# Pharmacy Medical Necessity Guidelines: Products with Quantity Limitations

*Effective: November 1, 2023*

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| 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:<br>☒ Tufts Health RITogether – A Rhode Island Medicaid Plan | | **Fax Numbers:**<br>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 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, abuse, 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. 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 continues to require pain management

**AND**

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

**AND**

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

**AND**

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

**AND**

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

**AND**

6. 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. Approval duration for non-controlled substance medications will be limited to one year.
6. 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.
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.
8. Requests to exceed quantity limits will only be approved for FDA-approved indications or those supported by compendia. Requests to exceed quantity limitations for experimental or investigational use will be denied.

## 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, Ragan KR, Jones CM, et al. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2022. *MMWR*. 2022;71(3):1-95.


## APPROVAL HISTORY

September 13, 2022: Reviewed by the Pharmacy and 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 buprenorphine/naloxone products to remove requirement that the member must be in a structured drug addiction program or counseling.

## 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