I. Medication Description

Idiopathic thrombocytopenia purpura (ITP) is a hematologic disorder marked by platelet counts below 100,000/mm³ and mucocutaneous bleeding. Primary immune thrombocytopenic purpura occurs in the absence of another underlying disease. Promacta is an orally bioavailable, small-molecule TPO receptor agonist that interacts with the transmembrane domain of the human TPO-receptor and initiates signaling cascades that induce proliferation and differentiation of megakaryocytes from bone marrow progenitor cells.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Promacta is provided for the following:

- For the treatment of thrombocytopenia in members with chronic immune thrombocytopenia (ITP) [defined by platelet counts below 100,000/mm³]:
  - When the member is at least one year of age AND
  - When the member has had an inadequate response to treatment with corticosteroids, immunoglobulins, or splenectomy AND
    - Platelet counts are <30,000/mm³ OR
    - Platelet counts are >30,000/mm³ AND member has active bleeding or is at risk for bleeding based on their clinical condition
- For the treatment of thrombocytopenia in adult members with chronic hepatitis C:
  - To allow the initiation and maintenance of interferon-based therapy when the degree of thrombocytopenia prevents the initiation of interferon therapy or limits the ability to maintain optimal interferon-based therapy AND
  - Promacta is not used in combination with a direct-acting antiviral agent used without interferon
- For the first-line treatment of severe aplastic anemia in adult and pediatric patients 2 years and older, in combination with standard immunosuppressive therapy.
- For the treatment of severe aplastic anemia in adult members who have had an insufficient response to immunosuppressive therapy.
IV. **Quantity Limitations**

Coverage is available for pertinent indications as follows:

- Chronic ITP: up to 75 mg/day
- Thrombocytopenia in Hepatitis C: up to 100 mg/day
- Severe aplastic anemia: up to 150 mg/day

V. **Coverage Duration**

Coverage is provided for up to 6 months depending on need for therapy and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Demonstrated response to therapy (e.g. increase in platelet counts, resolution of bleeding symptoms, etc.) **AND**
- Continued need for therapy as evidenced by platelet counts **AND**
- For chronic hepatitis C patients, coverage is limited to the duration of time that interferon therapy is still administered.

VII. **Billing/Coding Information**

Promacta is available as:

- Tablets: 12.5mg, 25mg, 50mg, and 75mg
- Oral Suspension:
  - 12.5mg unit-dose packets for oral suspension
  - 25mg unit-dose packets for oral suspension

VIII. **Summary of Policy Changes**

- 12/15/12: renewal criteria changed to specify that continued need must be established via platelet counts; dosing adjustment recommendations added for Nplate; references to Nplate NEXUS and Promacta CARES programs removed.
- 12/2012: removed to own policy, addition of new indication for treatment of thrombocytopenia in chronic hepatitis C patients
- 12/15/13:
  - Update coverage renewal criteria language for use in chronic hepatitis C patients
  - Updated policy section to include limitation of use language for chronic hepatitis C patients
- 1/1/15: addition of severe aplastic anemia to criteria based on FDA approval
- 7/1/15: formulary distinctions made, age requirements outlined according to updated prescribing information for Promacta
- 3/16/15: age requirements updated to allow for coverage in patients 1 year of age or older
- 1/1/17: removed 100 mg tablets from policy as they are no longer available
IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.