

Specialty Guideline Management

eltrombopag olamine-Promacta-Alvaiz

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Promacta	eltrombopag olamine
Alvaiz	eltrombopag choline

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2}

Promacta and eltrombopag olamine are indicated for:

- Treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Eltrombopag tablets and tablets for oral suspension should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Eltrombopag tablets and tablets for oral suspension should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.

- First-line treatment of severe aplastic anemia in adult and pediatric patients 2 years and older in combination with standard immunosuppressive therapy (Promacta only).
- Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Alvaiz is indicated for:

- Treatment of thrombocytopenia in adult and pediatric patients 6 years and older with persistent or chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- Treatment of thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.
- Treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Compendial Uses

- MYH9-related disease with thrombocytopenia⁴
- Myelodysplastic syndromes (MDS)^{5,6}
- Thrombocytopenia post-hematopoietic cell transplant⁵
- Immune checkpoint inhibitor-related toxicity^{5,14}

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Immune thrombocytopenia (ITP):

- For initial requests: Untransfused platelet count
- For continuation requests: Current platelet count

Aplastic anemia:

- For continuation requests: Current platelet count

Myelodysplastic syndromes (MDS), Immune checkpoint inhibitor-related toxicity, and Thrombocytopenia Post-Hematopoietic Cell Transplant⁵

- For continuation requests: Chart notes or medical record documentation supporting benefit from therapy

Exclusions

Coverage will not be provided when the requested drug will be used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse).

Prescriber Specialties

This medication must be prescribed by or in consultation with either of the following:

- Immune thrombocytopenia (ITP), aplastic anemia, MYH9-related disease with thrombocytopenia, myelodysplastic syndromes, thrombocytopenia post-hematopoietic cell transplant, and immune checkpoint inhibitor-related toxicity: hematologist or oncologist
- Thrombocytopenia with hepatitis C: hematologist or a provider experienced in the management of hepatitis C infection

Coverage Criteria

Immune Thrombocytopenia (ITP)^{1,2,7-10}

Authorization of 6 months may be granted for treatment of immune thrombocytopenia (ITP) when both of the following criteria are met:

- Member has had an inadequate response or intolerance to prior therapy with corticosteroids, immunoglobulins, or splenectomy.
- Member has an untransfused platelet count at any point prior to the initiation of the requested medication of either of the following:
 - Less than $30 \times 10^9/L$
 - $30 \times 10^9/L$ to $50 \times 10^9/L$ with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (see Appendix)

Thrombocytopenia Associated with Chronic Hepatitis C^{1,2}

Authorization of 12 months may be granted to members who are prescribed the requested drug for the initiation and maintenance of interferon-based therapy for the treatment of thrombocytopenia associated with chronic hepatitis C.

Severe Aplastic Anemia^{1,2,12,13}

Promacta

- Authorization of 6 months may be granted for first-line treatment of severe aplastic anemia when the requested drug will be used in combination with standard immunosuppressive therapy (e.g., horse antithymocyte globulin [h-ATG] and cyclosporine).
- Authorization of 6 months may be granted for treatment of severe aplastic anemia in members who have had an insufficient response to immunosuppressive therapy.

Alvaiz

Authorization of 6 months may be granted for treatment of severe aplastic anemia in members who have had an insufficient response to immunosuppressive therapy.

MYH9-Related Disease with Thrombocytopenia⁴

Authorization of 12 months may be granted to members with thrombocytopenia associated with MYH9-related disease.

Myelodysplastic Syndromes(MDS)^{5,6}

Authorization of 12 months may be granted for treatment of myelodysplastic syndromes (MDS).

Thrombocytopenia Post-Hematopoietic Cell Transplant⁵

Authorization of 6 months may be granted for treatment of prolonged thrombocytopenia in members who are post-allogeneic transplant and have poor graft function.

Immune Checkpoint Inhibitor-Related Toxicity^{5,14}

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the requested medication will be used for immunotherapy-related G3 (25,000/mm³-50,000/mm³) or G4 (less than 25,000/mm³) thrombocytopenia if the member did not have a response to corticosteroids after 1 to 2 weeks.

Continuation of Therapy

Immune Thrombocytopenia (ITP)^{1,2,7-10}

- Authorization of 3 months may be granted to members with current platelet count less than 50x10⁹/L for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received a maximal dose of the requested drug for at least 4 weeks.

- Authorization of 12 months may be granted to members with current platelet count less than $50 \times 10^9/L$ for whom the current platelet count is sufficient to prevent clinically important bleeding.
- Authorization of 12 months may be granted to members with current platelet count of $50 \times 10^9/L$ to $200 \times 10^9/L$.
- Authorization of 12 months may be granted to members with current platelet count greater than $200 \times 10^9/L$ to less than or equal to $400 \times 10^9/L$ for whom dosing for the requested drug will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

Thrombocytopenia Associated with Chronic Hepatitis C^{1,2}

Authorization of 12 months may be granted to members who are continuing to receive interferon-based therapy.

Severe Aplastic Anemia^{1,2,11}

- Authorization of up to 16 weeks total may be granted to members with current platelet count less than $50 \times 10^9/L$ who have not received appropriately titrated therapy with the requested drug for at least 16 weeks.
- Authorization of 12 months total may be granted to members with current platelet count less than $50 \times 10^9/L$ who are transfusion-independent.
- Authorization of 12 months may be granted to members with current platelet count of $50 \times 10^9/L$ to $200 \times 10^9/L$.
- Authorization of 12 months may be granted to members with current platelet count greater than $200 \times 10^9/L$ to less than or equal to $400 \times 10^9/L$ for whom dosing for the requested drug will be adjusted to achieve and maintain an appropriate target platelet count.

MYH9-related Disease with Thrombocytopenia⁴

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Myelodysplastic Syndromes, Immune Checkpoint Inhibitor-Related toxicity, and Thrombocytopenia Post-Hematopoietic Cell Transplant^{5,6}

Authorization of 12 months may be granted for continued treatment of myelodysplastic syndromes, immune checkpoint inhibitor-related thrombocytopenia, or thrombocytopenia post-hematopoietic cell transplant in members who experience benefit from therapy (e.g., increased platelet counts, decreased bleeding events, reduced need for platelet transfusions).

Appendix

Examples of risk factors for bleeding (not all inclusive)^{8,9}

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidities for bleeding (e.g., peptic ulcer disease)
- Mandated anticoagulation therapy
- Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes member to trauma

References

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