Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Cablivi® (caplacizumab-yhdp)**

Effective: June 13, 2023

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

Cablivi (caplacizumab-yhdp) is a von Willebrand factor (vWP)-directed antibody fragment indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

Clinical Guideline Coverage Criteria

The plan may authorization coverage of Cablivi for Members when all of the following criteria are met:

1. Documented diagnosis of acquired thrombotic thrombocytopenia purpura

AND

2. The patient 18 years of age or older

AND

3. Prescribed by or in consultation with a hematologist

AND

4. Documentation Cablivi was initiated in the inpatient (hospital) setting in combination with plasma exchange

AND

5. Documentation Cablivi is used in combination with immunosuppressive therapy (e.g., glucocorticoids, rituximab)

AND

6. If patient has previously received Cablivi, documentation the patient has not experienced more than two (2) recurrences of acquired thrombotic thrombocytopenia purpura while receiving Cablivi

Limitations

1. Authorizations will be provided for 12 months.

Codes

None

References

1. Cablivi (caplacizumb-yhdp) [prescribing information]. Cambridge, MA: Genzyme Corporation; February 2022.

Approval And Revision History

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

- June 13, 2023: No changes. Minor wording updates for criterion 6 (administrative update).

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.