CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Doptelet (avatrombopag)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) Alternative preferred products include Promacta QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Doptelet (avatrombopag) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

IMMUNE THROMBOCYTOPENIC PURPURA (ITP)

For **initial** authorization:

1. Member is 18 year of age or older; AND
2. Member has a documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) with an insufficient response to a previous treatment; AND
3. Medication must be prescribed by or in consultation with a hematologist; AND
   Member has ONE of the following conditions:
   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) Symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma);
      ii) Have risk factors for bleeding (i.e., on anticoagulant, lifestyle that predisposes member to trauma, comorbidity such as peptic ulcer disease, undergoing medical procedure where blood loss is anticipated); AND
4. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with ONE of the following treatments:
   a) Corticosteroids (prednisone, prednisolone, methylprednisolone, and dexamethasone);
   b) Immunoglobulins;
   c) Splenectomy;
   d) Other medications: cyclosporine A, mycophenolate mofetil, azathioprine, danazol, cyclophosphamide and/or rituximab.
5. **Dosage allowed:** 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. Do not exceed 40 mg per day.

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

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND

2. Chart notes have been provided that show the member has shown improvement in platelet count from baseline; AND
3. Member's platelet count is less than 200 x 10^9/L.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

THROMBOCYTOPENIA (with chronic liver disease)

For **initial** authorization:

1. Member is 18 years of age or older with diagnosis of thrombocytopenia with chronic liver disease and is scheduled to undergo a procedure; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member's platelet count is < 50 x10^9/L; AND
4. Member does **not** have ANY of the following:
   a) Thrombosis;
   b) Hematologic disorders;
   c) Significant cardiovascular disease;
   d) Platelet transfusion or receipt of blood products containing platelets within 7 days (exception packed red blood cells);
   e) Heparin, warfarin, NSAID, aspirin, verapamil, and antiplatelet therapy with ticlopidine, glycoprotein iib/iiia antagonists (e.g., tirofiban), or erythropoietin stimulating agents within 7 days;
   f) Interferon use within 14 days;
   g) Estrogen-containing hormonal contraceptive or hormone replacement therapy use within 30 days;
   h) Advanced hepatocellular carcinoma.
5. **Dosage allowed:** Once daily for 5 consecutive days. Begin Doptelet dosing 10-13 days prior to the scheduled procedure. The recommended daily dose of Doptelet is based on the member's platelet count, if platelet count < 40 x10^9/L – 60 mg (3 tabs) once daily for 5 days, if platelet count 40-50 x10^9/L – 40 mg (2 tabs) once daily for 5 days. Member should undergo their procedure 5 to 8 days after the last dose of Doptelet.

Note: Doptelet will not be approved for more than 5 days of treatment.

If member meets all the requirements listed above, the medication will be approved for 1 month.

For **reauthorization**:

1. Doptelet will not be reauthorized.

CareSource considers Doptelet (avatrombopag) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Thrombocytopenia due to Myelodysplastic syndrome (MDS)

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.

References:

1. Doptelet [package insert]. Durham, NC: Dova Pharmaceuticals, Inc., June, 2019.

2. Terrault et al. Avatrombopag Before Procedures Reduces Need for Platelet Transfusion in Patients With Chronic Liver Disease and Thrombocytopenia. Gastroenterology 2018;155:705–718.
3. ClinicalTrials.gov. Identifier: NCT01976104. Treatment of Thrombocytopenia in Patients With Chronic Liver Disease Undergoing an Elective Procedure. Available at: https://clinicaltrials.gov/ct2/show/NCT01976104?term=avatrombopag&recrs=e&rank=6.
4. ClinicalTrials.gov. Identifier: NCT01972529. Treatment of Thrombocytopenia in Patients With Chronic Liver Disease Undergoing an Elective Procedure. Available at: https://clinicaltrials.gov/ct2/show/NCT01972529?term=avatrombopag&recrs=e&rank=7.
5. NCCN Guidelines. Myelodysplastic Syndromes. V.1.2019.
6. Jurczak W, et al. Phase 3 randomised study of avatrombopag, a novel thrombopoietin receptor agonist for the treatment of chronic immune thrombocytopenia. Br J Haematol. 2018 Nov;183(3):479-490.
7. ClinicalTrials.gov. Identifier: NCT00441090. Study of AKR-501 Tablets Taken Orally Once Daily for 28 Days in Patients With Chronic Idiopathic Thrombocytopenic Purpura (ITP). Available at: https://clinicaltrials.gov/ct2/show/NCT00441090?term=avatrombopag&rank=8.
8. ClinicalTrials.gov. Identifier: NCT01438840. Efficacy and Safety of Oral E5501 Plus Standard of Care for the Treatment of Thrombocytopenia in Adults With Chronic Immune Thrombocytopenia (Amendment 02). Available at: https://www.clinicaltrials.gov/ct2/show/NCT01438840?term=avatrombopag&recrs=e&rank=8.

Effective date: 09/26/2019
Revised date: 07/24/2019