

PRIOR AUTHORIZATION POLICY

POLICY: Thrombocytopenia – Doptelet Prior Authorization Policy

- Doptelet[®] (avatrombopag tablets – Dova/AkaRx)

REVIEW DATE: 03/23/2022

OVERVIEW

Doptelet, a thrombopoietin receptor agonist, is indicated for the following uses:¹

- **Immune thrombocytopenia (ITP)**, chronic for treatment in adults who have had an insufficient response to a previous treatment.
- **Chronic liver disease**, adults with **thrombocytopenia** as a treatment for who are scheduled to undergo a procedure.

For chronic ITP, Doptelet should be discontinued if the platelet count does not increase to $\geq 50 \times 10^9/L$ within 4 weeks at the maximum dose of 40 mg once daily. The safety and efficacy of Doptelet have not been established in pediatric patients. For chronic liver disease in patients undergoing a procedure, Doptelet is given as a 5-day course beginning 10 to 13 days before the scheduled procedure. In general, patients in the pivotal studies had a platelet count $< 50 \times 10^9/L$.

Guidelines

In 2019 the American Society of Hematology updated guidelines for ITP.⁴ Doptelet is not addressed specifically, but there are several recommendations. For adults with ITP for at least 3 months who are corticosteroid-dependent or unresponsive to corticosteroid, a thrombopoietin receptor agonist (either Promacta[®] [eltrombopag tablets and oral suspension] or Nplate[®] [romiplostim injection for subcutaneous use]) or a splenectomy are recommended. In children with newly diagnosed ITP who have non-life-threatening mucosal bleeding, corticosteroids are recommended. For children who have non-life-threatening mucosal bleeding and do not respond to first-line treatment, thrombopoietin receptor agonists are recommended. Other treatment options in children and adults include intravenous immunoglobulin, anti-D immunoglobulin, and rituximab.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Doptelet. All approvals are provided for the duration noted below. 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, approval may require Doptelet to be prescribed by or in consultation with a physician who specializes in the condition being treated in certain indications.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Chronic Immune Thrombocytopenia.** Approve if the patient meets the following criteria (A or B):
 - A) **Initial Therapy.** Approve for 3 months if the patient meets all of the following (i, ii, iii, and iv):
 - i. Patient is ≥ 18 years of age; AND
 - ii. Patient meets one of the following (a or b):
 - a) Patient has a platelet count $< 30 \times 10^9/L$ ($< 30,000/mcL$); OR
 - b) Patient meets both of the following [(1) and (2)]:
 - (1) Patient has a platelet count $< 50 \times 10^9/L$ ($< 50,000/mcL$); AND
 - (2) According to the prescriber, the patient is at an increased risk of bleeding; AND
 - iii. Patient meets one of the following (a or b):
 - a) Patient has tried at least one other therapy; OR
Note: Examples of therapies are systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Promacta (eltrombopag tablets and oral suspension), Nplate (romiplostim subcutaneous injection), Tavalisse (fostamatinib tablets), and rituximab.
 - b) Patient has undergone splenectomy; AND
 - iv. The medication is prescribed by or in consultation with a hematologist; OR
 - B) **Patient is Currently Receiving Doptelet.** Approve for 1 year if the patient meets both of the following criteria: (i and ii):
 - i. According to the prescriber, the patient demonstrates a beneficial clinical response; AND
Note: A beneficial response can include increased platelet counts, maintenance of platelet counts, and/or a decreased frequency of bleeding episodes.
 - ii. Patient remains at risk for bleeding complications.
2. **Thrombocytopenia in a Patient with Chronic Liver Disease.** Approve for 5 days if the patient meets the following criteria (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has a current platelet count $< 50 \times 10^9/L$ ($< 50,000/mcL$); AND
 - C) Patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Doptelet is recommended in the following situations:

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

REFERENCES

1. Doptelet® tablets [prescribing information]. Durham, NC: AkaRx/Dova; July 2021.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv.* 2019;3(23):3829-3866.

