Pharmacy Medical Necessity Guidelines:
Pharmacy Products Without Specific Criteria

Effective: March 16, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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 Plan 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 of current literature

AND

2. Member must try 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. Member must try and fail 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 must have 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 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 dose that exceeds 90 MME/day and demonstration that lower doses (if available) have resulted in an inadequate response or are not appropriate

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 could result in instability of the Member's medical condition provided the medication is not in the schedule II, III or IV (i.e., narrow therapeutic index medications and non-controlled substances)

OR

3. One of the following
   a) The Member had a treatment failure with two or more formulary alternative medications (when available), including the A-rated generic

   OR

   b) Provider documentation that the Member had an allergic reaction to an ingredient in the A-rated generic that is no 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 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 dose that exceeds 90 MME/day and demonstration that lower doses (if available) have resulted in an inadequate response or are not appropriate

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

1. The Member has experienced an improvement in function/pain while on the prescribed analgesic

AND

2. The provider attests that there are no concerns of substance abuse/misuse while taking the prescribed analgesic

AND

3. The Member has not experienced respiratory depression or cognitive impairment while taking the prescribed analgesic

AND

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

AND

5. 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

LIMITATIONS

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.
4. Approval for schedule II, III, IV analgesics for a cancer diagnosis will be limited to one year.
5. Durable medical equipment (with the exception of blood glucose/ketone test strips and monitors), immunization agents (with the exception of the varicella vaccine for Members > 60 years old, and influenza vaccine), blood plasma products, infant formulas, nutritional supplements, and contraceptive implants should be deferred to the medical benefit for coverage.
6. Medications requiring skilled healthcare administration should be provided by healthcare providers and deferred to the medical benefit for coverage determination.
7. Requests for medications used for the treatment of cosmetic purposes, investigational or experimental purposes, infertility, or sexual dysfunction are excluded.
8. Requests that exceed quantity limits must additionally meet Quantity Limit Medical Necessity Guidelines.

Medications without specific criteria that 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. Drugs on the Preferred Drug List (PDL) with restrictions must additionally meet drug- or class-specific Medical Necessity Guidelines.
4. Drugs not listed on the PDL must additionally meet Drugs Without Drug- or Drug Class-Specific Medical Necessity Guidelines.
5. Requests that exceed quantity limits must additionally meet Quantity Limit Medical Necessity Guidelines.

Medications new to the market

1. The Plan does not approve requests for medications 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. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. *MMWR Recomm Rep*. 2016;65(RR-1):1-49.

APPROVAL HISTORY

November 8, 2007: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

6. September 9, 2014: Added criteria for new-to-market products.
7. April 9, 2015: Updated to separate criteria for new-to-market products; no change in clinical content
8. November 10, 2015: Noted in the limitations section that medications requiring healthcare administration should be provided by healthcare providers and covered under the medical benefit.
9. January 1, 2016: Administrative change to rebranded template.
10. June 14, 2016: Incorporated Brand Name Medications (with A-rated Generics; DAW-1) Medical Necessity Guideline into the Noncovered Medications Medical Necessity Guideline.
11. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Renamed MNG "Drugs Without Drug- or Drug Class Specific-Criteria". Added language stating that requests for medications new to the market will not be approved until they are reviewed by the P&T Committee. Removed weight loss medications from the list of drugs that are excluded from coverage.
12. June 12, 2018: No changes.

13. January 18, 2019: Updated MNG to include criteria for schedule II, III, and IV analgesics and updated the approval duration for these agents. Added renewal criteria for the schedule II, III, IV analgesics. Administrative changes made to template.
14. October 15, 2019: Updated the criteria for analgesic schedule II, III, and IV medications to remove malignant pain and add sickle cell-related pain to the list of approvable diagnoses. For requests exceeding 90 MME/day, added palliative care specialist, rheumatologist, and headache specialist to the list of approvable specialists. Updated the name of the MNG to "Pharmacy Products Without Specific Criteria"
15. March 10, 2020: Effective March 16, 2020, for requests exceeding 90 MME/day, added physiatrist to the list of approvable specialists. Increased the length of approval for sickle cell-related and end-of-life pain to one year. Updated the criteria for schedule II, III, IV analgesic medications to remove the requirement of stability on the product for those members who have a sickle cell-related, cancer-related, or end-of-life pain. Added "Requests that exceed quantity limits must additionally meet Quantity Limit Medical Necessity Guidelines" to the limitations section of the MNG

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.