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Policy Number: C6663-A

Eltrombopag (Alvaiz, Promacta)

PRODUCTS AFFECTED

Alvaiz (eltrombopag), Promacta (eltrombopag)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Severe aplastic anemia, Chronic hepatitis C-associated thrombocytopenia, Chronic immune thrombocytopenia

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. ALL INDICATIONS:
1. Eltrombopag is NOT being used concurrently with another thrombopoietic agent or spleen tyrosine kinase inhibitor [e.g., Doptelet (avatrombopag), Nplate (romiplostim), Mulpleta (lusutrombopag), or Tavalisse (fostamatinib)]
   AND

2. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

B. CHRONIC IMMUNE THROMBOCYTOPENIA (ITP):
1. Documented diagnosis of chronic immune thrombocytopenia (ITP)
AND
2. Documentation of ONE of the following [DOCUMENTATION REQUIRED]:
a) Platelet count less than 20 x 10^9/L (20,000/mm3)
OR
b) Platelet count less than 30 x 10^9/L with ITP whose degree of thrombocytopenia and clinical condition(s) increase the risk of bleeding (e.g., hypertension, renal insufficiency, concomitant antiplatelet agents or anticoagulant medications, alcoholism, infections, undergoing a medical or dental procedure with blood loss anticipation, recent surgery, head trauma)
AND
3. Documented failure, serious side effects, or contraindication to at least ONE of the following ITP treatments:
a) Corticosteroids (i.e., prednisone, methylprednisolone, dexamethasone) at immunosuppressive doses (See Appendix)
OR
b) Intravenous immune globulin (IVIG)
OR
c) Immunosuppressive therapy (i.e., cyclosporine, mycophenolate mofetil, sirolimus)
OR
d) Has had splenectomy or is not a surgery candidate
AND
4. Prescriber attests or the clinical reviewer has found the medication is NOT being used to normalize platelet counts

C. CHRONIC HEPATITIS C ASSOCIATED THROMBOCYTOPENIA:
1. Documented diagnosis of hepatitis C-associated thrombocytopenia
AND
2. Documentation baseline platelet count is < 75 x10^9/L (75,000mm^3) [DOCUMENTATION REQUIRED]
AND
3. Eltrombopag is prescribed to increase platelet counts sufficiently to initiate (or maintain) interferon-based therapy (pegylated interferon + ribavirin)
NOTE: The following conditions do not meet criterion and are considered an exclusion: Member is on direct-acting antiviral agents (DAA) for the treatment of chronic hepatitis C infection in addition to interferon-based therapy with ribavirin; OR member is on DAA used without interferon for treatment of chronic hepatitis C infection.

D. APLASTIC ANEMIA, SEVERE:
1. Documented diagnosis of severe aplastic anemia
AND
2. Documentation at least TWO of the following are present [DOCUMENTATION REQUIRED]:
a) Absolute reticulocyte count <50,000/microL (<50 x 10^9/L; the threshold may range from <40,000 to <60,000/microL at various centers)
b) Platelet count <20,000/microL (<20 x 10^9/L)
c) Absolute neutrophil count (ANC) <500/microL (<0.5 x 10^9/L)
AND
3. (a) If prescribed for use as first-line therapy, member must be: i) 2 years or older, AND ii) has not received prior immunosuppressive therapy with antithymocyte globulin-based (ATG) immunosuppressive therapy (i.e., Atgam, Thymoglobulin), alemtuzumab, or cyclophosphamide, AND

iii) Prescribed for use in combination with standard immunosuppressive therapy [i.e., ATG, prednisone, methylprednisolone, cyclosporine, or cyclophosphamide]
OR
(b) If prescribed for use in refractory disease or second-line treatment following an intolerance to another drug, member must be: i) 18 years of age or older, AND ii) had at least a 3- month trial and failure with ONE immunosuppressive therapy (i.e., antithymocyte globulin (ATG) [i.e., Atgam, Thymoglobulin], prednisone, methylprednisolone, cyclosporine, or cyclophosphamide)

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or the clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

B. CHRONIC IMMUNE THROMBOCYTOPENIA (ITP):

1. Documentation of positive clinical response to therapy as evidenced by increase in platelet count to a level sufficient to avoid clinically important bleeding, OR increase or achievement of platelet count to 50 x 10^9/L or greater [DOCUMENTATION REQUIRED]
   NOTE: Per the FDA label, discontinue eltrombopag if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy .
   AND
2. Prescriber attests member still requires eltrombopag to maintain a platelet count sufficient to avoid clinically important bleeding

C. CHRONIC HEPATITIS C ASSOCIATED THROMBOCYTOPENIA:

1. Documentation platelet count is ≥ 90 x 10^9/L OR platelet count has increased sufficiently to initiate or maintain interferon-based therapy for the treatment of hepatitis C [DOCUMENTATION REQUIRED]
   AND
2. Documentation of concurrent interferon-based antiviral hepatitis C therapy
   NOTE: Eltrombopag should be discontinued when antiviral therapy is discontinued

D. APLASTIC ANEMIA, SEVERE:

1. Documentation of positive clinical response to therapy as evidenced by a hematologic response: increase in platelet count, increase in hemoglobin, increase in absolute neutrophil count, reduction in frequency of platelet or RBC transfusions [DOCUMENTATION REQUIRED]
   NOTE: Discontinue if there is no hematologic response after 16 weeks of therapy at the maximum daily dose being given with standard immunosuppressive therapy (i.e., ATG, prednisone, methylprednisolone, cyclosporine, or cyclophosphamide) per the FDA label.

DURATION OF APPROVAL:

Chronic ITP: Initial authorization: 3 months, Continuation of Therapy: 12 months
Chronic Hepatitis C: Initial authorization: 3 months, Continuation of Therapy: length of Hepatitis C therapy approval
Aplastic anemia: Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified hematologist/oncologist or physician specializing in the treatment of thrombocytopenia in patients with chronic ITP, gastroenterologist, hepatologist, or infectious disease specialist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
Chronic ITP:
Promacta: 1 year of age and older
Alvaiz: 6 years of age and older

Chronic hepatitis C-associated thrombocytopenia: Promacta and Alvaiz: 18 years of age and older

Aplastic anemia, severe:
Promacta: 2 years of age and older
Alvaiz: 18 years of age and older

QUANTITY:
Promacta (eltrombopag olamine) and Alvaiz (eltrombopag choline) are NOT interchangeable.
Chronic ITP:
Promacta: 75 mg/day
Alvaiz: 54 mg/day

Chronic hepatitis C:
Promacta: 100 mg/day
Alvaiz: 72 mg/day

Aplastic anemia, severe:
Promacta: 150 mg/day
Alvaiz: 108 mg/day

Maximum Quantity Limits – based on FDA label for indication, age, platelet count, ancestry, hepatic impairment, and/or AST/ALT elevations

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Thrombopoietin (TPO) Receptor Agonists

FDA-APPROVED USES:
Promacta is indicated:

- For the 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. Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- For the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Promacta 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.
- In combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia

- For the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy

Limitations of Use: Promacta is not indicated for the treatment of patients with myelodysplastic syndrome (MDS). Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

Alvaiz is indicated:

- For the 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. Alvaiz should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- For the treatment of thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Alvaiz 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.
- For the treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Limitations of Use: Alvaiz is not indicated for the treatment of patients with myelodysplastic syndrome (MDS). Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

COMPENDIAL APPROVED OFF-LABELED USES:
Thrombocytopenia post-hematopoietic cell transplant (NCCN Hematopoietic Growth Factors)

APPENDIX

APPENDIX:
Systemic corticosteroid immunosuppressive doses include:
≥ 14 days therapy with doses ≥ 80 mg per day of prednisone.
Equivalent doses include:

- ≥ 400mg/day cortisone
- 320mg/day hydrocortisone
- 80mg/day prednisolone
- 64mg/day methylprednisolone
- 12mg/day dexamethasone

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Eltrombopag is an oral nonpeptide-selective, thrombopoietin-receptor agonist. Eltrombopag, an oral thrombopoietin receptor agonist, induces the proliferation and differentiation of bone marrow stem cells to increase production of blood cells. It activates intracellular signal-transduction pathways, leading to increased proliferation and differentiation of megakaryocytes from bone marrow progenitor cells.
Eltrombopag does not affect platelet aggregation or platelet activation.
Eltrombopag does not increase proliferation in leukemia or solid tumor cell lines; a reduction in proliferation has been observed in a variety of solid and hematologic tumor cell lines tested.
Eltrombopag increased platelet counts in healthy subjects in a dose-dependent manner. Increases more than those observed with placebo occurred in subjects receiving daily 50 and 75 mg doses. In clinical trials, platelet counts usually rose within 1 to 2 weeks after initiating eltrombopag therapy and declined within 1 to 2 weeks after discontinuing eltrombopag.

Chronic Immune Thrombocytopenia (ITP)

The goal of ITP treatment is to achieve platelet count associated with adequate hemostasis to provide a safe platelet count to prevent clinically important bleeding, rather than to normalize the platelet count.

Guideline recommendations for when to initiate treatment: International Consensus Report does not provide a threshold platelet count [ref: International consensus report on the investigation and management of primary immune thrombocytopenia] American Society of Hematology (ASH) guideline suggests treating patients with newly diagnosed ITP with platelet count $< 30 \times 10^9$/L (ASH Grade 2C) [ref: The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia] ASH guideline states: 'We found no evidence that could allow us to determine a minimum platelet count threshold or specific age at which a typical member with ITP should be treated. We recognize that the majority of clinicians use the platelet threshold of $< 30 \times 10^9$/L as a trigger for treatment, and we find no evidence to contradict this practice.' Guidelines from other national societies give varying platelet thresholds as an indication to initiate treatment for patients with persistent ITP who have experienced clinically important bleeding despite first-line therapy with glucocorticoids, it is recommended to proceed to second-line therapy rather than observation or chronic glucocorticoid administration. Options for second line therapy include splenectomy, rituximab, and thrombopoietin receptor agonists (TPO-Ras) which include romiplostim (Nplate), eltrombopag (Promacta), and avatrombopag (Doptelet). No head-to-head trials have been conducted between eltrombopag or romiplostim and other agents used to treat chronic ITP, such as IVIg, anti-D, or rituximab. The choice of therapy has been based on factors such as availability, severity of bleeding, and comorbidities predisposing to bleeding, such as uremia and hypertension.

Chronic Hepatitis C infection-associated Thrombocytopenia

Thrombocytopenia is the most common hematological abnormality encountered in patients with chronic liver disease with an estimated occurrence in 64%–84% of patients with cirrhosis or fibrosis (Mitchell et al 2016). HCV is known to cause thrombocytopenia even in the absence of overt hepatic disease and is considered a surrogate marker for the severity of liver disease (Afdhal et al., 2008). The level of thrombocytopenia is associated with the severity of liver disease and the degree of portal hypertension. Eltrombopag (Promacta) is a thrombopoietin receptor agonist that selectively binds to thrombopoietin receptors on megakaryocyte precursors and megakaryocytes leading to increased platelet production. Promacta is indicated for the treatment of thrombocytopenia, including adult patients with chronic HCV infection to allow for the initiation and maintenance of peginterferon-based therapy, which is the focus of this review. In two randomized controlled trials in adults with chronic HCV infection and thrombocytopenia (ENABLE-1 and ENABLE-2), studied the use of eltrombopag to ensure initiation and completion of interferon and ribavirin therapy. In ENABLE-1 trial patients with HCV infection and platelet count of < 75,000/μL received progressively increasing doses of eltrombopag (25, 50, 75 and 100 mg) to achieve a platelet count of >90,000/μL. The use of Eltrombopag increased platelet numbers in thrombocytopenic patients with HCV and advanced fibrosis and cirrhosis, thus allowed otherwise ineligible or marginal patients to begin and maintain antiviral therapy and led to significantly increased rates of HCV cure. The median time to achieve the target platelet count was approximately 2 weeks and 95% percent of patients were able to initiate antiviral therapy. The majority of patients treated with Eltrombopag (76%) maintained a platelet count greater than or equal to 50,000/μL compared with 19% for placebo. Also a greater proportion of patients on Eltrombopag did not require any antiviral dose reduction as compared with placebo (45% versus 27%). Additionally, a significantly higher proportion of eltrombopag recipients than placebo recipients achieved a sustained virological response (primary endpoint) 24 weeks after the completion of antiviral therapy. However, the additional benefit over placebo was relatively small (<10%). Compared with placebo, eltrombopag was associated with fewer patients discontinuing antiviral therapy early and a numerically greater proportion of patients not requiring antiviral dose reduction. Oral eltrombopag had an acceptable tolerability profile; however, there is an increased risk of adverse events, including potentially fatal hepatic decompensation and thromboembolic events. Eltrombopag provides a

treatment option for thrombocytopenia in patients with chronic HCV infection to allow for optimal antiviral therapy.

Severe Aplastic Anemia (SAA)

Aplastic anemia is a syndrome of bone marrow failure characterized by peripheral pancytopenia and marrow hypoplasia. Although the anemia is often normocytic, mild macrocytosis can also be observed in association with stress erythropoiesis and elevated fetal hemoglobin levels. Therapy for aplastic anemia may consist of supportive care only, immunosuppressive therapy, or hematopoietic cell transplantation (HCT). FDA approval was based on results of a phase 2 study conducted by the National Heart, Lung and Blood Institute, involving 43 patients with severe aplastic anemia who have had an insufficient response to at least 1 prior immunosuppressive therapy.

Eltrombopag was administered at an initial dose of 50 mg once daily for 2 weeks and increased over the course of 2-week periods to a maximum dose of 150 mg once daily. The primary endpoint was hematologic response, which was initially assessed after 12 weeks. Treatment was discontinued after 16 weeks if no hematologic response was observed. 40% of patients experienced a hematologic response in platelets, red blood cells, or white blood cells after week 12 on eltrombopag. In an extension phase, 8 patients achieved a multilineage response. Four of these patients subsequently tapered off treatment and maintained the response during a median follow-up of 8.1 months.

The FDA expanded the use of Promacta (eltrombopag) to include first-line treatment for patients from the age of two years who have SAA. Eltrombopag will be used in combination with standard immunosuppressive therapy (IST) and is the first new treatment in decades for newly-diagnosed SAA patients in the U.S. The approval was based on data from a single-arm, open-label sequential cohort study in which patients received Promacta in combination with horse antithymocyte globulin (h-ATG) and cyclosporine; efficacy was established on the basis of complete hematological response at 6 months, defined as hematological parameters meeting all 3 of the following values on 2 consecutive serial blood count measurements at least 1 week apart: absolute neutrophil count (ANC) >1000/mcL, platelet count >100 x 109/L and hemoglobin >10g/dL, or reticulocyte count >60,000/mcL. Alvaiz does not currently have this same expanded indication.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of eltrombopag are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to eltrombopag include: No labeled contraindications.

Exclusions/Discontinuation:

Discontinue if platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy at the maximum daily dose for ITP.

Discontinue if no hematologic response has occurred after 16 weeks of therapy for aplastic anemia.

Discontinue if ALT levels increase to 3 times the ULN or more in patients with normal hepatic function or at least 3 times baseline (or greater than 5 times the ULN, whichever is the lower) in those with preexisting transaminase elevations and that are progressively increasing, or persistent (at least 4 weeks), accompanied by increased direct bilirubin, or accompanied by clinical symptoms of liver injury or evidence of hepatic decompensation.

Discontinue if Platelet count is > 400 x 10^9/L (≥ 400,000 /mm_3) after 2 weeks of therapy at the lowest dose.

OTHER SPECIAL CONSIDERATIONS:

Eltrombopag has a Black Box Warning for risk for hepatic decompensation in patients with chronic Hepatitis C and risk of hepatotoxicity. Liver enzymes should be measured prior to drug initiation, every two weeks during dose adjustments, and monthly thereafter. In patients with chronic hepatitis C, eltrombopag in combination with interferon and ribavirin may increase the risk of hepatic decompensation. Eltrombopag may increase the risk of severe and potentially life-threatening hepatotoxicity; hepatic function should be monitored, and therapy discontinued if necessary. Package insert indicates warnings/precautions of increased risk of death and progression of myelodysplastic syndromes to acute myeloid leukemia; and

thrombotic/thromboembolic complications: portal vein thrombosis has been reported in patients with chronic liver disease receiving Eltrombopag.
Monitor platelet counts regularly.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Alvaiz TABS 9MG, 18MG, 36MG, 54MG
Eltrombopag Olamine 12,5MG, 25MG, 50MG, 75MG
Eltrombopag Olamine PACK 12.5MG, 25MG

Promacta TABS 12.5MG, 25MG, 50MG, 75MG
Promacta PACK 12.5MG, 25MG

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Contraindications/Exclusions/ Discontinuation Other Special Considerations Available Dosage Forms References	Q3 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Compendial Approved Off-Labeled Uses References	Q3 2024

REVISION- Notable revisions: Name change Products Affected Age Restrictions Quantity FDA-Approved Uses Available Dosage Forms References	Q2 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy FDA-Approved Uses Appendix Other Special Considerations Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Contraindications/Exclusions/Discontinuation References	Q4 2022
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Contraindications/Exclusions/Discontinuation References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file