Eltrombopag:
Promacta®; Alvaiz™ Ψ
(Oral)

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I. Length of Authorization [1,2]

Coverage is provided for 3 months and may be renewed.

- First-Line Therapy for Aplastic Anemia *(Promacta ONLY)*: Use is limited to a maximum of 6 months of treatment (i.e., may be renewed one time only).
- Chronic Hepatitis C: Use is limited to a maximum of 48 weeks of treatment (in combination with interferon)

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Promacta 12.5 mg tablets: 1 tablet per day
- Promacta 25 mg tablets: 1 tablet per day
- Promacta 50 mg tablets: 1 tablet per day
- Promacta 75 mg tablets: 2 tablets per day
- Promacta 12.5 mg packet for oral suspension: 1 packet per day
- Promacta 25 mg packet for oral suspension: 3 packets per day
- Alvaiz 9 mg tablets: 1 tablet per day
- Alvaiz 18 mg tablets: 1 tablet per day
- Alvaiz 36 mg tablets: 1 tablet per day
- Alvaiz 54 mg tablets: 1 tablet per day

B. Max Units (per dose and over time) [HCPCS Unit]:

Diagnosis	Promacta	Alvaiz
Immune Thrombocytopenia	75 mg daily	54 mg daily
Hepatitis C-Associated Thrombocytopenia	100 mg daily	72 mg daily
Aplastic Anemia	150 mg daily	108 mg daily

Chemotherapy-Induced Thrombocytopenia	150 mg daily	54 mg daily
MDS	300 mg daily	N/A

III. Initial Approval Criteria [1,2,16-18]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age, unless otherwise specified; **AND**

Universal Criteria [1,2]

- Patient is not on any other thrombopoietin receptor agonist or mimetic (e.g., romiplostim, avatrombopag, lusutrombopag, etc.) or fostamatinib; **AND**
- Laboratory values are current (i.e., drawn within the previous 28 days); **AND**
- Eltrombopag is not being used to attempt to normalize platelet count (i.e., use is limited to decreasing the risk of bleeding from thrombocytopenia by increasing platelet levels and not normalizing them); **AND**

Persistent or Chronic Immune (idiopathic) Thrombocytopenia (ITP) † Φ [1-3,7-10,14,19]

- Patient is at least 1 year of age (Promacta) OR at least 6 years of age (Alvaiz); **AND**
- Patient has had persistent or chronic ITP for at least 6 months (or meets the corticosteroid requirement below); **AND**
- Patient has previously failed any of the following treatments for ITP:
  - Patient has failed previous therapy with corticosteroids (i.e., patient had no response to at least a 3-month trial or is corticosteroid-dependent); **OR**
  - Patient has failed previous therapy with immunoglobulins; **OR**
  - Patient has had splenectomy; **AND**
- The patient is at increased risk for bleeding as indicated by platelet count of less than 30 × 10^9/L (30,000/mm^3)

Chronic Hepatitis C-Associated Thrombocytopenia † [1,2,11,12]

- Patient will be initiating and/or continuing interferon-based therapy to treat chronic hepatitis C; **AND**
- Patient is diagnosed with thrombocytopenia as indicated by platelet count of less than 75 × 10^9/L (75,000/mm^3); **AND**
- The patient's degree of thrombocytopenia precludes administration of interferon-based therapy in the absence of eltrombopag

***Note**: Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon*

Severe Aplastic Anemia † Φ [1,2,6,13,15]

- Patient is diagnosed with severe aplastic anemia; **AND**
- Patient has one of the following:
  - Patient has bone marrow (BM) cellularity < 25%; **OR**
  - Patient has bone marrow (BM) cellularity 25-50% if < 30% of BM is residual hematopoietic cells; **AND**
- Patient has at least two (2) of the following:
  - Peripheral blood neutrophil count/absolute neutrophil count (ANC) < 0.5 x 10^9/L
  - Peripheral blood platelet count < 20 x 10^9/L
  - Peripheral blood reticulocyte count < 60 x 10^9/L; **AND**
- Used in one of the following treatment settings:
  - Used as first-line therapy *(Promacta ONLY)*; **AND**
    - Patient is at least 2 years of age; **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 has had at least a 3-month trial and failed previous therapy with ONE immunosuppressive therapy such as antithymocyte globulin, cyclosporine, or cyclophosphamide

Chemotherapy-Induced Thrombocytopenia (CIT) ‡ [20-26]

- Used for prolonged thrombocytopenia; **AND**
- Patient is post-allogeneic transplant with poor graft function

Myelodysplastic Syndromes (MDS) *(Promacta ONLY)* ‡ [16-18,20]

- Patient has lower risk disease [i.e., IPSS-R (Very Low, Low, Intermediate)]; **AND**
  - Used in combination with antithymocyte globulin (ATG) with or without cyclosporine; **AND**
    - Patient is ≤60 years of age with ≤5% marrow blasts OR has hypocellular marrows, paroxysmal nocturnal hemoglobinuria (PNH) clone positivity, or STAT-3 mutant cytotoxic T-cell clones; **AND**
      - Disease is associated with clinically relevant thrombocytopenia or neutropenia; **OR**
    - Patient has symptomatic anemia with no del(5q) and ring sideroblasts <15% (or ring sideroblasts <5% with an SF3B1 mutation), with serum erythropoietin >500 mU/mL; **AND**
      - Patient has a good probability to respond to immunosuppressive therapy; **OR**

- Used as a single agent; **AND**
  - Patient has severe thrombocytopenia (i.e., platelet count <30 x 10^9/L or higher with a history of bleeding); **OR**
  - Patient has refractory thrombocytopenia and has progressed or had no response to hypomethylating agents (e.g., azacitidine, decitabine, etc.) or immunosuppressive therapy

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatic decompensation in patients with chronic hepatitis C, hepatotoxicity (abnormal liver enzymes), risk of progression of myelodysplastic syndromes to acute myelogenous leukemia, thrombotic/thromboembolic complications (blood clots), cataracts, etc.; **AND**
- Platelet count (within the preceding 28 days) does not exceed 400 x 10^9/L; **AND**

Persistent or Chronic Immune (idiopathic) Thrombocytopenia (ITP) † [1,2]

- Disease response as indicated by the achievement and maintenance of a platelet count of at least 50 × 10^9/L as necessary to reduce the risk for bleeding

Chronic Hepatitis C-Associated Thrombocytopenia † [1,2]

- Patient has not exceeded 48 weeks of therapy in combination with interferon; **AND**
- Continued administration is necessary in order to continue to receive interferon

Severe Aplastic Anemia † [1,2,13,15]

- First-line therapy *(Promacta ONLY)*:
  - Patient has not received more than 6 months of treatment; **AND**
  - 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 greater than 20 x 10^9/L
    - Hemoglobin greater than 10 g/dL
    - ANC greater than 0.5 x 10^9/L
    - Reticulocyte count greater than 60,000/mcL
- Refractory disease:
  - Disease response indicated by one (1) or more of the following criteria:

- Platelet count increases to 20 x 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 x 10^9/L

Chemotherapy-Induced Thrombocytopenia [20-26]

- Disease response as indicated by the achievement and maintenance of a platelet count of at least 50 × 10^9/L as necessary to reduce the risk for bleeding

Myelodysplastic Syndromes (MDS) *(Promacta ONLY)*‡ [16-18,20]

- Patient has not developed acute myeloid leukemia (AML); **AND**
- Disease response indicated by an increase in platelet count compared to pretreatment baseline, reduction in bleeding events, or reduction in platelet transfusion requirements

V. Dosage/Administration [1,2,16-18,21-26]

Indication	Dose

Persistent or Chronic ITP	**Promacta**
	• Pediatric patients aged 1-5 years: Initiate at a dose of 25 mg orally once daily.
	• Adults and pediatric patients 6 years and older: Initiate at a dose of 50 mg orally once daily.
	  ○ *Decrease initial dose to 25 mg once daily for patients of East-/Southeast-Asian ancestry OR those with hepatic impairment (Child-Pugh Class A, B, C).*
	  ○ *Decrease initial dose to 12.5 mg once daily for patients of East-/Southeast-Asian ancestry with hepatic impairment (Child-Pugh Class A, B, C).*
	• Adjust the dose to maintain platelet count of at least 50 x 10^9/L. Do not exceed 75 mg daily.
	Alvaiz
	• Adults and pediatric patients 6 years and older: Initiate at a dose of 36 mg orally once daily.
	  • *Decrease initial dose to 18 mg once daily for patients of East-/Southeast-Asian ancestry OR those with hepatic impairment (Child-Pugh Class A, B, C).*
	  • *Decrease initial dose to 9 mg once daily for patients of East-/Southeast-Asian ancestry with hepatic impairment (Child-Pugh Class A, B, C).*
	• Adjust the dose to maintain platelet count of at least 50 x 10^9/L. Do not exceed 54 mg daily

Chronic Hepatitis C-Associated Thrombocytopenia	**Promacta**
	• Initiate at a dose of 25 mg orally once daily.
	  ○ Adjust the dose in 25-mg increments every 2 weeks as necessary to achieve the target platelet count required to initiate antiviral therapy. Do not exceed 100 mg daily.
	  ○ Administered in combination with an interferon-based regimen. Total duration of treatment is not to exceed 48 weeks.
	Alvaiz
	• Initiate at a dose of 18 mg orally once daily.
	  ○ Adjust the dose in 18-mg increments every 2 weeks as necessary to achieve the target platelet count required to initiate antiviral therapy. Do not exceed 72 mg daily.
	  ○ Administered in combination with an interferon-based regimen. Total duration of treatment is not to exceed 48 weeks.

Severe Aplastic Anemia (First-line therapy)	**Promacta ONLY** Age 2-5 years: • 2.5 mg/kg orally once daily for 6 months. Total duration of treatment is 6 months. Age 6-11 years: • 75 mg orally once daily for 6 months. Total duration of treatment is 6 months. Age 12 years and older: • 150 mg orally once daily for 6 months. Total duration of treatment is 6 months. ***Decrease dose by 50% for patients of East-/Southeast-Asian ancestry OR those with hepatic impairment (Child-Pugh Class A, B, C).*

Refractory Severe Aplastic Anemia	**Promacta**
	• Initiate at a dose of 50 mg orally once daily.
	  ○ Adjust the dose in 50-mg increments every 2 weeks to maintain platelet count of at least 50 x 10^9/L. Do not exceed 150 mg per day.
	  ○ *Decrease initial dose to 25 mg for patients of East-/Southeast-Asian ancestry OR those with hepatic impairment (Child-Pugh Class A, B, C).*
	Alvaiz
	• Initiate at a dose of 36 mg orally once daily.
	  ○ Adjust the dose in 36-mg increments every 2 weeks to maintain platelet count of at least 50 x 10^9/L. Do not exceed 108 mg per day.
	  ○ *Decrease initial dose to 18 mg for patients of East-/Southeast-Asian ancestry OR those with hepatic impairment (Child-Pugh Class A, B, C).*

Chemotherapy-Induced	**Promacta** • Initiate at a dose of 50 mg orally once daily.

Thrombocytopenia (CIT)	• Adjust the dose to maintain platelet count of at least 50 x 10^9/L. Do not exceed 150 mg daily. **Alvaiz** • Initiate at a dose of 36 mg orally once daily. • Adjust the dose to maintain platelet count of at least 50 x 10^9/L. Do not exceed 54 mg daily. *****NOTE:** Decrease dose by 50% for patients of East-/Southeast-Asian ancestry*
MDS	**Promacta ONLY** Initiate at a dose of 100 mg orally once daily. Do not exceed a maximum of 300 mg per day. *****NOTE:** Decrease dose by 50% for patients of East-/Southeast-Asian ancestry.*

VI. Billing Code/Availability Information

HCPCS Code:

- J8499 – Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

NDC(s):

- Promacta 12.5 mg tablets: 00078-0684-xx
- Promacta 25 mg tablets: 00078-0685-xx
- Promacta 50 mg tablets: 00078-0686-xx
- Promacta 75 mg tablets: 00078-0687-xx
- Promacta 12.5 mg packet for oral suspension: 00078-0972-xx
- Promacta 25 mg packet for oral suspension: 00078-0697-xx
- Alvaiz 9 mg tablets: 00480-3273-xx Ψ
- Alvaiz 18 mg tablets: 00480-3274-xx Ψ
- Alvaiz 36 mg tablets: 00480-3275-xx Ψ
- Alvaiz 54 mg tablets: 00480-3276-xx Ψ

Ψ *Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations / Orange Book / FDA*

VII. References

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20. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for eltrombopag. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to www.nccn.org/. Accessed December 2023.
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Appendix 1 – Covered Diagnosis Codes

Promacta

ICD-10	ICD-10 Description
B18.2	Chronic viral hepatitis C

C93.10	Chronic myelomonocytic leukemia not having achieved remission
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.4	Refractory anemia, unspecified
D46.9	Myelodysplastic syndrome, unspecified
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.Z	Other myelodysplastic syndromes
D69.59	Other secondary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D61.3	Idiopathic aplastic anemia
D61.9	Aplastic anemia, unspecified
D69.3	Immune thrombocytopenic purpura
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela

Alvaiz

ICD-10	ICD-10 Description
B18.2	Chronic viral hepatitis C
D69.59	Other secondary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D61.3	Idiopathic aplastic anemia
D61.9	Aplastic anemia, unspecified
D69.3	Immune thrombocytopenic purpura
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations

(NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/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