Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Quantity Limit Exceptions

Effective: March 1, 2025

Guideline Type	☐ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☒ Administrative

Applies to:
Commercial Products
☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988
☒ Tufts Health Plan Commercial products; Fax: 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products
☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Quantity limits are in place to ensure safe and appropriate prescribing supported by FDA-approved labeling, medically accepted compendia, or evidence-based clinical literature. The plan limits the quantity of selected medications that a patient can receive, for clinical and/or cost reasons. A quantity limit exception may be requested when it's medically necessary to exceed quantity limitations.

Clinical Guideline Coverage Criteria

Medications with Quantity Limitation

The plan may authorize additional quantities for drugs that are restricted under the Quantity Limitations (QL) Program when the following criteria is met:

1. Physician 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

2. Requested quantity is supported by FDA-approved labeling, medically accepted compendia, or evidence-based clinical literature.

AND

3. If there are existing clinical coverage criteria for the requested medication, those criteria will also need to be met.

Oral Phosphodiesterase 5-Inhibitors for Erectile Dysfunction

The plan may authorize erectile dysfunction medications that are restricted under the Quantity Limitations (QL) Program when the following criteria is met:

1. Treatment of penile rehabilitation due to a recent (within the previous 3 months) prostatectomy

AND

2. Patient has NOT previously received a 6 month course of therapy with sildenafil (Viagra), tadalafil (Cialis), vardenafil tablet (Levitra), vardenafil ODT (Staxyn), or Stendra post prostatectomy

Note: Criteria applies oral phosphodiesterase 5-inhibitors only.

Note: If using Viagra (sildenafil) or Cialis (tadalafil) for the treatment of pulmonary hypertension, please refer to Clinical Coverage Criteria entitled "Pulmonary Arterial Hypertension".

Note: If using Cialis 2.5mg or 5 mg (tadalafil) to treat the signs and symptoms of benign prostatic hyperplasia (BPH) please refer to below criteria:

Cialis (tadalafil) for Benign Prostatic Hyperplasia (BPH)

The plan may authorize coverage of **tadalafil (Cialis) 2.5mg or 5mg tablets for benign prostatic hypertrophy (BPH)** for patients, when the following criteria are met:

1. Diagnosis of Benign Prostatic Hyperplasia (BPH)

AND

2. Requested dosage of tadalafil (Cialis) does not exceed the Food and Drug Administration (FDA)-approved recommended dose of up to 5 mg per day for the treatment of Benign Prostatic Hyperplasia (BPH).

AND

3. Documented trial and failure with adverse reaction to, or contraindication to a trial of at least two medications from either of the following drug classes:
    a. Alpha-1 Adrenergic Blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin)
    b. 5-Alpha Reductase Inhibitors (e.g., finasteride, Avodart)

Opioid Coverage Criteria

The plan may authorize opioid medications that are restricted under the Quantity Limitations (QL) Program when the following criteria is met:

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

OR

2. **All** of the following:

AND

    a. The patient has a diagnosis of Pain

AND

    b. The patient signed a pain agreement consistent with the American Academy of Pain Management guidelines

AND

    c. The analgesic is prescribed by or in consultation with a pain specialist, addiction specialist, palliative care specialist, hematologist/oncologist, physiatrist, rheumatologist or headache specialist (board certified) OR there is a plan for the patient to be referred to a pain specialist, addiction specialist, palliative care specialist, hematologist/oncologist, physiatrist, rheumatologist or headache specialist (board certified) OR rationale provided why the patient is not a candidate to see a specialist

AND

    d. 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 patient

AND

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

AND

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

Limitations

1. Duration of coverage will be determined based on one of the following:
    a. The specified duration of approval in existing coverage criteria for the requested drug or drug class
    b. The length of treatment required for the requested drug and indication according to the medication's FDA-approved packet insert
    c. Exception requests for additional quantities of the drugs indicated for insomnia may be authorized in 12-month intervals.
    d. Approval quantities and duration of medications for erectile dysfunction medications being used for penile rehabilitation due to prostatectomy will be limited to 30 tablets/30 days for up to 180 days of therapy post-prostatectomy
    e. Duration of approval for opioid analgesic medications over the quantity limit is for no longer than one year. The specified duration of approval in existing coverage criteria for the requested drug or drug class
    f. Quantity limit exceptions due to drug shortages will be authorized for three (3) months.
2. For Oral Phosphodiesterase 5-Inhibitors for Erectile Dysfunction, the plan quantity limitation is 4 tablets/30 days total of any combination of Cialis (tadalafil) of any strength, Levitra (vardenafil), Staxyn (vardenafil), Stendra (avanafil) and Viagra (sildenafil).
3. For Cialis (tadalafil) 2.5mg or 5mg tablet for Benign Prostatic Hyperplasia (BPH):
    a. The plan does not authorize any requests over the QL of 4 tablets/30 days, not meeting the BPH criteria.

b. For BPH, coverage of Cialis (tadalafil) is limited to 30 tablets per 30 days of the 2.5mg or 5mg tablet.

4. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.
5. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

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Approval And Revision History

September 12, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 11, 2022: Effective 1/1/23, updated opioid criteria to clarify criteria for sickle-cell, cancer-related, or end-of-life pain vs pain (Chronic).
- July 11, 2023: Removed QL criteria for medications for Hyperemesis Gravidarum, clarified limitation that opioid analgesics over the QL should be approved for no longer than one year, and specified duration of approval in existing coverage criteria for the requested drug or drug class.
- October 10, 2023: Effective January 1, 2024, consolidated Cialis for Benign Prostatic Hypertrophy (BPH) MNG with Quantity Limit Exceptions MNG. No additional criteria changes.
- October 8, 2024: Effective November 1, 2024, removed criterion for oral PDE-5 inhibitors that member is not taking nitrates or non-selective alpha blocker.
- December 10, 2024: Effective March 1, 2025, quantity limit criteria was updated to add a requirement that the requested quantity is supported by FDA-approved labeling, medically accepted compendia, or evidence-based literature. Administrative update to remove limitation statement that member should not be using an alpha blocker with tadalafil. Approval duration for drug shortages was added.
- January 14, 2025: Effective March 1, 2025, quantity limit criteria was updated to add criterion to review clinical coverage criteria if applicable.

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 popula tion 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.