PHARMACY POLICY STATEMENT **North Carolina Marketplace**	
DRUG NAME	Promacta (eltrombopag)
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 immune globulins QUANTITY LIMIT — 30 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Promacta (eltrombopag) 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 1 year of age or older; AND
2. Member has a documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND
3. Medication must be prescribed by or in consultation with a hematologist; AND
4. Member has ONE of the following conditions:
   a) Current platelet count is $<30x10^9$/L;
   b) $30x10^9$/L to $50x10^9$/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
5. 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.
6. **Dosage allowed:** Administer 50 mg by mouth once daily for most patients 6 years and older; 25 mg by mouth once daily for 1 to 5 years of age. Max dose of 75 mg daily.

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

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.

CHRONIC HEPATITIS C ASSOCIATED THROMBOCYTOPENIA

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Member has a documented diagnosis of Thrombocytopenia associated with chronic Hepatitis C infection; AND
3. Medication must be prescribed by or in consultation with a hematologist or an infectious disease specialist; AND
4. Member has a platelet count of less than 75 x 10^9/L; AND
5. Member does not have any of the following:
   a) Decompensated liver disease (Child-Pugh score > 6, class B and C);
   b) History of ascites;
   c) Hepatic encephalopathy.
6. **Dosage allowed:** Initiate at a dose of 25 mg by mouth once daily, then adjust in 25 mg increment every week to achieve target platelet count. Max dose of 100 mg daily.

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

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 below 400 x 10^9/L; AND
4. Member is taking ribavirin or peginterferon concurrently as documented in chart notes and/or pharmacy claims.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 3 months.

SEVERE APLASTIC ANEMIA

For **initial** authorization:
1. Member is 17 years of age or older; AND
2. Member has a documented diagnosis of severe aplastic anemia defined as a marrow cellularity <25% plus at least 2 of the following criteria:
   a) Neutrophils or ANC < 0.5 x 10^9/L (500/mm^3);
   b) Platelets < 20 x 10^9/L (20,000/mm^3);
   c) Reticulocyte count < 20 x 10^9/L (20,000/mm^3); AND
3. Member has a baseline platelet count of less than or equal to 30 x 10^9/L; AND
4. Medication must be prescribed by or in consultation with a hematologist; AND
5. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with at least one course of immunosuppressive therapy (e.g., anti-thymocyte globulin (ATGAM), thymoglobulin, or cyclosporine).

6. **Dosage allowed:** Initiate at a dose of 50 mg by mouth once daily, then adjust in 50 mg increment every 2 weeks to achieve target platelet count ≥ 50 x 10^9/L. Max dose of 150 mg daily.

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

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 400 x 10^9/L.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 3 months.

CareSource considers Promacta (eltrombopag) 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:

- ITP with previous documented failure of Promacta
- Thrombocytopenia due to Myelodysplastic syndrome (MDS)

DATE	ACTION/DESCRIPTION
05/02/2018	New policy for Promacta created. Baseline liver enzymes levels requirement was removed. Four months of immunosuppressive therapy requirement for Severe Aplastic Anemia was removed. Platelets requirement threshold expanded.
11/17/2021	Annual review, no changes

References:

1. Promacta [Package Insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2017.
2. Diagnosis and treatment of idiopathic thrombocytopenic purpura: recommendations of the American Society of Hematology. Ann Intern Med. 1997 Feb 15;126(4):319-26.
3. McHutchinson JG, Dusheiko G, Shiffman ML, et al. Eltrombopag for Thrombocytopenia in Patients with Cirrhosis Associated with Hepatitis C. N Engl J Med 2007; 357:2227-2236.
4. Killick SB, Bown N, Cavenagh J, et al. Guidelines for the diagnosis and management of adult aplastic anemia. Br J Haematol. 2016 Jan;172(2):187-207.

Effective date: 01/01/2023
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