MEDICAL MUTUAL®

Drug Policy

Policy:	Doptelet (avatrombopag)	Annual Review Date: 10/17/2024 Last Revised Date: 10/17/2024

OVERVIEW

Doptelet is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure. Doptelet should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts. Dosing of Doptelet begins 10 to 13 days prior to scheduled procedure. The patient should undergo the procedure within 5 to 8 days after the last dose. Recommended dosing of Doptelet is 60 mg daily for 5 days with platelet count < 40 x 10^9/L; and 40 mg daily for 5 days with platelet count ≥ 40 to < 50 x10^9/L. Doptelet was assessed in 2 randomized, placebo controlled, phase 3 trials in patients with thrombocytopenia and CLD undergoing scheduled procedures to establish safety and efficacy. In both studies, Doptelet was superior to placebo in reducing the need for platelet transfusions or rescue procedures for bleeding. Doptelet is also indicated for the treatment of adults with chronic immune thrombocytopenia who have had an insufficient response to prior therapies.

POLICY STATEMENT

This policy involves the use of Doptelet. Prior authorization is recommended for pharmacy benefit coverage of Doptelet. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Doptelet as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Doptelet be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Doptelet is recommended in those who meet the following criteria:

1. **Thrombocytopenia in adults with chronic liver disease**
   Criteria. *Patient must meet the following criteria (A, B, C, and D):*
   A. ≥ 18 years of age; AND

B. Has been diagnosed with chronic liver disease; AND
C. Has thrombocytopenia with platelet count < 50,000 mcL; AND
D. Is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy

2. **Chronic Immune Thrombocytopenia - initial therapy**
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The patient has been diagnosed with chronic immune thrombocytopenia for at least 12 months; AND
C. The patient has previously tried corticosteroids or IVIG, unless contraindicated; AND
D. The patient's platelet count is < 50,000/mcL prior to use of any thrombopoietin receptor agonist; AND
E. Doptelet will NOT be used in combination with another therapy for chronic immune thrombocytopenia; AND
F. Doptelet is prescribed by or in consultation with a hematologist

3. **Chronic Immune Thrombocytopenia - continuation of therapy**
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The patient has had a platelet response after 4 weeks of Doptelet therapy as evidenced by platelet count greater than 50,000/mcL; AND
C. The patient is not using Doptelet in combination with another therapy for chronic immune thrombocytopenia (for example: Promacta, Nplate); AND
D. Doptelet is prescribed by or in consultation with a hematologist

Initial Approval/ Extended Approval.

A) *Initial Approval:* 7 days for thrombocytopenia in chronic liver disease
3 months for chronic immune thrombocytopenia

B) *Extended Approval:* Not recommended for thrombocytopenia in chronic liver disease
6 months for chronic immune thrombocytopenia

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Doptelet has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Doptelet ® tablet [prescribing information]. Durham, NC: Dova Pharmaceuticals, Inc; June 2021.
2. Terrault N, Chen YC, Izumi N, et al. Avatrombopag before procedures reduces need for platelet transfusion in patients with chronic liver disease and thrombocytopenia [published online May 17, 2018]. *Gastroenterology*. doi: 10.1053/j.gastro.2018.05.025.Accessed on June 12, 2018.
3. Doptelet (avatrombopag). IPD analytics. May 2018
4. Avatrombopag. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated9 July 2019. Accessed on 21 July 2019.