretion by an adrenal adenoma
	AND
	• Documentation that surgery is not an option or has not been curative
	AND
	• A mean of at least three 24-hour Urine Free Cortisol (mUFC) levels greater than 1.5 times the upper limit of normal (ULN)

Appropriate Treatment Regimen & Other Criteria:	• Documented clinical failure to maximally tolerated dose of ketoconazole for at least 8 weeks OR • Intolerable adverse event to ketoconazole and the adverse event was not an expected adverse event attributed to the active ingredient **Reauthorization**: documentation of treatment success as determined by mUFC less than or equal to the ULN based on central laboratory results
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

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

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) (*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 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) • Requests for Perseris require documentation of failure or clinical rationale for avoidance of Risperdal Consta **Continuation of Therapy** • Documentation showing that member is stable on current treatment with Perseris or Risperdal Consta
Appropriate Treatment Regimen & Other Criteria:	• **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Diagnosis of dementia-related psychosis. • Prior hypersensitivity reaction (anaphylactic reactions and/or angioedema) to paliperidone or risperidone
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

POLICY NAME:
LUMASIRAN
Affected Medications: Oxlumo (lumasiran)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Primary hyperoxaluria type 1 (PH1)
Required Medical Information:	**Requirements for Initial Authorization:** • Must have genetic testing confirming diagnosis of PH1 via presence of AGXT mutation AND ONE of the following: • Elevated urine oxalate (UOx) excretion as measured by BSA-normalized daily UOx output greater than upper limit of normal • Elevated UOx excretion as measured by UOx: creatinine ratio above age-specific upper limit of normal. • Elevated plasma oxalate (POx) concentration (POx concentration greater than upper limit of normal) **Urinary Oxalate (UOx) Excretion in 24 hour urine samples reference values** • Urinary Oxalate (UOx) Excretion in 24 hour urine samples ○ All ages: less than 0.5 mmol/1.73 m^2/day

Appropriate Treatment Regimen & Other Criteria:	• Oxlumo is supplied in 0.5 mL single-use vials containing 94.5 mg
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced.
	• Documentation of efforts to increase fluid intake to at least 3 L/m2 BSA per day
	• Trial of conventional therapy for at least 12 weeks (pyridoxine).
	
	Oxlumo Weight-Based Dosing
	• Body weight less than 10 kg
	  ○ Loading Dose: 6 mg/kg once monthly for 3 doses
	  ○ Maintenance Dose: Start 1 month after last loading dose; 3 mg/kg once monthly
	• Body weight between 10 kg to less than 20 kg
	  ○ Loading Dose: 6 mg/kg once monthly for 3 doses
	  ○ Maintenance Dose: Start 1 month after last loading dose; 6 mg/kg once every 3 months
	• Body weight 20 kg or greater
	  ○ Loading Dose: 3 mg/kg once monthly for 3 doses
	  ○ Maintenance Dose: Start 1 month after last loading dose; 3 mg/kg once every 3 months
	
	Requirements for Reauthorization:
	• Liver or kidney transplant has not occurred since previous authorization.

	AND ONE of the following criteria related to treatment success: • Must show reduction from baseline urine or plasma oxalate levels at 6 months. • Improvement, stabilization, or slowed worsening of one or more clinical manifestation of PH1 (i.e., nephrocalcinosis, renal stone events, renal impairment, systemic oxalosis).
Exclusion Criteria:	• History of liver or kidney transplant. • Genetic tests positive for other form of primary hyperoxaluria including type 2 and type 3 primary hyperoxaluria. • Secondary hyperoxaluria.
Age Restriction:	
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

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

POLICY NAME:
MANNITOL
Affected Medications: Bronchitol

1. Is the request for add on maintenance therapy for Cystic Fibrosis?	Yes – Go to #2	No – Criteria not met
2. Is the diagnosis of Cystic Fibrosis (CF) confirmed by appropriate diagnostic or genetic testing? a. Additional testing should include evaluation of overall clinical lung status and respiratory function (eg pulmonary function tests, lung imaging, etc.)	Yes – Go to #3	No – Criteria not met
3. Is there documentation that the Bronchitol Tolerance Test has been passed?	Yes – Go to #4	No – Criteria not met
4. Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to appropriate section below
Indication: Add on maintenance therapy for Cystic Fibrosis		
1. Is there documented failure of 6 months with twice daily hypertonic saline defined as one of the following despite at least 80% adherence with hypertonic saline: a. Increase in pulmonary exacerbations from baseline? b. Decrease in FEV1?	Yes – Document and go to #2	No – Criteria not met
2. Will Bronchitol be used in conjunction with standard therapies for Cystic Fibrosis?	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 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

POLICY NAME:

MARALIXIBAT
Affected Medications: LIVMARLI (Maralixibat)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Cholestatic pruritus in patients with Alagille syndrome (ALGS)

Required Medical Information:	• Documentation of Alagille syndrome confirmed by:
	  ○ Genetic test detecting a JAG1 or NOTCH2 mutation, or
	  ○ Liver biopsy
	• Documentation of patient's current weight
	• Documentation of history of significant pruritus

Appropriate Treatment Regimen & Other Criteria:	• Documented failure with an adequate trial (at least 30 days) of all the following: rifampin, ursodiol, AND cholestyramine **Reauthorization**: Documented treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Decompensated cirrhosis • History or presence of other concomitant liver disease (e.g., biliary atresia, liver cancer, non-PFIC related cholestasis) • Prior liver transplant
Age Restriction:	
Prescriber Restrictions:	• Prescribed by a gastroenterologist or a specialist with experience in the treatment of ALGS
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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 post-transplant CMV infection • Documentation of patient's current weight
Appropriate Treatment Regimen & Other Criteria:	• Documented clinical failure (not due to drug intolerance) with an adequate trial (of at least 14 days) of at least ONE of the following: ganciclovir, valganciclovir, cidofovir or foscarnet **<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.
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: 4 months, unless otherwise specified

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 • Pregnancy should be excluded prior to treatment
Appropriate Treatment Regimen & Other Criteria:	• Use of effective contraception in females of reproductive potential • Trial with a beta blocker or if unable to tolerate (or contraindication to) beta blockers, trial with verapamil. • 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:	• 18 years or older
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: 3 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

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

POLICY NAME:
MECHLORETHAMINE
Affected Medications: VALCHLOR (mechlorethamine hydrochloride)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded from plan design. • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher
Required Medical Information:	• Diagnosis of Stage IA or Stage IB mycosis fungoides-type cutaneous T-cell lymphoma ○ Extent of skin involvement (limited/localized or generalized)
Appropriate Treatment Regimen & Other Criteria:	• Documentation of all prior therapies used for the given indication • Documentation of counseling on applicable special handling procedure Limited/localized skin involvement • Documentation of failure or contraindication of at least 1 topical retinoid (tretinoin 0.05%, etc) AND topical corticosteroid Generalized skin involvement • Documentation of failure or contraindication to at least ≥1 skin-directed therapy (topical corticosteroids, topical retinoids, phototherapy, topical chemotherapy [e.g. carmustine], topical imiquimod, local radiation) **<u>Reauthorization</u>:** • Documentation of monitoring for non-melanoma skin cancer • Documentation of improvement with treatment based either on CAILS score or decrease in severity of scaling, plaque elevation or surface area
Exclusion Criteria:	• Use in the management of onychomycosis, • treatment or prevention of vaginal or vulvovaginal candidiasis, tinea cruris, tinea manuum, tinea pedis, tinea faciei, tinea capitis, tinea barbae, tinea corporis, tinea versicolor (pityriasis versicolor), or other superficial fungal infections. • Coverage is not recommended for circumstances not listed in the Covered Uses.
Age Restriction:	• 18 years and older.
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist or dermatologist
Coverage Duration:	• Initial Approval: 3 months, unless otherwise specified

	• Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
MEPOLIZUMAB
Affected Medications: NUCALA (mepolizumab)

• Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #2
• Is the request to treat a diagnosis according to one of the Food and Drug Administration (FDA)-approved indications? ○ 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).	Yes – Go to appropriate section below	No – Criteria not met
Severe Eosinophilic Asthma		
• Is there documentation of severe eosinophilic asthma defined by the following: ○ Baseline eosinophil count at least 300 cells/µL AND ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal	Yes – Document and go to #2	No – Criteria not met
• Is there documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms?	Yes – Document and go to #3	No – Criteria not met
• Is there a documented history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months while on inhaled combination treatment and at least 80% adherence?	Yes – Go to #5	No – Go to #4

• Is there documentation that chronic daily oral corticosteroids are required?	Yes – Go to #5	No – Criteria not met
• Is the drug prescribed by, or in consultation with, an Allergist, Immunologist, or Pulmonologist?	Yes – Approve up to 6 months	No – Criteria not met
Eosinophilic granulomatosis with polyangiitis (EGPA)		
• Is there a confirmed diagnosis of relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) with the following: o Chronic rhinosinusitis o Asthma o Blood eosinophilia (at least 1,500 cells/microL and/or 10% eosinophils on differential) at baseline o Diagnosis must be confirmed by a second clinical opinion	Yes – Document and go to #2	No – Criteria not met
• Is there documented relapsing disease while on the highest tolerated oral corticosteroid dose?	Yes – Document and go to #3	No – Criteria not met
• Is there documentation that the disease has been refractory to at least two oral immunosuppressive drugs for at least 12 weeks each (Azathioprine, Methotrexate, Leflunomide)?	Yes – Document and go to #4	No – Criteria not met
• Is the drug prescribed by a specialist in the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) (e.g., immunologist or rheumatologist)?	Yes – Approve up to 6 months	No – Criteria not met
Hypereosinophilic Syndrome		
1. Is there documentation of hypereosinophilic syndrome (HES) with all of the following: Blood eosinophil count greater than 1000 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	Yes – Document and go to #2	No – Criteria not met

factor receptor alpha (FIP1L1-PDGFRα) mutation negative disease - Non-hematologic secondary HES has been ruled out (drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)		
2. Is the HES currently controlled using the highest tolerated glucocorticoid dose (defined as an improvement in clinical symptoms and a decrease in eosinophil count by at least 50% from baseline)?	Yes – Document and go to #3	No – Criteria not met
3. Is there documentation showing that the patient has a lymphocytic variant of HES (L-HES)?	Yes – Document and go to #5	No – Go to #4
4. Is there documentation of treatment failure to at least 12 weeks of hydroxyurea?	Yes – Document and go to #5	No – Criteria not met
5. Is there documentation of treatment failure with interferon-alfa?	Yes – Document and go to #6	No – Criteria not met
6. Is the drug prescribed by a specialist for the treatment of HES (e.g., immunologist or hematologist)?	Yes – Approve up to 6 months	No – Criteria not met
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)		
• Is there documentation of chronic sinusitis after total ethmoidectomy with a need for revision endoscopic sinus surgery due to continued symptoms of nasal congestion/obstruction from recurrent bilateral sinus obstruction due to nasal polyps?	Yes – Document and go to #2	No – Criteria not met
• Is there documented failure with at least 1 intranasal corticosteroid (such as fluticasone) after ethmoidectomy?	Yes – Document and go to #3	No – Criteria not met
• Is there documented failure with Sinuva implant?	Yes – Document and go to #4	No – Criteria not met
• Is the drug prescribed by a specialist in the treatment of nasal polyps (otolaryngologist)?	Yes – Approve up to 6 months	No – Criteria not met
Renewal Criteria		

• 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
• Is the request for use in combination with another monoclonal antibody (e.g., Fasenra, Dupixent, Xolair, Cinqair)?	Yes – Criteria not met; combination use is experimental	No – Go to #3
• 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

- **Nucala**
  - Availability: 100 mg/mL single-use vial or prefilled syringe or auto-injector
  - Dosing:
    - Severe asthma: 100 mg every 4 weeks for age 12 and up, 40 mg every 4 weeks for age 6 to 11
    - EGPA: 300 mg every 4 weeks
    - HES: 300 mg every 4 weeks
    - CRSwNP: 100 mg every 4 weeks

*Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced for all medical infusion drugs

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.
Required Medical Information:	• Weight • Baseline serum leptin levels, HbA1c, fasting glucose, fasting triglycerides, fasting serum insulin • Prior Myalept use will require test of anti-metrepeptin antibodies
Appropriate Treatment Regimen & Other Criteria:	• Serum leptin < 6.0 ng/mL females and < 3.0 ng/mL males, obtained on at least 2 occasions • If treating acquired generalized lipodystrophy with concurrent hypertriglyceridemia defined as triglycerides ≥ 500 mg/dL despite optimizing with statin and/or fibrate • If treating acquired generalized lipodystrophy with concurrent diabetes, baseline HbA1c ≥ 7% despite optimal treatment with metformin, TZD, sulfonylurea, GLP-1 agonist or DPP-4 inhibitor, SGLT-2, and insulin • Treatment success defined by improvement in HbA1c, fasting glucose, and fasting triglycerides • Worsening metabolic control and/or severe infection = indicators of possible anti-metreleptin antibodies • Maximum daily dose for individuals <40kg = 0.13mg/kg • Maximum daily dose for individuals >40kg = 10mg/day **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Partial lipodystrophy • General obesity not associated with leptin deficiency • HIV-related lipodystrophy • Metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of generalized lipodystrophy • Age > 65 years
Age Restriction:	• Age ≥ 1 year
Prescriber Restrictions:	• Prescribed by, or in consultation with, an Endocrinologist • Myalept is available only through the MYALEPT REMS Program
Coverage Duration:	• Initial: 4 months, unless otherwise specified • Subsequent: 12 months, unless otherwise specified

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.
Required Medical Information:	• Diagnosis of Type 1 Gaucher disease • Mild to moderate disease • Diagnosis of Gaucher disease confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity
Appropriate Treatment Regimen & Other Criteria:	• Enzyme replacement therapy (ERT) is not a therapeutic option for the patient (e.g., due to allergy, hypersensitivity, or poor venous access) • The patient will use adequate contraception throughout miglustat therapy and for 3 months thereafter **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Female of childbearing potential who is pregnant or planning a pregnancy
Age Restriction:	• 18 years of age and older
Prescriber Restrictions:	
Coverage Duration:	• Initial Approval: 4 months, unless otherwise specified • Subsequent approval: 12 months, unless otherwise specified

POLICY NAME:
MILTEFOSINE
Affected Medications: IMPAVIDO (miltefosine)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	• Current weight • Documentation of Visceral leishmaniasis OR Cutaneous leishmaniasis OR Mucosal leishmaniasis
Appropriate Treatment Regimen & Other Criteria:	• Food and Drug Administration (FDA) approved dosing of 30 to 44 kg: one 50 mg capsule twice daily for 28 consecutive days OR 45 kg or greater: one 50 mg capsule three times daily for 28 consecutive days • Weight equal to or greater than 30kg (66lbs)
Exclusion Criteria:	• Pregnancy (category D) • Sjögren-Larsson-Syndrome
Age Restriction:	• Age less than 12 years of age • Weight less than 30 kg (66 lbs)
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist
Coverage Duration:	• Initial coverage: 1 month unless otherwise specified • Subsequent coverage: 1 month unless otherwise specified

PacificSource Community Solutions

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

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

Required Medical Information:	• Diagnosis of pyruvate kinase deficiency (PKD), defined by **ALL** the following:
	  ○ Presence of at least two mutant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene
	  ○ At least one of the mutant alleles is a missense mutation
	
	ONE of the following applies:
	• If receiving regular transfusions, documentation of **ALL** the following:
	  ○ A minimum of 6 transfusion episodes in the 12-month period prior to treatment
	  ○ Baseline transfusion amount, including date of transfusion and number of red blood cell (RBC) units transfused
	
	OR
	• If not receiving regular transfusions, documentation of **ALL** the following:
	  ○ No more than 4 transfusions in the 12-month period prior to treatment and no transfusions in the 3-month period prior to treatment
	  ○ Baseline hemoglobin (Hb) must be less than or equal to 10 g/dL

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 • Discontinue therapy after 6 months if no benefit in transfusion requirement or Hb has been observed • Dose: Approve 5 mg, 20 mg, and 50 mg tablets (QL of 56 per 28 days) per dosing schedule below

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<table>
<tr><td></td><td>
Table 1: Dose Titration Schedule
<table>
<tr><th>Duration</th><th>Dosage</th></tr>
<tr><td>Week 1 through Week 4</td><td>5 mg twice daily</td></tr>
<tr><td>Week 5 through Week 8</td><td>If Hb is below normal range or patient has required a transfusion within the last 8 weeks:
Increase to 20 mg twice daily and maintain for 4 weeks.
If Hb is within normal range and patient has not required a transfusion within the last 8 weeks:
Maintain 5 mg twice daily.</td></tr>
<tr><td>Week 9 through Week 12</td><td>If Hb is below normal range or patient has required a transfusion within the last 8 weeks:
Increase to 50 mg twice daily and maintain thereafter.
If Hb is within normal range and patient has not required a transfusion within the last 8 weeks:
Maintain current dose (5 mg twice daily or 20 mg twice daily).</td></tr>
<tr><td>Maintenance</td><td>If Hb decreases, consider up-titration to the maximum of 50 mg twice daily as per the above schedule.</td></tr>
</table>
</td></tr>
<tr><td>Exclusion Criteria:</td><td>• Homozygous for the c.1436G>A (p.R479H) variant or have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene
• Splenectomy scheduled during treatment or have undergone within the 12-month period prior to starting treatment
• Previous bone marrow or stem cell transplant
• Receiving hematopoietic stimulating agents or anabolic steroids (including testosterone preparations) within 28 days prior to treatment</td></tr>
<tr><td>Age Restriction:</td><td>• Must be 18 years or older</td></tr>
<tr><td>Prescriber Restrictions:</td><td>• Prescribed by, or in consultation with, a hematologist</td></tr>
<tr><td>Coverage Duration:</td><td>• Initial Authorization: 6 months, unless otherwise specified
• Reauthorization: 12 months, unless otherwise specified</td></tr>
</table>

POLICY NAME:
MITOXANTRONE
Affected Medications: MITOXANTRONE (mitoxantrone)

Covered Uses:	• National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or higher • Breast cancer, recurrent or metastatic • Hodgkin's lymphoma • Liver carcinoma • Non-Hodgkin lymphoma with following subtypes: Adult T-cell leukemia/lymphoma, AIDS-related B-cell lymphoma, Diffuse large B-cell lymphoma, Follicular lymphoma, Gastric and nongastric MALT lymphoma, Lymphoblastic lymphoma, Mantle cell lymphoma, Mycosis Fungoides/Sézary syndrome, Peripheral T-cell lymphoma, Primary cutaneous B-cell lymphoma, Splenic marginal zone lymphoma, T-cell prolymphocytic leukemia • Ovarian cancer • Multiple sclerosis, Secondary progressive, progressive relapsing, or worsening relapsing-remitting; to reduce neurologic disability and/or frequency of clinical relapses
Required Medical Information:	• Referral for mitoxantrone • Assessed for cardiac signs and symptoms by history, physical exam, and ECG prior to starting mitoxantrone • Baseline evaluation of left ventricular ejection fraction • Diagnosis of Non- Hodgkin Lymphoma with one of the subtypes listed in the above section (If yes, skip directly to coverage duration), OR • Diagnosis of any other cancers listed in the above section (If yes, skip directly to coverage duration), OR • Assessed for cardiac signs and symptoms by history, exam, and ECG prior to each dose • Patient will undergo quantitative reevaluation of LVEF prior to each dose using the same methodology that was used to assess baseline LVEF. Additional doses of Mitoxantrone should not be administered to MS patients who have experienced either a drop in LVEF to below the lower limit of normal or a clinically significant reduction in LVEF during Mitoxantrone therapy • Should undergo yearly quantitative LVEF evaluation after stopping Mitoxantrone to monitor for late occurring cardiotoxicity **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Appropriate Treatment	Dosing for MS Patients: • 12mg/m^2 IV every 3 months

Regimen & Other Criteria:	
Exclusion Criteria:	For MS Patients: • Baseline LVEF below the lower limit of normal • Receive a cumulative Mitoxantrone dose greater than 140 mg/m2
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval (Non-Hodgkin Lymphoma): 6 months, unless otherwise specified • Approval (All other covered cancer diagnoses): 6 months, unless otherwise specified • Approval (MS): 12 months, unless otherwise specified

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
Required Medical Information:	• Documentation of chronic sinusitis status post total ethmoidectomy. • Indicated for revision endoscopic sinus surgery due to continued symptoms of nasal congestion/obstruction from recurrent bilateral sinus obstruction due to sinonasal polyposis
Appropriate Treatment Regimen & Other Criteria:	• Documentation of failure with at least 1 intranasal corticosteroid after ethmoidectomy
Exclusion Criteria:	• History of previous Sinuva implant use • Known history of resistant or poor response to oral steroids • Acute bacterial or invasive fungal sinusitis • Immune deficiency (including cystic fibrosis)
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an otolaryngologist
Coverage Duration:	• Initial approval: 1 month, unless otherwise specified • Reauthorization: Not eligible, there are no studies evaluating repeat implantation of the SINUVA Sinus Implant


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

Covered Uses:	**Casimersen (Amondys 45)** • Duchenne muscular dystrophy with mutations amenable to exon 45 skipping • Deletions potentially amenable to exon 45 skipping include, but are not limited to: 12 to 44, 18 to 44, 44, 46 to 47, 46 to 48, 46 to 49, 46 to 53, or 46 to 55 **Eteplirsen (Exondys 51)** • Duchenne muscular dystrophy with mutations amenable to exon 51 skipping • Mutations include but are not limited to: Deletion of exons 43 to 50; 45 to 50; 47 to 50; 48 to 50; 49 to 50; 50; or 52 **Golodirsen (Vyondys 53)** • Duchenne muscular dystrophy with mutations amenable to exon 53 skipping • Mutations include but are not limited to: Deletion of exons 42 to 52; 45 to 52; 47 to 52; 48 to 52; 49 to 52; 50 to 52; 52; or 54 to 58 **Viltepso (viltolarsen)** • Duchenne muscular dystrophy with mutations amenable to exon 53 skipping • Mutations include but are not limited to: Deletion of exons 42 to 52; 45 to 52; 47 to 52; 48 to 52; 49 to 52; 50 to 52; 52; or 54 to 58
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.)
Appropriate Treatment Regimen & Other Criteria:	**Casimersen (Amondys 45)** • 30 milligrams per kilogram administered once weekly • Provided as a 100 mg/2mL single-dose vial **Eteplirsen (Exondys 51)** • Dosing: 30 milligrams per kilogram administered once weekly • Provided as a 100 mg/2 mL or 500 mg/10 mL single-dose vial **Golodirsen (Vyondys 53)** • Dosing: 30 milligrams per kilogram administered once weekly • Provided as a 100 mg/2 mL single-dose vial **Viltepso (viltolarsen)** • Dosing: 80mg/kg administered once weekly as 60-min IV infusion

	<u>Reauthorization</u> requires that the patient's baseline functional status 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:	• Concurrent treatment with more than one antisense oligonucleotide
Age Restriction:	
Prescriber Restrictions:	• Prescribed by 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), ZIEXTENZO (Pegfilgrastim-bmez), UDENYCA (pegfilgrastim-cbqv), 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)

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. Mobilization allows for the collection of increased numbers of progenitor cells capable of engraftment as compared with collection without mobilization. After myeloablative chemotherapy, the transplantation of an increased number of progenitor cells can lead to more rapid engraftment, which may result in a decreased need for supportive care. Myeloid reconstitution is further accelerated by administration of Leukine following peripheral blood progenitor cell transplantation <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 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)</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</u>** **When requested via the MEDICAL benefit:** Coverage for the non-preferred products, Neupogen, Releuko 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, Zarxio, Releuko and Granix, is provided when the member meets the following criteria: • Documented treatment failure or intolerable adverse event to **Nivestym, Zarxio, and Releuko** **<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</u>** Coverage for the non-preferred product, Rolvedon, 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:** o High risk (greater than 20% risk) for febrile neutropenia based on chemotherapy regimen **OR** o Intermediate risk (10-20% risk) for febrile neutropenia based on chemotherapy regimen with documentation of significant patient risk factors for serious medical consequences **OR** o Has experienced a dose-limiting neutropenic event on a previous cycle of current chemotherapy to be continued • **Palliative Therapy:** o 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 **<u>For Treatment of Severe Chronic Neutropenia:</u>** • Must meet ALL the following: o 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

POLICY NAME:
NAFARELIN
Affected Medications: SYNAREL (nafarelin)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Central Precocious Puberty in children of both sexes
	  ○ Management of endometriosis

Required Medical Information:	**Central Precocious Puberty** • Documentation of central precocious puberty (CPP) confirmed by basal luteinizing hormone (LH), follicle-stimulating hormone (FSH), and either estradiol or testosterone concentrations **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 three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and continuous (no placebo pills) hormonal contraceptives • Maximum treatment duration 6 months total ○ Retreatment is not recommended
Exclusion Criteria:	• Use for infertility • Undiagnosed abnormal vaginal bleeding
Age Restriction:	• Endometriosis: 18 years of age and older • Central precocious puberty (CPP): age 11 or younger (females), age 12 or younger (males)
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist or gynecologist
Coverage Duration:	Authorization: • Endometriosis (no reauthorization): 6 months, unless otherwise specified • CPP: 12 months, unless otherwise specified

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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 disease (SPMS)
	  ○ Crohn's Disease (CD)

Required Medical Information:	• Screening for seropositivity for anti-JC virus (JCV) antibodies prior to Tysabri therapy **Multiple Sclerosis** • 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 **Clinically Isolated Syndrome** • Documentation of CIS (as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event). **Secondary-Progressive MS** • Documentation of prior history of RRMS with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e., new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • 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:	**All Uses** • **Reauthorization for patients with baseline positive JCV**: documentation of response to therapy and periodic MRI to monitor for Progressive Multifocal Leukoencephalopathy (PML) occurrence **MS** • No concurrent use with disease modifying therapies (DMTs).

	• 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 OR
	  ○ Documentation of pregnancy and severe disease.
	Crohn's disease
	• Documented treatment failure with at least two oral treatments for minimum of 12 weeks trial: corticosteroids, 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, Renflexis, Avsola)
	  AND
	  ○ One of the following: Entyvio or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz)

Exclusion Criteria:	• Current history of PML
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


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POLICY NAME:
NAXITAMAB
Affected Medications: DANYELZA (naxitamab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Treatment of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow in patients who have demonstrated a partial response, minor response, or stable disease to prior therapy • 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.
	• Diagnosis of neuroblastoma as defined per the International Neuroblastoma Response Criteria (INRC):
	  ○ An unequivocal histologic diagnosis from tumor tissue by light microscopy [with or without immunohistochemistry, electron microscopy, or increased urine (or serum) catecholamines or their metabolites]
	OR
	  ○ Evidence of metastases to bone marrow on an aspirate or trephine biopsy with concomitant elevation of urinary or serum catecholamines or their metabolites
	• Evidence of high-risk neuroblastoma, including:
	  ○ Stage 2/3/4/4S disease with amplified MYCN (any age)
	  ○ Stage 4 disease in patients greater than 18 months of age
	• Disease is evaluable in the bone and/or bone marrow, as documented by histology and/or appropriate imaging [e.g. metaiodobenzylguanidine (MIBG) scan]
	• Documented history of previous treatment with at least one systemic therapy to treat disease outside of the bone or bone marrow

Appropriate Treatment Regimen & Other Criteria:	• Must be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF). **Dosing**: • Availability: 40 mg/10 mL single-dose vial • 3 mg/kg/day (maximum: 150 mg/day) on days 1, 3, and 5 of each treatment cycle (in combination with GM-CSF). One treatment cycle is 4 or 8 weeks. **Reauthorization** will require documentation of disease responsiveness to therapy
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Patients with progressive disease

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Age Restriction:	• 1 year of age or older
Prescriber Restrictions:	• Must be prescribed by, or in consultation with, a hematologist/oncologist with expertise in neuroblastoma
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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POLICY NAME:
NEONATAL FC RECEPTOR ANTAGONISTS
Affected Medications: VYVGART (efgartigimod alfa), VYVGART HYTRULO (efgartigimod alfa and hyaluronidase), RYSTIGGO (rozanolixizumab)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design **Vyvgart & Vyvgart Hytrulo** • Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive **Rystiggo** • Generalized myasthenia gravis (gMG) in adult patients who are AChR or anti-muscle-specific tyrosine kinase (MuSK) 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 or MuSK antibodies (for Rystiggo)
	• MG-Activities of Daily Living (MG-ADL) total score of 5 or greater
	• Documentation of baseline Quantitative Myasthenia Gravis (QMG) score

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 Vyvgart, Vyvgart Hytrulo, 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)
	  ○ Need for ongoing rescue therapy (at least 3 courses in the past 12 months) with plasmapheresis, plasma exchange, or intravenous immunoglobulin (IVIG) while consistently taking immunosuppressive therapy (azathioprine, mycophenolate, tacrolimus, cyclosporine, methotrexate)
	• Coverage for Rystiggo is provided when one of the following is met:
	  ○ Currently receiving treatment with Rystiggo, 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 MG
	  ○ Documented treatment failure to rituximab for MuSK antibody positive MG
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization 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 ✧ 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
Exclusion Criteria:	• Immunoglobulin G (IgG) levels less than 600 mg/dL at baseline • 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:
NILOTINIB
Affected Medications: TASIGNA (nilotinib)

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, and prescribed treatment regimen • Documentation Philadelphia chromosome-positive mutation, BCR-ABL1 positive mutation,
Appropriate Treatment Regimen & Other Criteria:	• For patients with low-risk score, documented clinical failure with Imatinib • **Reauthorization** requires documentation of treatment success (as applicable, BCR-ABL1 transcript levels, cytogenetic response)
Exclusion Criteria:	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater • Hypokalemia, hypomagnesemia, or long QT syndrome
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

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POLICY NAME:
NOXAFIL
Affected Medications: NOXAFIL (posaconazole) oral suspension, posaconazole tablets

Covered Uses:	• All Food and Drug Administration (FDA)-approved and compendia supported indications not otherwise excluded by plan design
Required Medical Information:	• Susceptibility cultures matching posaconazole activity • Current body weight (for pediatric patients) • Documentation of an Oregon Health Authority (OHA) funded condition

Appropriate Treatment Regimen & Other Criteria:	**Treatment of invasive aspergillosis**
	• Documentation of resistance (or intolerable adverse event) to voriconazole
	
	Prophylaxis of invasive Aspergillus and Candida infections
	• Documentation of severely immunocompromised state, such as hematopoietic stem cell transplant (HSCT) recipients with graft versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy
	• Documentation of resistance (or intolerable adverse event) to one other compendia-supported systemic agent (e.g., fluconazole, itraconazole, voriconazole)
	
	Treatment of oropharyngeal candidiasis (OPC):
	• Documented failure (or intolerable adverse event) to 10 days or more of treatment with all of the following:
	  ○ Fluconazole
	  ○ Itraconazole

Exclusion Criteria:	
Age Restriction:	• Posaconazole delayed release tablets – 2 years of age or older who weigh greater than 40kg • Noxafil oral suspension – 13 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease specialist
Coverage Duration:	• Approval: 6 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.

Appropriate Treatment Regimen & Other Criteria:	<u>Presumptive diagnosis of MoCD Type A can be based on any one of the following</u>:
	
	• Family history
	  ○ Affected siblings 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 (usually appear within the first 28 days after birth but can also present later):
	  ○ 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
	
	<u>Genetic confirmation using a panel which includes MOCS1 to confirm MoCD Type A:</u>
	
	• In patients with a presumptive diagnosis of MoCD Type A, the diagnosis must be confirmed immediately using a genetic test
	
	<u>Dosing</u>:
	
	• Available as: 9.5 mg single-dose vial for reconstitution.
	• Administered via intravenous (IV) infusion.
	• One year of age or older: 0.9 mg/kg (based on actual body weight) once daily.

	• Less than one year of age (by gestational age): dosing is based on actual body weight and should be titrated to the target dose of 0.9 mg/kg/day over a period of 3 months. Please refer to label instructions for titration schedule. **Reauthorization**: • 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:	• Initial Authorization: 1 month, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
NUSINERSEN
Affected Medications: SPINRAZA (nusinersen)

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

Required Medical Information:	• Patient must have documentation of a confirmed diagnosis of spinal muscular atrophy (SMA) type 1, 2, or 3 defined as ONE of the following genetic tests of 5q13 demonstrating:
	  ○ Homozygous SMN1 gene deletion OR
	  ○ Homozygous SMN1 gene mutation OR
	  ○ Compound heterozygous SMN1 gene mutation
	• Patient has at least 2 or more copies of the SMN2 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 ventilator use status
	  ○ Is the patient ventilator dependent (using it 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

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with or intolerable adverse event on Evrysdi
	• Loading dose: 12 mg once every 14 days for 3 doses; then 12 mg once 30 days after the third dose
	• Maintenance dose: 12 mg once every 4 months
	Reauthorization: documentation of clinically significant improvement from baseline motor function demonstrated by:
	  ○ Improvement from baseline motor function score documented within one month of renewal request **AND**
	  ○ More areas of motor function improved than worsened
	  ○ HINE-2:
	  ▪ at least a 2-point increases in ability to kick **OR**
	  ▪ at least a 1-point increase in the motor milestones of head control, rolling, sitting, crawling, standing or walking using Section 2 of the Hammersmith Infant Neurologic Exam (HINE) **AND**

	▪ More areas of motor function improved than worsened ○ Hammersmith Functional Motor Scale (HFSME) ▪ At least 3 points increase in score from pretreatment baseline **AND** ▪ More areas of motor function improved than worsened ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) ▪ At least a 4 point increase in score from the pretreatment baseline **AND** ▪ More areas of motor function improved than worsened ○ Upper Limb Module (ULM) ▪ At least a 3 point increase from pretreatment baseline ○ 6-Minute Walk Test (6MWT) ▪ At least a 30 meter increase from pretreatment baseline
Exclusion Criteria:	• SMA type 4 • Ventilator dependent (using at least 16 hours per day on at least 21 of the last 30 days) ○ Does not apply to patients who require non-invasive ventilator assistance • Prior treatment with Zolgensma (AVXS-101)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pediatric neurologist or provider who is experienced in treatment of spinal muscular atrophy
Coverage Duration:	• Initial approval: 5 doses to be administered in a 6 month period • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
NON-PREFERRED SODIUM-GLUCOSE CO-TRANSPORTERS (SGLT2)
Affected Medications: JARDIANCE (empagliflozin), Farxiga (dapagliflozin), 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 (Jardiance)
	  ○ Heart failure with reduced ejection fraction (Farxiga)
	  ○ Chronic kidney disease at risk of progression (Farxiga)

Required Medical Information:	• Documentation of diagnosis of Type 2 Diabetes • Documentation of diagnosis of heart failure (Jardiance) • Documentation of diagnosis of heart failure with reduced ejection fraction (Farxiga) • Documentation of diagnosis of chronic kidney disease (Farxiga only)

Appropriate Treatment Regimen & Other Criteria:	**Jardiance**
	Patients with Type 2 Diabetes AND:
	• Documented treatment failure (or intolerable adverse event) with Steglatro
	OR
	• Documentation of established cardiovascular disease (CVD)
	
	Heart Failure (adjunctive agent):
	• Documentation of diagnosis of heart failure
	
	Farxiga
	Patients with Type 2 Diabetes AND:
	• Documented treatment failure (or intolerable adverse event) with Steglatro
	OR
	• Documentation of one of the following:
	  ○ Established cardiovascular disease (CVD)
	  ○ Multiple risk factors for cardiovascular disease (ex. Dyslipidemia, hypertension, family history of CVD, etc.)
	  ○ Established chronic kidney disease
	
	Heart Failure (adjunctive agent):
	• Documentation of diagnosis of heart failure with reduced ejection fraction (40% or less)

	Chronic Kidney Disease: • Documentation of chronic kidney disease at risk of progression: eGFR between 25 and 60 mL/min/1.73m^2 AND albuminuria (urine albumin creatinine ratio greater than 300 mg/g) **<u>Invokana/Invokamet</u>** • Documented treatment failure (or intolerable adverse event) with Steglatro • OR • Documented diagnosis of established cardiovascular disease (Coronary artery disease, history of stroke, or peripheral artery disease) • OR • Documented diagnosis of diabetic nephropathy and albuminuria greater than 300mg/day **<u>Reauthorization:</u>** • Documentation of treatment success and clinically significant response to therapy.
Exclusion Criteria:	• Concurrent use of more than one SGLT2 • Weight Loss
Age Restriction:	• Greater than or equal to 18 years
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OBETICHOLIC ACID
Affected Medications: OCALIVA (obeticholic acid)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
	  ○ Primary biliary cholangitis
	  ▪ Without cirrhosis or
	  ▪ With compensated cirrhosis who do not have evidence of portal hypertension

Required Medical Information:	• Liver function tests (including alkaline phosphatase and bilirubin) • Child-Pugh score

Appropriate Treatment Regimen & Other Criteria:	• The patient has an alkaline phosphatase level (ALP) at least 1.67 times the upper limit of normal (ULN) and/or bilirubin above the upper limit of normal while on ursodiol (with demonstrated adherence) after at least 12 months of therapy or has demonstrated a clinical inability to tolerate ursodiol
	  ○ ULN ALP defined as 118 U/L for females or 124 U/L for males
	  ○ ULN of total bilirubin defined as 1.1 mg/dL for females or 1.5 mg/dL for males
	
	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 (eg, Child-Pugh Class B or C) or a prior decompensation event • Compensated cirrhosis with evidence of portal hypertension (eg, ascites, gastroesophageal varices, persistent thrombocytopenia)
Age Restriction:	• 18 years and older
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

PacificSource Community Solutions

POLICY NAME:
OCRELIZUMAB
Affected Medications: OCREVUS (ocrelizumab)

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 isolating syndrome (CIS)
	  ○ Relapsing-remitting multiple sclerosis (RRMS)
	  ○ Active secondary progressive disease (SPMS)

Required Medical Information:	• 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
	
	<u>Clinically Isolated Syndrome</u>
	• Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event
	
	<u>Primary Progressive MS</u>
	• Documentation of diagnosis of PPMS using the McDonald criteria require evidence of one year of disease progression (retrospectively or prospectively determined), independent of clinical relapse, plus two of the three following criteria:
	  ○ One or more hyperintense T2 lesions characteristic of MS in one or more of the periventricular, cortical or juxtacortical, or infratentorial areas
	  ○ Two or more hyperintense T2 lesions in the spinal cord
	  ○ Presence of CSF-specific oligoclonal bands
	
	<u>Secondary-Progressive MS</u>
	• Documentation of prior history of relapsing-remitting MS (RRMS) with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses
	• Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e. new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years
	• Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5

Appropriate Treatment	• RRMS: Coverage of Ocrevus requires documentation of one of the following: ○ A documented intolerable adverse event to the preferred Rituximab products, Truxima, Riabni and Ruxience, and the adverse event was not an expected adverse event attributed to the active ingredient

Regimen & Other Criteria:	○ Currently receiving treatment with Ocrevus, excluding via samples or manufacturer's patient assistance program • PPMS: Documentation of at least one year of disease progression and Baseline Expanded Disability Status Scale (EDSS) of 3-6.5 • 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 infection
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
ODEVIXIBAT
Affected Medications: BYLVAY (odevixibat)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Pruritus due to progressive familial intrahepatic cholestasis (PFIC)
Required Medical Information:	• Documentation of confirmed molecular diagnosis of PFIC type 1 or type 2 ○ Documentation of absence of ABCB11 gene variant if PFIC type 2 • Documentation of patient's current weight • Documentation of history of significant pruritus
Appropriate Treatment Regimen & Other Criteria:	• Documented failure with an adequate trial (at least 30 days) of all of the following: rifampin, ursodiol, AND cholestyramine **Reauthorization**: Documented treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Prior hepatic decompensation events • Concomitant liver disease (e.g., biliary atresia, liver cancer, non-PFIC related cholestasis) • INR greater than 1.4 • ALT or total bilirubin greater than 10-times the upper limit of normal (ULN) • Prior liver transplant
Age Restriction:	• 3 months and older
Prescriber Restrictions:	• Prescribed by a hepatologist or a specialist with experience in the treatment of PFIC
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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
	  ○ Chronic fibrosing interstitial lung diseases with a progressive phenotype
	  ○ Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Required Medical Information:	• Documentation of baseline liver function tests in all patients, at regular intervals during the first three months, then periodically thereafter or as clinically indicated
	
	<u>Idiopathic Pulmonary Fibrosis (IPF):</u>
	• Documentation of diagnosis of idiopathic pulmonary fibrosis supported by one of the following:
	  ○ Presence of usual interstitial pneumonia (UIP)
	  ○ High resolution computed tomography (HRCT)
	  ○ Surgical lung biopsy
	• Documentation of baseline forced vital capacity (FVC) greater than or equal to 50% of the predicted value
	• Documentation of predicted diffuse capacity for carbon monoxide (DLCO) greater than or equal to 30%
	
	<u>Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)</u>
	• Documentation of diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease from the American College of Rheumatology / European League Against Rheumatism classification criteria
	• Documentation of onset of disease (first non-Raynaud symptom) of less than 7 years
	• 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 Diseases with a Progressive Phenotype</u>
	• Documentation of a diagnosis of chronic fibrosing interstitial lung diseases with a progressive phenotype
	• Documentation of relevant fibrosis (greater than 10% fibrotic features) on chest high resolution computed tomography (HRCT) scan with clinical signs of progression (defined as FVC decline at least 10%, FVC decline at least 5% with worsening symptoms and/or imaging in the previous 24 months)
	• FVC greater than or equal to 45% of predicted
	• DLCO 30% to less than 80% of predicted

Appropriate Treatment Regimen & Other Criteria:	**IPD** • Documented treatment failure, contraindication, or intolerance to pirfenidone. **SSc-ILD:** • Documented treatment failure with each of the following: mycophenolate (MMF), cyclophosphamide **Reauthorization** requires documentation of treatment success
Exclusion Criteria:	• Documentation of airway obstruction (i.e., pre-bronchodilator FEV/FVC less than 0.7) • Concomitant administration of moderate or strong CYP3A4 and P-gp inhibitors / inducers should be avoided while taking Ofev • Transaminases more than 5 times the upper limit of normal or elevated transaminases accompanied by symptoms (jaundice, hyperbilirubinemia). • Ofev is not approved for use in combination with Esbriet
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

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 acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients

Required Medical Information:	• Documentation of acid sphingomyelinase deficiency as evidenced by
	  ○ Enzyme assay showing diminished (less than 10% of controls) or absent acid sphingomyelinase activity (ASM)
	  ○ Gene sequencing showing biallelic pathogenic SMPD1 mutation
	  ○ Documentation of clinical presentation (ex hepatosplenomegaly, interstitial lung disease, liver fibrosis, growth restriction of childhood) outside the central nervous system
	• Documentation of baseline measures of affected systems: (examples below)
	  ○ Lungs: Diffusion capacity of lungs (DLCO) and pulmonary function tests (PFT)
	  ○ Liver and spleen: volume, liver function tests, imaging
	  ○ Bones: platelet counts, z-score (pediatric)

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 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.
	  ○ Nasal Polyps
	  ○ Severe Allergic Asthma
	  ○ Treatment of chronic idiopathic urticaria up to a maximum age of 20 years

Required Medical Information:	**Severe Allergic Asthma**
	• Documentation of severe allergic asthma defined by all the following:
	  ○ A positive skin test or in vitro reactivity to a perennial aeroallergen
	  ○ A serum total IgE level at baseline of
	  ▪ At least 30 IU/mL and less than 700 IU/mL in patients age 12 years or older; OR
	  ▪ At least 30 IU/mL and less than 1,300 IU/mL in patients age 6 to 11 years
	  ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal
	
	Nasal Polyps
	• Documentation of use as add on treatment of nasal polyps in adults who have had inadequate response to nasal corticosteroids.
	• Documentation of chronic sinusitis after total ethmoidectomy with a need for revision endoscopic sinus surgery due to continued symptoms of nasal congestion/obstruction from recurrent bilateral sinus obstruction due to nasal polyps.
	
	Chronic Idiopathic Urticaria
	• Documentation of active chronic idiopathic urticaria 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 NSAIDs)
	• Documented severe disease (despite treatment) based on score from an objective clinical evaluation tool, such as:
	  ○ Urticaria Activity Score (UAS7) (Score of 28 or higher)
	  ○ Urticaria Control Test (UCT)) (Score under 12)
	  ○ Dermatology Life Quality Index (DLQI) (Score of 21 or higher)
	  ○ Chronic Urticaria Quality of Life Questionnaire (CU-QoL) (Score of 75 or higher)
	• Documentation of pruitis severe enough to interfere with the ability to grow, develop and participate in school despite treatment with at least 80% adherence.

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Appropriate Treatment Regimen & Other Criteria:	**Severe 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
	• 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.
	• Documentation that chronic daily oral corticosteroids are required
	Nasal Polyps
	• Documented failure with at least 1 intranasal corticosteroid (such as fluticasone) after ethmoidectomy
	• Documented failure with Sinuva implant
	
	Chronic Idiopathic Urticaria
	• Documented failure of at least one month trial with scheduled dosing of up to 4-fold standard dosing of one of the following second generation H1- antihistamine products: cetirizine, fexofenadine, loratadine, desloratadine, or levocetirizine
	• Documented failure to one or more month trial on previous therapy with scheduled dosing of ALL of the following:
	  ○ Add-on therapy with a leukotriene antagonist (montelukast or zafirlukast)
	  ○ Add-on therapy with a H2-antagonist (famotidine or cimetidine)
	  ○ Add-on therapy with corticosteroid

Exclusion Criteria:	• Request for use in combination with another monoclonal antibody (Fasenra, Nucala, Tezspire, Dupixent, Cinqair) • Ages 20 and up for Chronic Idiopathic Urticaria (Below line of coverage)
Age Restriction:	• 6 years of age and older for Severe Allergic Asthma • 18 years of age and older for Nasal Polyps • Up to age 20 for Chronic Idiopathic Urticaria
Prescriber Restrictions:	• Severe Allergic Asthma- Allergist, immunologist, or pulmonologist • Nasal Polyps- Otolaryngologist • Chronic Idiopathic Urticaria- Allergist or immunologist
Coverage Duration:	• Initial Authorization: 6 months • Reauthorization:12 months

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

POLICY NAME:
ONASEMNOGENE ABEPARVOVEC XIOI
Affected Medications: ZOLGENSMA (onasemnogene abeparvovec xioi + IV)

<table>
<tr><td>Covered Uses:</td><td>• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by benefit design.</td></tr>
<tr><td>Required Medical Information:</td><td>• Documentation of previous treatment history AND
• Diagnosis of spinal muscular atrophy (SMA) by genetic test showing:
• Fewer than 3 copies of SMN2
AND
• Documentation of anti-adeno-associated virus (AAV) serotype 9 antibody titer less than or equal to 1:50 AND
• Documentation of ventilator use status</td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>• Dosed 1.1 x 10-14 vectors per kilogram of body weight with prophylactic prednisolone 1 mg/kg/day prior to and following administration for a total of 30 days
<table>
<tr><th>Patient Weight Range (kg)</th><th>Dose volume (mL)</th></tr>
<tr><td>2.6-3.0</td><td>16.5</td></tr>
<tr><td>3.1-3.5</td><td>19.3</td></tr>
<tr><td>3.6-4.0</td><td>22.0</td></tr>
<tr><td>4.1-4.5</td><td>24.8</td></tr>
<tr><td>4.6-5.0</td><td>27.5</td></tr>
<tr><td>5.1-5.5</td><td>30.3</td></tr>
<tr><td>5.6-6.0</td><td>33.0</td></tr>
<tr><td>6.1-6.5</td><td>35.8</td></tr>
<tr><td>6.6-7.0</td><td>38.5</td></tr>
<tr><td>7.1-7.5</td><td>41.3</td></tr>
<tr><td>7.6-8.0</td><td>44.0</td></tr>
<tr><td>8.1-8.5</td><td>46.8</td></tr>
<tr><td>8.6-9.0</td><td>49.5</td></tr>
<tr><td>9.1-9.5</td><td>52.3</td></tr>
<tr><td>9.6-10.0</td><td>55.0</td></tr>
<tr><td>10.1-10.5</td><td>57.8</td></tr>
<tr><td>10.6-11.0</td><td>60.5</td></tr>
<tr><td>11.1-11.5</td><td>63.3</td></tr>
<tr><td>11.6-12.0</td><td>66.0</td></tr>
<tr><td>12.1-12.5</td><td>68.8</td></tr>
<tr><td>12.6-13</td><td>71.5</td></tr>
<tr><td>13.1-13.5</td><td>74.3</td></tr>
</table></td></tr>
<tr><td>Exclusion Criteria:</td><td>• Concurrent treatment with Spinraza
• Previous treatment with Zolgensma (AVXS-101) in their lifetime
• Advanced SMA at baseline (e.g., complete paralysis of limbs)
• Breathing assistance: tracheostomy, permanent ventilator dependence
• Pre-existing hepatic insufficiency</td></tr>
</table>

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), ALKERAN, ALIMTA (pemetrexed disodium), ALIQOPA (copanlisib), ALUNBRIG (brigatinib), ASPARLAS (asparaginase), ARZERRA (ofatumumab), AYVAKIT (avapritinib), BAVENCIO (avelumab), BALVERSA (erdafitinib), BELRAPZO (bendamustine), BENDEKA (bendamustine), BESPONSA (inotuzumab ozogamicin), BESREMI (ropeginterferon), BLENREP (belantamab mafodotin-blmf), BORTEZOMIB, BOSULIF (bosutinib), 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), DARZALEX, DARZALEX FASPRO (daratumumab-hyaluronidase), DAURISMO (glasdegib), ELAHERE, EMPLICITI, ENHERTU (fam-trastuzumab deruxtecan), EPKINLY (epcoritamab), ERBITUX (cetuximab), ERIVEDGE, ERLEADA (apalutamide), ERLOTINIB, ERWINAZE, EVOMELA, EXKIVITY (mobocertinib), FARYDAK, FOTIVDA (tivozanib), GAVRETO (pralsetinib), GAZYVA, GILOTRIF, HYCAMTIN, IBRANCE (palbociclib), ICLUSIG, IDHIFA (enasidenib), IMATINIB, IMBRUVICA (ibrutinib), IMFINZI (durvalumab), IMJUDO (tremelimumab), IMLYGIC (talimogene laherparepvec), INLYTA, INQOVI (decitabine and cedazuridine), INREBIC, GEFITINIB, ISTODAX (romidepsin), 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, LENVIMA (lenvatinib mesylate), LIBTAYO (cemiplimab-rwlc), LIPOSOMAL DOXORUBICIN, LONSURF, LORBRENA, LUMAKRAS (sotorasib), LUMOXITI, LUNSUMIO (mosunetuzumab), LUTATHERA, LYNPARZA, LYTGOBI (futibatinib), MARGENZA (margetuximab-cmkb), MARQIBO (liposomal vincristine), MEKINIST (trametinib), MEKTOVI (binmetinib), MONJUVI (tafisitamab-cxix), MYLOTARG, NERLYNX (neratinib), SORAFENIB TOSYLATE, NILANDRON, NINLARO (ixazomid), NUBEQA, ODOMZO, ONCASPAR, ONIVYDE (irinotecan), ONUREG (azacitidine), OPDIVO (nivolimumab), OPDUALAG (nivolimumab/relatlimab), ORSERDU (elacestrant), PADCEV (enfortumab vedotin), PEMAZYRE (pemigatinib), PEMETREXED, PEMFEXY(pemetrexed), 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), REVLIMID, REZLIDHIA (olutasidenib), REZUROCK (belumosudil), ROZLYTREK, RUBRACA, RYBREVANT (amivantamab), RYDAPT, RYLAZE (asparaginase erwinia chrysanthemi), SARCLISA (isatuximab), STIVARGA (regorafenib), SUTENT, SYNRIBO (omacetaxine), TABRECTA (capmatinib), TAFINLAR (dabrafenib), TAGRISSO, TALZENNA (talazopairb), TAZVERIK (tazemetostat), TECARTUS (brexucabtagene autoleucel), TECENTRIQ (atezolizumab), TECVAYLI, TEMOZOLOMIDE, TEPADINA (thiotepa), TEPMETKO (tepotinib), TIBSOVO (ivosidenib), TIVDAK (tisotumab), TORISEL (temsirolimus), TREANDA (bendamustine), TRODELVY (sacituzumab govitecan), TRUSELTIQ (infigratinib), TYKERB, UKONIQ (umbralisib tosylate), VANTAS (histrelin acetate implant), VECTIBIX, VELCADE (bortezomib), VENCLEXTA (venetoclax), VERZENIO (abemaciclib), VIDAZA (Azacitidine), VIVIMUSTA (bendamustine), VIZIMPRO (dacotiminib), VONJO (pacritinib), VOTRIENT, VYXEOS (Daunorubicin and Cytarabine (Liposomal)), XALKORI, XELODA, XOFIGO (Radium 223), XOSPATA (gilteritinib), XPOVIO (selinexor), XTANDI (enzalutamide), YERVOY (ipilimumab), YESCARTA (axicabtagene ciloleucel), YONDELIS (trabectedin), ZALTRAP (ziv-aflibercept), ZEJULA (niraparib), ZELBORAF, ZEPZELCA (lurbinectedin), ZOLINZA, ZYDELIG, ZYKADIA, ZYNLONTA (loncastuximab tesirine), ZYNYZ (retifanlimab-dlwr) injection

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:
PATISIRAN
Affected Medications: ONPATTRO (patisiran sodium)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

Required Medical Information:	• Documented pathogenic mutation in transthyretin (TTR) confirmed by genetic testing
	• Diagnosis of hereditary transthyretin (hATTR) amyloidosis with polyneuropathy
	• Presence of clinical signs and symptoms of disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction)
	• Documented failure with diflunisal
	• Documentation with one of the following:
	  ○ Baseline polyneuropathy disability (PND) score of less than or equal to IIIb
	  ○ Baseline neuropathy impairment (NIS) score between 10 and 130
	  ○ Baseline FAP stage 1 or 2

Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced **<u>Reauthorization:</u>** • Documentation of a positive clinical response to patisiran (e.g., improved neurologic impairment, motor function, cardiac function, quality of life assessment, serum TTR levels, etc.)
Exclusion Criteria:	• Prior or planned liver transplantation • NYHA class III or IV • Combined use with TTR-lowering therapy including inotersen or vutrisiran • Combined use with TTR-stabilizing therapy including diflunisal, tafamidis, or tafamidis meglumine
Age Restriction:	• Adults age 18 and up
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or provider with experience in the management of amyloidosis
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
OPICAPONE
Affected Medications: ONGENTYS (Opicapone)

Covered Uses:	• All Food and Drug Administration-approved indications not otherwise excluded by plan design ○ Parkinson's Disease
Required Medical Information:	• Diagnosis of advanced Parkinson's Disease (PD) • Documentation of at least one well defined acute intermittent hypomobility or "off" episode for 2 hours or more during the waking day, despite optimized therapy with other agents

Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure of the following:
	  ○ Concurrent therapy with levodopa/carbidopa at the maximum tolerated dose and a second agent from one of the following alternate anti-Parkinson's drug classes:
	  ▪ Monoamine oxidase-B (MAO-B) inhibitors (ex: selegiline, rasagiline)
	  ▪ Dopamine agonists (ex: amantadine, pramipexole, ropinirole)
	AND
	  ○ Concurrent therapy with levodopa/carbidopa at the maximum tolerated dose and entacapone
	
	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: Reauthorization: 12 months, unless otherwise specified

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

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 • As of June 17, 2019, chronic use of opioids with a Morphine Milligram Equivalents (MME) per day greater than 90 MME is not funded by PacificSource
Required Medical Information:	• Exceptions require that opioid use greater than 90 MME is not chronic and is being used for short term exceptional circumstances
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:	• Based on exceptional circumstance, not to exceed 3 months

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
Required Medical Information:	**Severe Atopic Dermatitis and Nonsegmental Vitiligo** • Documentation of severe inflammatory skin disease defined as functional impairment (inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) AND • Body Surface Area (BSA) of at least 10% OR Hand, foot, or mucous membrane involvement
Appropriate Treatment Regimen & Other Criteria:	**Severe Atopic Dermatitis** • Documented 12-week trial and clinical failure with all of the following alternatives: tacrolimus ointment, pimecrolimus cream, phototherapy, cyclosporine, azathioprine, methotrexate, mycophenolate, Dupixent, AND Adbry (prior authorization required for Dupixent and Adbry). **Reauthorization** No reauthorization permitted: treatment beyond 8 weeks has not been studied or found to be safe and effective. **Nonsegmental Vitiligo** • Documented 12-week trial and clinical failure with all of the following alternatives: tacrolimus ointment, pimecrolimus cream, mometasone furoate, clobetasol, prednisone, dexamethasone, phototherapy, cyclosporine, methotrexate, AND mycophenolate.
Exclusion Criteria:	**Severe Atopic Dermatitis** • Combination use with monoclonal antibody (such as Dupixent) • Previous 8-week treatment course **Nonsegmental Vitiligo** • Previous 24-week treatment course
Age Restriction:	• 12 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist (example: dermatologist, allergist, or immunologist)
Coverage Duration:	**Severe Atopic Dermatitis** • Initial: Maximum for 8 weeks, unless otherwise specified • Reauthorization: No reauthorization permitted.

	<u>Nonsegmental Vitiligo</u> • Initial: 8 weeks, unless otherwise specified **<u>Reauthorization</u>**: Additional 16 weeks, unless otherwise specified. Further reauthorization not permitted. (Maximum lifetime approval of 24 weeks).

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 ○ Chronic cancer pain, management of breakthrough pain episodes

Required Medical Information:	• Documentation that a long-acting opioid is being prescribed for around-the clock treatment of the cancer pain.
	• The patient is opioid tolerant, defined as:
	  ○ Taking at least 60 mg of oral morphine per day **OR**
	  ○ 25 mcg of transdermal fentanyl/hr **OR**
	  ○ 30 mg of oral oxycodone daily **OR**
	  ○ 8 mg of oral hydromorphone daily **OR**
	  ○ 25 mg oral oxymorphone daily **OR**
	  ○ An equianalgesic dose of another opioid for a week or longer

Appropriate Treatment Regimen & Other Criteria:	• Patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting **OR** • Patient is unable to take **2** other short-acting narcotics (e.g., oxycodone, morphine sulfate, hydromorphone, etc.) secondary to allergy or severe adverse events **AND** • Patient is on or will be on a long-acting narcotic (e.g., Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (e.g., morphine sulfate, hydromorphone, fentanyl citrate)
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)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	**Pulmonary arterial hypertension (PAH) WHO Group 1** • Documentation of PAH confirmed by right-heart catheterization • Etiology of PAH: (idiopathic, heritable, or associated with connective tissue disease) • NYHA/WHO Functional Class II to III symptoms • Documentation of acute vasoreactivity testing (positive result requires trial/failure to calcium channel blocker) unless there are contraindications such as low systemic blood pressure (systolic blood pressure less than 90), or low cardiac index
Appropriate Treatment Regimen & Other Criteria:	• Documentation of failure with Remodulin • For initiation of therapy patient must have mean pulmonary artery pressure least 20 mmHg at rest, an elevated pulmonary vascular resistance (PVR) of at least 2.0 Wood units, and a mean pulmonary capillary wedge pressure less than 15 **AND** • The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition • Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out • Documentation that treprostinil is used as a single route of administration (Remodulin, Tyvaso, Orenatriam should not be used in combination) • 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.) • Subsequent approvals require documentation of treatment success such as improved walking distance or improvements in functional class
Exclusion Criteria:	• Severe hepatic impairment (Child Pugh Class C)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a Cardiologist or Pulmonologist
Coverage Duration:	• 12 months, unless otherwise specified

POLICY NAME:
ORGOVYX
Affected Medications: ORGOVYX (relugolrix)

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. (For non-cancer use only)
Required Medical Information:	**Prostate cancer** • Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course
Appropriate Treatment Regimen & Other Criteria:	**Prostate Cancer** • Documented treatment failure or intolerable adverse event with leuprolide or degarelix • Dosing: 360 mg on Day 1, followed by 120 mg daily starting on Day 2 **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:	• Oncologist
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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:
ORKAMBI
Affected Medications: ORKAMBI (lamacaftor/ivacaftor)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Cystic fibrosis in patients homozygous for the F508del mutation in the CFTR gene
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 homozygous for the F508del mutation in the CFTR gene
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success
Exclusion Criteria:	• Concurrent use of strong CYP3A inducers: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort
Age Restriction:	• 1 year and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pulmonologist or provider who specializes in CF
Coverage Duration:	• Initial approval: 12 months, unless otherwise specified • Reauthorization: 24 months, 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 four 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 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 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. • Documented provider attestation that the patient has been informed of the risk of pregnancy given their fertility status (such as tubal ligation failure, misdiagnosed/temporary menopause, etc.), the severe fetal harm that can occur with pregnancy that follows the administration of Vivjoa, AND documentation that the patient acknowledges and understands these risks and agrees to be vigilant in avoiding pregnancy during Vivjoa therapy and for a minimum of 2 years following their last dose of Vivjoa. **Dosing:** • **Vivjoa-ONLY regimen:** Day 1 – 600mg as one dose Day 2 – 450 mg as one dose Starting Day 14 – 150 mg every 7 days for 11 weeks (weeks 2 through 12) • **Fluconazole-Vivjoa regimen:** Day 1, Day 4, Day 7 – fluconazole 150 mg Day 14 through Day 20 – Vivjoa 150 mg once daily Starting day 28 – Vivjoa 150 mg every 7 days for 11 weeks (weeks 4 through 14) • **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

Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Authorization: 3 months, unless otherwise specified

POLICY NAME:
OSILODROSTAT
Affected Medications: ISTURISA (osilodrostat)

• Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #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 –
Persistent or recurrent Cushing's disease or patients with de novo Cushing's disease for whom pituitary surgery is not an option or has not been curative.		
• Is there documentation that the patient has persistent or recurrent Cushing's disease for whom surgery has not been curative OR a new diagnosis of Cushing's disease in which surgery is not an option	Yes – Document and go to #2	No – Criteria not met
• Is there documentation that the patient has a 24-hour mean Urine Free Cortisol (UFC) greater than 1.5 times the upper limit of normal (above 67 µg/24 hours).	Yes – Document and go to #3	No – Criteria not met
• Is there documentation that the patient has risk factors for Torsades de Pointe or taking other medications that may prolong the QTc interval?	No – Document and go to #4	Yes – Criteria not met
• Is there documentation that the treatment is in consult with an endocrinologist, neurologist or adrenal surgeon with confirmation of a titration schedule including urine free cortisol monitoring every 1-2 weeks until adequate clinical response is maintained?	Yes – Approve up to 6 months	No – Criteria not met
Renewal Criteria		
• Is there documentation of treatment success as determined by the mean urine free cortisol levels less than or equal to the upper limit of normal based on laboratory results?	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 12 months	No – Criteria not met
Quantity Limitations		

• **Isturisa 1 mg tablets**
  ○ 180/30
• **Isturisa 5 mg tablets**
  ○ 180/30
• **Isturisa 10 mg tablets**
  ○ 180/30		

POLICY NAME:
OXERVATE
Affected Medications: OXERVATE (cenegermin-bkbj)

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

Required Medical Information:	• Documentation of decreased corneal sensitivity (≤ 4 cm using the Cochet-Bonnet aesthesiometer) within the area of the persistent epithelial defect or corneal ulcer and outside of the area of the defect in at least one corneal quadrant
	• Documentation of stage 2 or stage 3 neurotrophic keratitis
	  ○ Stage 2 neurotrophic keratitis
	  ▪ Persistent corneal epithelial defect **OR**
	  ▪ Descemet's membrane folds and stromal swelling **OR**
	  ▪ Anterior chamber inflammatory reaction
	  ○ Stage 3 neurotrophic keratitis
	  ▪ Corneal ulcer **OR**
	  ▪ Corneal perforation **OR**
	  ▪ Corneal stromal melting

Appropriate Treatment Regimen & Other Criteria:	• Documentation of progression in severity with treatment of preservative-free artificial tears, gel, or ointments; **AND** • Therapeutic corneal or scleral contact lenses; **AND** • Amniotic membrane transplantation and conjunctival flap surgery OR tarsorrhaphy OR cyanoacrylate glue OR soft-bandage contact lens • Dose may not exceed more than 1 vial per eye per day • Dosing does not exceed 8 weeks for first treatment • Reauthorization will require documentation of improvement in corneal sensitivity and grade of severity determined by corneal fluorescein staining using the modified Oxford scale
Exclusion Criteria:	• Active or suspected ocular or periocular infections
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an ophthalmologist
Coverage Duration:	• Authorization: 8 weeks • Reauthorization: 8 weeks, maximum approval (total of 16 weeks)

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
	  ○ Narcolepsy with cataplexy
	  ○ Narcolepsy with excessive daytime sleepiness (EDS)

Required Medical Information:	**<u>Narcolepsy with cataplexy confirmed by the following:</u>**
	• Polysomnography and multiple sleep latency test
	• Documentation of cataplexy episodes defined by transient muscle weakness
	
	<u>Narcolepsy with EDS confirmed by the following:</u>
	  ○ Polysomnography and multiple sleep latency test
	  ○ Current evaluation of symptoms and Epworth Sleepiness Scale (ESS) score of at least 15 at baseline

Appropriate Treatment Regimen & Other Criteria:	**<u>Narcolepsy with cataplexy:</u>**
	• Documented treatment failure with each of the following for at least 1 month unless contraindicated:
	  ○ Venlafaxine, fluoxetine, and a tricyclic antidepressant.
	
	<u>Narcolepsy with EDS:</u>
	• Current ESS score of at least 13 despite current therapy
	• 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
	• Authorization for Xywav and Lumryz for current and new utilizers requires documented treatment failure with sodium oxybate
	
	<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 alcohol use disorder • Concurrent use of sedative/hypnotic drugs or other central nervous system depressants • Diagnosis of hypersomnia not related to narcolepsy

Age Restriction:	• 7 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a sleep specialist enrolled in Xyrem REMS program
Coverage Duration:	• Initial approval: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
OZANIMOD
Affected Medications: 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:
	  ▪ Clinically isolated syndrome (CIS)
	  ▪ Relapsing-remitting multiple sclerosis (RRMS)
	  ▪ Active secondary progressive disease (SPMS)
	  ○ Ulcerative Colitis

Required Medical Information:	<u>Multiple Sclerosis</u> • 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 <u>Clinically Isolated Syndrome</u> • Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event <u>Secondary-Progressive MS</u> • Documentation of prior history of RRMS with progressive increase in disability over at least 6 months independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e., new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years. • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5 <u>Ulcerative Colitis</u> • Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy
Appropriate Treatment Regimen & Other Criteria:	**<u>Multiple Sclerosis</u>** • Documentation of treatment failure (or intolerable adverse event) to dimethyl fumarate or Bafiertam (monomethyl fumarate) • No concurrent use of other disease-modifying medications indicated for the treatment of MS **<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 failure (or intolerable adverse event) with at least 12 weeks of all available formulary alternatives: infliximab (preferred biosimilar products: Inflectra, Renflexis, Avsola), Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), Xeljanz, Entyvio **Reauthorization** requires provider attestation of treatment success
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist, MS specialist, or gastroenterologist appropriate for diagnosis.
Coverage Duration:	• Initial Authorization: 6 months (Ulcerative Colitis only), all other indications: 12 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
PALFORZIA
Affected Medications: PALFORZIA (peanut allergen powder-dnfp oral capsules)

○ Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #2
Mitigation of allergic reactions due to accidental exposure to peanut		
○ Is the request age-appropriate, as defined below? • Initial Dose Escalation and Up-Dosing: 4 to 17 years of age. • Maintenance: 4 to 17 years of age, OR 18 years of age, or greater, for those who began Palforzia maintenance before becoming 18 years of age.	Yes – Document and go to #3	No – Criteria not met
○ Is there a documented history of allergic reactions to peanut that meet the criteria below? • Signs and symptoms of a significant systemic allergic reaction to peanut, such as: hives, swelling, wheezing, hypotension, and 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 medication.	Yes – Document and go to #4	No – Criteria not met
○ Is there documentation of a positive skin prick test (SPT) response to peanut with a wheal diameter at least 3 mm larger than control OR peanut-specific positive IgE of greater than or equal to 0.35kUa/L?	Yes – Document and go to #5	No – Criteria not met
○ Is there documentation of peanut allergy confirmed by provider-supervised food challenge?	Yes – Document and go to #6	No – Criteria not met
○ Is there documentation indicating a significant impact on quality of life due to peanut allergies?	Yes – Document and go to #7	
○ Are there known contraindications to treatment with Palforzia, as defined below? • Currently uncontrolled asthma. • A history of cardiovascular disease, including uncontrolled	Yes – Criteria not met	No – Document and go to #8

or inadequately controlled hypertension. • A history of eosinophilic esophagitis or other eosinophilic gastrointestinal diseases. • A history of a mast cell disorders, including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema.		
○ Is Palforzia being prescribed by, or in consultation with, an allergist or immunologist?	Yes – Approve up to 6 months	No – Criteria not met
Renewal Criteria		
• Is this a renewal request following the completion of the Up-Dosing phase?	Yes – Document and go to #2	No – Go to #3
• Is there documentation of treatment success and a clinically significant response to therapy defined by a successful completion of all Up-Dosing levels for the required lengths of time?	Yes – Document and go to #4	No – Criteria not met
• Is there documentation of treatment success and a clinically significant response to therapy, as defined below? • An improvement in quality of life (for those in the Maintenance phase). • A decrease in SPT wheal diameter of at least 0.5mm from baseline.	Yes – Document and go to #4	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 12 months	No – Criteria not met
Quantity Limitations		

Dosing Phase and Dosage Form	Quantity Limit
Palforzia cap escalation	1 kit/14 days
Palforzia cap level 1	1 kit/14 days
Palforzia cap level 2	1 kit/14 days
Palforzia cap level 3	1 kit/14 days
Palforzia cap level 4	1 kit/14 days
Palforzia cap level 5	1 kit/14 days
Palforzia cap level 6	1 kit/14 days
Palforzia cap level 7	1 kit/14 days
Palforzia cap level 8	1 kit/14 days
Palforzia cap level 9	1 kit/14 days
Palforzia cap level 10	1 kit/14 days
Palforzia pow level 11 (#15 for Up-Dosing)	1 kit/14 days
Palforzia pow level 11 (#30 for maintenance)	30/30 days

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:	**Documentation of one of the following conditions:**
	
	• 1. Congenital heart disease (CHD):
	  ○ With cardiac transplantation, cardiac bypass, or extra-corporeal membrane oxygenation
	  ○ That is hemodynamically significant (eg acyanotic heart disease, congestive heart failure, or moderate to severe pulmonary hypertension)
	
	• 2. Chronic lung disease (CLD) of prematurity:
	  ○ In the first year of life, born less than 32 weeks gestation and requiring greater than 21% oxygen for at least the first 28 days of life
	  ○ In the second year of life necessitating continued medical support within the 6 month period prior to RSV season (eg corticosteroids, diuretics, supplemental oxygen)
	
	• 3. Cystic Fibrosis **and**:
	  ○ Clinical evidence of CLD and/or nutritional compromise
	  ○ Severe lung disease (eg previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or computed tomography that persist when stable)
	  ○ A weight for length less than the 10th percentile
	
	• 4. Congenital airway abnormality or neuromuscular condition (not cystic fibrosis) that impairs the ability to clear airway secretions
	
	• 5. Premature infants without above conditions

Appropriate Treatment Regimen & Other Criteria:	**Prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV)** • The first dose of Synagis should be administered prior to commencement of the RSV season • Remaining doses should be administered monthly throughout the RSV season (Exception: dose administration should occur immediately post cardiopulmonary bypass surgery, even if dose is administered earlier than a month from previous dose, then dosing schedule should resume monthly) • No more than 5 monthly doses During the RSV season, November 1 through March 31 • Discontinue prophylaxis therapy if hospitalized for RSV

Exclusion Criteria:	• For use in the treatment of RSV disease
Age Restriction:	**Refer to numbered conditions above in "Required Medical Information":** • 1a. Less than 2 years of age • 1b. Less than 2 years of age • 2a. Less than 2 years of age; Gestational Age less than 32 weeks • 2b. Less than 2 years of age; Gestational Age less than 32 weeks • 3a. Less than 2 years of age • 3b. Less than 2 years of age • 3c. Less than 2 years of age • 4. Less than 2 years of age • 5. Less than 2 years of age; Gestational Age less than 29 weeks
Prescriber Restrictions:	
Coverage Duration:	Approval: • 5 months (November 1 through March 31) 5 monthly doses, unless otherwise specified • 1 month for off-season when RSV activity greater than or equal to 10% for the region according to the CDC 1 monthly dose, unless otherwise specified

POLICY NAME:
PALYNZIQ
Affected Medications: PALYNZIQ (pegvaliase-PQPZ)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan.
Required Medical Information:	• Documentation of anticipated treatment course, including target phenylalanine (Phe) level set by specialist • Documentation of failure to Phe restricted diet as monotherapy • Documentation of failure to Kuvan AND phenylalanine-restricted diet as dual-therapy • Current patient weight • Baseline (pre-treatment) blood Phe levels Baseline Phe concentration must be consistent with the following: • Phe level must be greater than 10mg/dL (600 microM) . **Reauthorization** after initial approval requires documentation of updated Phe labs decreased by 20% or greater from baseline • Treatment with Palynziq should be discontinued in patients whose blood Phe has not decreased by at least 20% from baseline **or** a blood phenylalanine concentration less than or equal to 600 microM/L after 16 weeks with max dose of 40 mg/day **Reauthorization** for continued long-term approval (12 months) requires updated Phe labs meeting one of the following criteria: • Phe level less than 20 percent of baseline OR • Phe level lower than baseline and meets specialist's target level
Appropriate Treatment Regimen & Other Criteria:	If patient has failed dual-therapy with Kuvan and Phe restricted diet, and Palynziq is warranted, treatment must be consistent with the following: • Initial dose must be 2.5mg once weekly x 4 weeks • Titration (after 4-week induction): 2.5 mg twice weekly for 1 week, then 10 mg once weekly for 1 week, then 10 mg twice weekly for 1 week, then 10 mg 4 times/week for 1 week, then 10 mg once daily for 2 week. • Maintenance (after induction and titration): 20 mg once daily for at least 24 weeks. May increase to 40 mg once daily if a response (20% reduction from baseline in blood phenylalanine **or** blood phenylalanine concentration 600 micromol/L or less) has not been achieved after administering 20 mg once daily for 24 weeks.
Exclusion Criteria:	• Prior intolerance or allergic reaction to requested medication • Doses greater than 40mg/day
Age Restriction:	• Adults 18 years and older

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

POLICY NAME:
PARATHYROID HORMONE
Affected Medications: NATPARA (parathyroid hormone)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Adjunct to calcium and vitamin D to control hypocalcemia in hypoparathyroidism

Required Medical Information:	• Documentation of the following lab values:
	  ○ 25-hydroxyvitamin D levels within normal limits (approximately 30-74 ng/mL) while on standard of care (such as calcitriol)
	  ○ Total serum calcium (albumin-corrected) greater than 7.5 mg/dL

Appropriate Treatment Regimen & Other Criteria:	• Documented failure with at least 8 weeks of a consistent supplementation regimen as follows:
	  ○ Calcium 2000 mg daily
	  ○ Vitamin D (metabolite or 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 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)
	• For glucocorticoid-induced osteoporosis, in addition to the above, must also provide documentation of the following:
	  ○ Treatment with 5 mg of prednisone (or equivalent) per day for at least 3 months

Appropriate Treatment Regimen & Other Criteria:	• Treatment failure, contraindication, or intolerance to both of the following:
	  ○ Oral or Intravenous bisphosphonate (e.g., alendronate, risedronate, zoledronic acid or ibandronate)
	  ○ Prolia
	OR
	  ○ T-score -3.5 or lower, or -2.5 or lower with a history of fragility fractures
	
	For Forteo requests: documented treatment failure with Tymlos and teriparatide
	
	<u>Maximum duration of therapy should not exceed 2 years</u>

Exclusion Criteria:	• Paget's Disease • Open epiphyses (i.e., 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:	• 18 years of age and older with fully fused epiphyses
Prescriber Restrictions:	
Coverage Duration:	• Approval: 24 months (no reauthorization), unless otherwise specified

POLICY NAME:
PCSK9 INHIBITORS
Affected Medications: REPATHA (evolocumab) & PRALUENT (alirocumab)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan plan design. • Adjunct to diet and maximally tolerated statin therapy to reduce the risk of myocardial infarction (MI), stroke, and coronary revascularization in adults with established cardiovascular disease (CVD) • Adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g. statins, ezetimibe), for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C) • As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C • Adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C
Required Medical Information:	<u>All indications:</u> • Documentation of current complete lipid panel within last 3 months • Documentation of baseline LDL-C (untreated) • Documentation of dietary measures being undertaken to lower cholesterol. • **<u>Reauthorization</u>** will require updated lipid panel (once since starting therapy and then yearly thereafter) showing reduction in LDL AND documentation of adherence to therapy. <u>HeFH/HoFH:</u> • HeFH diagnosis confirmed based on WHO criteria/Dutch Lipid Clinical Network criteria with score of greater than 8 points **OR** Simon Broome register diagnostic criteria with a criterion for definite FH **OR** genotype test confirming mutation at one of the following gene loci: low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1). • HoFH diagnosis confirmed based on untreated LDL-C greater than 500 mg/dL **OR** treated LDL-C greater than 300 mg/dL AND one of the following: (1) history of cutaneous or tendinous xanthoma prior to age 10 years or (2) documentation of untreated LDL-C greater than 190 mg/dL consistent with heterozygous familial hypocholesteremia in both parents **OR** genotype test confirming multiple mutant alleles at one of the gene loci above (excluding double-null LDLR mutations). • Documentation of current rosuvastatin 20-40 mg or atorvastatin 40-80 mg and/or ezetimibe if no contraindication. <u>Hyperlipidemia or Clinical ASCVD:</u>

	• Documentation of failure of 6 months of combination therapy with maximally tolerated high-intensity statin (rosuvastatin 20-40 mg or atorvastatin 40-80 mg) plus ezetimibe therapy as seen by inadequate reduction of LDL to target level (LDL target of less than or equal to 70 mg/dL) OR • Documentation of cardiovascular event (myocardial infarction, ischemic stroke, coronary revascularization procedure, etc.) while on optimized doses of and optimized adherence (80% or greater) to statin and/or ezetimibe OR • Documentation of statin intolerance as evidenced by of failure to 8 week trials with three of the following: atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin, fluvastatin, separated by an adequate 'holiday' of 2 weeks and employing strategies such as every other day dosing to minimize muscular effects AND Documentation of evaluation of other causes of muscle symptoms (hypothyroidism, vitamin D deficiency, rheumatologic or musculoskeletal disease, exercise, steroid myopathy, antipsychotics, immunosuppressants, bisphosphonates, alcohol or drug abuse, drug or food interactions) <u>Request for PCSK9 due to rhabdomyolysis:</u> • Documentation of creatinine kinase (CK) levels greater than 10-times upper limit of normal **OR** • Chart documentation of diagnosis

Appropriate Treatment Regimen & Other Criteria:	• Repatha dosing:
	  ○ Primary hyperlipidemia, clinical ASCVD and HeFH: 140mg every 2 weeks or 420mg once monthly
	  ○ HoFH: 420mg once monthly. May increase to 420 mg every 2 weeks if a clinically meaningful response is not achieved in 12 weeks
	• Praluent dosing:
	  ○ Primary hyperlipidemia, clinical ASCVD and HeFH: 75mg every 2 weeks or 300mg monthly. May increase/adjust to 150mg every 2 weeks if LDL-response is inadequate
	  ○ HoFH: 150mg every 2 weeks
	
	<u>HeFH/HoFH:</u>
	• Must take along with maximally tolerated doses of statin and ezetimibe if no contraindication
	
	<u>Clinical ASCVD:</u>
	• Documentation of failure of 6 months of combination therapy with maximally tolerated high-intensity statin (rosuvastatin 20-40 mg or atorvastatin 40-80 mg) plus ezetimibe therapy as seen by inadequate reduction of LDL to target level OR

	• Documentation of cardiovascular event (myocardial infarction, ischemic stroke, coronary revascularization procedure, etc.) while on optimized doses of and optimized adherence (80% or greater) to statin and/or ezetimibe • Must take along with maximally tolerated doses of statin and/or ezetimibe if no contraindication
Exclusion Criteria:	• Fasting serum triglycerides greater than 400 mg/dL • New starts with history of documented ASCVD and LDL-C less than 50 mg/dL • New starts with no history of documented ASCVD and LDL-C less than 100 mg/dL • Treatment of HoFH due to known double-null LDLR mutations.
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a Cardiologist, Endocrinologist, or Lipid Specialist
Coverage Duration:	• 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PEDIATRIC WEIGHT LOSS
Affected Medications: Saxenda (liraglutide), Wegovy (semaglutide), Qsymia (phentermine/topiramate)

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

Required Medical Information:	• 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:	• Current intensive health behavior and lifestyle treatment which includes
	  ○ Physical activity goals
	  ○ Nutrition education
	  ○ Behavior change counseling
	
	<u>Saxenda and Wegovy</u>
	• Documentation of treatment failure with Qsymia, defined as failure to experience 5% reduction in BMI after 12 weeks at max tolerated dosage
	
	<u>Reauthorization</u>
	• Qsymia: documentation of reduction of weight of at least 5% of baseline BMI since initiation
	Saxenda and Wegovy: documentation of at least 2.4mg daily dose and reduction of weight of at least 1% of 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

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:	• Pediatric patients greater than or equal to 1 month old and less than 18 years of age
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.
Required Medical Information:	Chronic Hepatitis C (CHC): • Documentation chronic hepatitis C virus (HCV) genotype by liver biopsy or by FDA-approved serum test • Baseline HCV RNA level • Documentation of anti-hepatitis C virus regimen to be used with AND anticipated dose and duration of therapy Chronic Hepatitis B (CHB): • Documentation of HBeAg-positive or HBeAg-negative chronic hepatitis B virus (HBV) infection • Baseline HBV DNA level • Documentation of anti-hepatitis B virus regimen to be used with AND anticipated dose and duration of therapy Chronic Hepatitis C and B: • Baseline HIV-1 RNA level • Current documentation of hepatic impairment severity with Child-Pugh Classification OR bilirubin, albumin, INR, ascites status, and encephalopathy status to calculate Child-Pugh score within 12 weeks prior to anticipated start of therapy • Current estimated creatinine clearance OR serum creatinine, height, and weight to calculate by Cockcroft-Gault within 12 weeks prior to anticipated start of therapy • Current complete blood count AND liver function tests within 12 weeks prior to anticipated start of therapy • Documentation if HIV/HCV/HBV coinfection • Documentation of abstinence from alcohol and any illegal drug use for at least 6 months
Appropriate Treatment Regimen & Other Criteria:	Chronic Hepatitis C: • Approve if used in combination with FDA- and/or AASLD/IDSA- recommended regimen and if not otherwise excluded from PacificSource policies of other medications in the regimen • Preferred regimen should include concomitant ribavirin Chronic Hepatitis B (one of the following 4 scenarios must be met): • HBeAg-positive **AND** baseline serum HBV DNA greater than 20,000 copies/mL **AND** baseline serum aminotransferase (ALT) two times greater than the upper limit of normal range

	• HBeAg-positive **AND** baseline serum HBV DNA greater than 20,000 copies/mL **AND** baseline serum aminotransferase (ALT) one to two times greater than the upper limit of normal range **AND** moderate-severe inflammation/fibrosis • HBeAg-negative **AND** baseline serum HBV DNA greater than 2,000 copies/mL **AND** baseline serum aminotransferase (ALT) two times greater than the upper limit of normal range • HBeAg-negative **AND** baseline serum HBV DNA greater than 2,000 copies/mL **AND** baseline serum aminotransferase (ALT) one to two times greater than the upper limit of normal range **AND** moderate-severe inflammation/fibrosis Chronic Hepatitis C and B: • Creatinine clearance less than 50 ml/min, adjust dose: 135 mcg subcutaneously once weekly • Baseline platelet count greater than or equal to 90,000 cells/mm3 • Baseline absolute neutrophil count 1,500 cells/mm3 or more
Exclusion Criteria:	• Treatment of patients with CHC who have had solid organ transplantation • Autoimmune hepatitis • Hepatic decompensation (Child-Pugh score greater than 6)
Age Restriction:	• CHC: 5 years of age or older • CHB: 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration:	• CHC: 12 weeks, unless otherwise specified (depends on regimen and diagnosis) • CHB: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
PEGCETACOPLAN
Affected Medications: EMPAVELI (pegcetacoplan)

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)

Required Medical Information:	• Patients must be administered a meningococcal vaccine at least two weeks prior to initiation of Empaveli therapy and revaccinated according to current Advisory Committee on Immunization Practices (ACIP) guidelines
	• 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)
	• 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

Appropriate Treatment Regimen & Other Criteria:	• Documented inadequate response, contraindication, or intolerance to ravulizumab (Ultomiris) **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:	• Current meningitis infection • Concurrent use with other biologics (eculizumab, ravulizumab, etc.)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 3 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

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

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:	• Diagnosis of pheochromocytoma and one of the following:
	  ○ Documentation of preoperative preparation for surgical resection.
	  ○ Documentation of chronic treatment for metastatic pheochromocytoma.

Appropriate Treatment Regimen & Other Criteria:	• If use is projected to be greater than 14 days: ○ Documentation of failure or contraindication to a selective alpha-1 adrenergic receptor blocker (e.g., doxazosin, terazosin, prazosin). • Initial: 10 mg twice daily, increase by 10 mg every other day until optimal blood pressure response is achieved; usual range: 20-40 mg 2-3 times/day. Doses up to 240 mg/day have been reported
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist in the management of pheochromocytoma.
Coverage Duration:	• **Preoperative preparation**: 1 month, unless otherwise specified • **Chronic treatment**: 12 months **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy.

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+ IHC testing or positive FISH test
Appropriate Treatment Regimen & Other Criteria:	• Coverage for Phesgo requires documentation of one of the following: ○ A documented intolerable adverse event to all the preferred products (Perjeta in combination with Kanjinti, and Perjeta in combination with Ogivri) and the adverse event was not an expected adverse event attributed to the active ingredients ○ Currently receiving treatment with Phesgo, excluding via samples or manufacturer's patient assistance programs **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 approval: 4 months, unless otherwise specified • Reauthorization: 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

Required Medical Information:	• Documentation of all the following:
	  ○ Presence of usual interstitial pneumonia (UIP) or high-resolution computed tomography (HRCT), and/or surgical lung biopsy
	  ○ Baseline forced vital capacity (FVC) greater than or equal to 50 percent of the predicted value **AND**
	  ○ Predicted diffuse capacity for carbon monoxide (DLCO) great than or equal to 30 percent

Appropriate Treatment Regimen & Other Criteria:	• Pirfenidone is not approved for use in combination with Ofev. **Reauthorization** requires documentation of treatment success.
Exclusion Criteria:	
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

POLICY NAME:
PLEGRIDY
Affected Medications: PLEGRIDY (peglyated 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 disease (SPMS)

Required Medical Information:	• 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 inadequate response or intolerance to at least one preferred product (Avonex, dimethyl fumarate, Extavia, fingolimod, glatiramer, Glatopa) • No concurrent use of other disease-modifying medications indicated for the treatment of MS **Reauthorization:** provider attestation of treatment success
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist.
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
PRAMLINTIDE
Affected Medications: SYMLINPEN (pramlintide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
	  ○ Type 1 diabetes mellitus
	  ○ Type 2 diabetes mellitus

Required Medical Information:	• Documentation of inadequate glycemic control (HbA1c greater than 7 percent) on optimal insulin therapy **AND** • Patient will take SymlinPen in addition to mealtime insulin therapy
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• HbA1c level greater than 9 percent. • Weight loss treatment.
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified

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POLICY NAME:
PRETOMANID
Affected Medications: pretomanid

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Extensively drug resistant tuberculosis (XDR-TB)
	  ○ Treatment-intolerant multidrug-resistant tuberculosis (TI MDR-TB)
	  ○ Nonresponsive multidrug-resistant tuberculosis (NR MDR-TB)

Required Medical Information:	• Patient has failed, is resistant, or is allergic to quad therapy of any combination of the following: Isoniazid, Rifampin, Ethambutol, Pyrazinamide, Fluoroquinolone, Capreomycin (Kanamycin, Amikacin, Streptomycin), Ethionamide/Prothinamide, Cycloserine/Terizidone, Aminosalicylic acid (acidic salt)
Appropriate Treatment Regimen & Other Criteria:	• Documentation of being administered by directly observed therapy (DOT)
Exclusion Criteria:	• Drug-sensitive TB (DS-TB) • Latent Infection due to Mycobacterium tuberculosis • Extrapulmonary TB (e.g., central nervous system)
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, infectious disease specialist.
Coverage Duration:	• Initial approval: 26 weeks, unless otherwise specified

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POLICY NAME:
PROLIA
Affected Medications: PROLIA (denosumab)

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:	• 18 years of age and older
Prescriber Restrictions:	
Coverage Duration:	• Approval: 24 months, unless otherwise specified

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

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

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

Required Medical Information:	• Diagnosis of neuropathic pain associated with one of the following
	  ○ Post-herpetic neuralgia
	  ○ Diabetic peripheral neuropathy of the feet
	
	• Documented treatment failure with at least 12 weeks of ALL of the following:
	  ○ gabapentin
	  ○ pregabalin
	  ○ carbamazepine or oxcarbazepine or valproic acid/divalproex sodium
	  ○ amitriptyline or nortriptyline
	  ○ topical lidocaine

Appropriate Treatment Regimen & Other Criteria:	• 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

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POLICY NAME:
RAVULIZUMAB
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

Required Medical Information:	• Patients must be administered a meningococcal vaccine at least two weeks prior to initiation of Ultomiris therapy and revaccinated according to current Advisory Committee on Immunization Practices (ACIP) guidelines
	
	<u>Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis:</u>
	• 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
	
	<u>Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-medicated thrombotic microangiopathy:</u>
	• 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
	
	<u>Generalized Myasthenia Gravis (gMG)</u>
	• Diagnosis of generalized Myasthenia Gravis (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

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	• Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV • Positive serologic test for anti-acetylcholine receptor (AchR) antibodies • MG-Activities of Daily Living (MG-ADL) total score of greater than or equal to 6 • Documentation of baseline Quantitative Myasthenia Gravis (QMG) score

Appropriate Treatment Regimen & Other Criteria:	**<u>Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy</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>Generalized Myasthenia Gravis (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)
	  ○ Need for ongoing rescue therapy (at least 3 courses in the past 12 months) with plasmapheresis, plasma exchange or intravenous immunoglobulin (IVIG) while consistently taking an immunosuppressive therapy (azathioprine, mycophenolate, tacrolimus, cyclosporine, methotrexate)
	• Documented inadequate response, contraindication, or intolerance to efgartigimod-alfa (Vyvgart)
	
	<u>Reauthorization</u> requires:
	• gMG: documentation of treatment success defined as an improvement in MG-ADL and 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

Exclusion Criteria:	• Current meningitis infection • Concurrent use with other biologics (eculizumab, pegcetacoplan, efgartigimod, etc.)
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
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
REBIF
Affected Medications: 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 disease (SPMS)

Required Medical Information:	• 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 inadequate response or intolerable adverse event to at least one preferred product (Avonex, dimethyl fumarate, Extavia, fingolimod, glatiramer, Glatopa) • No concurrent use of other disease-modifying medications indicated for the treatment of MS **Reauthorization**: Provider attestation of treatment success
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist.
Coverage Duration:	• Approval: 12 months, unless otherwise specified.

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

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	• Diagnosis of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions OR • Diagnosis of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). • Baseline complete blood count (CBC) within 2 months and then prior to each administration, or more frequently as indicated • Documentation of current RBC transfusion regimen • Negative pregnancy test for female patients of reproductive potential

Appropriate Treatment Regimen & Other Criteria:	• Dosing:
	  ○ Starting dose of 1mg/kg every 3 weeks
	  ○ Not to exceed 1.25mg/kg every 3 weeks (beta thalassemia)
	  ○ Not to exceed 1.75mg/kg every 3 weeks (MDS-RS or MDS/MPN-RS-T)
	  ○ Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	• Reauthorization requires documentation of a 20% reduction in red blood cell (RBC) transfusion burden 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:	• Prescribed by, or in consultation with, a hematologist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
RELYVRIO
Affected Medications: RELYVRIO (sodium phenylbutyrate-taurursodiol)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Amyotrophic lateral sclerosis (ALS)
Required Medical Information:	• Definite or probable Amyotrophic lateral sclerosis (ALS) based on El Escorial revised (Airlie House) criteria • Symptom onset within 18 months • Slow vital capacity (SCV) of at least 60 percent • 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:	• Documentation of one of the following:
	  ○ Member is stable on riluzole
	  ○ Prescriber has indicated clinical inappropriateness of riluzole
	• Reauthorization: Documentation of treatment success as determined by prescriber including retaining most activities of daily living

Exclusion Criteria:	• Presence of a tracheostomy • Use of permanent assisted ventilation
Age Restriction:	
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

POLICY NAME:
REMODULIN
Affected Medications: REMODULIN INJECTION (treprostinil), treprostinil injection

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

Required Medical Information:	**<u>Pulmonary arterial hypertension (PAH) WHO Group 1</u>**
	• Documentation of PAH confirmed by right-heart catheterization
	• 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 to IV symptoms
	• Documentation of acute vasoreactivity testing (positive result requires trial/failure to calcium channel blocker) unless contraindications such as 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:	• For initiation of therapy patient must have mean pulmonary artery pressure at least 20 mmHg at rest, an elevated pulmonary vascular resistance (PVR) of at least 3 Wood units or more, and a mean pulmonary capillary wedge pressure less than 15 mmHg
	AND
	• The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition
	• Treatment with oral calcium channel blocking agents dependent on vasoreactivity testing results has been tried and failed, or has been considered and ruled out
	• Documentation that treprostinil is used as a single route of administration (Remodulin, Tyvaso, Orenitram should not be used in combination)
	• 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
	  ○ Ambrisentan and tadalafil
	  ○ Bosentan and riociguat
	  ○ Bosentan and tadalafil

	• Subsequent approvals require documentation of treatment success such as improved walking distance or improvements in 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-interleukin-5 antagonist monoclonal antiboty (IgG4 kappa))

• Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #2
• Is the request for use in combination with another monoclonal antibody (e.g., Fasenra, Nucala, Xolair, Dupixent)?	Yes – Criteria not met; combination use is experimental	No – Go to #3
• Is the request to treat a diagnosis according to one of the Food and Drug Administration (FDA)-approved indications? ○ Add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype	Yes – Go to appropriate section below	No – Criteria not met
Severe Eosinophilic Asthma		
• Is there documentation of severe eosinophilic asthma defined by the following: ○ Baseline eosinophil count at least 400 cells/µL AND ○ FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal	Yes – Document and go to #2	No – Criteria not met
• Is there documented use of high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms?	Yes – Document and go to #3	No – Criteria not met
• Is there 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 and at least 80% adherence?	Yes – Go to #5	No – Go to #4
• Is there documentation that chronic daily oral corticosteroids are required?	Yes – Go to #5	No – Criteria not met
• Is there a documented trial and failure or intolerable adverse event with all of the preferred products –	Yes – Go to #6	No – Criteria not met

Dupixent, Fasenra, Nucala, Xolair?		
• Is the drug prescribed by, or in consultation with, an Allergist, Immunologist or Pulmonologist?	Yes – Approve up to 6 months	No – Criteria not met
Renewal Criteria		
• 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
• Is the request for use in combination with another monoclonal antibody (e.g., Fasenra, Nucala, Xolair, Dupixent)?	Yes – Criteria not met; combination use is experimental	No – Go to #3
• 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		

• **Cinqair**
  ○ Availability: 100 mg/10 mL single-use vial
  ○ Dosing: 3 mg/kg infusion once every 4 weeks
 	
*Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced for all medical infusion drugs		

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
Required Medical Information:	• Presence of one of the following syndromic disorders confirmed by genetic testing: ○ Complete DiGeorge Syndrome with Chromosome 22q11 deletion ○ Forkhead box N1 (FOXN1) deficiency ○ CHARGE (coloboma, heart defect, choanal atresia, growth and development retardation, genital hypoplasia, ear defects including deafness) syndrome with CHD7 mutation present ○ Chromosome region 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:	• Diagnosis of Severe Combined Immunodeficiency • 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

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

Appropriate Treatment Regimen & Other Criteria:	**All Indications:**
	• Documented treatment failure or intolerable adverse event with trial of Kineret (anakinra)
	
	Recurrent Pericarditis:
	• Documented treatment failure or intolerable adverse event to triple therapy with colchicine AND aspirin AND a glucocorticoid
	
	• Dosing for CAPS or Recurrent Pericarditis:
	  ○ 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)
	• Dosing for DIRA:
	  ○ Adults: 320 mg once weekly
	  ○ Pediatric patients (weighing 10 kg or more): 4.4 mg/kg (maximum 320 mg) once weekly
	
	• **Reauthorization** 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 specialist (such as a rheumatologist, immunologist, cardiologist, or dermatologist)
Coverage Duration:	• Initial approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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POLICY NAME:
RIOCIGUAT
Affected Medications: ADEMPAS (riociguat)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	Chronic thromboembolic pulmonary hypertension (CTEPH) • WHO Group 4 with documented thromboembolic occlusion of proximal or distal pulmonary vasculature and mean pulmonary arterial pressure of at least 25 mmHg at rest in the absence of elevated pulmonary capillary wedge pressure (i.e. PCWP not more than 15 mmHg) Pulmonary arterial hypertension (PAH) • WHO Group 1 confirmed by right heart catheterization • Etiology of PAH (idiopathic, heritable, or associated with connective tissue disease) • NYHA/WHO Functional Class II to III symptoms • Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blocker) unless contraindications such as low systemic blood pressure (systolic blood pressure less than 90), low cardiac index, or presence of severe symptoms (functional class IV) • Liver Function Test and creatinine clearance, baseline exercise testing (6MWD)
Appropriate Treatment Regimen & Other Criteria:	CTEPH • Documentation of failure of or inability to receive pulmonary endarterectomy surgery • Current therapy with anticoagulants PAH • Failure/Contraindication to the following therapy classes: Phosphodiesterase type 5 (PDE5) inhibitors AND endothelin receptor antagonists • Safety and efficacy have not been demonstrated in patients with creatinine clearance less than or equal to 15 ml/min or on dialysis • Safety and efficacy have not been demonstrated in patients with severe (Child-Pugh class C) hepatic impairment • **Reauthorization:** Subsequent approvals require documentation of treatment success such as improved walking distance or improvements in functional class
Exclusion Criteria:	• Pregnancy • Concomitant use with nitrates or nitric oxide donors (such as amyl nitrite) • Concomitant use with specific PDE-5 inhibitors (such as sidenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline)

	• Use in patients with symptomatic pulmonary hypertension associated with in idiopathic interstitial pneumonias (PH-IIP)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• 12 months, unless otherwise specified

POLICY NAME:
RISANKIZUMAB-rzaa
Affected Medications: SKYRIZI

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis
	  ○ Crohn's Disease

Required Medical Information:	• Documentation of moderate to severe disease despite current treatment (indication must be documented in chart notes within the last six months)
	• Documentation of complete and current treatment history
	• Documentation of current level of disease activity/disease control
	
	<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 (DQLI) 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</u>

	• Documentation of moderate to severely active disease despite current treatment

Appropriate Treatment Regimen & Other Criteria:	**<u>Plaque Psoriasis (PP)</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, Renflexis, Avsola)
	  AND
	  ○ One of the following: Otezla, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), or Ilumya
	
	<u>Psoriatic Arthritis (PsA)</u>
	• 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, Renflexis, Avsola)
	  AND
	  ○ One of the following: Otezla, Simponi Aria, Orencia, or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz)
	
	<u>Crohn's Disease (CD)</u>
	• Documented failure with at least two oral treatments for a minimum of 12 weeks: corticosteroids, 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, Renflexis, Avsola)
	  AND
	  ○ One of the following: Entyvio or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz)
	
	Dosing:
	
	PP and PsA
	• QL – Initial (one time only)– 150 mg at week 0, 4
	• QL – Continuation – 150mg every 12 weeks
	
	CD
	• Initial infusion -600mg at week 0,4 and 8
	• QL continuation- 360mg at week 12 then every 8 weeks

Exclusion Criteria:	• Concurrent use with any other biologic therapy or Otezla 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, an appropriate specialist for condition
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 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 type 1, 2 or 3

Required Medical Information:	• Documentation of spinal muscular atrophy diagnosis confirmed by genetic tests demonstrating 5q-autosomal recessive disease
	  ○ Documentation of four or fewer copies of SMN2
	• For symptomatic patients, 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)

Appropriate Treatment Regimen & Other Criteria:	• Documentation of Food and Drug Administration approved dosing and treatment plan
	Reauthorization: documentation of clinically significant improvement from baseline motor function demonstrated by:
	• Improvement from baseline motor function score documented within one month of renewal request **AND**
	• More areas of motor function improved than worsened
	• HINE-2:
	  ○ at least a 2-point increase in ability to kick OR
	  ○ at least a 1-point increase in the motor milestones of head control, rolling, sitting, crawling, standing or walking using Section 2 of the Hammersmith Infant Neurologic Exam (HINE) **AND**
	  ○ More areas of motor function improved than worsened
	• Hammersmith Functional Motor Scale (HFSME)
	  ○ At least 3 points increase in score from pretreatment baseline **AND**
	  ○ More areas of motor function improved than worsened
	• Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
	  ○ At least a 4 point increase in score from the pretreatment baseline **AND**
	  ○ More areas of motor function improved than worsened
	• Upper Limb Module (ULM)
	  ○ At least a 3 point increase from pretreatment baseline
	• 6-Minute Walk Test (6MWT)
	At least a 30 meter increase from pretreatment baseline

Exclusion Criteria:	• SMA type 4 • Prior treatment with Zolgensma (AVXS-101) • Concurrent therapy with Spinraza (nursinersen)
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: 8 months • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
RITUXIMAB
Affected Medications: RITUXAN (rituximab), RITUXAN HYCLEA (Rituximab & hyaluronidase subcutaneous–Genentech), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), Riabni (rituximab-arrx)

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 2 or higher
Required Medical Information:	• Documentation of disease staging, all prior therapies used, and anticipated treatment course **Rheumatoid Arthritis (RA)** • Documentation of moderate to severe disease despite current treatment • Documented current level of disease activity with one of the following (or equivalent objective scale): o The Disease Activity Score derivative for 28 joints (DAS-28) greater than 3.2 o The Simplified Disease Activity Index (SDAI) greater than 11 o The Clinical Disease Activity Index (CDAI) greater than 10 o Weighted RAPID3 of at least 2.3 **Non-Hodgkin Lymphoma (NHL)** • Documentation of CD20-positive B-Cell NHL **Chronic Lymphocytic Leukemia (CLL)** • Documentation of advanced or active CLL: o Binet Stage A or B with active disease o Binet Stage C o Modified Rai Stage 0, I, or II with symptoms o Modified Rai Stage III or IV **Microscopic Polyangiitis (MPA) or Granulomatosis with Polyangiitis (GPA)** • Documentation of active GPA or MPA **Relapsing Remitting Multiple Sclerosis (RRMS)** • Diagnosis confirmed with magnetic resonance imaging (MRI) (per revised McDonald diagnostic criteria for Multiple Sclerosis (MS)) o Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS **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
	
	<u>Thrombocytopenia in patients with Idiopathic Thrombocytopenic Purpura (ITP)</u>
	• Documentation of splenectomy status
	• 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 platelets did not increase to at least 50,000/mcl)
	
	<u>Neuromyelitis Optica Spectrum Disorder (NMOSD)</u>
	• Diagnosis of NMOSD with aquaporin-4 immunoglobulin G (AQP4-IgG) requiring all of the following:
	  ○ At least one core clinical characteristic:
	  ▪ Optic neuritis
	  ▪ Acute myelitis
	  ▪ Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
	  ▪ Acute brainstem syndrome
	  ▪ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMSOD-typical diencephalic magnetic resonance imaging (MRI) lesions
	  ▪ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
	  ○ Positive test for AQP4-IgG using best available detection method
	  ○ Exclusion for alternative diagnoses
	• History of at least 1 attack in the past year, or at least 2 attacks in the past 2 years, requiring rescue therapy
	• Expanded Disability Status Scale (EDSS) score of 8 or less
	
	<u>Eosinophilic granulomatosis with polyangiitis (EGPA)</u>
	• Documentation of active EGPA
	  ○ For severe EGPA: documentation of organ or life-threatening manifestations as defined by the American College of Rheumatology/Vasculitis Foundation (ACR/VF) guidelines

Appropriate Treatment Regimen & Other Criteria:	**<u>All Uses</u>** • 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 ○ Currently receiving treatment with Rituxan, excluding via samples or manufacturer's patient assistance programs **Oncology Uses:** • Documentation of ECOG performance status of 1 or 2 OR Karnofsky performance score greater than 50% • **Reauthorization**: documentation of disease responsiveness to therapy **RA** • Initial Course: Documented treatment failure (or documented intolerable adverse event) with at least 12 weeks of Infliximab (preferred biosimilar products: Inflectra, Renflexis, Avsola) • 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** • For initial immunosuppression: in combination with a glucocorticoid • Dose is approved for up to two doses of 1,000 mg annually ○ Higher doses (e.g., 1,000 mg x 2 every 6 months) will require documentation to support **RRMS** • Studied treatment regimens vary slightly • Dose is approved for up to two doses of 1,000 mg annually ○ Higher doses (e.g., 1,000 mg x 2 every 6 months) will require documentation to support **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

	NMOSD
	• Documented treatment failure with 12 weeks of at least two of the following immunosuppressive therapies: azathioprine, mycophenolate, methotrexate
	
	EGPA
	• Non-severe
	  ○ Documented treatment failure with a corticosteroid
	  ○ Documented treatment failure with an oral immunosuppressive therapy: azathioprine, methotrexate, mycophenolate, leflunomide
	• Severe
	  ○ Documentation that rituximab will be administered in combination with a systemic glucocorticoid
	
	All other indications
	• A Food and Drug Administration (FDA)-approved or compendia supported dose, frequency, and duration of therapy
	• Failure (or reason for avoidance) of first line recommended and conventional therapies
	
	Reauthorization: documentation of disease responsiveness to therapy

Exclusion Criteria:	• No concurrent use with targeted immune modulators
Age Restriction:	
Prescriber Restrictions:	• For RA, GPA, MPA – Prescribed by, or in consultation with, a rheumatologist • For CLL, NHL– Prescribed by, or in consultation with, an oncologist • For MS- Prescribed by, or in consultation with, a neurologist or MS specialist • For PV- Prescribed by, or in consultation with, a dermatologist
Coverage Duration:	• For RA – Initial approval: 6 months, unless otherwise specified • For Oncology – Initial Approval: 4 months, unless otherwise specified • For MPA/GPA – Initial approval: 3 months, unless otherwise specified • For MS- Initial approval - 6 months (up to two doses of 1,000 mg), unless otherwise specified • For PV – Initial approval - 3 months, unless otherwise specified **Reauthorization** - 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
ROFLUMILAST
Affected Medications: Roflumilast

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by benefit design.
Required Medical Information:	• Documentation of Stage III, or Stage IV COPD • Documentation of recent FEV1, and FVC. • Documentation of current treatment regimen.
Appropriate Treatment Regimen & Other Criteria:	• Documentation that this product is being used in combination with a long acting anti-muscarinic agent or a long acting bronchodilator that is approved for the treatment of COPD **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Moderate or severe hepatic impairment (Child-Pugh class B or C).
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified

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:	• Patient Weight
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Thrombocytopenia in patients with ITP:
	• 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 ITP, including corticosteroids or immunoglobulin
	  ○ Splenectomy
	• Documented inability to respond adequately to Promacta
	
	Hematopoietic syndrome of acute radiation syndrome:
	• Approved for one-time single subcutaneous injection of 10 mcg/kg
	
	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
Exclusion Criteria:	• Treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) • Use in combination with another thrombopoietin receptor agonist (Promacta or Doptelet), or similar treatments.
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 for fracture, defined as one of the following:
	  ▪ History of osteoporotic fracture
	  ▪ Multiple risk fractures for fracture
	  ▪ 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 of the following:
	  ▪ Intravenous bisphosphonate (zoledronic acid or ibandronate)
	  ▪ Prolia
	• Dosage: 210 mg once monthly, 12-month lifetime maximum

Exclusion Criteria:	• Heart attack or stroke event within the preceding year • Concurrent use of bisphosphonates, parathyroid hormone analogs or RANK ligand inhibitors • Preexisting hypocalcemia
Age Restriction:	• 18 years of age or older
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months lifetime maximum

POLICY NAME:
RUFINAMIDE
Affected Medications: BANZEL (rufinamide)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• Diagnosis of Lennox-Gastaut Syndrome
Appropriate Treatment Regimen & Other Criteria:	• QL: 3200 mg daily • **Reauthorization:** documentation of treatment success
Exclusion Criteria:	• Familial Short QT syndrome
Age Restriction:	• 1 year of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a Neurologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

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:	**<u>Plasminogen Deficiency type 1 (must meet all of the following):</u>**
	• Diagnosis of symptomatic congenital plasminogen deficiency (C-PLGD) as evidenced by documentation of all of the following
	  ○ Genetic testing showing presence of biallelic pathogenic variants in plasminogen (PLG)
	  ○ Baseline plasminogen activity level less than or equal to 45% of laboratory standard
	  ○ Presence of (ligneous) pseudomembranous lesions with documented size, location and number of total lesions
	• Abnormal plasminogen antigen plasma level less than 9 mg/dL as confirmed by an enzyme-linked immunosorbent assay
	• Presence of clinical signs and symptoms of the disease (such as ligneous conjunctivitis, gingivitis, tonsillitis, abnormal wound healing)

Appropriate Treatment Regimen & Other Criteria:	Initial dosing: 6.6 mg/kg every three days
	
	Obtain a trough plasminogen activity level approximately 72 hours following the initial dose and prior to the second dose (same time of day as initial dosing)
	• If plasminogen activity is less than 10% above baseline level then increase to every 2 day dosing
	• If between 10-20% of baseline then maintain every 3 day dosing
	• If above 20% of baseline then change dosing to every 4 days.
	
	<u>Maintain dosing frequency as determined above for 12 weeks while treating active lesions</u>
	• If lesions do not resolve by 12 weeks, or there are new or recurrent lesions, increase dosing frequency in one-day increments every 4-8 weeks up to Q2D dosing while reassessing clinical improvement until lesion resolution or until the lesions stabilize without further worsening.
	• If desired clinical change does not occur by 12 weeks, check trough plasminogen activity level.
	  ○ If plasminogen activity is greater than 10% above baseline level then consider other treatment options, such as surgical removal of the lesion in addition to plasminogen treatment.
	  ○ If plasminogen activity is less than 10% above baseline level then obtain a second trough plasminogen activity level to confirm. If low plasminogen activity level is

	confirmed in combination with no clinical efficacy, consider discontinuing plasminogen treatment due to the possibility of neutralizing antibodies ***If lesions resolve by 12 weeks, continue at same dosing frequency and monitor for new or recurrent lesions every 12 weeks. • 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 (must meet all of the following):** • Trough plasminogen activity level (taken 72 hours after dose) greater than 10% above baseline level • Documented improvement (reduction) in lesion size and number • Dosing may not exceed 6.6 mg/kg every 2 days.
Exclusion Criteria:	• Prior treatment failure with Ryplazim • Treatment of idiopathic pulmonary fibrosis
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a hematologist in coordination with Hemophilia Treatment Center (HTC) or other specialized center of excellence
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
SACROSIDASE
Affected Medications: SUCRAID (Sacrosidase)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	• Documentation of confirmed congenital sucrose-isomaltase deficiency, diagnosed by duodenal or jejunal mucosal biopsy assayed for lactase, sucrose, isomaltase, and maltase. • **Reauthorization**: requires documentation of treatment success (fewer stools, lower number of symptoms)
Appropriate Treatment Regimen & Other Criteria:	**Symptoms of congenital sucrose-isomaltase deficiency include:** • Diarrhea • Abdominal pain or cramping • Bloating • Gas • Loose Stools • Abdominal pain or cramping • Bloating • Nausea • Vomiting
Exclusion Criteria:	• Known hypersensitivity to years, yeast products, glycerin (glycerol), or papain
Age Restriction:	• 5 months or older
Prescriber Restrictions:	
Coverage Duration:	• Initial approval: 1 month, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
SARILUMAB
Affected Medications: KEVZARA (Sarilumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis
	  ○ Polymyalgia Rheumatica (PMR)

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) is greater than 3.2
	  ○ The Clinical Disease Activity Index (CDAI) is greater than 10
	  ○ Weighted RAPID3 of at least 2.3
	
	<u>Polymyalgia Rheumatica:</u>
	• Age 50 years or older at onset
	• Elevated 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

Appropriate Treatment Regimen & Other Criteria:	**<u>Rheumatoid Arthritis:</u>**
	• Documented treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy
	  ○ Methotrexate plus sulfasalazine
	  ○ Methotrexate plus hydroxychloroquine
	  ○ Sulfasalazine plus hydroxychloroquine
	  ○ Leflunomide plus sulfasalazine
	  ○ Leflunomide plus hydroxychloroquine
	• Documentation of treatment failure (or documented intolerable adverse event) for 12 weeks or greater with Infliximab (preferred products Inflectra, Renflexis, Avsola) or Actemra IV
	
	<u>Polymyalgia Rheumatica:</u>
	• 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

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

PacificSource Community Solutions

POLICY NAME:
SATRALIZUMAB-MWGE
Affected Medications: ENSPRYNG (satralizumab – mwge)

Covered Uses:	• 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

Required Medical Information:	• Diagnosis of NMOSD with aquaporin-4 immunoglobulin G (AQP4-IgG) antibody positive disease confirmed by all the following:
	  ○ At least one core clinical characteristic:
	  ▪ Optic neuritis
	  ▪ Acute myelitis
	  ▪ Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
	  ▪ Acute brainstem syndrome
	  ▪ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMSOD-typical diencephalic MRI lesions
	  ▪ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
	  ○ Documentation of positive test for AQP4-IgG antibodies via cell-based assay
	  ○ Exclusion of alternative diagnoses (such as multiple sclerosis)
	• History of at least one attack in the past year, or at least two attacks in the past 2 years, requiring rescue therapy
	• Expanded Disability Status Scale (EDSS) score of 6.5 or less

Appropriate Treatment Regimen & Other Criteria:	• Documented inadequate response, contraindication, or intolerance to rituximab (preferred agents Truxima, Riabni, and Ruxience) **Reauthorization** requires documentation of treatment success
Exclusion Criteria:	• Active Hepatitis B Virus (HBV) infection • Active or untreated latent tuberculosis • Concurrent use with other biologics (rituximab, eculizumab, tocilizumab, inebilizumab, etc.)
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
Required Medical Information:	• Diagnosis of lysosomal acid lipase (LAL) deficiency or Rapidly Progressive LAL deficiency within the first 6 months of life via enzyme assay that measures the level and activity of LAL or a genetic sequencing analysis test • Documentation of patient weight • Documentation of prescribed treatment regimen (dose and frequency) • Baseline fasting lipid panel 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 • **Reauthorization** for Rapidly Progressive LAL deficiency requires documentation of improvement in weight for-age Z-score • **Reauthorization** for lysosomal acid lipase (LAL) deficiency requires documentation of improvement in fasting lipid panel • If documentation of anti-drug antibodies to Kanuma, documentation of continued response to therapy required
Exclusion Criteria:	
Age Restriction:	• 1 month or older
Prescriber Restrictions:	
Coverage Duration:	• Initial Approval: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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POLICY NAME:
SECUKINUMAB
Affected Medications COSENTYX (secukinumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis
	  ○ Ankylosing Spondylitis
	  ○ Non-radiographic Axial Spondyloarthritis
	  ○ Enthesitis-Related Arthritis
	  ○ Juvenile Psoriatic Arthritis

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 (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 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>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>Enthesitis-Related Arthritis (ERA) or Juvenile Psoriatic Arthritits (JPsA)</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
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, Renflexis, Avsola)

	AND • One of the following: Otezla, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), or Ilumya **<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, Renflexis, Avsola) **AND** ○ One of the following: Orencia, Otezla, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), or Simponi Aria **<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, Renflexis, Avsola) **AND** ○ One of the following: Simponia Aria or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz) **<u>Enthesitis-Related Arthritis (ERA) or Juvenile Psoriatic Arthritits (JPsA)</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>QL:</u>** • Induction ○ Adult Plaque Psoriasis: 4 two-packs (300 mg) in first 28 days ○ Pediatric Plaque Psoriasis/Juvenile Psoriatic Arthritis/Enthesitis-Related Athritis: ▪ 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 • Maintenance ○ Adult Plaque Psoriasis: 1 two-pack (300 mg) per 28 days ○ Pediatric Plaque Psoriasis/Juvenile Psoriatic Arthritis/Enthesitis-Related Athritis: ▪ Less than 50 kg: 75 mg per 28 days ▪ Greater than or equal to 50 kg: 150 mg per 28 days ○ Psoriatic arthritis without plaque psoriasis/AS: 1 injection (150 mg) per 28 days ▪ If a patient continues to have active disease, a dosage of 300 mg may be considered **Reauthorization** • 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:
SELEXIPAG FOR INJECTION
Affected Medications: UPTRAVI Intravenous (IV)

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 confirmed by right heart catheterization • Etiology of PAH (idiopathic, heritable, or associated with connective tissue disease) • New York Heart Association (NYHA)/WHO Functional Class II to III symptoms • Current and complete treatment course • Current and/or anticipated barriers to continuing oral therapy
Appropriate Treatment Regimen & Other Criteria:	• For temporary use in patients established on a stable dose of oral Uptravi who are temporarily unable to continue oral therapy. • Dose of twice daily intravenous infusion corresponds to current dose of Uptravi tablets.
Exclusion Criteria:	• Use in patients not established on a stable dose of oral Uptravi to initiate therapy.
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• 1 month, 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:	

POLICY NAME:
SELUMETINIB
Affected Medications KOSELUGO (selumetinib)

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 2 years of age and older • National Comprehensive Cancer Network (NCCN) indications with evidence level of 2A or better

Required Medical Information:	<u>Neurofibromatosis type 1 (NF1) with inoperable plexiform neurofibromas</u>
	• Documentation of diagnosis of 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 (1 or more if patient has a parent who is diagnosed with NF1) as evaluated by a multidisciplinary specialist care team:
	  ○ Six or more café-au-lait macules over 5 mm in greatest diameter in prepubertal individuals and over 15 mm in greatest diameter in postpubertal 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:	• Documented body surface area (BSA) and prescribed dose <u>Reauthorization:</u> documentation of disease responsiveness to therapy For NF1: evidenced by lack of plexiform neurofibroma growth

Exclusion Criteria:	Neurofibromatosis type 1 (NF1) with inoperable plexiform neurofibromas
	• Patient has experienced any of the following adverse effects while taking Kaselugo:
	  ○ Symptomatic decreased LVEF
	  ○ Grade 3 or 4 decreased LVEF
	  ○ Retinal vein occlusion
	  ○ Grade 4 diarrhea
	  ○ Grade 3 or 4 colitis
	  ○ Rhabdomyolysis
	• Patient is unable to tolerate Kaselugo after 2 dose reductions
	
	NCCN Indications
	• Karnofsky Performance Status 50% or less or ECOG performance score 3 or greater

Age Restriction:	Neurofibromatosis type 1 (NF1) with inoperable plexiform neurofibromas 2 years of age to less than 19 years of age
Prescriber Restrictions:	Neurofibromatosis type 1 (NF1) with inoperable plexiform neurofibromas • Prescribed by, or in consultation with, a pediatric oncologist or specialist with experience in the treatment of neurofibromatosis NCCN Indications • Prescribed by, or in consultation with, an oncologist
Coverage Duration:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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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 body mass index (BMI), weight, and ideal body weight (IBW) **For initial approval members must meet all the following criteria:** • Diagnosis of cachexia or wasting syndrome associated with HIV infection. • Serostim is used in combination with antiretroviral therapy to which the patient has documented compliance • Alternative causes of wasting (eg, 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 (eg, megestrol, dronabinol, cyproheptadine, or testosterone therapy if hypogonadal) unless contraindicated or not tolerated • Patient has unintentionally lost more than 10% of body weight over last 12 months or more than 5% over last 6 months OR; • member weighs less than 90% of ideal body weight OR; • patient has a body mass index (BMI) less than 20 kg/m^2 **For continuation of therapy members must meet the following criteria**: • Patients treated with Serostim for 12 or more weeks have demonstrated a response to therapy (ie, body mass index has improved or stabilized). • Currently on antiretroviral therapy

Appropriate Treatment Regimen & Other Criteria:	• 0.1 mg/kg once daily at bedtime (maximum: 6 mg/day) OR
	• Based on the following body weights:
	  ○ Less than 35 kg, 0.1 mg/kg SUBQ at bedtime
	  ○ 35 to 45 kg, 4 mg SUBQ at bedtime
	  ○ 45 to 55 kg, 5 mg SUBQ at bedtime
	  ○ Over 55 kg, 6 mg SUBQ at bedtime

	• Patients at risk for adverse effects (eg, glucose intolerance) may be started at 0.1 mg/kg every other day.
Exclusion Criteria:	• Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure • Active malignancy • Acute respiratory failure • Active proliferative or severe non-proliferative diabetic retinopathy • Hypersensitivity to Serostim
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)

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POLICY NAME:
SIGNIFOR
Affected Medications: SIGNIFOR (pasireotide diaspartate)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	• Diagnosis of Cushing's Disease • The patient had surgery that was not curative or is not a candidate for surgery
Appropriate Treatment Regimen & Other Criteria:	**If the patient is currently receiving Signifor therapy**, • The patient has shown a clinically meaningful reduction in 24-hour urinary free cortisol levels and/or improvement in signs or symptoms of the disease. • Electrocardiogram (ECG) obtained prior to dose adjustment **If the patient is not currently receiving Signifor,** • Baseline fasting plasma glucose and/or hemoglobin A1C (HbA1c) levels were obtained • The patient has controlled blood glucose levels OR the patient is receiving optimized antidiabetic therapy • ECG obtained • Liver function tests evaluated prior to initiation
Exclusion Criteria:	• Poorly controlled diabetes mellitus (HbA1c >8%) • Severe hepatic impairment (Child Pugh C)
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an endocrinologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
SIGNIFOR LAR
Affected Medications: SIGNIFOR LAR (pasireotide diaspartate)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	**For Acromegaly:** Patient meets the following criteria for initiation of therapy: • Clinical evidence of acromegaly, • Pre-treatment high inslulin-like growth factor-1 (IGF-1) level for age/gender, • Patient has had an inadequate or partial response to octreotide or lanreotide **OR** patient is intolerant to or has a contraindication to octreotide or lanreotide **AND** • Patient has had an inadequate or partial response to surgery and/or radiotherapy **OR** there is a clinical reason for why the patient has not had surgery or radiotherapy (e.g., medically unstable conditions, patient is at high risk for complications of anesthesia because of airway difficulties, lack of an available skilled surgeon, patient refuses surgery or prefers the medical option over surgery, major systemic manifestations of acromegaly including cardiomyopathy, severe hypertension and uncontrolled diabetes). **Reauthorization:** the IGF-1 level decreased or normalized **For Cushing's Disease:** Patient meets the following criteria for initiation of therapy: • Clinical evidence of Cushing's disease in whom pituitary surgery is not an option or has not been curative • Mean urinary free cortisol level (mUFC) between 1.5 and 5 times the upper limit of normal • Documented inadequate response, intolerable adverse event, or contraindication to ALL of the following: ketoconazole, cabergoline, mifepristone • Initial starting dose is 10mg every 4 weeks, may be increased after 4 months to a maximum of 40mg every 4 weeks if 24-hour Urinary Free Cortisol has not normalized **Reauthorization:** mUFC equal to or less than the upper limit of normal
Appropriate Treatment Regimen & Other Criteria:	• Prior to initiation of therapy hypokalemia or hypomagnesemia must be corrected. • Prior to initiation of therapy baseline hemoglobin A1c (HbA1c), Liver function tests, and electrocardiogram (ECG) should be obtained • Blood glucose monitoring should be done weekly for the first 3 months after initiation and the first 4 to 6 weeks after dose increases • New assessment of liver function should be obtained 3 weeks after initiation and then monthly for 3 months • Quantity limit 1 injection (maximum 60 mg) every 28 days

Exclusion Criteria:	• Poorly controlled diabetes mellitus (HbA1c greater than 8%) • Severe hepatic impairment (Child Pugh C)
Age Restriction:	• Must be 18 years of age or older
Prescriber Restrictions:	
Coverage Duration:	• Initial: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
SILDENAFIL
Affected Medications: Sildenafil Citrate TABLET 20 MG

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	• Pulmonary Arterial Hypertension (PAH) (WHO Group 1) confirmed by right heart catheterization • Etiology of PAH (idiopathic or associated with connective tissue disease) • NYHA/WHO Functional Class II or III symptoms • Documentation of Acute Vasoreactivity Testing (positive result requires trial/failure to calcium channel blocker)
Appropriate Treatment Regimen & Other Criteria:	• Subsequent approvals require documentation of treatment success such as improved walking distance or improvements in functional class
Exclusion Criteria:	• Concomitant nitrate therapy on a regular or intermittent basis • Concomitant use of riociguat, a guanylate cyclase stimulator
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or pulmonologist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

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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:	• Consider delaying first dose if absolute neutrophil count (ANC) less than 1.0 x 10^9/L, platelets less than 75 x 10^9/L, and hemoglobin less than or equal to 17 g/dL • Subsequent doses may be delayed if ANC less than 1.0 x 10^9/L, platelets less than 50 x 109/L, and hemoglobin less than or equal to 17 g/dL Dosing: 11 mg/kg intravenous (IV) infusion once every 3 weeks until treatment failure **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:	• Initial Authorization: 4 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified • Cytokine release syndrome: 1 month, unless otherwise specified

POLICY NAME:
SIROLIMUS GEL
Affected Medications: HYFTOR

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. • Current and baseline description of FA including lesion count, associated symptoms and complications, and overall severity. • Complete treatment history related to FA.
Appropriate Treatment Regimen & Other Criteria:	• Documented treatment failure with laser therapy and/or surgery, unless contraindicated. • FAs are rapidly changing in size and/or number, causing functional interference, pain or bleeding or are inhibiting social interactions. **Reauthorization** requires documentation of a positive clinical response to therapy (decrease in size and/or redness of FAs).
Exclusion Criteria:	• Those on systemic mammalian target of rapamycin inhibitors. • Treatment of non-facial angiofibroma.
Age Restriction:	• 6 years of age and older
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.

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)
	  ○ All patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life)
	  ○ Patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a 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 • The prescribed medication will be used in combination with dietary protein restriction **Reauthorization** will require documentation of treatment success (i.e., ammonia levels maintained within normal limits) and that this drug continues to be used in combination with dietary protein restriction
Exclusion Criteria:	• Used to manage acute hyperammonemia
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a metabolic disease specialist or specialist who focuses on the treatment of metabolic diseases
Coverage Duration:	• Approval: 12 months, unless otherwise specified

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POLICY NAME:
SOMATOSTATIN ANALOGS
Affected Medications: BYNFEZIA, OCTREOTIDE, SANDOSTATIN LAR, LANREOTIDE (Somatuline Depot)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design **Octreotide, Sandostatin LAR:** • 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**
	• Initiation of therapy, patient meets the following:
	  ○ Clinical evidence of acromegaly
	  ○ Pre-treatment high insulin-like growth factor (IGF-1) level for age/gender
	  ○ Patient has had an inadequate or partial response to surgery and/or radiotherapy OR there is a clinical reason for avoidance of surgery or radiotherapy
	  ○ Clinical reasons for avoidance of surgery or radiotherapy include:
	  ▪ Medically unstable conditions
	  ▪ Patient is at high risk for complications of anesthesia because of airway difficulties
	  ▪ Lack of an available skilled surgeon
	  ▪ Patient refuses surgery or prefers the medical option over surgery
	  ▪ Major systemic manifestations of acromegaly including cardiomyopathy
	  ▪ Severe hypertension
	  ▪ Uncontrolled diabetes
	
	All other indications
	Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course

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Appropriate Treatment Regimen & Other Criteria:	**<u>All indications</u>** • May use the long-acting IM depot formulation as initial therapy OR may consider 1 or 2 doses of subcutaneous (SQ) octreotide to assess tolerability prior to starting the long-acting IM depot • For patients experiencing breakthrough symptoms while taking the long-acting depot, supplementary doses of SQ octreotide may be necessary **<u>Bynfezia</u>** • **Bynfezia** authorization requires a trial and inadequate treatment response or contraindication to octreotide solution for injection **<u>Lanreotide (Somatuline Depot)</u>** • GEP-NETs must use 120 mg injection **<u>Reauthorization:</u>** **Acromegaly:** requires that the IGF-1 level is decreased or normalized **All other indications:** requires documentation of disease responsiveness to therapy
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, an oncologist, endocrinologist, or gastroenterologist
Coverage Duration:	• Initial Approval = 6 months, unless otherwise specified • Reauthorization = 12 months, unless otherwise specified

POLICY NAME:
SPEVIGO
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 are (BSA) covered with erythema and the presence of pustules
	• Documented treatment failure of acute disease flare (or documented intolerable adverse event) with:
	  ○ A 1-week trial of cyclosporine; AND
	  ○ Infliximab (preferred biosimilars Inflectra, Renflexis, Avsola)

Appropriate Treatment Regimen & Other Criteria:	• 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:	• Adults 18 years of age or older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a dermatologist.
Coverage Duration:	• Initial Authorization: One month with no reauthorization.

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POLICY NAME:
SPRAVATO
Affected Medications: SPRAVATO (esketamine nasal spray)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded ○ Indicated, in conjunction with an oral antidepressant, 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
Required Medical Information:	<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) <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 above 15 or other standard rating scale indicating severe depression
Appropriate Treatment Regimen & Other Criteria:	**<u>Treatment – resistent depression:</u>** • Failure to clinically respond to four 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); OR • Demonstrated intolerance to four antidepressant drugs with distinct side effects; AND • 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 • Will use Spravato in addition to oral antidepressant therapy • **<u>Reauthorization</u>** (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 reliably measures depressive symptoms and that Spravato continues to be used in addition to antidepressant therapy • Dose: Approve #8 dose packs in first 28 days, then limit of #4 per 28 days (maximum). Per table below **Recommended Dosage for SPRAVATO**

<table>
<tr><td></td><td>
<table>
<tr><td colspan="2"></td><td>Adults</td></tr>
<tr><td>Induction Phase</td><td><u>Weeks 1 to 4:</u></td><td>Day 1 starting dose: 56 mg</td></tr>
<tr><td></td><td>Administer twice per week</td><td>Subsequent doses: 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>
<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

<u>MDD with acute suicidal ideation or behavior:</u>
• Documentation of current inpatient psychiatric hospitalization OR documentation of why patient is not currently at inpatient level of care
• Newly initiated or optimized oral antidepressant (AD) (AD monotherapy or AD plus augmentation therapy)
Dosing: 84 mg twice weekly for 4 weeks maximum (No reauthorization unless requirements for TRD met)
</td></tr>
<tr><td>Exclusion Criteria:</td><td>• 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</td></tr>
<tr><td>Age Restriction:</td><td>• 18 years of age and older</td></tr>
<tr><td>Prescriber Restrictions:</td><td>• REMS Program certified (others will be unable to order drug)</td></tr>
</table>

	• Behavioral health specialist
Coverage Duration:	**<u>Initial authorization</u>** • 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 **<u>Reauthorization</u>** (TRD indication only): 6 months, unless otherwise specified

POLICY NAME:
STIRIPENTOL
Affected Medications: Diacomit (stiripentol) capsules, Diacomit (stiripentol) powder for suspension

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

Required Medical Information:	• Patient 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
	• Documented treatment and inadequate control of seizures with at least four guideline directed therapies including:
	  ○ Valproate and
	  ○ Onfi and
	  ○ Topiramate and
	  ○ Clonazepam, levetiracetam, or zonisamide

Appropriate Treatment Regimen & Other Criteria:	• Dosing: 50 mg/kg/day, in 2 or 3 divided doses, not to exceed 3,000mg/day • **Reauthorization** will require documentation of at least 50% reduction in generalized clonic or tonic-clonic seizure frequency
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist
Coverage Duration:	• Initial Authorization: 3 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

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:	• Baseline 6 minute walk test
	• Bone density testing (such as DEXA scan)
	
	<u>Diagnosis of Perinatal/infantile or Juvenile onset hypophosphatasia (HPP) with ALL of the following:</u>
	• Age of onset less than 18 years
	• Clinical manifestations consistent with hypophospatasia at onset prior to age 18 including any of the following: vitamin B6 dependent seizures, skeletal abnormalities (such as rachitic chest deformity or bowed arms/legs), failure to thrive
	• Radiographic imaging to support presence of skeletal abnormalities
	• Molecular genetic test confirming mutations in the ALPL gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP)
	• Low level of serum alkaline phosphatase (ALP) evidenced by lab result below lab standard for age and gender adjusted normal range
	• One of the following:
	  ○ elevated (urine or serum) concentration of phosphoethanolamine (PEA)
	  ○ elevated serum concentration of pyridoxal 5'-phosphate (PLP/Vitamin B6) in the absence of vitamin supplements within one week prior to the test
	  ○ elevated urinary inorganic pyrophosphate (PPi)

Appropriate Treatment Regimen & Other Criteria:	Weight based dosing according to package insert (following recommendations for appropriate vial size selection) **<u>Perinatal/Infantile-Onset HPP</u>** • Maximum dose 9 mg/ kg per week **<u>Juvenile-Onset HPP</u>** • Maximum dose 6 mg/ kg per week ****Please note 80mg/0.8ml vial is for patients greater than 40kg** • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced

	Reauthorization requires documentation of:
	• All of the above criteria at time of initiation
	• Laboratory results confirming a decrease in urine concentration of phosphoethanolamine (PEA), serum concentration of pyridoxal 5'-phosphate (PLP) or urinary inorganic pyrophosphate (PPi)
	• Chart notes showing one or more of the following
	  ○ Radiographic evidence of improvement in skeletal deformities or growth
	  ○ Improvement in 6 minute walk test
	  ○ Improved bone density
	  ○ Reduction in fractures

Exclusion Criteria:	• 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: 4 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, 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]
	  ▪ Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Required Medical Information:	• Monthly intravenous immune globulin (IVIG) dose for those transitioning
	• Patient weight
	
	<u>Primary Immunodeficiency (PID)</u>
	• Type of immunodeficiency
	• A documented deficiency in producing antibodies in response to vaccination
	• Titers were drawn before challenging with vaccination
	• Titers were drawn between 4 and 8 weeks of vaccination
	• Documented recent IgG level less than 200 **OR**
	• 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

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

POLICY NAME:
SUBLOCADE
Affected Medications: SUBLOCADE (Buprenorphine extended-release injection)

PA applies to Pharmacy Benefit only: Authorization required after first two doses

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Moderate to severe opioid use disorder
Required Medical Information:	• Documentation that member is part of a comprehensive management program that includes psychosocial support AND • Documentation of abstinence from alcohol/benzodiazepines/opioids through the first 1-2 months of treatment
Appropriate Treatment Regimen & Other Criteria:	• **Reauthorization:** Subsequent approvals require documentation of treatment success
Exclusion Criteria:	
Age Restriction:	• Age greater than or equal to 18 years
Prescriber Restrictions:	
Coverage Duration:	• Approval Duration: 12 months

POLICY NAME:
SUTIMLIMAB
Affected Medications: ENJAYMO (sutimlimab-jome)

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

Required Medical Information:	**Cold Agglutinin Disease (CAD)**
	• Documentation of 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 total 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

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

POLICY NAME:
SYMDEKO
Affected Medications: SYMDEKO (tezacaftor/ivacaftor tablets)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Cystic fibrosis in patients homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
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 homozygous for the F508del mutation in the CFTR gene or who have at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success
Exclusion Criteria:	• Concurrent use of strong CYP3A inducers: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort
Age Restriction:	• 6 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a pulmonologist or provider who specializes in CF
Coverage Duration:	• Initial approval: 12 months, unless otherwise specified • Reauthorization: 24 months unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
SP1 RECEPTOR MODULATORS
Affected Medications: MAYZENT (siponimod), Fingolimod, PONVORY (ponesimod)

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 disease (SPMS)

Required Medical Information:	• 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 **<u>Clinically Isolated Syndrome</u>** • Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event **<u>Secondary-Progressive MS</u>** • Documentation of prior history of RRMS with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e., new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5

Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure (or documented intolerable adverse event) to all the following:
	  ○ Dimethyl fumarate or Bafiertam (monomethyl fumarate)
	  AND
	  ○ Rituximab (preferred biosimilar products: Truxima and Ruxience) OR Ocrevus (ocrelizumab) if previously established on treatment

	• No concurrent use of other disease-modyfing medications indicated for the treatment of MS
	
	• Fingolimod dosing: 0.5 mg once daily
	• Mayzent dosing: 2 mg orally once daily starting on Day 6. Dosage adjustment is required in patients with a CYP2C9*1/*3 or *2/*3 genotype
	  ○ If one titration dose is missed for more than 24 hours, treatment needs to be reinitiated with Day 1 of the titration regimen
	  ○ In patients with a CYP2C9*1/*3 or *2/*3 genotype, after treatment titration, the recommended maintenance dosage of Mayzent is 1 mg taken orally once daily starting on Day 5
	• Ponvory dosing: 20 mg once daily, beginning on day 15.
	  ○ Starter pack for days 1-14
	  ○ Greater than or equal to 4 consecutive doses missed: Reinitiate treatment with day 1 of the initial titration regimen, including first-dose monitoring when appropriate.
	  ○ Discontinuation of treatment if liver enzymes exceed three times the upper limit of normal (ULN) with signs of liver dysfunction (unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, rash with eosinophilia, or jaundice and/or dark urine)
	
	• **Reauthorization**: provider attestation of treatment success

Exclusion Criteria:	• Mayzent only: CYP2C9*3/*3 genotype
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a neurologist or MS specialist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
TAFAMIDIS
Affected Medications: VYNDAQEL (tafamidis meglumine 20 mg), VYNDAMAX (tafamidis 61 mg)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ For the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

Required Medical Information:	• Documented diagnosis of cardiomyopathy of wild-type (ATTRwt) or hereditary (ATTRm) transthyretin-mediated amyloidosis confirmed by
	  ○ Presence of amyloid deposits on analysis of cardiac biopsy specimens
	OR
	  ○ Presence of grade 2 or 3 positive bone tracer cardiac scintigraphy in the absence of monoclonal protein (i.e., free light chain ratio is normal and serum and urine immunofixation results are both normal)
	• Genetic test results identifying a mutation in the transthyretin (TTR) gene (Val122Ile or Thr60Ala mutation) or wild-type amyloidosis
	  ○ For those with ATTRwt: documented presence of transthyretin precursor protein confirmed on immunohistochemical analysis, scintigraphy, or mass spectrometry is required
	• Cardiac involvement has been confirmed by echocardiography or cardiac magnetic resonance imaging
	• Diagnosis of heart failure with NYHA Class I to III symptoms

Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** requires documentation of a positive clinical response to tafamidis (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)
Exclusion Criteria:	• Heart Failure NYHA Class IV • Presence of light-chain amyloidosis • Prior liver or heart transplant • Implanted cardiac mechanical assist device • Combined use with TTR-lowering therapy, including inotersen or patisiran
Age Restriction:	• 18 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a cardiologist or a physician who specializes in the treatment of amyloidosis
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, 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
Required Medical Information:	• Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) made by a board certified Hematopathologist or Dermatopathologist. • If diagnosis of BPDCN is based on skin biopsy, clear plasmacytoid dendritic blast cells are present by morphology and confirmed by IHC and flow cytometry. Features excluding AML and Leukemia cutis must be present. • If BPDCN presents as the leukemic form or it there is bone marrow involvement, AML, T-cell lymphoblastic leukemia, and NK-cell Leukemia must be excluded. • Documentation of performance status, disease staging, all prior therapies used, and anticipated treatment course.
Appropriate Treatment Regimen & Other Criteria:	• The recommended dose and schedule is 12 mcg/kg administered intravenously over 15 minutes once daily on day 1 to 5 of a 21-day cycle. <u>Reauthorization</u>: documentation of disease responsiveness to therapy
Exclusion Criteria:	• Renal toxicity: Withhold tagraxofusp until serum creatinine is ≤1.8 mg/dL or CrCl is ≥60 mL/minute. • Hepatotoxicity: Withhold tagraxofusp until AST and/or ALT are ≤2.5 times ULN • Persistent clinically significant toxicities from prior chemotherapy • Receiving immunosuppressive therapy • Pregnancy
Age Restriction:	• For adults and pediatric patients 2 years and older only
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

POLICY NAME:
TALIGLUCERASE
Affected Medications: ELELYSO (taliglucerase alfa)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	• Diagnosis of Type 1 Gaucher Disease • Diagnosis confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity • At least one of the following disease complications: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly
Appropriate Treatment Regimen & Other Criteria:	• Dosing: 60 units/kg every 2 weeks; dosing is individualized based on disease severity ○ Supplied as 200 unit vials • 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:	• Patients currently taking miglustat (Zavesca) or eliglustat (Cerdelga)
Age Restriction:	• 4 years of age or older
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified

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 proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression
Required Medical Information:	• Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed with biopsy • Documentation of risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) equal to or greater than 1.5g/g (labs current within 30 days of request) **OR** • Proteinuria defined as equal to or greater than 1g/day (labs current within 30 days of request)
Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure of a minimum of 12 weeks of Angiotensin-converting enzyme (ACE) inhibitor or Angiotensin Receptor Blocker (ARB) **AND** • Documented treatment failure with a minimum of 12 weeks of glucocorticoid therapy such as oral prednisone or methylprednisolone (treatment failure defined as proteinuria equal to or greater than 1 g/day or an adverse effect to two glucocorticoid therapies that is not associated with the corticosteroid class) **AND** • Documented treatment failure with a minimum of 12 weeks of Filspari (treatment failure defined as proteinuria equal to or greater than 1 g/day or an adverse effect to Filspari) **No reauthorization** – Recommended duration of therapy is 9 months followed by a 2-week dose taper prior to discontinuation
Exclusion Criteria:	• Patients with other glomerulopathies and 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

POLICY NAME:
TEDIZOLID
Affected Medications: Sivextro powder for IV 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**: 200 mg once daily for 6 days
	
	Trial and failure with either intravenous antibiotics or oral antibiotics per below:
	
	Intravenous
	• Documentation of treatment failure of intravenous Linezolid, or contraindication to therapy **AND**
	• Documentation of treatment failure of at least 2 of the following drugs/drug classes, or contraindication to therapy:
	  ○ 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)
	
	Oral tablets
	• Documentation of treatment failure of oral Linezolid, or contraindication to therapy **AND**

	• Documentation of treatment failure of at least 2 of the following drugs/drug classes, or contraindication to therapy:
	  ○ Trimethoprim-Sulfamethoxazole
	  ○ Tetracycline (Doxycycline, Minocycline)
	  ○ Clindamycin

Exclusion Criteria:	
Age Restriction:	• 12 years of age and older
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.
Required Medical Information:	• Colonoscopy results within 6 months • Bilirubin, alkaline phosphatase, lipase, amylase within 6 months • Recent fluid and electrolyte status and documented plan to assess • Serum Creatinine • Review of REMS criteria • Documentation of any malignancy and disclosure of increased risk of malignancy to patient with risk benefit consideration • Clinical justification of need for reduction in PN/IV volume • Plan to assess weekly PN/IN volume and evaluation of success of treatment and continued need • Documentation of Short Bowel Syndrome (SBS) with current dependence on parenteral support
Appropriate Treatment Regimen & Other Criteria:	• Dose: 0.05 mg/kg SQ QD dose • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced • 50% reduction for CrCl less than 50ml/min **Reauthorization**: Documentation of clinically significant success defined by parenteral support reduction of 1 day or greater a week
Exclusion Criteria:	
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

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 12 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:	• 12 years 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:	• Initial diagnosis was made less than 10 years ago
	• Euthyroid with the baseline disease under control prior to starting therapy
	• 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 • No previous Tepezza treatment • No prior orbital irradiation, orbital decompression, or strabismus surgery • 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:	
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)

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

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

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

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

</td></tr>
<tr><td>Appropriate Treatment Regimen & Other Criteria:</td><td>
Approved for one-time 14-day infusion only, based on the following dosing schedule:
<table>
<tr><td>Treatment Day</td><td>Dose</td></tr>
<tr><td>Day 1</td><td>65 mcg/m^2</td></tr>
<tr><td>Day 2</td><td>125 mcg/m^2</td></tr>
<tr><td>Day 3</td><td>250 mcg/m^2</td></tr>
<tr><td>Day 4</td><td>500 mcg/m^2</td></tr>
<tr><td>Days 5 - 14</td><td>1,030 mcg/m^2</td></tr>
</table>
</td></tr>
</table>

	• 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)

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POLICY NAME:
TERIFLUNOMIDE
Affected Medications: TERIFLUNOMIDE

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
Required Medical Information:	• Documentation of diagnosis of relapsing forms of Multiple Sclerosis (MS) confirmed with magnetic resonance imaging (MRI) (Revised McDonald diagnostic criteria for MS) ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS **<u>Clinically Isolated Syndrome (CIS)</u>** • Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event **<u>Secondary-Progressive MS (SPMS)</u>** • Documentation of prior history of relapsing-remitting MS (RRMS) with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e., new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5

Appropriate Treatment Regimen & Other Criteria:	• Documentation of treatment failure (or documented intolerable adverse event) to
	  ○ dimethyl fumarate or Bafiertam (monomethyl fumarate) AND
	  ○ Zeposia (ozanimod) AND
	  ○ rituximab (preferred biosimilar products Truxima and Ruxience) OR Ocrevus (ocrelizumab) if previously established on treatment
	
	• Aubagio dosing: 7 or 14 mg once daily

Exclusion Criteria:	• Primary Progressive Multiple Sclerosis

	• Recent (in the past 6 months) myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization or class III or IV HF • Concurrent use of medications indicated for treatment of relapsing-remitting multiple sclerosis
Age Restriction:	
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a neurologist or multiple sclerosis specialist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
TESTOPEL AND TESTOSTERONE
Affected Medications: Testopel (testosterone pellets), Testosterone gel, Jatenzo capsules (testosterone undecanoate capsules), Tlando (testosterone undecanoate capsules), Kyzatrex (testosterone undecanoate capsules)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• All therapies tried/failed for indicated diagnosis • 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 • Testopel: dosage (in milligrams) or number of pellets to be administered and frequency • If age greater 65 years and older: • Yearly evaluation of need is completed discussing need for hormone replacement therapy. • Yearly documentation that provider has educated patient on risks of hormone replacement (heart attack, stroke) • Yearly documentation that provider has discussed limited efficacy and safety for hormone replacement in patients experiencing age related decrease in testosterone levels **<u>Gender Dysphoria hormone supplementation under 18 years of age</u>** • Documentation of current Tanner stage 2 or greater OR documentation of baseline and current estradiol and testosterone levels to confirm onset of puberty • Documentation from a licensed mental health professional (LMHP) confirming diagnosis and addressing the patient's general identifying characteristics; o The initial and evolving gender and any associated mental health concerns, and other psychiatric diagnoses; o The duration of the referring licensed mental health professional's relationship with the client, including the type of evaluation and psychotherapy to date; o The clinical rationale for supporting the client's request for cross-hormone therapy and statement that the client meets eligibility criteria; o Informed consent required from both patient and guardian documented by prescribing provider o Permission to contact the licensed mental health professional for coordination of care • Comprehensive mental health evaluation should be provided in accordance with most current version of the World Professional Association for Transgender Health (WPATH) Standards of Care o 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	**STEP 1 MEDICATIONS:** • Testosterone injections

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Regimen & Other Criteria:	**STEP 2 MEDICATIONS:** • transdermal testosterone, Kyzatrex capsules, Tlando, and Jatenzo capsule • Initial approval requires documented failure, intolerance, or clinical rationale for avoidance of the testosterone injections **STEP 3 MEDICATIONS:** • Testopel • Approval requires documented failure, intolerance, or clinical rationale for avoidance of generic transdermal testosterone, Tlando, OR Jatenzo capsules AND Kyzatrex capsules • Maximum of 450 mg per treatment **Reauthorization Criteria:** • Documentation of recent testosterone level while on replacement therapy 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:	• Testopel: Maximum of 4 treatments in 12 months, unless otherwise specified • All other formulations: 12 months, unless otherwise specified

POLICY NAME:
TEZEPELUMAB-EKKO
Affected Medications: TEZSPIRE

• Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #2
• Is the request for use in combination with another monoclonal antibody (e.g., Fasenra, Nucala, Xolair, Cinqair, Dupixent)?	Yes – Criteria not met; combination use is experimental	No – Go to #3
• Is the request to treat a diagnosis according to one of the Food and Drug Administration (FDA)-approved indications? o Add-on maintenance treatment of patients with severe asthma aged 12 years and older	Yes – Go to appropriate section below	No – Criteria not met
Severa Asthma		
• Is there documentation of severe asthma defined by the following: For adults: o FEV1 less than 80% at baseline or FEV1/FVC reduced by at least 5% from normal For those between the age of 12-17: o FEV1 less than 90% at baseline or FEV1/FVC reduced by at least 5% from normal	Yes – Document and go to #2	No – Criteria not met
• Is there documented use of a high-dose inhaled corticosteroid (ICS) plus a long-acting beta agonist (LABA) for at least three months with continued symptoms?	Yes – Document and go to #3	No – Criteria not met
• Is there 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 and at least 80% adherence?	Yes – Document and go to #4	No – Criteria not met

• Is the drug prescribed by, or in consultation with, an Allergist, Immunologist, or Pulmonologist?	Yes – Approve up to 6 months	No – Criteria not met
Renewal Criteria		
• 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
• 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		
• **Tezspire** ○ Availability: 210 mg/1.91 ml prefilled syringe; 210 mg/1.91 ml single-dose vial ○ Dosing: 210 mg every 4 weeks		

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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)
	• 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** • Used in combination with dexamethasone in newly diagnosed MM **Erythema nodosum leprosum** • **Acute treatment** of the cutaneous manifestations of moderate to severe ENL ○ Not indicated as monotherapy in the presence of moderate to severe neuritis • **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

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:
THYMOGLOBULIN
Affected Medications: THYMOGLOBULIN (antithymocyte globulin - rabbit derived)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Renal transplant acute rejection treatment and induction therapy
	• Off-label uses:
	  ○ Heart transplant
	  ○ Intestinal and multivisceral transplantation
	  ○ Lung transplant
	  ○ Chronic graft-versus-host disease prevention

Required Medical Information:	• For prophylaxis:
	  ○ 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:
	  ▪ 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.
	  ○ Recipient risk factors include:
	  ▪ repeated transplantation,
	  ▪ panel-reactive antibody value exceeding 20% before transplant,
	  ▪ black race, and
	  ▪ one or more HLA antigen mismatches with the donor.

Appropriate Treatment Regimen & Other Criteria:	**Treatment of acute renal graft rejection – **No PA required for this diagnosis****
	  ○ Prophylaxis: 1.5 mg/kg of body weight administered daily for 4 to 7 days.
	  ○ Clinical rationale for avoiding Simulect (Basiliximab) in prophylaxis
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced

Exclusion Criteria:	• Active acute or chronic infections that contraindicates any additional immunosuppression
Age Restriction:	
Prescriber Restrictions:	• Physicians experienced in immunosuppressive therapy for the management of renal transplant patients.
Coverage Duration:	• Initial approval: 1 Month, unless otherwise specified • Reauthorization: 1 Month, unless otherwise specified

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POLICY NAME:
TILDRAKIZUMAB
Affected Medications: ILUMYA (tildrakizumab)

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

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 (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

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 Infliximab (preferred biosimilar products: Inflectra, Renflexis, Avsola) **QL:** • 100mg 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 biologic therapy or Otezla 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: 12 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

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POLICY NAME:
TOCILIZUMAB
Affected Medications: ACTEMRA IV, ACTEMRA ACTPEN SOLUTION, ACTEMRA PREFILLED SYRINGE

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Rheumatoid Arthritis
	  ○ Giant Cell Arteritis
	  ○ Polyarticular and Juvenile Idiopathic Arthritis
	  ○ Cytokine Release Syndrome
	  ○ Systemic sclerosis-associated interstitial lung disease

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>Giant Cell Arteritis (GCA)</u>
	• 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
	
	<u>Cytokine Release Syndrome</u>
	• Documentation of previous chimeric antigen receptor (CAR) T cell therapy treatment plan
	• Documentation of active cytokine release syndrome
	
	<u>Polyarticular and Juvenile Idiopathic Arthritis (JIA)</u>
	• Documentation of current level of disease activity with physician global assessment (MD global score) or active joint count
	
	<u>Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)</u>
	• Documentation of diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease from the American College of Rheumatology / European League Against Rheumatism classification criteria with
	  ○ 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 Regimen & Other Criteria:	**<u>Rheumatoid Arthritis</u>** • Documented treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy: ○ Methotrexate plus sulfasalazine ○ Methotrexate plus hydroxychloroquine ○ Sulfasalazine plus hydroxychloroquine ○ Leflunomide plus sulfasalazine ○ Leflunomide plus hydroxychloroquine • Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with intravenous formulation or Infliximab (preferred biosimilar products Inflectra, Renflexis, Avsola) **<u>Giant Cell Arteritis (GCA) and Cytokine Release Syndrome (CRS)</u>** • Documentation of disease refractory to glucocorticoid treatment • Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with intravenous formulation **<u>Polyarticular and 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 • Subcutaneous formulation requires documented treatment failure (or documented intolerable adverse event) with intravenous formulation **<u>Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)</u>** • Documented clinical treatment failure or intolerable adverse event with mycophenolate (MMF) and with cyclophosphamide **<u>QL:</u>** Intravenous: ○ Availability: 400 mg, 200 mg & 80 mg single-dose vials ○ RA: 4 mg/kg once every 4 weeks; may be increased to 8 mg/kg once every 4 weeks based on clinical response (maximum dose: 800 mg) ○ CRS: For patients less than 30kg, recommended dose is 12mg/kg; patients 30kg or greater recommended dose is 8mg/kg up to maximum of 800mg (Maximum 4 doses) ○ Polyarticular JIA: <30 kg: 10 mg/kg every 4 weeks; 30 kg or greater: 8 mg/kg every 4 weeks (maximum dose: 800 mg) ○ Systemic JIA: <30 kg: 12 mg/kg every 2 weeks; 30 kg or greater: 8 mg/kg every 2 weeks (maximum dose: 800 mg)

	○ Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced Subcutaneous: ○ RA: <100 kg – 2 injections (162 mg) per 28 days (may be increased to four based on clinical response)**;** 100 kg or greater – 4 injections (162 mg) per 28 days ○ GCA: 4 injections (162 mg) per 28 days ○ Polyarticular JIA: <30 kg: one injection (162 mg) every 3 weeks; 30 kg or greater: one injection (162 mg) every 2 weeks ○ Systemic JIA: <30 kg: one injection (162 mg) every 2 weeks; 30 kg or greater: one injection (162 mg) every week ○ SSc-ILD: one injection (162 mg) once every week **<u>Reauthorization</u>** • Documentation of treatment success and clinically significant response to therapy
Exclusion Criteria:	
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

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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) o Arthritis o Enthesitis o Uveitis o Dactylitis (inflammation of entire digit) o Psoriasis o Crohn's disease/ulcerative colitis o Good response to NSAIDs o Family history of SpA o 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 treatment failure with at least 12 weeks of combination disease-modifying antirheumatic drug (DMARD) therapy: o Methotrexate plus sulfasalazine o Methotrexate plus hydroxychloroquine o Sulfasalazine plus hydroxychloroquine o Leflunomide plus sulfasalazine o Leflunomide plus hydroxychloroquine • 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, Renflexis, Avsola), Actemra 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) **<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: o Infliximab (preferred biosimilar products: Inflectra, Renflexis, Avsola) **AND** o One of the following: Otezla, Simponi Aria, Orencia, or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz)

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	<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, Renflexis, Avsola)
	  AND
	  ○ One of the following: Entyvio or Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz)
	
	<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 Actemra 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, Renflexis, Avsola)
	  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)
Required Medical Information:	• Definite or probable Amyotrophic lateral sclerosis (ALS) based on El Escorial revised (Airlie House) 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

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: JYNARQUE, tolvaptan (15 mg, 30 mg)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ **Tolvaptan:** 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)
	  ○ **Jynarque:** 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 • Age 18 to 55 years old and 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** • Patients should be in hospital for initiation and re-initiation of therapy • Do not administer for more than 30 days **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

POLICY NAME:
TOPICAL DERMATITIS AND PSORIATIC AGENTS
Affected Medications: TACROLIMUS OINTMENT (0.1%, 0.03%), PIMECROLIMUS; CALCIPOTRIENE 0.005% CREAM; VTAMA CREAM (1%), ZORYVE CREAM (0.3%)

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

Required Medical Information:	<u>All Ages</u>
	• Documentation of 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 (DQLI) 11 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
	  ○ Body Surface Area (BSA) of at least 10% OR
	  ○ Hand, foot, face or mucous membrane involvement

Appropriate Treatment Regimen & Other Criteria:	**<u>Topical Tacrolimus, Pimecrolimus, Calcipotriene cream:</u>** • Documented failure with prescription strength topical corticosteroids and emollients or facial involvement **<u>Zoryve cream:</u>** • Documented failure with a high or super-high potency topical corticosteroid (such as betamethasone dipropionate, clobetasol, fluocinonide, or halobetasol) • Documented failure with calcipotriene cream • Documented treatment failure with 12 weeks of one of the following: phototherapy, cyclosporine, methotrexate, acitretin **<u>Vtama cream:</u>** • Documented failure with a high or super-high potency topical corticosteroid (such as betamethasone dipropionate, clobetasol, fluocinonide, or halobetasol) • Documented failure with calcipotriene cream • Documented treatment failure with 12 weeks of one of the following: phototherapy, cyclosporine, methotrexate, acitretin • Documented treatment failure with 8 weeks of Zoryve cream

	Reauthorization: Documentation of disease responsiveness to therapy defined as Body Surface Area (BSA) reduction from baseline
Exclusion Criteria:	• Atopic dermatitis or plaque psoriasis 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% for children 2-15 years old • Tacrolimus ointment 0.03% and 0.1% for adults • Vtama: Adutls 18 years and older • Zoryve: 12 years of age and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, a specialist, (example: dermatologist, allergist or immunologist)
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
TRALOKINUMAB
Affected Medications: ADBRY (tralokinumab)

• Is the request for continuation of therapy currently approved through insurance?	Yes – Go to renewal criteria	No – Go to #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		
• 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
• 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
• Is there documented failure with at least 6 weeks of treatment with one of the following: Tacrolimus ointment, pimecrolimus cream?	Yes – Document and go to #4	No – Criteria not met
• Is there documented treatment failure with two of the following for at least 12 weeks: Phototherapy, cyclosporine, azathioprine, methotrexate, mycophenolate?	Yes – Document and go to #5	No – Criteria not met

• 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		
• 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
• 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
  ○ Dosing: 600mg as single dose then 300mg every 2 weeks.
  ▪ If less than 100kg and clear/almost clear is achieved dosing may be reduced to 300mg every 4 weeks		

PacificSource Community Solutions

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)

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
	
	All Indications
	• Coverage for a non-preferred product (Herceptin or Herceptin Hylecta) requires documentation of one of the following:
	  ○ A documented intolerable adverse event to the preferred products Kanjinti, Trazimera, Herzuma, Ontruzant and Ogivri, and the adverse event was not an expected adverse event attributed to the active ingredient
	  ○ Currently receiving treatment with a non-preferred product, excluding via samples or manufacturer's patient assistance programs
	
	Reauthorization 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

POLICY NAME:
TRIKAFTA
Affected Medications: TRIKAFTA (elexacaftor, tezacaftor and ivacaftor tablets; ivacaftor tablets kit)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design ○ Cystic Fibrosis in those with at least one F508del mutation in the CFTR gene
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 at least one F508del mutation in the CFTR gene OR a mutation in the CFTR gene that is responsive based on in vitro data.
Appropriate Treatment Regimen & Other Criteria:	**Reauthorization** will require documentation of treatment success
Exclusion Criteria:	• Concurrent use of strong CYP3A inducers: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort
Age Restriction:	• Approved in patients ages 2 years and older
Prescriber 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:
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>Prostate cancer</u>**
	• Documentation of performance status, disease staging, all prior therapies used, and prescribed treatment regimen
	• Documentation that Trelstar is being used as NCCN 2A level of evidence regimen
	
	<u>Central Precocious Puberty (CPP)</u>
	• Documentation of central precocious puberty (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)
	• Age greater than or equal to 2 years to less than 13 years
	• Bone age greater than 2 standard deviations (SD) beyond chronological age
	
	<u>Gender Dysphoria</u>
	• Documentation of current Tanner stage 2 or greater OR Documentation of baseline and current estradiol and testosterone levels to confirm onset of puberty
	• Documentation from a licensed mental health professional (LMHP) confirming diagnosis and addressing the patient's general identifying characteristics:
	  ○ The initial and evolving gender and any associated mental health concerns, and other psychiatric diagnoses
	  ○ The duration of the referring licensed mental health professional's relationship with the client, including the type of evaluation and psychotherapy to date
	  ○ The clinical rationale for supporting the client's request for hormone therapy and statement that the client meets eligibility criteria; and
	  ○ Permission to contact the licensed mental health professional for coordination of care

	• Comprehensive mental health evaluation should be provided in accordance with 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) **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Use as neoadjuvant ADT for radical prostatectomy • CPP-Treatment beyond 13 years of age
Age Restriction:	
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

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.
Required Medical Information:	• Documentation of all prior therapies used • Documentation of active antiretroviral therapy for at least 6 months • Documentation of multidrug resistant HIV-1 with resistance to at least one antiretroviral medication from each of the following classes: Nucleoside Reverse Trancriptase Inhibitors (NRTIs), Non-Nucleoside Reverse Transcriptase Inhibitors, and Protease Inhibitors (PIs). • Failure with current regimen or not on current antiretroviral therapy and failure with most recent regimen (viral load greater than 1,000 copies/mL)
Appropriate Treatment Regimen & Other Criteria:	• Loading dose 2000mg • Maintenance dose 800mg every 2 weeks • Initial **reauthorization** will require documentation of greater than or equal to a 0.5 $\log_{10}$ reduction in viral load • **Reauthorization:** Continued authorization will require undetectable viral load
Exclusion Criteria:	
Age Restriction:	• 18 years and older
Prescriber Restrictions:	• Prescribed by, or in consultation with, an infectious disease or specialist in HIV treatment
Coverage Duration:	• Initial approval: 3 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

POLICY NAME:
TURALIO
Affected Medications: TURALIO (pexidartinib)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design. ○ Symptomatic tenosynovial giant cell tumor (TGCT)

Required Medical Information:	• A diagnosis of TGCT that has been histologically confirmed either by a pathologist at the treating institution or a central pathologist, and where surgical resection would be associated with potentially worsening functional limitation or severe morbidity (locally advanced disease), with morbidity determined consensually by qualified personnel (Two surgeons or a multi-disciplinary tumor board)
	• Measurable disease of at least 2 cm , assessed from MRI scans by a central radiologist
	• Symptomatic disease because of active TGCT, defined as one or more of the following:
	  ○ A worst pain of at least 4 at any time during the week preceding the Screening Visit (based on scale of 0 to 10, with 10 representing “pain as bad as you can imagine”
	  ○ A worst stiffness of at least 4 at any time during the week preceding the Screening Visit (based on a scale of 0 to 10, with 10 representing “stiffness as bad as you can imagine”)

Appropriate Treatment Regimen & Other Criteria:	• Documented failure or contraindication of imatinib • Reauthorization requires documentation of treatment success
Exclusion Criteria:	• Liver Disease • Pregnancy
Age Restriction:	• Age greater than or equal to 18 years
Prescriber Restrictions:	• Prescribers enrolled in REMS program
Coverage Duration:	• Initial approval: 4 months • Reauthorization 12 months

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 from benefit design.

Required Medical Information:	**Pulmonary arterial hypertension (PAH) WHO Group 1**
	• Documentation of PAH confirmed by right-heart catheterization
	• 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
	• Documentation of acute vasoreactivity testing (positive result requires trial/failure to calcium channel blocker)
	  ○ New York Heart Association (NYHA)/World Health Organization (WHO) Functional Class III symptoms
	
	Pulmonary Hypertension Associated with Interstitial Lung Disease WHO GROUP 3
	• 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:	• For initiation of therapy patient must have mean pulmonary artery pressure at least 20 mmHg at rest, an elevated pulmonary vascular resistance (PVR) of at least 3 Wood units or more, and a mean pulmonary capillary wedge pressure less than 15 mmHg **AND** • The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition • Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out (not required for WHO group 3) • Documentation that treprostinil is used as a single route of administration (Remodulin, Tyvaso, Orenitram should not be used in combination) • Subsequent approval requires documentation of treatment success: exercise endurance, echocardiographic testing, hemodynamic testing, BNP, functional class

	• 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 symptoms, (not required for WHO group 3)
	  ○ Ambrisentan and tadalafil
	  ○ Bosentan and riociguat
	  ○ Macitentan and sildenafil

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:	• 18 years of age and older
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 isolating syndrome (CIS)
	  ○ Relapsing-remitting multiple sclerosis (RRMS)
	  ○ Active secondary progressive disease (SPMS)

Required Medical Information:	<u>Relapsing-remitting multiple sclerosis</u> • Diagnosis of relapsing or active secondary progressive forms of multiple sclerosis (MS) confirmed with magnetic resonance imaging (MRI) (Revised McDonald diagnostic criteria for multiple sclerosis) ○ Clinical evidence alone will suffice; additional evidence desirable but must be consistent with MS <u>Clinically Isolated Syndrome</u> • Documentation of CIS as shown by patients who do not fulfill McDonald criteria for a diagnosis of MS but have an abnormal brain MRI with one or more hyperintense T2 lesions that are characteristic of MS in at least two of four MS-typical regions at presentation or within three to six months of the event <u>Secondary-Progressive MS</u> • Documentation of prior history of relapsing-remitting MS (RRMS) with progressive increase in disability over at least 6 months, independent of, or in the absence of, relapses • Documentation of active disease classified as the presence of clinical relapse or inflammatory activity (i.e. new or enlarging T2 lesions or gadolinium enhancing lesions on MRI) in the last 2 years • Documentation of Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5
Appropriate Treatment Regimen & Other Criteria:	• Relapsing forms of MS: Coverage of Briumvi requires documentation of one of the following: o A documented intolerable adverse event to the preferred Rituximab products, Truxima, Riabni and Ruxience, and the adverse event was not an expected adverse event attributed to the active ingredient o Currently receiving treatment with Briumvi, excluding via samples or manufacturer's patient assistance programs.

	• No concurrent use of medications indicated for treatment of relapsing-remitting multiple sclerosis • How Supplied: ○ 150 MG/6 ML • 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: STELARA (ustekinumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Plaque Psoriasis
	  ○ Psoriatic Arthritis
	  ○ Crohn's Disease
	  ○ Ulcerative Colitis

Required Medical Information:	• Documentation of moderate to severe disease despite current treatment (Indication must be documented in chart notes within the last 6 months)
	• Documentation of complete and current treatment history
	• Documented current level of disease activity/disease control
	
	<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 (DQLI) 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</u>
	• Documentation of moderate to severely active disease despite current treatment
	
	<u>Ulcerative Colitis</u>
	• Documentation of disease severity Mayo Clinic Score for Assessment of Ulcerative Colitis Activity score
	
	<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
Appropriate Treatment Regimen & Other Criteria:	**<u>All use:</u>** • Currently receiving treatment with Stelara, excluding via samples or manufacturer's patient assistance programs will not be required to have documented failure with all formulary alternatives **<u>Plaque psoriasis</u>** • Failure of at least two systemic therapies with minimum of 12 weeks trial: methotrexate, cyclosporine, acitretin OR phototherapy (UVB, PUVA) **AND** • Failure of a minimum 12 weeks (or documented intolerable adverse event) of all available formulary alternatives: Infliximab, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), Enbrel, Cosentyx, Otezla, Ilumya, Cimzia • QL – Initial (one time only)– 0.5 to 1 ml per 28-day supply (based on patient weight) • QL – Continuation – 1 ml per 84-day supply (based on patient weight) **<u>Psoriatic Arthritis (PsA)</u>** • Failure of at least 12 weeks with methotrexate, or if unable to tolerate or contraindicated to methotrexate, another disease modifying antirheumatic drug (sulfasalazine, cyclosporine, leflunomide) **AND** • Failure of a minimum 12 weeks (or documented intolerable adverse event) of all available formulary alternatives: Infliximab, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), Enbrel, Otezla, Cosentyx, Xeljanz, Simponi Aria, Cimzia, Orencia (SQ or IV) • QL – Initial (one time only)– 0.5 to 1 ml per 28-day supply • QL – Continuation – 0.5 to 1 ml per 84-day supply **<u>Crohn's Disease</u>** • Documented failure with at least two oral treatments for a minimum of 12 weeks: ○ corticosteroids, 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
	• Failure of minimum 12 weeks or provided rationale for avoidance of all available formulary alternatives: Infliximab, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), Cimzia, Entyvio
	• QL – Initial (one time only) IV dose based on weight, followed by 1 ml per 56-day supply
	  ○ 55 kg or less: 260 mg
	  ○ More than 55 kg to 85 kg: 390 mg
	  ○ More than 85 kg: 520 mg
	
	<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
	• Failure of minimum 12- weeks (or documented intolerable adverse event) to all available formulary alternatives: Infliximab, Adalimumab (preferred biosimilars: Adalimumab-fkjp, Hadlima, Adalimumab-adaz), Cimzia, Entyvio
	• QL – Initial (one time only) IV dose based on weight, followed by 1 ml per 56-day supply
	  ○ 55 kg or less: 260 mg
	  ○ More than 55 kg to 85 kg: 390 mg
	  ○ More than 85 kg: 520 mg
	
	<u>Reauthorization</u> will require 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:	• 6 years and older
Prescriber/Site of Care Restrictions:	**Plaque psoriasis and Psoriatic arthritis:** prescribed by, or in consultation with, a dermatologist/rheumatologist **Crohn's Disease and Ulcerative Colitis:** prescribed by, or in consultation with, a GI specialist
Coverage Duration:	Initial Authorization: 6 months initiation, unless otherwise specified Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
VAGINAL CONTRACEPTIVES
Affected Medications: Annovera (J7294), Nuvaring (J7295)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	**For Annovera and Nuvaring through the medical benefit:** • Failure, contraindication, or reason for avoidance to all covered formulary products for treatment of your condition.
Appropriate Treatment Regimen & Other Criteria:	• FDA-approved or compendia supported dosing.
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
VAGINAL PROGESTERONE
Affected Medications: FIRST-PROGESTERONE VGS 100,200, or 400MG (vaginal progesterone)

Covered Uses:	• Prevention of preterm birth in pregnant women with a singleton pregnancy and prior history of preterm delivery before 37 weeks gestation or short cervical length
Required Medical Information:	• Singleton pregnancy • History of singleton spontaneous preterm birth before 37 weeks gestation or short cervical length defined as less than 20 mm
Appropriate Treatment Regimen & Other Criteria:	**History of singleton spontaneous preterm birth (HSPB)** • May initiate therapy beginning at 16 to 20 weeks gestation and continue until 36+6 weeks gestation **Short cervical length (SCL)** • May initiate therapy beginning at 0 to 24 weeks gestation (with pregnancy confirmed by positive test) and continue until 36+6 weeks gestation
Exclusion Criteria:	• Treatment of infertility
Age Restriction:	
Prescriber Restrictions:	• Prescribed by, or in consultation with, a gynecologist or obstetrician
Coverage Duration:	• HSPB: up to 20 weeks, unless otherwise specified • SCL: up to 36+6 weeks, unless otherwise specified

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 (Vedolizumab)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
	  ○ Crohn's disease
	  ○ Ulcerative Colitis

Required documentation:	**<u>All Indications:</u>** • Diagnosis supported by colonoscopy/endoscopy/sigmoidoscopy/biopsy • Documentation of moderate to severe disease despite current treatment (Indication must be documented in chart notes within the last 6 months) • Documentation of complete and current treatment course **<u>Crohn's disease</u>** • Documentation of moderate to severely active disease despite current treatment **<u>Ulcerative Colitis</u>** • Documentation of disease severity Mayo Clinic Score for Assessment of Ulcerative Colitis Activity score

Appropriate Treatment Regimen:	**<u>Crohn's disease</u>**
	• Documented treatment failure with at least two oral treatments for minimum of 12 weeks trial: corticosteroids, azathioprine, 6-mercaptopurine, methotrexate, sulfasalazine, balsalazide
	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
	• 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 12 weeks of Infliximab (preferred biosimilar products Inflectra, Renflexis, Avsola)
	
	<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 12 weeks of Infliximab (preferred biosimilar products Inflectra, Renflexis, Avsola)
	
	• Quantity Limit:
	  ○ Initial: 300mg at week 0,2, and 6
	  ○ Maintenance: 300mg every 8 weeks
	
	<u>Consideration of every 4 week dosing for all indications:</u>
	• Documented clinical failure to Entyvio at standard dosing for at least 6 months
	• Clinical failure defined as failure to achieve a clinical response (greater than or equal to 70 point improvement in CDAI score for Crohn's)
	
	<u>Dosing:</u>
	• Availability: 300 mg single-use vials
	• Crohn's/UC: 300 mg at 0, 2 and 6 weeks followed by every 8 weeks thereafter
	  ○ May be decreased to every 4 weeks
	
	<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:	
Provider Restriction:	• Prescribed by, or in consultation with, a gastroenterologist
Approval Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified

POLICY NAME:
VELAGLUCERASE ALFA
Affected Medications: VPRIV (velaglucerase alfa)

Covered Uses:	• All Food and Drug Admninistration (FDA)-approved indications not otherwise excluded by plan design.
Required Medical Information:	• Patient has a diagnosis of type 1 Gaucher disease. • Diagnosis of Gaucher disease is confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity. • Therapy is initiated for a patient with one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly.
Appropriate Treatment Regimen & Other Criteria:	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced for all medical infusion drugs **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Concomitant therapy with miglustat
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified.

PacificSource Community Solutions

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

POLICY NAME:
VERTEPORFIN INJECTION
Affected Medications: VISUDYNE (verteporfin)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Predominantly classic subfoveal choroidal neovascularization (CNV) due to age-related macular degeneration (AMD), pathologic myopia or presumed ocular histoplasmosis
Required Medical Information:	• Subfoveal choroidal neovascularization (CNV) lesions caused by age-related macular degeneration (AMD); *or* • Chronic (greater than 4 months) central serous chorioretinopathy; or • Ocular histoplasmosis; *or* • Pathologic myopia • Note: Most individuals treated with verteporfin will need to be re-treated every 3 months. All individuals having a re-treatment will need to have a flourescein angiogram or ocular coherence tomography (OCT) performed prior to each treatment. Re-treatment is necessary if fluorescein angiograms or OCT show any signs of recurrence or persistence of leakage

Appropriate Treatment Regimen & Other Criteria:	• Approval requires documented treatment failure or intolerable adverse event with at least 3 months of Avastin and ranibizumab (preferred biosimilar products: Byooviz, Cimerli)
	• Dosing: 6 mg/m2 body surface area given intravenously; may repeat at 3-month intervals (if evidence of choroidal neovascular leakage)
	  ○ Available as 15 mg vials
	  ○ Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	• Reauthorization requires documented treatment success and continued need for treatment with the non-preferred product

Exclusion Criteria:	
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:
VESTRONIDASE ALFA
Affected Medications: MEPSEVII (vestronidase alfa-vjbk)

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

Required Medical Information:	• Definitive diagnosis of Mucopolysaccharidosis VII (MPS VII; Sly syndrome) syndrome confirmed by BOTH of the following:
	  ○ Beta-glucuronidase enzyme deficiency in peripheral blood leukocytes AND
	  ○ Detection of pathogenic mutations in the GUSB gene by molecular genetic testing
	• Baseline value for one or more of the following:
	  ○ Bruininks-Oseretsky Test of Motor Proficiency
	  ○ 6-minute walk test
	  ○ Liver and/or spleen volume
	  ○ Pulmonary function tests

Appropriate Treatment Regimen & Other Criteria:	• 4 mg/kg infusion every 2 weeks
	• Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced
	
	Reauthorization will require:
	• Documentation of absence of unacceptable toxicity (ex. anaphylaxis or severe allergic reactions) AND
	• Patient has responded to therapy compared to pretreatment baseline in one or more of the following:
	  ○ Improvement in Bruininks-Oseretsky Test of Motor Proficiency
	  ○ Improvement in 6-minute walk test
	  ○ Reduction in liver and/or spleen volume
	  ○ Stability or improvement in pulmonary function tests

Exclusion Criteria:	
Age Restriction:	• Age 8 - 25 years
Prescriber Restrictions:	• Prescribed by, or in consultation with, a prescriber with experience in treating MPS
Coverage Duration:	• Initial approval: 2 months, unless otherwise specified • Reauthorization: 6 months, unless otherwise specified

POLICY NAME:
VIGABATRIN
Affected Medications: SABRIL (vigabatrin), vigabatrin packet

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:	• Documentation of baseline vision assessment by an ophthalmologist • Documentation that the potential benefits outweigh the risk of vision loss
Appropriate Treatment Regimen & Other Criteria:	**Infantile Spasm** • Use as monotherapy for pediatric patients (1 month to 2 years of age) **Refractory Complex Partial Seizures (focal seizures with impaired awareness)** • As adjunctive therapy only • Documentation the patient has tried at least 2 alternative therapies: carbamazepine, phenytoin, levetiracetam, topiramate, oxcarbazepine, or lamotrigine **Reauthorization:** • Vision assessment by an ophthalmologist with no documented vision loss from baseline • Documented planned reassessments every 3 months during therapy • Documentation of substantial clinical benefit (within 3 months of initiation; within 2-4 weeks of initiation for patients with infantile spasms or sooner if treatment failure becomes obvious)
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:	
Coverage Duration:	• Initial approval: 6 months, unless otherwise specified • Reauthorization: 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 ○ PIK3CA-related overgrowth spectrum (PROS)
Required Medical Information:	• Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) with severe clinical manifestations of lesions as assessed by the treating provider (such as those associated with CLOVES, Megalencephaly-Capillary Malformation Polymicrogyria [MCAP], Klippel-Trenaunay Syndrome [KTS], Facial Infiltrating Lipomatosis [FIL]) • Documentation of PIK3CA gene mutation • 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:	• Documentation that severe 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
	• 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:	• Ensure use is within 96 hours of fluorouracil/capecitabine treatment • Administer full course of 20 doses • Not recommended for non-emergent treatment of adverse events associated with fluorouracil or capecitabine because it may diminish the efficacy of these drugs
Exclusion Criteria:	
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)

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:	**<u>Chorea related to Huntington's Disease</u>**
	• Diagnosis of Huntington's Disease with Chorea requiring treatment
	
	<u>Tardive Dyskinesia</u>
	• 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:	**<u>Tardive Dyskinesia</u>** • 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:	• Untreated or inadequately treated depression or suicidal ideation • Concomitant use of a monoamine oxidase inhibitors (MAOIs) • 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 6 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. * Lifetime maximum 12 months of therapy.		

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

POLICY NAME:
VORICONAZOLE
Affected Medications: VFEND tablet; Voriconazole tablet; VFEND Intravenous; Voriconazole Intravenous

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded from benefit design. • Empiric treatment of presumed fungal infections in febrile neutropenic, high-risk patients pending susceptibility cultures. • Continuation therapy for patients started/stabilized on intravenous (IV) or oral voriconazole for a systemic infection.

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
	• **Esophageal candidiasis**
	  ○ Trial of one other systemic agent (such as fluconazole, IV amphotericin B, itraconazole)

Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	
Age Restriction:	• Patients older than 2 years of age
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 month, unless otherwise specified

PacificSource Community Solutions

POLICY NAME:
VOSORITIDE
Affected Medications: VOXZOGO

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 who are 5 years of age and older with open epiphyses.
Required Medical Information:	• Genetic test results confirming achondroplasia. • Baseline height, growth velocity, and patient weight.

Appropriate Treatment Regimen & Other Criteria:	• For initial approval, documentation of the following is required:
	  ○ Evaluation of epiphyses (growth plates) documenting they are open.
	  ○ Growth velocity greater than or equal to 1.5 cm/yr.
	• **Reauthorization:**
	  ○ 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:	• Age 5 to 18 years
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

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

POLICY NAME:
XEOMIN, DYSPORT and MYOBLOC
Affected Medications: XEOMIN (incobotulinumtoxinA), DYSPORT (AbobotulinumtoxinA), MYOBLOC (RimabotulinumtoxinB), JEUVEAU (prabotulinumtoxinA-xvfs)

Covered Uses:	• All Food and Drug Administration (FDA)-approved indications not otherwise excluded by plan design
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, hemifacial spasm, orofacial dyskinesia, upper or lower limb spasticity **Xeomin** • For the uses of cervical dystonia and upper limb spasticity documented failure with Botox and Dysport is required • In the treatment of blepharospasm, documented failure with Botox is required **Myobloc** • For the treatment of cervical dystonia documented failure with Botox and Dysport is required • For the treatment of overactive bladder or urinary incontinence due to spinal cord injury, documented failure with Botox is required **Jeuveau** • Jeuveau is only indicated in the treatment of cosmetic conditions and is excluded from coverage **Other criteria** • All indications not listed are considered experimental/investigational and are not a covered benefit • Maximum of 4 treatments per 12 months (2 treatments for Myobloc in overactive bladder) **Reauthorization** requires documented treatment success and a clinically significant response to therapy
Exclusion Criteria:	• Cosmetic procedures • Headaches/Migraines • Hemifacial spasm: no longer above the line on the prioritized list • For intradetrusor injections: documented current/recent urinary tract infection or urinary retention • Current aminoglycoside use (or current use of other agents interfering with neuromuscular transmission) • Use in the treatment of sialorrhea

Age Restriction:	• ≥18 years old for Myobloc
Prescriber Restrictions:	• Blepharospasm: ophthalmologist or optometrist • OAB or urinary incontinence due to neurologic condition: urologist or neurologist • Documentation of consultation with any of the above specialists mentioned
Coverage Duration:	Overactive Bladder: • Initial approval: 3 months • Reauthorization: 12 months, unless otherwise specified All other indications • 12 months, unless otherwise specified

POLICY NAME:
XGEVA
Affected Medications: XGEVA (denosumab)

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:	• One of these diagnoses
	  ○ **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 of the Bone: Adolescents (at least 12 years of age and skeletally mature) weighing at least 45 kg • All other indications: Age 18 years and 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 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:	• Prior intolerance or allergic reaction to requested medication
Age Restriction:	
Provider Restriction:	
Coverage Duration:	• Dupuytren's: 12 weeks, unless otherwise specified per impacted contracture (separate approval is required for each impacted cord for treatment of Dupuytren's contracture)

PacificSource Community Solutions

POLICY NAME:
XIFAXAN
Affected Medications: XIFAXAN (rifaximin)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design. • Treatment of complex Clostridium difficile infection in select populations
Required Medical Information:	• Documentation of complete & current treatment course required. • Previous antibiotic history and documented allergies/hypersensitivity
Appropriate Treatment Regimen & Other Criteria:	**For C. difficile disease:** • Patient must have failed oral vancomycin for coverage to be considered **For recurrent or persistent hepatic encephalopathy:** • Patient has failed or has contraindication to 30 day attempt of lactulose therapy, with documentation of continued altered mental status or elevated ammonium levels despite adequate upward titration of lactulose. **Reauthorization** will require documentation of treatment success and a clinically significant response to therapy
Exclusion Criteria:	**For C. difficile disease:** • Xifaxan 200 mg tablets with a quantity supply exceeding 20 days of a quantity of 120 for C. diff infection. **For recurrent or persistent hepatic encephalopathy:** • Xifaxan exceeding the recommended dose of two 550 mg tablets daily for treatment or 400 mg 3 times daily for the prevention of hepatic encephalopathy.
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Clostridium difficile infection: 20 days, unless otherwise specified • Hepatic encephalopathy: 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.
Required Medical Information:	• Diagnosis of hereditary orotic aciduria • Urine orotic acid levels • Patient weight
Appropriate Treatment Regimen & Other Criteria:	• Documentation of weight based dosing • **Reauthorization** requires documentation of treatment success based on laboratory values
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	• In consultation with geneticist specialist
Coverage Duration:	• Approval: 12 months, unless otherwise specified

PacificSource Community Solutions

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

POLICY NAME:
ZAFIRLUKAST
Affected Medications: Zafirlukast

Covered Uses:	• All Food and Drug Admninistration (FDA)-approved indications not otherwise excluded by plan design ○ Prophylaxis and chronic treatment of asthma in adults and children 5 years of age and older
Required Medical Information:	• Documentation of current diagnosis of asthma OR exercise induced bronchospasm AND • Treatment failure with montelukast • Reauthorization requires documentation of treatment success
Appropriate Treatment Regimen & Other Criteria:	
Exclusion Criteria:	
Age Restriction:	
Prescriber Restrictions:	
Coverage Duration:	• Approval: 12 months, unless otherwise specified

POLICY NAME:
ZORBTIVE
Affected Medications: ZORBTIVE (somatropin)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design.
Required Medical Information:	• Diagnosis of short bowel syndrome (SBS) receiving specialized nutritional support.
Appropriate Treatment Regimen & Other Criteria:	• Patients must be receiving specialized nutritional support (e.g., TPN, IPN, PPN, rehydration solutions, electrolyte replacement, high complex-carbohydrate, low-fat diet) in conjunction with optimal management of SBS. • Dose-rounding to the nearest vial size within 10% of the prescribed dose will be enforced for all medical infusion drugs
Exclusion Criteria:	• Active malignancy (newly diagnosed or recurrent). • Acute critical illness due to complications following open heart or abdominal surgery, accidental trauma or acute respiratory failure. • Active proliferative or severe non-proliferative diabetic retinopathy.
Age Restriction:	• 18 years or older
Prescriber Restrictions:	
Coverage Duration:	• Approval: 4 weeks with no reauthorization, unless otherwise specified.

PacificSource Community Solutions

POLICY NAME:
ZYNTEGLO
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 able to provide a minimum number of cells ($5x10^6$ 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