BlueCross BlueShield
Federal Employee Program

PROMACTA, ALVAIZ*
(eltrombopag)

*Prior authorization for this product applies only to formulary exceptions due to being a non-covered medication

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Promacta and Alvaiz are used to treat patients with chronic immune thrombocytopenia (ITP), who have not responded adequately to corticosteroids, immunoglobulins, or to the removal of their spleen (splenectomy). ITP is a blood disorder that results in a low number of platelets which can lead to serious bleeding. Promacta and Alvaiz work by stimulating the bone marrow to produce needed platelets (1-2).

Regulatory Status

FDA-approved indications: Promacta is a thrombopoietin receptor agonist indicated for the treatment of (1-2):

1. **Promacta** is a thrombopoietin receptor agonist indicated for the treatment of:
    a. Thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
    b. Thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
    c. Patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy
    d. In combination with standard immunosuppressive therapy for first line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia
2. **Alvaiz** is a thrombopoietin receptor agonist indicated for the treatment of:
    a. Thrombocytopenia in adult and pediatric patients 6 years and older persistent or chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
    b. Thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy

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c. Adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy

Limitations of Use: (1-2)

1. Promacta and Alvaiz should not be used to normalize platelet counts.
2. Promacta and Alvaiz should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
3. Promacta and Alvaiz should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon therapy or limits the ability to maintain optimal interferon-based therapy.
4. Promacta and Alvaiz are not indicated for the treatment of patients with myelodysplastic syndrome (MDS).
5. Safety and efficacy have not been established in combination with direct acting antiviral agents approved for treatment of chronic hepatitis C infection.

Promacta and Alvaiz carry boxed warnings regarding the risk for hepatic decompensation in patients with chronic hepatitis C and risk of hepatotoxicity. Serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin levels must be measured prior to initiation of Promacta and Alvaiz, every 2 weeks during the dose adjustment phase, and monthly following establishment of a stable dose. Monitor serum liver tests weekly until the abnormality/abnormalities resolve, stabilize, or return to baseline levels. Promacta and Alvaiz should be discontinued for the development of important liver test abnormalities. Promacta and Alvaiz, in combination with interferon and ribavirin in patients with chronic hepatitis C, may increase the risk of hepatic decompensation (1-2).

Promacta and Alvaiz must be discontinued if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy at the maximum daily dose. Discontinue if ALT levels increase to ≥3X upper limit of normal (ULN) in patients with normal liver function or ≥3X baseline in patients with pre-treatment elevations in transaminases and are: 1) progressive 2) persistent for ≥4 weeks 3) accompanied by increased direct bilirubin, or 4)

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accompanied by clinical symptoms of liver injury or evidence for hepatic decompensation. Promacta and Alvaiz should be discontinued when antiviral therapy is discontinued (1-2).

Promacta and Alvaiz must be held when platelet levels reach >400 x 10^9/L and platelet levels monitored twice weekly to evaluate any decrease in levels and need for re-initiation of therapy. If platelet levels remain above 400 x 10^9/L after two weeks, therapy must be discontinued. If platelet count drops to <150 x 10^9/L, therapy can be restarted at a decreased dose (1-2).

Thrombotic/thromboembolic complications may result from increases in platelet counts with Promacta and Alvaiz. There is an increased risk of thromboembolism when administering Promacta and Alvaiz to patients with known risk factors (e.g., Factor V Leiden, ATIII deficiency, antiphospholipid syndrome, chronic liver disease). To minimize the risk for thrombotic/thromboembolic complications, do not use Promacta or Alvaiz in an attempt to normalize platelet counts (1-2).

During the dose adjustment phase of therapy, complete blood counts (CBCs) with differentials (including platelet counts) should be obtained weekly then monthly after stabilization of dose, then weekly for 4 weeks after discontinuation of therapy (1-2).

The safety and efficacy of Promacta in pediatric patients less than 1 year of age with chronic ITP have not been established. The safety and efficacy of Promacta in patients less than 2 years of age with severe aplastic anemia has not been established. The safety and efficacy of Promacta and Alvaiz in pediatric patients with thrombocytopenia associated with chronic hepatitis C have not been established. The safety and efficacy of Alvaiz in pediatric patients less than 6 years of age with chronic ITP have not been established. The safety and efficacy of Alvaiz in pediatric patients with severe aplastic anemia have not been established (1-2).

Summary

Promacta and Alvaiz are indicated for the treatment of thrombocytopenia in patients with persistent or chronic immune (idiopathic) thrombocytopenia (ITP), thrombocytopenia in patients with chronic

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hepatitis C, and severe aplastic anemia. The safety and efficacy of Promacta in pediatric patients less than 1 year of age with chronic ITP have not been established. The safety and efficacy of Promacta in patients less than 2 years of age with severe aplastic anemia has not been established. The safety and efficacy of Promacta and Alvaiz in pediatric patients with thrombocytopenia associated with chronic hepatitis C have not been established. The safety and efficacy of Alvaiz in pediatric patients less than 6 years of age with chronic ITP have not been established. The safety and efficacy of Alvaiz in pediatric patients with severe aplastic anemia have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Promacta and Alvaiz while maintaining optimal therapeutic outcomes.

References

1. Promacta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2023.
2. Alvaiz [package insert]. Parsippany, NJ: Teva Pharmaceuticals; November 2023.