PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Promacta (eltrombopag)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Promacta, approved by the FDA in 2008, is a small molecule thrombopoietin receptor agonist (TPO-RA) indicated for the treatment of persistent or chronic immune thrombocytopenia (ITP), for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy, and for the treatment of severe aplastic anemia. It is important to take Promacta without a meal or with a meal low in calcium, and separated from any medication or product containing polyvalent cations. Promacta has a boxed warning for risk of hepatic decompensation in patients with chronic hepatitis C and risk of hepatotoxicity. Dose reductions are needed for patients with hepatic impairment and some patients of East-/SoutheastAsian ancestry.
ITP is a rare autoimmune disorder characterized by low levels of platelets due to platelet destruction and insufficient platelet production. Aplastic anemia (AA) is a bone marrow failure syndrome characterized by marrow hypoplasia and hematopoietic stem cell (HSC) deficiency. Most cases of AA are acquired rather than inherited. Acquired AA results from immune-mediated destruction of bone marrow.
does not produce blood cells, causing pancytopenia.

Promacta (eltrombopag) will be considered for coverage when the following criteria are met:

Immune Thrombocytopenia (ITP)

For **initial** authorization:

1. Member is at least 1 year of age; AND
2. Medication is prescribed by or in consultation with a hematologist; AND
3. Member has a documented diagnosis of persistent or chronic ITP for at least 3 months; AND
4. Member meets one of the following:
   a) Current platelet count is $<30x10^9$/L
   b) $30x10^9$/L to $50x10^9$/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
5. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with at least one of the following treatments:
   a) Corticosteroid
   b) Immunoglobulin
   c) Splenectomy; AND
6. Members 6 years of age and older requesting oral suspension must provide clinical rationale why tablets cannot be used; AND
7. Member does NOT have any of the following:
   a) Thromboembolic condition
   b) Any cause of thrombocytopenia other than primary ITP
   c) Concurrent use with another TPO-RA or with Tavalisse.

3. Members 6 years of age and older requesting oral suspension must provide clinical rationale why tablets cannot be used; AND
4. Member has a documented diagnosis of severe aplastic anemia defined as a marrow cellularity < 25% (or 25 50% with <30% residual haematopoietic cells) plus at least 2 of the following:
   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
5. Member meets one of the following:
   a) 1st line therapy: Will be using Promacta in combination with immunosuppressive therapy, i.e., anti-thymocyte globulin (ATG) and cyclosporine
   b) Refractory disease: Member had an insufficient response to immunosuppressive therapy.
6. **Dosage allowed/Quantity limit:**
   Severe aplastic anemia first-line: Initial doses:

   Refractory severe aplastic anemia: Initiate at a dose of 50 mg by mouth once daily, then adjust in 50 mg increment every 2 weeks as necessary
   150 mg daily.
   QL: 60 tablets per 30 days or 30 packets per 30 days (oral suspension kit).

If all the above requirements are met , the medication will be approved for 6 months if using as first -line treatment; for 4 months for refractory patients. .

For **reauthorization**:
1. If continuing therapy for refractory disease, chart notes must show improvement from baseline with at least one of the following:
   a) Platelet response (increased platelet count)
   b) Neutrophil response (increased ANC)
   c) Erythroid response (increased hemoglobin)
   d) Transfusion independence; AND
2. 200 x 10^9/L or the dose is being reduced.

If all the above requirements are met , the medication will be approved for an additional 6 months if the member has severe refractory aplastic anemia. Do not reauthorize if member was using as part of first -line therapy regimen .

CareSource considers Promacta (eltrombopag) 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
05/02/2018	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
03/07/2019	

Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource.