Pharmacy Medical Necessity Guidelines: Thrombopoietin Receptor Agonists

Effective: November 16, 2020

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:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

Doptelet (avatrombopag) and Mulpleta (lusutrombopag) are both thrombopoietin receptor agonists indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Doptelet is also approved for Thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

COVERAGE GUIDELINES

The plan may authorize coverage of **Doptelet** or **Mulpleta** for Chronic Liver Disease for members who are scheduled to undergo a procedure when all of the following criteria are met:

1. The member is at least 18 years of age

AND

2. The Member has a documented diagnosis of chronic liver disease

AND

2. The member has thrombocytopenia, as indicated by a documented platelet count of $50x10^9$/L or less

AND

3. The member is scheduled to undergo a procedure

The plan may authorize coverage of **Doptelet** for Chronic Immune Thrombocytopenia when all of the following criteria are met:

Initial Authorization Criteria:

1. The member is at least 18 years of age

AND

2. The Member has a documented diagnosis of Chronic Immune Thrombocytopenia (documented platelet count of $50x10^9$/L or less)

AND

3. The member has had an inadequate response to, or not a candidate for an initial treatment option (corticosteroids, rituximab, or splenectomy)

AND

4. The medication is prescribed by or in consultation with a specialist (e.g., hematologist, oncologist, immunologist, hepatologist, transplant specialist)

Reauthorization Criteria:

1. The member has had a documented of improvement in clinical response as evidenced by increased platelet counts

AND

2. The member remains at risk for bleeding complications

LIMITATIONS

1. Authorizations for Doptelet and Mulpleta for Chronic Liver Disease for members who are scheduled to undergo a procedure will be approved for one course of therapy per authorization for a period of one month
2. Initial authorizations for Doptelet for Chronic Immune Thrombocytopenia will be for 12 weeks and reauthorizations will be for a period of one year.

CODES

None

REFERENCES

1. Afdhal NH, Giannini EG, Tayyab G, et al. Eltrombopag before procedures in patients with cirrhosis and thrombocytopenia. N Engl J Med. 2012;367:716-24.
2. Centers for Disease Control and Prevention (CDC). Chronic Liver Disease and Cirrhosis. URL: cdc.gov/nchs/fastats/liver-disease.htm. Available from Internet. Accessed 2018 September 18.
3. Doptelet prescribing information. Durham, NC: Dova Pharmaceuticals, Inc.; 2020 August.
4. Food and Drug Administration. Developing products for rare diseases & conditions. 2018b. URL: fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm. Available from Internet. Accessed 2018 May 10.
5. Food and Drug Administration. Drugs@FDA. 2018a. URL: accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2018 May 25.
6. Food and Drug Administration (FDA). Drugs@FDA. URL: accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2018 September 5.
7. Food and Drug Administration. Fast track. 2018b January. URL: fda.gov/ForPatients/Approvals/Fast/ucm405399.htm. Accessed 2018 January 30.
8. Hayashi H, Beppu T, Shirabe K, et al. Management of thrombocytopenia due to liver cirrhosis: a review. World J Gastroenterol. 2014; 20(10): 2595–605.
9. Izumi N, Osaki Y, Yamamoto K, et al. A phase 3, randomized, double-blind, placebo-controlled study of lusutrombopag for thrombocytopenia in patients with chronic liver disease undergoing elective invasive procedures in Japan (L-PLUS 1). Abstract LB-30. 2015. URL: aasld.org/sites/default/files/documents/2015/TLM_Abstracts/LB30.pdf. Available from Internet. Accessed 2018 August 10.
10. Maan R, de Knegt RJ, Veldt BJ. Management of thrombocytopenia in chronic liver disease: focus on pharmacotherapeutic strategies. Drugs. 2015;75:1981-92.
11. Mitchell O, Feldman DM, Diakow M, et al. The pathophysiology of thrombocytopenia in chronic liver disease. Hepat Med. 2016;8:39-50.
12. Mulpleta prescribing information. Florham Park, NJ: Shionogi Inc.; 2018 July.
13. National Institute of Health and Care Excellence (NICE). Avatrombopag for treating thrombocytopenia in people with chronic liver disease needing elective surgery (ID1105). URL: nice.org.uk/guidance/proposed/gid-ta10348. Available from Internet. Accessed 2018 June 20.
14. Peck-Radosavljec M. Thrombocytopenia in chronic liver disease. Liver Int. 2017;37(6):778-79.
15. RxPipeline. Available with subscription at caremark.com/wps/portal/client. Accessed 2018 June 20.
16. Terrault N, Chen Y-C, Izumi N, et al. Avatrombopag before procedures reduces need for platelet transfusion in patients with chronic liver disease and thrombocytopenia. Gastroenterology 2018; doi: 10.1053/j.gastro.2018.05.025.

APPROVAL HISTORY

September 18, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- February 18, 2019: Update the name of the MNG from "Doptelet® (avatrombopag)" to "Thrombopoietin Receptor Agonists", added Mulpleta to existing criteria.
- November 10, 2020: Added coverage criteria for Doptelet for the expanded indication, Chronic Immune Thrombocytopenia. Updated authorization timeframe.

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.