Promacta® (eltrombopag)  
(Oral Formulation)

I. Length of Authorization

Coverage is provided for three months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - 12.5 mg tablets – 1 tablet per day
   - 25 mg tablets – 1 tablet per day
   - 50 mg tablets – 1 tablet per day
   - 75 mg tablets – 1 tablet per day
   - 100 mg tablets - 1 tablet per day
   - 25 mg packet for oral suspension – 3 kits (each containing 30 packets) per 30 days

B. Max Units (per dose and over time) [Medical Benefit]:
   - 150 mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient does not have myelodysplastic syndrome (MDS): AND

Chronic immune (idiopathic) thrombocytopenia (ITP) †

- Patient aged 1 year or older: AND
- Patient has previously failed any of the following treatments for ITP:
  - Patient has failed previous therapy with corticosteroids; OR
  - Patient has failed previous therapy with immunoglobulins; OR
  - Patient has had splenectomy or is not a surgery candidate; AND
- The patient is at increased risk for bleeding as indicated by platelet count of less than 30 × 10^9/L (30,000/mm³); AND
- Promacta is not being used to attempt to normalize platelet count
Chronic Hepatitis C-associated thrombocytopenia †

- Patient aged 18 years or older: AND
- Patient will be initiating and/or continuing interferon-based therapy to treat Hepatitis C; AND
- Patient is diagnosed with thrombocytopenia as indicated by platelet count of less than 60 × 10⁹/L (60,000/mm³)

Severe Aplastic Anemia †

- Patient aged 18 years or older: AND
  - Patient has bone marrow (BM) cellularity < 25%; OR
  - Patient has bone marrow (BM) cellularity < 50% if < 30% of BM is hematopoietic cells; AND
- Patient is diagnosed with severe aplastic anemia and has at least two (2) of the following:
  - Peripheral blood neutrophil count < 0.5 x 10⁹/L
  - Peripheral blood platelet count < 20 x 10⁹/L
  - Peripheral blood reticulocyte count < 20 x 10⁹/L; AND
- Patient has had at least a 3 month trial and failed previous therapy with ONE immunosuppressive therapy such as antithymocyte globulin, cyclosporine, or cyclophosphamide.

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III: AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hepatotoxicity (abnormal liver enzymes) and thrombotic/thromboembolic complications (blood clots), etc: AND

Thrombocytopenia

- Disease response indicated by the achievement and maintenance of a platelet count of at least 50 × 10⁹/L as necessary to reduce the risk for bleeding

Aplastic Anemia

- Disease response indicated by one (1) or more of the following criteria:
  - Platelet count increases to 20 x 10⁹/L 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 a 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 0.5 x 10^9/L.

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITP</td>
<td>• Pediatric patients aged 1-5 years: initiate at a dose of 25 mg daily</td>
</tr>
<tr>
<td></td>
<td>• Adults and pediatric patients 6 years and older: initiate at a dose of 50 mg daily</td>
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<tr>
<td></td>
<td>Adjust to maintain platelet count greater than 50 x 10^9/L. Do not exceed 75mg daily.</td>
</tr>
<tr>
<td>Chronic Hepatitis C-associated thrombocytopenia</td>
<td>Initiate at 25 mg daily. Do not exceed 100 mg daily</td>
</tr>
<tr>
<td>Severe Aplastic Anemia</td>
<td>Initiate at 50 mg once daily. Adjust to maintain platelet count greater than 50 x 10^9/L. Do not exceed 150 mg per day.</td>
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</tbody>
</table>

VI. Billing Code/Availability Information

Jcode:
J8499- Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

NDC:
• 12.5 mg tablets: 00078-0684-xx
• 25 mg tablets: 00078-0685-xx
• 50 mg tablets: 00078-0686-xx
• 75 mg tablets: 00078-0687-xx
• 100 mg tablets: 00078-0688-xx
• 25 mg packet for oral suspension: 00078-0697-xx

VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B18.2</td>
<td>Chronic viral hepatitis C</td>
</tr>
<tr>
<td>D61.3</td>
<td>Idiopathic aplastic anemia</td>
</tr>
<tr>
<td>D61.9</td>
<td>Aplastic anemia, unspecified</td>
</tr>
<tr>
<td>D69.3</td>
<td>Immune thrombocytopenic purpura</td>
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</table>

Appendix 2 – Centres for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

<table>
<thead>
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<th>Jurisdiction</th>
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<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
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<td>Novitas Solutions, Inc.</td>
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<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
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<tr>
<td>N (9)</td>
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<td>First Coast Service Options, Inc.</td>
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<tr>
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<td>M (11)</td>
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<tr>
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<td>Novitas Solutions, Inc.</td>
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<td>K (13 &amp; 14)</td>
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<td>15</td>
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<td>CGS Administrators, LLC</td>
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