2026 PacificSource Health Plans Formulary Exception and Tier Exception Criteria

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PacificSource HEALTH PLANS

Contents

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COMMERCIAL FORMULARY EXCEPTION CRITERIA

Purpose:

The purpose of this policy is to establish criteria for which exceptions to the formulary, or drug list, may be allowed. A drug formulary is used to encourage safe, effective, and economical prescribing of drugs.

Exception criteria:

- The member has documented intolerance or failure to the formulary alternatives for the submitted diagnosis.
- The dosage and indication are within the Food and Drug Administration (FDA) approved labeling.
- The requested drug will not be used in a manner that is considered experimental. This includes concomitant use with other drugs in a manner considered experimental.
- The provider has demonstrated that there are no other medically reasonable formulary options.

Resources used for making utilization decisions and developing criteria may include:

- Food and Drug Administration (FDA) approved label
- Nationally recognized utilization management criteria and established practice guidelines, such as National Comprehensive Cancer Network (NCCN)
- Medicare-approved compendia (American Hospital Formulary Service-Drug Information (AHFS-DI), NCCN, Micromedex)
- Peer-reviewed medical literature
- In-network and out-of-network physician specialty consultants
- Members of the Pharmacy and Therapeutics (P&T) committee or outside consultants
- Other commercial health plan criteria, including posted PacificSource medical prior authorization criteria for requested treatment

Reauthorization will require documentation of treatment success and a clinically significant response to therapy.

Approval duration: 12 months, unless otherwise specified.
*If approved, drug will pay at Tier 3 (if non-specialty) and Tier 4 (if specialty) copay.
**Maximum allowable cost (MAC) penalty may apply.

COMMERCIAL TIER EXCEPTION CRITERIA

Purpose:

The purpose of this policy is to establish criteria for which exceptions to the benefit tier structure may be allowed.

A Tier Exception (TE) is when a drug is covered at a lower cost sharing tier. Considerations for TE approval include:

- Tier exceptions are only available from Tier 3 to Tier 2
- Tier 1 and Specialty drugs are not eligible for Tier Exceptions
- All lower tier options have been tried and found not effective
- Must be considered high risk medication:
    - Anti-seizure treatment
    - Transplant immunosuppressant
- Drug must be on member's current formulary (non-formulary drugs, including approved formulary exception authorizations, are not eligible for a tier exception)

Approval Duration: 12 months, unless otherwise specified

POLICY NAME:
FORMULARY EXCEPTION CRITERIA - ZEPBOUND
Affected Medications: ZEPBOUND (tirzepatide)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design ○ Treat moderate to severe obstructive sleep apnea (OSA) in combination with a reduced-calorie diet and increased physical activity in adults with obesity
Required Medical Information:	• Diagnosis of moderate to severe obstructive sleep apnea (OSA) with Apnea-Hypopnea Index (AHI) of at least 15 on polysomnography or home sleep study from the past 5 years • Body mass index (BMI) of 30 kg/m^2 or greater • Current symptoms of OSA such as excessive daytime sleepiness, loud snoring, choking, gasping, pauses in breathing, sleep arousals, and difficulty maintaining sleep throughout the night • Documentation of being used in combination with a physician-directed weight loss program that involves a reduced calorie diet, increased physical activity, and behavioral modification

Appropriate Treatment Regimen & Other Criteria:	• Documented intolerance or treatment failure with the formulary alternatives for the submitted diagnosis
	• Documentation of one of the following:
	  ○ Treatment failure with positive airway pressure (PAP) therapy, defined as having continued symptoms of OSA despite four or more hours of PAP use per night for 70 percent or more of nights
	  ○ Contraindication to PAP therapy (such as upper airway anatomic abnormalities, pneumothorax or invasive mechanical ventilation)
	• Documentation of being prescribed concurrently with positive airway pressure (PAP) therapy, unless contraindicated or clinically significant adverse effects are experienced
	
	Reauthorization requires documentation of treatment success defined by all the following:
	• Improvement in AHI score or OSA symptoms such as excessive daytime sleepiness, loud snoring, choking, gasping, pauses in breathing, sleep arousals, and difficulty maintaining sleep throughout the night
	• Achieved and maintained 10 percent or greater weight loss after starting Zepbound (tirzepatide)
	• Continued adherence to a reduced calorie diet, increased physical activity, and behavioral modification program

Exclusion Criteria:	• Use for weight loss (no OSA diagnosis) or other excluded diagnosis • Diagnosis of type 1 or type 2 diabetes with or without OSA • Diagnosis of central or mixed sleep apnea • Diagnosis of obesity hypoventilation syndrome or daytime hypercapnia • History of ketoacidosis • Personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) • Concurrent use of other glucagon-like peptide-1 (GLP-1) receptor agonists

Age Restriction:	• 18 years of age or older
Prescriber/Site of Care Restrictions:	• All approvals are subject to utilization of the most cost-effective site of care
Coverage Duration:	• Authorization: 12 months

POLICY NAME:
FORMULARY EXCEPTION CRITERIA - WEGOVY
Affected Medications: WEGOVY (semaglutide)

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
	  ○ Treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults in combination with a reduced calorie diet and increased physical activity
	  ○ To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight

Required Medical Information:	**<u>Major Adverse Cardiovascular Event (MACE) Risk Reduction:</u>**
	• Documented history of a prior cardiovascular event defined as one of the following:
	  ○ Myocardial infarction
	  ○ Stroke (ischemic or hemorrhagic stroke)
	  ○ Symptomatic peripheral artery disease (PAD) such as intermittent claudication with ankle-brachial index (ABI) less than 0.85 at rest, or history of peripheral arterial revascularization procedure
	• Body mass index (BMI) of 27 kg/m2 or greater
	• Used in combination with caloric restriction (diet), increased physical activity, and behavioral modification
	
	<u>Metabolic dysfunction-associated steatohepatitis (MASH):</u>
	• Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or MASH with moderate to advanced (F2 to F3) liver fibrosis confirmed by ONE of the following:
	  ○ Conclusive result from a well-validated non-invasive test such as:
	  ▪ Fibroscan-AST (FAST) score
	  ▪ MAST (score from MRI–proton density fat fraction, Magnetic resonance elastography [MRE], and serum AST)
	  ▪ MEFIB (Fibrosis-4 Index greater than or equal to 1.6 and MRE greater than or equal to 3.3 kPa)
	  ○ Liver biopsy (also required if non-invasive testing is inconclusive or other causes for liver disease have not been ruled out)
	• Other causes for liver steatosis have been ruled out (such as alcohol-associated liver disease, chronic hepatitis C, Wilson disease, drug-induced liver disease)
	• Baseline lab values for AST and ALT

Appropriate Treatment	**<u>MACE Risk Reduction:</u>** • Documented intolerance or treatment failure with the formulary alternatives for cardiovascular disease, including:

Regimen & Other Criteria:	○ Lipid lowering agents ○ Anti-platelets and anticoagulants ○ Antihypertensive agents **Reauthorization:** • Documentation of treatment success (MACE risk reduction) **<u>MASH:</u>** • Documented treatment failure (or intolerable adverse event) with at least 12 weeks of one of the following: Mounjaro, Ozempic, Trulicity, liraglutide, or Rybelsus • Documentation of abstinence from alcohol consumption • Documentation of comprehensive comorbidity management being undertaken, including all the following: ○ Use of diet and exercise for weight management ○ Medications to manage associated comorbid conditions, such as thyroid disease (must not have active disease), diabetes, dyslipidemia, hypertension, or cardiovascular conditions. **Reauthorization:** Documentation of disease responsiveness to therapy based on improvements or stability in laboratory results, such as ALT and AST, or fibrosis as evaluated by a non-invasive test
Exclusion Criteria:	• Use for weight loss (no MACE or MASH diagnosis) or other excluded diagnosis • Diagnosis of type 1 or type 2 diabetes without MACE or MASH
Age Restriction:	• 18 years of age or older
Prescriber/Site of Care Restrictions:	• Prescribed by, or in consultation with, a cardiologist (MACE reduction) • Prescribed by, or in consultation with, a gastroenterologist or hepatologist (MASH/NASH) • All approvals are subject to utilization of the most cost-effective site of care
Coverage Duration:	• Authorization: 12 months, unless otherwise specified

POLICY NAME:
FORMULARY EXCEPTION CRITERIA - NURTEC
Affected Medications: NURTEC

Covered Uses:	• All Food and Drug Administration (FDA) approved indications not otherwise excluded by plan design
Required Medical Information:	• The member has documented intolerance or failure to the formulary alternatives for the submitted diagnosis • The dosage and indication are within the Food and Drug Administration (FDA) approved labeling • The provider has demonstrated that there are no other medically reasonable formulary options
Appropriate Treatment Regimen & Other Criteria:	Quantity limits: • Acute treatment of migraine in adults: 8 tablets per 30 days • Preventative treatment of migraine in adults: 16 tablets per 30 days
Exclusion Criteria:	• Combined use with Botox for the prevention of migraine • Combined use with another calcitonin gene-related peptide (CGRP) inhibitor (acute or preventative)
Age Restriction:	
Prescriber/Site of Care Restrictions:	
Coverage Duration:	• Initial Authorization: 6 months, unless otherwise specified • Reauthorization: 12 months, unless otherwise specified