Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:

Chelating and Reducing Agents: Clovique, penicillamine tablets, tiotropin, trientine

Effective: March 12, 2024

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

Food and Drug Administration – Approved Indications

Generic penicillamine tablets are indicated in the treatment of Wilson's disease, Cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy.

Generic clovique and trientine is indicated for the treatment of patients with Wilson's disease who are intolerant of penicillamine.

Thiola (tiotropin) is indicated in combination with high fluid intake, alkali, and diet modification for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone.

Clinical Guideline Coverage Criteria

Cystinuria

The plan may authorize coverage of penicillamine tablets or tiotropin for Members when all of the following criteria are met:

1. Documented diagnosis of cystinuria

AND

2. Prescribed by or in consultation with a hepatologist, gastroenterologist, rheumatologist, or urologist

AND

3. Documentation of **one (1)** of the following:
   a. Patient has tried and failed ALL of the following conservative treatment measures for cystinuria: High fluid intake (urine output of at least three liters/day); sodium and protein dietary restrictions; and urinary alkalization with potassium citrate, potassium bicarbonate, or acetazolamide
   b. Provider has indicated that the patient requires the use of the requested drug initially with the conservative measures because of very high cystine levels

Rheumatoid Arthritis

The plan may authorize coverage of penicillamine tablets for Members when all of the following criteria are met:

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Documentation of **one (1)** of the following:
    a. Trial and failure with one (1) of the following: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
    b. Clinical rationale to avoid use of all of the following: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine

Wilson's Disease

The plan may authorize coverage of clovique, penicillamine tablets, or trientine for Members when all of the following criteria are met:

1. Documented diagnosis of Wilson's disease

AND

2. Prescribed by or in consultation with a hepatologist, gastroenterologist, rheumatologist, or urologist

Limitations

1. 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

1. Cuprimine (penicillamine) [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; October 2004.
2. Depen (penicillamine) [prescribing information]. Somerset, NJ: Meda Pharmaceuticals Inc; January 2019.
3. Syprine (trientine hydrochloride) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
4. Clovique (trientine hydrochloride) [prescribing information]. Warrendale, PA: Kadmon Pharmaceuticals; December 2018.
5. Thiola (tiopronin) [prescribing information]. San Antonio, TX. Mission Pharmacal Company; January 2021.

Approval And Revision History

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

- May 9, 2023: No changes.
- March 12, 2024: No changes

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.