Pharmacy Medical Necessity Guidelines: Drugs with Quantity Limitations

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

The plan limits the quantity of selected medications that a Member can receive, for clinical and/or cost reasons. A physician may submit a request for a medical exception to the Tufts Health Plan Clinical Review department in cases where it is medically necessary to exceed these quantity limits.

COVERAGE GUIDELINES

The plan may authorize additional quantities for drugs that are restricted under the Quantity Limitations (QL) Program when all of the following criteria for a particular regimen are met and limitations do not apply:

1. Provider documentation that the quantity of medication needed to clinically manage the patient's disease state within a given time frame is greater than the current quantity allowed under the QL program and that this amount is the minimum necessary therapeutic quantity

AND

For non-analgesic schedule II, III and IV medications, all of the following:

1. For non-ADHD medications, the Member has been evaluated by a specialist for his/her condition

For analgesic schedule II, III, and IV medications, all of the following:

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

OR

1. The Member has a diagnosis of pain

AND

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

AND

3. 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

4. The risks of use of a high dose schedule II, III, or IV analgesic use (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the member

AND

5. The provider has a plan to monitor for signs of misuse and addiction during therapy

AND

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

For buprenorphine/naloxone products, all of the following:

1. A diagnosis of opioid dependence

AND

2. The Member's treatment plan includes ongoing participation in a structured drug addiction treatment program and/or counseling

AND

3. Provider indicates that the Member is on the lowest effective dose for his/her current place in therapy

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 dose

OR

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

AND

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

AND

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

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 opioid 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

1. Approval duration for schedule II, III and IV medications, with the exception of buprenorphine/naloxone and CNS stimulant medications, will be limited to an initial 3 months for diagnoses other than cancer-related, sickle cell-related, or end-of-life pain, and then 6 months upon renewal.
2. Approval duration for schedule II, III and IV medications for cancer-related, sickle cell-related, or end-of-life pain will be limited to one year.
3. Approval duration for buprenorphine/naloxone medications will be limited to 1 year.
4. Approval duration for CNS stimulant medications will be limited to an initial 3 months, and then 1 year upon renewal.
5. For any schedule of medication (II-VI), approval durations will be limited to the length of the complete course of therapy as noted in the medication's FDA-approved package insert, should that length of treatment be less than the approval duration outlined above for the medication's corresponding schedule.
6. Approval duration for non-controlled substance medications will be limited to one year.
7. Triptan medications for migraine headache will be approved for up to 12 units per 30-day supply for up to a 6-month duration unless the Member had a treatment failure with at least two prophylactic therapies and they have been evaluated by a specialist (e.g. neurologist, pain

specialist). If the Member has been evaluated by a specialist and they are taking or had a treatment failure with at least two prophylactic therapies for migraines, greater quantities will be approved for 1 year.

CODES

None

REFERENCES

1. Rhode Island Prescription drug Monitoring Program. Available at: https://rhodeisland.pmpaware.net/login. Accessed April 25, 2018.
2. Center for Substance Abuse Treatment (2004). "Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction." *Treatment Improvement Protocol (TIP) series 40, Substance Abuse and Mental Health Services Administration*. Accessed at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.
3. Drug Addiction Treatment Act of 2000. Accessed at http://buprenorphine.samhsa.gov/data.html.
4. 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

August 12, 2014: Reviewed by the Pharmacy and Therapeutics Committee

Subsequent endorsement date(s) and changes made:

1. October 14, 2014: Added criteria specific to schedule II, III, and IV medications and limitations to approval durations.
2. December 9, 2014: Added criteria specific to buprenorphine/naloxone products.
3. April 14, 2015: Modified language for schedule II, III and IV medications to accommodate ADHD medications; modified criteria from Massachusetts PMP to state PMP.
4. May 12, 2015: Modified approval duration for select schedule II, III and IV medications based on diagnosis; modified approval duration for triptan medications.
5. November 10, 2015: Changes made to reflect the new quantity limit for buprenorphine/naloxone medications. The following criteria were added: a diagnosis of opioid dependence; Member's treatment plan includes ongoing participation in a structured drug addiction treatment program and/or counseling; urine drug screens with each visit was changed to consistent evaluation with toxicology screens (must document date of last screen within the last 60 days). The following criteria were removed: the Member's treatment plan includes psychosocial support , routine office visits, toxicology screening that includes buprenorphine, norbuprenorphine, and a full range of opiates and benzodiazepines, continued monitoring for dose tapers and discontinuation of therapy and provider attestation they are engaged in: Structured induction protocol (new starts), Review of Member-specific medication usage through state Online Prescription Monitoring Program(s), periodic pill counts, services to address other addictions, and Member-signed contracts to include informed consent, treatment contract, signed release for collaboration/sharing of information with other providers. Within the limitations the bullet point pertaining to drugs indicated for erectile dysfunction was removed.
6. November 16, 2015: Removed the criterion for schedule II, III and IV medications related to provider attestation that they have reviewed Member-specific medication usage through the state Online Prescription Monitoring Program.
7. December 8, 2015: Extended approval duration for schedule II, III and IV medications for a cancer diagnosis to one year; removed criteria requiring the date of the last toxicology screening.
8. January 1, 2016: Administrative change to rebranded template.
9. August 9, 2016: No changes.
10. January 10, 2017: Adjusted length of approval duration for renewal of CNS stimulant medications.
11. February 14, 2017: Limited approval duration to the length of therapy in the FDA-approved package insert, if length of treatment is less than the existing length of approval for schedules II-VI. Removed taper schedule from the buprenorphine/naloxone criteria, and replaced it with an attestation that the Member is on the lowest effective dose for his/her current place in therapy.
12. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
13. May 8, 2018: No changes.
14. January 18, 2019: Updated criteria for schedule II, III, and IV analgesic medications. Added renewal criteria for schedule II, III, and IV analgesic medications. Administrative changes made to template.

15. October 15, 2019: Effective 1/1/2020, updated the criteria for analgesic schedule II, III, IV medications to include sickle cell-related pain as an approvable diagnosis and removed malignant pain from the list of approvable diagnoses. Also added palliative care specialist, rheumatologist, and headache specialists to the list of approvable specialists. Effective 10/21/2019, updated length of approve for buprenorphine/naloxone products to 1 year.
16. 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 from three months to one year.

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.