Promacta and Alvaiz (eltrombopag)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. For this program, Alvaiz (eltrombopag choline) and eltrombopag olamine (generic Promacta) are the preferred products. Coverage for the non-preferred product, Promacta (brand only), is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. Submission of medical records documenting relevant history, physician evaluation information, and supporting compendia or current literature (if applicable) will be required for review of these exceptions.

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

FDA-Approved Indications

Promacta (eltrombopag olamine) is a thrombopoietin receptor agonist indicated for:

1. 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.
2. Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.
3. First-line treatment of severe aplastic anemia in adult and pediatric patients 2 years and older in combination with standard immunosuppressive therapy
4. Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy

Alvaiz (eltrombopag choline) is a thrombopoietin receptor agonist indicated for:

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

Compendial Uses

1. MYH9-related disease with thrombocytopenia
2. Myelodysplastic syndromes (MDS)
3. Chemotherapy-induced thrombocytopenia (CIT)/ thrombocytopenia post-hematopoietic cell transplant

POLICY

Documentation

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

1. Chronic or persistent immune thrombocytopenia:
    a. For initial requests: pretreatment platelet count
    b. For continuation requests: current platelet count
2. Aplastic anemia continuation of therapy: current platelet count

Exclusions

Coverage will not be provided for members with the following exclusion:

- Concomitant use of the requested drug with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta), or with spleen tyrosine kinase inhibitors (e.g., Tavalisse), or with Bruton's tyrosine kinase inhibitors (e.g., Wayrilz).

Preferred Drug Plan Design

Member must meet BOTH the Preferred Drug Plan Design and the Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Criteria for initial approval for Promacta (brand only) will only apply when one of the following criteria are met:

1. Criteria for initial approval for the non-preferred product, Promacta (brand only), will only apply when the member has had a documented intolerable adverse event with the preferred products, Alvaiz (eltrombopag choline) and eltrombopag olamine (generic Promacta), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
2. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome.

Prescriber Specialties

1. For diagnosis of persistent or chronic thrombocytopenia, aplastic anemia, MYH9-related disease with thrombocytopenia, myelodysplastic syndromes, and chemotherapy-induced thrombocytopenia (CIT), this medication must be prescribed by or in consultation with a hematologist or oncologist.
2. For diagnosis of thrombocytopenia with hepatitis C, this medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hematology, hepatology, or transplant.

Criteria for Initial Approval

A. Chronic or Persistent Immune Thrombocytopenia (ITP)

Authorization of 6 months may be granted for treatment of chronic or persistent ITP when ALL of the following criteria are met:

1. Inadequate response or intolerance to prior therapy with corticosteroids, immunoglobulins, or splenectomy
2. Untransfused platelet count at any point prior to the initiation of the requested medication is less than $30x10^9$/L OR $30x10^9$/L to $50x10^9$/L with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (see Appendix)

B. Thrombocytopenia associated with Chronic Hepatitis C

Authorization of 6 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.

C. Aplastic Anemia

1. Promacta
   a. 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).
   b. Authorization of 6 months may be granted for treatment of aplastic anemia in members who have had an insufficient response to immunosuppressive therapy.
2. Alvaiz
   a. Authorization of 6 months may be granted for treatment of severe aplastic anemia in members who have had an insufficient response to immunosuppressive therapy.

D. MYH9-related disease with thrombocytopenia

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

E. Myelodysplastic Syndromes

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

F. Chemotherapy-induced thrombocytopenia (CIT)

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

Continuation of Therapy

A. Chronic or Persistent ITP

1. Authorization of 3 months may be granted to members with current platelet count less than $50x10^9$/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.
2. Authorization of 12 months may be granted to members with current platelet count less than $50x10^9$/L for whom the current platelet count is sufficient to prevent clinically important bleeding.
3. Authorization of 12 months may be granted to members with current platelet count of $50x10^9$/L to $200x10^9$/L.
4. Authorization of 12 months may be granted to members with current platelet count greater than $200x10^9$/L to less than or equal to $400x10^9$/L for whom dosing for the requested drug will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

B. Thrombocytopenia associated with Chronic Hepatitis C

Authorization of 6 months may be granted to members who are continuing to receive interferon-based therapy.

C. Aplastic Anemia

1. Authorization of up to 16 weeks total may be granted to members with current platelet count less than $50x10^9$/L who have not received appropriately titrated therapy with the requested drug for at least 16 weeks.
2. Authorization of up to 16 weeks total may be granted to members with current platelet count less than $50x10^9$/L who are transfusion-independent.
3. Authorization of 12 months may be granted to members with current platelet count of $50x10^9$/L to $200x10^9$/L.
4. Authorization of 12 months may be granted to members with current platelet count greater than 200 $x10^9$/L to less than or equal to $400x10^9$/L for whom dosing for the requested drug will be adjusted to achieve and maintain an appropriate target platelet count.

D. MYH9-related disease with thrombocytopenia

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

E. Myelodysplastic Syndromes and chemotherapy-induced thrombocytopenia (CIT)

Authorization of 12 months may be granted for continued treatment of myelodysplastic syndromes or chemotherapy-induced thrombocytopenia (CIT) in members who experience benefit from therapy (e.g., increased platelet counts, decreased bleeding events, reduced need for platelet transfusions).

Promacta and Alvaiz (eltrombopag) are considered **not medically necessary** for members who do not meet the criteria set forth above.

Other

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication Name	Quantity Limit
Alvaiz (eltrombopag) 9 mg tab	30 tabs per 30 days
Alvaiz (eltrombopag) 18 mg tab	30 tabs per 30 days
Alvaiz (eltrombopag) 36 mg tab	60 tabs per 30 days
Alvaiz (eltrombopag) 54 mg tab	60 tabs per 30 days
Promacta (eltrombopag) 12.5 mg packet for oral administration	90 packets per 30 days
Promacta (eltrombopag) 25 mg packet for oral administration	90 packets per 30 days
Promacta (eltrombopag) 12.5 mg tablet for oral administration	30 tablets per 30 days
Promacta (eltrombopag) 25 mg tablet for oral administration	90 tablets per 30 days
Promacta (eltrombopag) 50 mg tablet for oral administration	90 tablets per 30 days
Promacta (eltrombopag) 75 mg tablet for oral administration	60 tablets per 30 days

Appendix

Examples of risk factors for bleeding (not all inclusive)

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

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

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POLICY HISTORY

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