Pharmacy Medical Necessity Guidelines:
Pharmacy Products Without Specific Criteria

Effective: October 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

In order to promote clinically appropriate and cost-effective prescription drug use, Tufts Health RITogether has several programs in place, one of which is the review process for drugs without drug- or drug class-specific criteria.

Drugs not listed on our Preferred Drug List (PDL) are reviewed against the criteria listed in this Medical Necessity Guideline. Drugs are not listed on our PDL because there are safe, comparably effective alternatives available or there are generic versions of the brand-name product available. Alternatives listed on our PDL are approved by the U.S. Food and Drug Administration (FDA) and are widely used and accepted by the medical community to treat the same condition as the medications that are not listed.

COVERAGE GUIDELINES

Products without specific criteria that do not have an A-rated generic

The plan may authorize coverage of products without an A-rated generic not included on the Preferred Drug List (PDL) for Members when **ALL** of the following criteria are met:

1. The requested drug must be FDA-approved for the medical condition or the off-label use must be supported by medical evidence from compendia or current literature

AND

2. Documentation that the Member had an inadequate response or adverse reaction to an alternative formulation if the generic ingredient is available as an alternative product and is listed on the PDL or over-the-counter (OTC) list; if an alternative product is available but restricted the Member must meet those coverage guidelines

AND

3. Documentation that the Member had an inadequate response or adverse reaction to therapy with at least **TWO** alternative agents included in the PDL or OTC list from the same therapeutic drug class, or **ONE** agent based on availability, or the Member has a contraindication to the alternative agents; if alternative agents are available but restricted the Member must meet those coverage guidelines

For combination products (in addition items 1, 2, and 3 above)

4. If the individual products are available and covered on the PDL, the provider must document concerns with using the individual products

AND

5. If the individual products are restricted the Member must meet those coverage guidelines

For schedule II, III, and IV analgesics (in addition to items 1, 2, and 3 above):

4. The Member is diagnosed with sickle cell-related, cancer-related, or end-of-life pain

OR

5. The Member has a diagnosis of pain

AND

If the request is for a long-acting agent, then the Member has had an inadequate response to an immediate-release opioid

AND

The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

AND

The risks of schedule II, III, and IV analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

AND

The provider has a plan in place to monitor the Member for misuse, abuse, and addiction during therapy

AND

For dosage forms that exceed 90 MME/day with one unit dose or as prescribed per the FDA-approved package labeling:

a. Clinical rationale why the member requires a higher opioid dose

AND

b. The analgesic is prescribed by or in consultation with a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist OR there is a plan for the member to be referred to a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist

AND

c. The provider has a taper plan in place or has a rationale as to why a dose taper is not appropriate at this time

Products without specific criteria that have an A-rated generic

In addition to any restrictions on the PDL for the A-rated generic, the plan may authorize coverage of products with an A-rated generic not included on the PDL for Members when the following criteria are met:

1. There is a drug shortage of the generic product

OR

2. Provider documentation that a change to the generic (for a narrow therapeutic index medication) could result in instability of the Member's medical condition provided the medication is not in the schedule II, III or IV

OR

3. Documentation of BOTH of the following
   a) The Member had a inadequate response or adverse reaction with two or more formulary alternative medications (when available), including the A-rated generic

   AND

   b) The Member has an allergy to an ingredient in the A-rated generic that is not contained in the brand-name product

For schedule II, III, and IV analgesics (in addition to items 1, 2, or 3 above):

4. The Member is diagnosed with sickle cell-related, cancer-related, or end-of-life pain

OR

5. The Member has a diagnosis of pain

AND

If the request is for a long-acting agent, the Member has had an inadequate response to an immediate-release opioid

AND

The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

AND

The risks of schedule II, III, and IV analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

AND

The provider has a plan in place to monitor the Member for misuse, abuse, and addiction during therapy

AND

For dosage forms that exceed 90 MME/day with one unit dose or as prescribed per the FDA-approved package labeling:

a) Clinical rationale why the member requires a higher opioid dose

AND

b) The analgesic is prescribed by or in consultation with a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or

hematologist/oncologist OR there is a plan for the member to be referred to a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist

AND

c) The provider has a taper plan in place or has a rationale as to why a dose taper is not appropriate at this time

Renewal of schedule II, III, IV analgesics

1. The Member continues to have a diagnosis of sickle cell-related, cancer-related, or end-of-life pain and is stable on the requested agent

OR

2. The Member meets **ALL** of the following:
   a) The Member continues to require pain management

   AND

   b) The Member has experienced an improvement in function/pain while on the prescribed analgesic

   AND

   c) The provider attests that there are no concerns of substance abuse or misuse while taking the prescribed analgesic

   AND

   d) The Member has not experienced respiratory depression or cognitive impairment while taking the prescribed analgesic

   AND

   e) The prescriber confirms that a current Member-signed pain management agreement consistent with the American Academy of Pain Management guidelines is in place

   AND

   f) Member's regimen has been reassessed and there is either a taper plan in place or documentation that tapering the agent is not appropriate at this time

Wegovy (semaglutide)

The plan may authorize coverage of Wegovy (semaglutide injection or tablet) for Members when the following criteria are met:

Risk Reduction of Major Adverse Cardiovascular Events

Initial Authorization

1. Member has established cardiovascular disease as defined by **ONE (1)** of the following:
   a. History of myocardial infarction
   b. History of stroke
   c. Symptomatic peripheral artery disease (e.g., intermittent claudication with ankle-brachial index less than 0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)

   AND

2. Member is at least 18 years of age or older

   AND

3. Member has baseline body mass index (BMI) greater than or equal to 27 kilograms per square meter

   AND

4. Requested medication will be used in combination with a reduced-calorie diet and increased physical activity

   AND

5. Member does not have diagnosis of type 1 or type 2 diabetes

   AND

6. Member is currently receiving at least **ONE (1)** of the following standard of care therapy for established cardiovascular disease, unless contraindicated:
   a. Lipid lowering therapy (e.g., statin)
   b. Antiplatelet therapy (e.g., aspirin, clopidogrel)
   c. Antihypertensive therapy (e.g., angiotensin converting enzyme inhibitor, angiotensin II receptor blocker, beta blocker)

   AND

7. Requested medication will not be used in combination with another GLP-1 receptor agonist

Reauthorization

1. Member has established cardiovascular disease as defined by **ONE (1)** of the following:
    a. History of myocardial infarction
    b. History of stroke
    c. Symptomatic peripheral artery disease (e.g., intermittent claudication with ankle-brachial index less than 0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)

AND

2. Requested medication will continue to be used in combination with a reduced-calorie diet and increased physical activity

AND

3. Member does not have diagnosis of type 1 or type 2 diabetes

AND

4. Member is currently receiving at least **ONE (1)** of the following standard of care therapy for established cardiovascular disease, unless contraindicated:
    a. Lipid lowering therapy (e.g., statin)
    b. Antiplatelet therapy (e.g., aspirin, clopidogrel)
    c. Antihypertensive therapy (e.g., angiotensin converting enzyme inhibitor, angiotensin II receptor blocker, beta blocker)

AND

5. Requested medication will not be used in combination with another GLP-1 receptor agonist

AND

6. Attestation from the provider that continuation of therapy with the requested medication is expected to maintain cardiovascular risk reduction and remains clinically beneficial for the Member

AND

7. Member is currently taking the requested medication at maintenance dose recommended by Food and Drug Administration (FDA) for cardiovascular risk reduction (e.g., either 1.7 milligram or 2.4 milligram once weekly for injection or 25 milligram once daily for tablet)

Noncirrhotic Metabolic Dysfunction-associated Steatohepatitis (MASH)

Initial Authorization

1. Member has documented diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) or nonalcoholic steatohepatitis (NASH)

AND

2. Submission of medical records confirming the diagnosis of MASH or NASH with moderate to advanced liver fibrosis consistent with stages F2 or F3 fibrosis as evidenced by liver biopsy or validated noninvasive fibrosis assessment [e.g., liver stiffness measurement (LSM) measured by vibration controlled transient elastography (VCTE), magnetic resonance elastography (MRE), enhanced liver fibrosis (ELF) score]

AND

3. Member is at least 18 years of age or older

AND

4. Requested medication is prescribed by or in consultation with hepatologist, gastroenterologist, or prescriber experienced in the management of chronic liver disease

AND

5. Requested medication will be used in combination with a reduced-calorie diet and increased physical activity

AND

6. Attestation from the provider that Member has been counseled to limit alcohol use

AND

7. Requested medication will not be used in combination with another GLP-1 receptor agonist

AND

8. Request is for Wegovy (semaglutide) injection

Reauthorization

1. Documentation that requested medication will continue to be used for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) or nonalcoholic steatohepatitis (NASH)

AND

2. Requested medication is prescribed by or in consultation with hepatologist, gastroenterologist, or prescriber experienced in the management of chronic liver disease

AND

3. Requested medication will continue to be used in combination with a reduced-calorie diet and increased physical activity

AND

4. Attestation from the provider that Member has been counseled to limit alcohol use

AND

5. Requested medication will not be used in combination with another GLP-1 receptor agonist

AND

6. Request is for Wegovy (semaglutide) injection

AND

7. Documentation that Member has demonstrated positive clinical response as evidenced by **ONE (1)** of the following:
    a. Improvement in liver histology assessed by liver biopsy
    b. Reduction from baseline in **ONE (1)** of the following assessments: vibration-controlled transient elastography liver stiffness measurement (VCTE LSM), magnetic resonance elastography liver stiffness measurement (MRE LSM), magnetic resonance imaging-proton density fat fraction (MRI-PDFF), alanine aminotransferase (ALT), or enhanced liver fibrosis testing (ELF)

AND

8. Member has not had progression to cirrhosis or hepatic decompensation

AND

9. Member is currently taking the requested medication at maintenance dose recommended by Food and Drug Administration (FDA) for noncirrhotic MASH (e.g., either 2.4 milligram once weekly or 1.7 milligram once weekly if member is intolerant to 2.4 milligram once weekly)

Zepbound (tirzepatide)

The plan may authorize coverage of Zepbound (tirzepatide) for Members when the following criteria are met:

Initial Authorization

1. Member has documented diagnosis of moderate to severe obstructive sleep apnea

AND

2. Submission of medical records confirming the diagnosis of moderate to severe obstructive sleep apnea defined as Apnea-Hypopnea Index (AHI) of at least 15 events per hour based on sleep study (polysomnography or home sleep apnea test)

AND

3. Member is at least 18 years of age or older

AND

4. Member has baseline body mass index (BMI) greater than or equal to 30 kilograms per square meter

AND

5. Documentation of inadequate response to at least 30 days trial, intolerance, or contraindication to **ONE (1)** of the following: constant positive airway pressure (CPAP), auto-adjusting positive airway pressure (APAP), or bilevel positive airway pressure (BiPAP)

AND

6. Member does not have diagnosis of type 2 diabetes mellitus

AND

7. Requested medication will be used in combination with a reduced-calorie diet and increased physical activity

AND

8. Requested medication will not be used in combination with another GLP-1 receptor agonist

Reauthorization

1. Documentation that requested medication will continue to be used for the treatment of obstructive sleep apnea

AND

2. Member does not have diagnosis of type 2 diabetes mellitus

AND

3. Requested medication will continue to be used in combination with a reduced-calorie diet and increased physical activity

AND

4. Requested medication will not be used in combination with another GLP-1 receptor agonist

AND

5. Documentation that Member has demonstrative positive clinical response as evidenced by **ONE (1)** of the following:
    a. Reduction in Apnea-Hypopnea Index (AHI) from baseline
    b. Improvement in obstructive sleep apnea symptoms (e.g., less daytime sleepiness, fewer sleep arousals, fewer partner reported snoring episodes or pauses in breathing)

AND

6. Member is currently taking the requested medication at maintenance dose recommended by Food and Drug Administration (FDA) for obstructive sleep apnea (e.g., either 10 milligram or 15 milligram once weekly)

LIMITATIONS

All requests:

1. Durable medical equipment (with the exception of blood glucose/ketone test strips and monitors [including continuous glucose monitors]), blood plasma products, infant formulas, nutritional supplements, and contraceptive implants should be deferred to the medical benefit for coverage.
2. Medications requiring skilled healthcare administration should be provided by healthcare providers and deferred to the medical benefit for coverage determination.
3. Requests for medications used for the treatment of cosmetic purposes, investigational or experimental purposes, infertility, or sexual dysfunction are excluded.
4. Requests that exceed quantity limits must additionally meet Quantity Limit Medical Necessity Guidelines.
5. Requests for glucagon-like peptide-1 (GLP-1) receptor agonists used solely for weight loss are excluded. Requests for Wegovy (semaglutide) and Zepbound (tirzepatide) must meet drug-specific criteria within the Pharmacy Products Without Specific Criteria Medical Necessity Guidelines and approval duration will be limited to 1 year time period. For members younger than 21 years of age, requests will be reviewed for medical necessity in accordance with Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) requirements.

Medications without specific criteria that do not have an A-rated generic

1. Approval for medications that are not schedule II, III, IV analgesics will be limited to a 1 year time period, or up to a complete course of therapy if less than 1 year as noted in the prescribing information.
2. Approvals for schedule II, III, IV analgesics for a diagnosis other than cancer-related, sickle cell-related, or end-of-life pain will be limited initially to a three-month duration, and upon renewal to a six-month duration.
3. Approvals for schedule II, III, IV analgesics for cancer-related, sickle cell-related, or end-of-life pain will be limited to one year.

Medications without specific criteria that have an A-rated generic

1. Approval duration will be limited to 3 months for drugs with shortage or availability issues.
2. Approval duration will be limited to 3 months for schedule II, III and IV medications.
3. Approval duration for all other requests will be limited to a 1 year time period, or up to a complete course of therapy if less than 1 year as noted in the prescribing information.
4. Drugs on the Preferred Drug List (PDL) with restrictions must additionally meet drug- or class-specific Medical Necessity Guidelines.

In those instances in which the A-rated generic is not listed on the PDL, the request must additionally meet Pharmacy Products Without Specific Criteria Medical Necessity Guidelines for the A-rated generic.

New-to-Market Products

1. The Plan does not approve requests for products that are new to the market until they are reviewed by the Plan's Pharmacy and Therapeutics (P&T) Committee. Once the Plan's P&T Committee reviews the medication, coverage status will be determined.

CODES

None

REFERENCES

1. Bansal MB, Patton H, Morgan TR, Carr RM, Dranoff JA, Allen AM. Semaglutide therapy for metabolic dysfunction–associated steatohepatitis: November 2025 updates to AASLD Practice Guidance *Hepatology*. 2025;83(5):1326-1340.
2. Dowell D, Ragan KR, Jones CM, et al. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2022. *MMWR*. 2022;71(3):1-95.
3. Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2017 Mar 15;13(3):479-504.
4. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2019 Feb 15;15(2):335-343.
5. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice guidance on the clinical assessment and management of nonalcoholic fatty liver disease. *Hepatology*. 2023 May 1. 77 (5):1797-835.
6. Wegovy (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; June 2026.
7. Zepbound (tirzepatide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; February 2026.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: Effective November 1, 2023, updated renewal criteria for schedule II, III, IV analgesics to include requirement that member continues to have a diagnosis of pain. Updated criteria for brand name products with A-rated generics to require trial and failure with two formulary alternatives and an allergy to an ingredient in the generic that isn't in the brand rather than one or the other. Updated new-to-market language to change "medications" to "products."
2. February 11, 2025: No changes to criteria. Administrative fax number update.
3. February 10, 2026: Effective March 1, 2026, updated trial language to specify as inadequate response or adverse reaction with formulary alternatives throughout the MNG.
4. September 15, 2026: Effective October 1, 2026, added coverage criteria for Wegovy and Zepbound. Updated Limitations to add the following statement: "Requests for glucagon-like peptide-1 (GLP-1) receptor agonists used solely for weight loss are excluded. Requests for Wegovy (semaglutide) and Zepbound (tirzepatide) must meet drug-specific criteria within the Pharmacy Products Without Specific Criteria Medical Necessity Guidelines and approval duration will be limited to 1 year time period. For members younger than 21 years of age, requests will be reviewed for medical necessity in accordance with Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) requirements".

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic. Provider Services