CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Doptelet (avatrombopag)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Doptelet, approved by the FDA in 2018, is a small molecule thrombopoietin (TPO) receptor agonist indicated for the treatment of thrombocytopenia in adults with chronic liver disease (CLD) who are scheduled to undergo a procedure, and for adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment, and for pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.
TPO is important for regulating thrombopoiesis. The agonistic effect of Doptelet upregulates the production of platelets. TPO receptor agonists (TPO-RA) have been associated with thrombotic and thromboembolic complications. Doptelet should not be administered in an attempt to normalize platelet counts. Doptelet was the first TPO-RA approved for the indicated CLD population.
Thrombocytopenia is a condition of low platelet counts. It is the most common hematologic complication in patients with CLD, and 1% experience severe thrombocytopenia (platelet count <50,000/µL). Advanced disease often requires numerous medical and/or surgical diagnostic and therapeutic procedures. Thrombocytopenia may be associated with increased bleeding risk in these invasive procedures.
ITP is a rare autoimmune disorder characterized by low levels of platelets due to platelet destruction and insufficient platelet production. ITP duration of less than 3 months is referred to as newly diagnosed, 3-12 months as persistent, and greater than 12 months is considered chronic.

Doptelet (avatrombopag) will be considered for coverage when the following criteria are met:

Thrombocytopenia with chronic liver disease (CLD)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist; AND
3. Member has a documented diagnosis of chronic liver disease (CLD); AND
4. Member has a diagnosis of severe thrombocytopenia with a platelet count < 50 $x10^9$/L within the last 30 days; AND
5. Member is scheduled to undergo an invasive procedure; AND
6. Member has NOT had a liver transplant.
7. Doptelet will NOT be used in combination with another TPO receptor agonist.
8. **Dosage allowed/Quantity limit:** Begin 10-13 days prior to procedure; undergo procedure 5-8 days after last dose.
   Platelet count less than 40 $x10^9$/L: 60 mg (3 tablets) once daily for 5 days
   Platelet count 40 to less than 50 $x10^9$/L: 40 mg (2 tablets) once daily for 5 days.
   QL: 15 tablets

If all the above requirements are met, the medication will be approved for 1 month.

For **reauthorization**:
1. Doptelet will not be reauthorized for continuous use.

Immune Thrombocytopenia (ITP)

For **initial** authorization:
1. Member is at least 1 year of age; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a documented diagnosis of persistent or chronic ITP of at least 3 months duration; AND
4. Member has had an insufficient response with at least one of the following treatments:
   a) Corticosteroids (i.e., prednisone, prednisolone, methylprednisolone, dexamethasone)
   b) Immunoglobulins
   c) Splenectomy; AND
5. Member meets one of the following:
   a) Current platelet count is < 30 $x10^9$/L
   b) 30 $x10^9$/L to < 50 $x10^9$/L with one of the following:
      i) Active symptomatic bleeding other than minor mucocutaneous bleeding
      ii) High risk factor for bleeding (i.e., on an anticoagulant, of older age (>60 years), other clearly identified comorbidity); AND
6. Member does NOT have secondary immune thrombocytopenia (i.e., non-idiopathic, due to another condition); AND
7. Member will NOT have concurrent use with another TPO-RA.
8. **Dosage allowed/Quantity limit:**
   Adult and pediatric 6 years of age and older: Start at 20 mg (1 tablet) once daily. Adjust the dose or frequency of dosing to maintain platelet count greater than or equal to 50 $x10^9$/L, per prescribing information. Do not exceed 40 mg per day.
   Pediatric 1 year to less than 6 years of age: Start 10 mg (1 sprinkle capsule) once daily. Adjust the dose or frequency of dosing to maintain platelet count greater than or equal to 50 $x10^9$/L, per prescribing information. Do not exceed 20 mg per day.
   QL: 60 tablets or sprinkle caps per 30 days

   Note: Discontinue if the platelet count does not increase to at least 50 x 10^9/L after 4 weeks at the maximum dose of 40 mg once daily. Discontinue if the platelet count is greater than 400 $x10^9$/L after 2 weeks of dosing at 20 mg once weekly.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes include documentation of achieving and maintaining a platelet count of at least 50 x 10^9/L; AND
2. Member's platelet count is less than 200 x 10^9/L or there is a plan to decrease the dose per prescribing information.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Doptelet (avatrombopag) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/06/2019	New policy for Doptelet created.
07/24/2019	New indication of Immune thrombocytopenia (ITP) added. Status changed to preferred.
01/23/2023	Transferred to new template. Updated and added references. CLD: Added hepatology and GI as accepted specialists. Specified platelet lab must be within past 30 days. Shortened list of exclusions. Added not to be used in combination with another TPO-RA. ITP: Specified duration of chronic disease as at least 6 months. Removed "Other medications: cyclosporine A, mycophenolate mofetil, azathioprine, danazol, cyclophosphamide and/or rituximab" from list of accepted trials; none of these are initial/first line options per guidelines. Edited criteria under PC of 30,000-50,000. Added exclusion for secondary ITP. Reduced initial approval duration from 12 months to 6 months. For renewal, specified platelet improvement as 50,000 per drug label. For renewal added "or plan to decrease dose" to criterion for 200,000 ceiling PC.
08/05/2025	CLD: Removed thrombosis exclusion (not an absolute contraindication; must monitor). ITP: Added references. Updated age and dosing per label expansion, added oral granule formulation, added "persistent" disease (label, ASH guidelines). Changed ITP duration of at least 6 months to at least 3 months (ASH guidelines). Added not to be used with another TPO-RA.

References:

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