Commercial PA Criteria

Effective: January 1, 2017

Prior Authorization: Eltrombopag

Products Affected: Promacta (eltrombopag olamine) oral tablet, Promacta (eltrombopag olamine) oral suspension, Alvaiz (eltrombopag) oral tablet, Eltrombopag oral tablet, Eltrombopag suspension packet

Medication Description: Eltrombopag is a TPO-receptor agonist that interacts with the transmembrane domain of the human TPO-receptor (also known as cMpl) and initiates signaling cascades that induce proliferation and differentiation of megakaryocytes leading to increased platelet production.

Covered Uses:

Promacta

1. **Aplastic anemia**, severe, in combination with standard immunosuppressive therapy for the first-line treatment of adults and pediatric patients ≥ 2 years of age as well as for treatment in patients who have had an insufficient response to immunosuppressive therapy.
2. **Chronic hepatitis C, treatment of thrombocytopenia**, to allow the initiation and maintenance of interferon-based therapy.
3. **Immune thrombocytopenia (ITP), treatment, in adults and pediatric patients ≥ 1 year of age** with persistent or chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Of note, Promacta should only be used in patients whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.

Alvaiz

1. **Aplastic anemia**, severe, in adults who have had an insufficient response to immunosuppressive therapy.
2. **Chronic hepatitis C, treatment of thrombocytopenia**, in adults to allow the initiation and maintenance of interferon-based therapy.
3. **Immune thrombocytopenia (ITP), treatment in adults and pediatric patients ≥ 6 year of age** with persistent or chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Of note, Alvaiz should only be used in patients whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.

Exclusion Criteria:

1. Use in the management of thrombocytopenia in myelodysplastic syndrome (MDS).
2. Use in combination with Nplate for treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura.
3. Use in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

Required Medical Information:

1. Diagnosis
2. Medical history
3. Current therapy regimen
4. Previous therapies tried.

Age Restrictions:

Promacta

1. Aplastic Anemia: patients ≥ 2 years of age and older
2. Chronic hepatitis C, treatment of thrombocytopenia: 18 years of age and older
3. Immune thrombocytopenia (ITP), treatment, in adults and pediatric patients ≥ 1 year of age and older

Alvaiz

4. Aplastic Anemia:18 years of age and older
5. Chronic hepatitis C, treatment of thrombocytopenia: 18 years of age and older
6. Immune thrombocytopenia (ITP), treatment, in adults and pediatric patients ≥ 6 years of age

Prescriber Restrictions:

1. Treatment of thrombocytopenia due to chronic immune (idiopathic) thrombocytopenic purpura (ITP) & Severe Aplastic Anemia: Prescribed by, or in consultation with, a hematologist.
2. Treatment of thrombocytopenia due to HCV-related cirrhosis: Prescribed by, or in consultation with, a hematologist, gastroenterologist, a hepatologist, or a physician who specializes in infectious disease.

Coverage Duration:

Initial: 3-4 months (see specific criteria)
Continuation: 12 months

Other Criteria:

I. Promacta

1. **Thrombocytopenia in Patients with Chronic Immune (Idiopathic) Thrombocytopenia Purpura (ITP)**
   Initial Therapy. Approve for 3 months if the patient meets the following (A and B):
   A. Patient meets one of the following (i **OR** ii):
      i. Patient has a platelet count < 30 x 10^9/L (< 30,000/mcL); **OR**
      ii. Patient meets both of the following [a **AND** b)]:
         a. Patient has a platelet count < 50 x 10^9/L (< 50,000/mcL); **AND**
         b. According to the prescriber, the patient is at an increased risk for bleeding; **AND**
   B. Patient meets one of the following (i **OR** ii):
      i. Patient has tried at least one other therapy; **OR**
      Note: Examples of therapies are systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate (romiplostim subcutaneous injection), Tavalisse (fostamatinib tablets), Doptelet (avatrombopag tablets), or rituximab.
      ii. Patient has undergone splenectomy.

2. **Treatment of Thrombocytopenia in Patients with Chronic Hepatitis C**
   Initial Therapy: Approve for 1 year if the patient meets the following (A, **AND** B):
   A. Patient has low platelet counts at baseline (pretreatment); **AND**
   Note: An example of a low platelet count is < 75 x 10^9/L (< 75,000/mcL).
   B. Patient will be receiving interferon-based therapy for chronic hepatitis C
   Note: Examples of therapies are pegylated interferon (Pegasys [peginterferon alfa-2a injection], PegIntron [peginterferon alfa-2b injection]), or Intron A (interferon alfa-2b).

3. **Aplastic Anemia**
   Initial Therapy: Approve for 4 months if the patient meets the following criteria (A, **AND** B)
   A. Patient has low platelet counts at baseline (pretreatment); **AND**
      Note: An example of a low platelet count is < 30 x 10^9/L (< 30,000/mcL).
   B. Patient meets one of the following (i **OR** ii):
      i. Patient had tried at least one immunosuppressant therapy; **OR**
         Note: Examples of therapies are cyclosporine, Atgam (lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution for intravenous use only), mycophenolate mofetil, or sirolimus.
      ii. Patient will be using Promacta in combination with standard immunosuppressive therapy
         Note: Examples of therapies are cyclosporine, Atgam (lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution for intravenous use only), mycophenolate mofetil, or sirolimus.

II. Alvaiz

1. **Aplastic Anemia**
   Initial Therapy. Approve for 4 months if the patient meets the following (A **AND** B):
   A. Patient has low platelet counts at baseline (pretreatment); **AND**
      Note: An example of a low platelet count is < 30 x 10^9/L (< 30,000/mcL).
   B. Patient meets one of the following (i **OR** ii):
      i. Patient had tried at least one immunosuppressant therapy; **OR**
         Note: Examples of therapies are cyclosporine, Atgam (lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution for intravenous use only), mycophenolate mofetil, or sirolimus.
      ii. Patient will be using Alvaiz in combination with standard immunosuppressive therapy
         Note: Examples of therapies are cyclosporine, Atgam (lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution for intravenous use only), mycophenolate mofetil, or sirolimus.

2. **Immune Thrombocytopenia.**
   Initial Therapy. Approve for 3 months if the patient meets all the following (A **AND** B):
   A. Patient meets one of the following (i **OR ii**):
      i. Patient has a platelet count < 30 x 10^9/L (< 30,000/mcL); **OR**
      ii. Patient meets both of the following [a **AND** b]:
         a. Patient has a platelet count < 50 x 10^9/L (< 50,000/mcL); **AND**
         b. According to the prescriber the patient is at an increased risk for bleeding; **AND**
   B. Patient meets one of the following (i **OR** ii):
      i. Patient has tried at least one other therapy; **OR**
         Note: Examples of therapies are systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate (romiplostim subcutaneous injection), Tavalisse (fostamatinib tablets), Doptelet (avatrombopag tablets), or rituximab.
      ii. Patient has undergone splenectomy

3. **Treatment of Thrombocytopenia in Patients with Chronic Hepatitis C**
   Initial Therapy: Approve for 1 year if the patient meets the following (A, **AND** B):
   A. Patient has low platelet counts at baseline (pretreatment); **AND**
      Note: An example of a low platelet count is < 75 x 10^9/L (< 75,000/mcL).
   B. Patient will be receiving interferon-based therapy for chronic hepatitis C
      Note: Examples of therapies are pegylated interferon (Pegasys [peginterferon alfa-2a injection], PegIntron [peginterferon alfa-2b injection]), or Intron A (interferon alfa-2b).

Continuation of therapy:

1. Approve if according to the prescriber, the patient demonstrates a beneficial clinical response **AND**
   Note: Examples include increases in platelet counts, reduction in red blood cell transfusions, hemoglobin increase, and/or absolute neutrophil count increase.
2. Patient remains at risk for bleeding complications.

References:

1. Product Information: PROMACTA® oral tablets, oral suspension, eltrombopag oral tablets, oral suspension. Novartis Pharmaceuticals Corporation (per manufacturer), East Hanover, NJ, 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/1/2017
2	Update	Addition of Alvaiz criteria and new criteria. Updated Promacta to approved FDA label indications/criteria. Coverage duration separate: 3-4 months for initial and 1 year for continuation.	All	3/28/2024
3	Update	Addition of Eltrombopag oral tablet, Eltrombopag suspension packet Policy name changed from Promacta-Alvaiz to Eltrombopag	All	6/2/2025