VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Thrombocytopenia – Doptelet Prior Authorization Policy
- Doptelet® (avatrombopag tablets – AkaRx)
- Doptelet® Sprinkle (avatrombopag oral granules – AkaRx)

REVIEW DATE: 04/23/2025; selected revision 08/06/2025 and 08/13/2025

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.
- **Immune thrombocytopenia (ITP), chronic**, for treatment in pediatric patients ≥ 1 year of age who have had an insufficient response to a previous treatment.
- **Thrombocytopenia**, as treatment in adults with **chronic liver disease** who are scheduled to undergo a procedure.

For chronic ITP, Doptelet should be discontinued if the platelet count does not increase to ≥ 50 x 10^9/L within 4 weeks at the maximum dose.[1] 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 x 10^9/L.

Doptelet tablets and Doptelet Sprinkle are not substitutable on a mg-to-mg basis.[1] For Doptelet Sprinkle, dosing is recommended only in pediatric patients 1 year to < 6 years of age with persistent or chronic ITP.

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 eltrombopag or Nplate® [romiplostim subcutaneous injection]) 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 did 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 for certain indications require Doptelet to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
I. Coverage of Doptelet (tablets) is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Immune Thrombocytopenia, Chronic or Persistent.** Approve if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient meets ONE of the following (a or b):
       - **a)** Patient has a platelet count < 30 x 10^9/L (< 30,000/mcL); OR
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** Patient has a platelet count < 50 x 10^9/L (< 50,000/mcL); AND
         - **(2)** According to the prescriber, the patient is at an increased risk of bleeding; AND
     - **ii.** 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, eltrombopag olamine tablets or oral suspension (Promacta, generic), Alvaiz (eltrombopag choline tablets), Nplate (romiplostim subcutaneous injection), Tavalisse (fostamatinib tablets), and rituximab.
       - **b)** Patient has undergone splenectomy; AND
     - **iii.** 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 (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 ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has a current platelet count < 50 x 10^9/L (< 50,000/mcL); AND
   - **C)** Patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy.

RECOMMENDED AUTHORIZATION CRITERIA
II. Coverage of Doptelet Sprinkle is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Immune Thrombocytopenia, Chronic or Persistent.** Approve if the patient meets ONE of the following (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 < 6 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has a platelet count < 30 x 10^9/L (< 30,000/mcL); OR
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** Patient has a platelet count < 50 x 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, eltrombopag olamine tablets or oral suspension (Promacta, generic), Alvaiz (eltrombopag choline tablets), 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 or Doptelet Sprinkle. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient is < 6 years of age; AND

ii. 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.

iii. Patient remains at risk for bleeding complications.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Doptelet is not 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 and Doptelet® Sprinkle oral granules [prescribing information]. Morrisville, NC; AkaRx; July 2025.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/12/2023
Annual Revision	No criteria changes.	04/24/2024
Annual Revision	No criteria changes.	04/23/2025
Selected Revision	**Chronic Immune Thrombocytopenia:** For initial therapy, the requirement that the patient is ≥ 18 years of age was removed. In the Note related to the requirement that the patient has tried one other therapy, Alvaiz (eltrombopag choline tablets) was added and it was noted that Promacta (eltrombopag olamine tablets and oral suspension) is available in generic formulations.	08/06/2025
Selected Revision	Doptelet® Sprinkle was added to the policy. The criteria were divided into two sections (Doptelet tablets and Doptelet Sprinkle). **Immune Thrombocytopenia, Chronic or Persistent:** For criteria that address Doptelet tablets, the indication was changed to as stated, previously, it was "Chronic Immune Thrombocytopenia". **Immune Thrombocytopenia, Chronic or Persistent:** New criteria were added to address Doptelet Sprinkle.	08/13/2025