

Promacta[®] (eltrombopag) (Oral Formulation)

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I. Length of Authorization

Coverage is provided for three months and may be renewed.

Use in first-line therapy is limited and may be renewed up to 6 months of treatment.

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
- 12.5 mg packet for oral suspension – 1 packet per day
- 25 mg packet for oral suspension – 3 packets per day

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 $30 \times 10^9/L$ ($30,000/mm^3$); **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 $60 \times 10^9/L$ ($60,000/mm^3$)

Severe Aplastic Anemia †

- Patient is diagnosed with severe aplastic anemia; **AND**
 - Patient has either of the following:
 - Patient has bone marrow (BM) cellularity < 25%; **OR**
 - Patient has bone marrow (BM) cellularity < 50% if < 30% of BM is hematopoietic cells; **AND**
 - Patient has at least two (2) of the following:
 - Peripheral blood neutrophil count < $0.5 \times 10^9/L$
 - Peripheral blood platelet count < $20 \times 10^9/L$
 - Peripheral blood reticulocyte count < $20 \times 10^9/L$; **AND**
- Used in first-line therapy; **AND**
 - Patient aged 2 years or older; **AND**
 - Patient has not received prior immunosuppressive therapy with antithymocyte globulin (ATG), alemtuzumab, or high-dose cyclophosphamide; **AND**
 - Used in combination with standard immunosuppressive therapy (i.e., antithymocyte globulin (ATG) and cyclosporine); **OR**
- Used in refractory disease; **AND**
 - Patient aged 18 years or older; **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 $50 \times 10^9/L$ as necessary to reduce the risk for bleeding

Aplastic Anemia

- First-line therapy disease response indicated by two (2) or more of the following criteria on 2 consecutive serial blood count measurements at least one week apart;
 - Platelet count increases to $20 \times 10^9/L$ above baseline
 - Hemoglobin greater than 10 g/dL
 - ANC increase greater than $0.5 \times 10^9/L$.
 - Reticulocyte count greater than 60,000/mcL
- Refractory disease response indicated by one (1) or more of the following criteria on 2 consecutive serial blood count measurements at least one week apart;
 - Platelet count increases to $20 \times 10^9/L$ 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 $0.5 \times 10^9/L$.
 - Reticulocyte count greater than 60,000/mcL

V. Dosage/Administration

Indication	Dose
ITP	<ul style="list-style-type: none"> • Pediatric patients aged 1-5 years: initiate at a dose of 25 mg daily • Adults and pediatric patients 6 years and older: initiate at a dose of 50 mg daily. <i>Decrease initial dose to 25 mg for patients of Asian ancestry or those with hepatic impairment (Child-Pugh Class A, B, C)</i> Adjust to maintain platelet count greater than $50 \times 10^9/L$. Do not exceed 75mg daily.
Chronic Hepatitis C-associated thrombocytopenia	Initiate at 25 mg daily. Do not exceed 100 mg daily
Severe Aplastic Anemia (First-line therapy)	<u>Age 2-5 years:</u> <ul style="list-style-type: none"> • 2.5 mg/kg once daily for 6 months. Total duration of treatment is 6 months. <u>Age 6-11 years:</u> <ul style="list-style-type: none"> • 75 mg once daily for 6 months. Total duration of treatment is 6 months.

	<p><u>Age 12 years and older:</u></p> <ul style="list-style-type: none"> 150 mg once daily for 6 months. Total duration of treatment is 6 months. <i>Decrease dose by 50% for patients of Asian ancestry or those with hepatic impairment (Child-Pugh Class A, B, C)</i>
Severe Refractory Aplastic Anemia	<p>Initiate at 50 mg once daily. Adjust the dose in 50-mg increments every 2 weeks to maintain platelet count greater than 50 x 10⁹/L. Do not exceed 150 mg per day.</p> <p><i>Decrease initial dose to 25 mg for patients of Asian ancestry or those with hepatic impairment (Child-Pugh Class A, B, C)</i></p>

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
- 12.5 mg packet for oral suspension: 00078-0972-xx
- 25 mg packet for oral suspension: 00078-0697-xx

VII. References

1. Promacta [package insert]. Research Triangle Park, NC; GlaxoSmithKline; November 2018. Accessed November 2018.
2. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. *Blood*. 2011 Apr 21; 117(16):4190-207. doi: 10.1182/blood-2010-08-302984. Epub 2011 Feb 16. Review.
3. Marsh JC, Ball SE, Cavenagh J, et al. Guidelines for the diagnosis and management of aplastic anaemia. *Br J Haematol*. 2009 Oct; 147(1):43-70. doi: 10.1111/j.1365-2141.2009.07842.x. Epub 2009 Aug 10.
4. Guinan EC. Diagnosis and management of aplastic anemia. *Hematology Am Soc Hematol Educ Program*. 2011; 2011:76-81. doi: 10.1182/asheducation-2011.1.76. Review.
5. Killick SB, Bown N, Cavenagh J, et al. Guidelines for the diagnosis and management of adult aplastic anaemia. *Br J Haematol*. 2016;172:187–207.

Appendix 1 – Covered Diagnosis Codes

ICD-10

ICD-10 Description

B18.2	Chronic viral hepatitis C
D61.3	Idiopathic aplastic anemia
D61.9	Aplastic anemia, unspecified
D69.3	Immune thrombocytopenic purpura

Appendix 2 – Centers 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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC