AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Promacta (eltrombopag olamine) Alvaiz (eltrombopag choline)	Page:	1 of 6
Effective Date:	4/25/2024	Last Review Date:	4/1/2024
Applies to:	☒Illinois ☒Pennsylvania Kids ☒Virginia	☒New Jersey ☒Michigan	☒Florida Kids ☒Maryland

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Promacta and Alvaiz under the patient's prescription drug benefit.

Description:

A. FDA-Approved Indications
- 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.
- Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of 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
- Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

B. 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.

C. Compendial Uses
1. MYH9-related disease with thrombocytopenia (Promacta only)
2. Myelodysplastic syndromes (MDS) (Promacta only)
3. Chemotherapy-induced thrombocytopenia (CIT)

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

Applicable Drug List:

Promacta
Alvaiz

Policy/Guideline:

Documentation

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

A. Persistent or chronic immune thrombocytopenia (ITP):
   1. For initial requests: pretreatment platelet count
   2. For continuation requests: current platelet count
B. 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).

Prescriber Specialties:

A. For diagnosis of persistent or chronic immune thrombocytopenia (ITP), 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.
B. For diagnosis of thrombocytopenia with hepatitis C, this medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

Criteria for Initial Approval:

A. Persistent or chronic immune thrombocytopenia (ITP)
Authorization of 6 months may be granted for treatment of persistent or chronic ITP when BOTH 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
      i. 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).

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

D. MYH9-related disease with thrombocytopenia (Promacta only)
Authorization of 12 months may be granted to members with thrombocytopenia associated with MYH9-related disease.

E. Myelodysplastic syndromes (Promacta only)
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.

Criteria for Continuation of Therapy

A. Persistent or chronic 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 (Promacta only)
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

E. Myelodysplastic syndromes (Promacta only) 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).

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

Quantity Restrictions

Quantity Level Limit:

Medication	Standard Limit	FDA-recommended dosing
Promacta (eltrombopag olamine) 12.5 mg tablets	60 per 30 days	Persistent or chronic immune thrombocytopenia (ITP): Initiate at 50 mg once daily for most adult and pediatric patients 6 years and older and at 25 mg once daily for pediatric patients aged 1 to 5 years. Dose reductions are needed for patients of East-/Southeast-Asian ancestry or those with hepatic impairment. Adjust to maintain platelet count greater than or equal to 50 x 10^9/L. Do not exceed 75 mg per day.
Promacta (eltrombopag olamine) 25 mg tablets	90 per 30 days	

Medication	Standard Limit	FDA-recommended dosing
Promacta (eltrombopag olamine) 12.5 mg oral susp pkts	120 packets per 30 days	Chronic Hep C-associated thrombocytopenia: Initiate at 25 mg once daily. Adjust to achieve target platelet count required to initiate antiviral therapy. Do not exceed a daily dose of 100 mg. First-line severe aplastic anemia: Initiate once daily at 2.5mg/kg (in pediatric patients aged 2 to 5 years old), 75 mg (pediatric patients aged 6 to 11 years old), or 150mg for patients aged 12 years and older concurrently with standard immunosuppressive therapy. Reduce initial dose in patients of East-/Southeast-Asian ancestry or those with hepatic impairment. Modify dosage for toxicity or elevated platelet counts. Refractory severe aplastic anemia: Initiate at 50mg once daily for most patients. Reduce initial dose in patients with hepatic impairment or patients of East-/Southeast-Asian ancestry. Adjust to maintain platelet count greater than or equal to 50 x 10^9/L. Do not exceed 150 mg per day.
Promacta (eltrombopag olamine) 25 mg oral susp pkts	180 packets per 30 days	
Promacta (eltrombopag olamine) 50 mg tablets	90 per 30 days	
Promacta (eltrombopag olamine) 75 mg tablets	60 per 30 days	
Alvaiz (eltrombopag choline) 9 mg tablets	60 per 30 days	Persistent or chronic ITP: Initiate at 36mg once daily for most adult and pediatric patients 6 years and older. Dose reductions are needed for patients of East-/Southeast-Asian ancestry or those with hepatic impairment. Adjust to maintain platelet count greater than or equal to 50 x 10^9/L. Do not exceed 54mg per day. Chronic hepatitis C-associated thrombocytopenia: Initiate at 18mg once daily. Adjust to achieve target platelet count required to initiate antiviral therapy. Do not exceed a daily dose of 72mg. Refractory severe aplastic anemia: Initiate at 36mg once daily for most patients. Reduce initial dose in patients with hepatic impairment or patients of East-/Southeast-Asian ancestry. Adjust to maintain platelet count greater than or equal to 50 x 10^9/L. Do not exceed 108 mg per day.
Alvaiz (eltrombopag choline) 18 mg tablets	90 per 30 days	
Alvaiz (eltrombopag choline) 36 mg tablets	90 per 30 days	
Alvaiz (eltrombopag choline) 54 mg tablets	60 per 30 days	

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