Drug Coverage Policy

Effective Date.....11/01/2025
Coverage Policy Number.....IP0152
Policy Title.....Doptelet

Thrombocytopenia – Doptelet

- Doptelet® (avatrombopag tablets - Dova/AkaRx)
- Doptelet® Sprinkle (avatrombopag oral granules – AkaRx)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

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POLICY STATEMENT
Prior Authorization is required for 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.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but not limited to, chart notes, laboratory tests, claims records, and/or other information.

I. Doptelet (tablets) is considered medically necessary when ONE of the following is met: 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) **[documentation required]**; 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) **[documentation required]**; 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 **[documentation required]**; 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 **[documentation required]**; 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) **[documentation required]**; AND
C) Patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy.

II. Doptelet Sprinkle is considered medically necessary when the following is met:

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) **[documentation required]**; 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) **[documentation required]**; 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 **[documentation required]**; 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 **[documentation required]**; 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 Covered

Doptelet for any other use is considered not medically necessary. 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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Updated** policy title to Thrombocytopenia – Doptelet; previously was Avatrombopag. **Chronic Immune Thrombocytopenia:** Updated pre-requisite therapy requirement from "Individual has had an inadequate response to ONE of the following OR Individual has a contraindication or is intolerant to ALL of the following: Systemic corticosteroids, Intravenous immunoglobulin, Anti-D immunoglobulin, Promacta, Nplate, Tavalisse, Rituximab" to now be "Patient has tried at least ONE other therapy" with examples relocated to a Note.	08/01/2024
Annual Review	No criteria changes.	06/15/2025
Selected Revision	**Added** documentation requirements throughout the policy.	09/01/2025
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." For initial therapy, the	11/01/2025

	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. Removed documentation requirements for patients currently receiving Doptelet. **Immune Thrombocytopenia, Chronic or Persistent:** New criteria were added to address Doptelet Sprinkle	

The policy effective date is in force until updated or retired.