## Prior Authorization Approval Criteria

*Promacta (eltrombopag)*

<table>
<thead>
<tr>
<th>Generic name:</th>
<th>Eltrombopag</th>
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</thead>
<tbody>
<tr>
<td>Brand name:</td>
<td>Promacta</td>
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<tr>
<td>Medication class:</td>
<td>Thrombopoietin receptor agonist</td>
</tr>
</tbody>
</table>

**FDA-approved uses:**
- Treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.
- Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

<table>
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<tr>
<th>Available dosage forms:</th>
<th>12.5 mg, 25 mg, 50 mg, 75 mg, and 100 mg tablets</th>
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**Usual dose:**

- **Chronic immune thrombocytopenic purpura (ITP):**
  - 50 mg once daily for most patients.
  - Adjust the daily dose to achieve and maintain a platelet count $\geq 50 \times 10^9/L$ in order to reduce the risk for bleeding. Do not exceed 75 mg/day.

- **Chronic hepatitis C-associated thrombocytopenia:**
  - Initiate at 25 mg once daily for all patients.
  - Adjust to achieve target platelet count required to initiate antiviral therapy. Do not exceed 100 mg/day.

- **Severe aplastic anemia:**
  - 50 mg once daily for most patients.
  - Adjust the daily dose to achieve and maintain a platelet count $\geq 50 \times 10^9/L$ in order to reduce the risk for bleeding. Do not exceed 150 mg per day.

**Approximate monthly cost:** $6,800/month based on 50 mg/day. (based on AWP 2014)

**Duration of therapy:** Indefinite

**Criteria for use (bullet points below are all inclusive unless otherwise noted):**

- **Chronic immune thrombocytopenic purpura (ITP):**
  - Confirmed diagnosis of chronic immune (idiopathic) thrombocytopenic purpura.
  - Required information is needed to complete review which includes: clinical notes from the patient’s medical records including any applicable labs and / or tests, supporting the diagnosis.
  - Patient must have tried and failed corticosteroids, immunoglobulins or splenectomy. (failure defined as platelets not increased to at least 50,000/mcl)
  - Must be prescribed by a hematologist.

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
• Platelet count must be less than 30,000/mcL.
• Patients’ degree of thrombocytopenia and clinical condition place patient at an increased risk for bleeding.

**Chronic hepatitis C-associated thrombocytopenia:**
• Confirmed diagnosis of chronic hepatitis C associated thrombocytopenia.
• Required information is needed to complete review which includes: clinical notes from the patient’s medical records including any applicable labs and / or tests, supporting the diagnosis.
• Must be prescribed by a gastroenterologist, infectious disease specialist or transplant specialist.
• Must have low platelets (<75,000/mcl)
• Patient must be prescribed interferon for treatment of chronic hepatitis C infection
• Patients’ degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.

**Severe aplastic anemia:**
• Confirmed diagnosis of severe aplastic anemia.
• Required information is needed to complete review which includes: clinical notes from the patient’s medical records including any applicable labs and / or tests, supporting the diagnosis.
• Must be prescribed by a hematologist.
• Patient must have tried and failed at least one prior immunosuppressive therapy.
• Platelet count must be less than 30,000/mcL.

**Criteria for continuation of therapy:**
**Chronic immune thrombocytopenic purpura (ITP):**
• Patient must show a response to treatment with a platelet count of at least 50,000/mcL but less than 200,000/mcL. (response rates should be seen at least 1 week after initiation of treatment with a maximum response seen at 2 weeks)

**Severe aplastic anemia:**
• Patient must show a response to treatment by meeting ONE of the following criteria:
  ▪ Platelet count increase of at least 20,000/mcl above baseline, or stable platelet counts with transfusion independence for a minimum of 8 weeks
  ▪ Hemoglobin increase by greater than 1.5 g/dl or reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks
  ▪ ANC increase of 100% or an ANC increase greater than 500/mcl

**Caution:**
• Hepatotoxicity
• Bone marrow reticulin formation and risk for bone marrow fibrosis
• Worsened thrombocytopenia after cessation of Promacta leading to serious hemorrhage
• Thrombotic/thromboembolic complications.
• Increased risk of hematological malignancies and progression of malignancy in patients with pre-existing hematological malignancy or myelodysplastic syndrome (MDS)

**Monitoring:**
• Liver function tests
• CBC’S including platelet counts and peripheral blood smears weekly during the dose adjustment and then monthly once on a stable dose.

**Contraindication:**

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
• None reported at this time.

Not approved if:
• Promacta is being used in an attempt to normalize platelet counts. (The goal of treatment is to prevent bleeding and to achieve a safe, but not necessarily normal, platelet count.)

Special considerations:
• Discontinuation may result in worsened thrombocytopenia than was present prior to therapy.

Authorization Approval Duration:
*Chronic immune thrombocytopenic purpura (ITP):*
• Initial 3 months
• Renewal 6 months
*Chronic hepatitis C-associated thrombocytopenia:*
• Initial Length of hepatitis C treatment (up to 48 weeks)
*Severe aplastic anemia:*
• Initial 3 months
• Renewal 6 months

Fallon Health Pharmacy and Therapeutics Committee approval: ________________________________

Date: ______________________

Adopted: 03/11/09R
Revised 12/30/13; 12/10/14
Effective: 2/10/15