Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Thrombocytopenia Agents (Doptelet, Mulpleta, Tavalisse)**

Effective: November 1, 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

Doptelet (avatrombopag) is a thrombopoietin receptor agonist indicated for the treatment of:

- Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure
- Thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment

Mulpleta (lusutrombopag) is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Tavalisse (fostamatinib disodium hexahydrate) is a kinase inhibitor indicated for the treatment of adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

Clinical Guideline Coverage Criteria

Thrombocytopenia in Chronic Liver Disease

The plan may authorize Doptelet or Mulpleta when all of the following criteria are met:

1. Documented diagnosis of severe thrombocytopenia as indicated by a baseline platelet count less than 50,000/mcL

AND

2. The patient is 18 years of age or older

AND

3. Documentation the patient has chronic liver disease

AND

4. Documentation the patient is scheduled to undergo a medical procedure

AND

5. Prescribed by or in consultation with an appropriate specialist (e.g., hematologist, oncologist, immunologist, hepatologist, transplant specialist)

AND

6. For Mulpleta (lustrombopag), documented trial and failure or contraindication to Doptelet (avatrombopag)

Immune Thrombocytopenia

The plan may authorize Doptelet or Tavalisse for patients when all the following criteria are met:

1. Documented diagnosis of immune thrombocytopenia

AND

2. The patient is 18 years of age or older

AND

3. Prescribed by or in consultation with an appropriate specialist (e.g., hematologist, oncologist, immunologist, hepatologist, transplant specialist)

AND

4. Documentation of **one (1)** of the following:
    a. Baseline platelet count is less than 30,000/mcL
    b. Medical necessity for platelet elevation (e.g., upcoming surgery, peptic ulcer disease or condition that may predispose patient to bleeding)

AND

5. Documented insufficient response or contraindication to **ALL of** the following:
    a. Splenectomy
    b. Corticosteroids
    c. Immunoglobulins
    d. Rituxan (rituximab)
    e. Thrombopoietin receptor agonist (i.e., Promacta [eltrombopag], Nplate [romiplostim])

Limitations

1. Doptelet and Mulpleta for thrombocytopenia or chronic liver disease will be approved for a duration of one month for a one-time fill.

Codes

None

References

1. Doptelet (avatrombopag) [prescribing information]. Durham, NC. Dova Pharmaceuticals, Inc. June 2021.
2. George J, Arnold D. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. In: Tirnauer J, ed. UpToDate [database online], 2021. www.uptodate.com. Accessed September 30, 2021.
3. George JN, Arnold DM. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. In: Tirnauer JS, ed. UpToDate [database online], 2021. www.uptodate.com. Accessed September 29, 2021.
4. Mulpleta (lusutrombopag) [prescribing information]. Florham Park, NJ: Shionogi Inc; April 2020.
5. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 Evidence-based practice guideline for immune thrombocytopenia. Available at: http://www.hematology.org/Practice/Guidelines/2934.aspx. Accessed September 10, 2019.
6. Neunert C, Terrell D, Arnold D, et al. The American Society of Hematology 2019 Evidence-based practice guideline for immune thrombocytopenia. Available at: https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Societyof-Hematology-2019-guidelines-for. Accessed September 29, 2021.
7. Tavalisse (fostamatinib) [prescribing information]. South San Francisco, CA. Rigel Pharmaceuticals, Inc. November 2020.

Approval And Revision History

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

- August 8, 2023: Removed reauthorization criteria for immune thrombocytopenia. Added age requirements for thrombocytopenia in chronic liver disease. Minor wording updates throughout the guideline to help clarify coverage requirements, including documented diagnosis (effective November 1, 2023).

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.