MEDICAL MUTUAL®

Drug Policy

Policy:	Eltrombopag Products Prior Authorization	Annual Review Date: 04/17/2025
	• Promacta® (eltrombopag tablets - Novartis) • Alvaiz (eltrombopag choline tablets -Teva)	Last Revised Date: 04/17/2025

OVERVIEW

Promacta, a thrombopoietin receptor agonist, is indicated for the following uses:[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.
- **Chronic hepatitis C, treatment of thrombocytopenia**, to allow the initiation and maintenance of interferon-based therapy.
- **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, a thrombopoietin receptor agonist, is indicated for the following uses:[8]

- **Aplastic anemia**, severe, in adults who have had an insufficient response to immunosuppressive therapy.
- **Chronic hepatitis C, treatment of thrombocytopenia**, in adults to allow the initiation and maintenance of interferon-based therapy.
- **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.

For patients with refractory severe aplastic anemia, if no hematologic response has occurred after 16 weeks of treatment with eltrombopag, discontinue therapy. For ITP, eltrombopag should be discontinued if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy with eltrombopag at the maximum daily dose. Use eltrombopag 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.[1] The safety and efficacy of eltrombopag have not been established in combination with direct-acting antiviral agents used without interferon for the treatment of chronic hepatitis C infection. For the management of chronic hepatitis C, eltrombopag should be stopped upon discontinuation of antiviral treatment futility.

POLICY STATEMENT

This policy involves the use of eltrombopag products. Prior authorization is recommended for pharmacy benefit coverage of eltrombopag products. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following

the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with eltrombopag products as well as the monitoring required for adverse events and long-term efficacy, initial approval requires eltrombopag products be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of eltrombopag products is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Aplastic Anemia.** Approve if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** 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).
     - **ii.** Patient meets ONE of the following (a or b):
       a. 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.
       b. Patient will be using eltrombopag in combination with standard immunosuppressive therapy; AND
       Note: Examples of therapies are cyclosporine, Atgam (lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution for intravenous use only), mycophenolate mofetil, or sirolimus.
     - **iii.** The patient meets one of the following (a or b):
       a. If request is for Promacta, patient is 2 years of age or older; OR
       b. If request is for Alvaiz, patient is 18 years of age or older; AND
     - **iv.** The medication is prescribed by or in consultation with a hematologist; OR
   - **B)** Patient is Currently Receiving Eltrombopag. Approve for 6 months if, according to the prescriber, the patient demonstrates a beneficial clinical response.
     Note: Examples include increases in platelet counts, reduction in red blood cell transfusions, hemoglobin increase, and/or absolute neutrophil count increase.

2. **Immune Thrombocytopenia.** Approve if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient meets ONE of the following (a or b):
       a. Patient has a platelet count < 30 x 10^9/L (< 30,000/mcL); OR
       b. Patient meets BOTH of the following [(1) and (2)]:
       (1) Patient has a platelet count < 50 x 10^9/L (< 50,000/mcL); AND

(2) According to the prescriber, the patient is at an increased risk for bleeding; AND

ii. Patient meets ONE of the following (a or b):
- a. 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), and rituximab.
- b. Patient has undergone splenectomy; AND

iii. The patient meets one of the following (a or b):
- a. If request is for Promacta, patient is 1 year of age or older; OR
- b. If request is for Alvaiz, patient is 6 years of age or older; AND

iv. The patient meets ONE of the following conditions (a or b):
- a. The patient is less than 18 years of age; OR
- b. The patient has tried Doptelet or Doptelet is contraindicated; AND

v. The medication is prescribed by or in consultation with a hematologist; OR

B) Patient is Currently Receiving Eltrombopag. Approve for 6 months if the patient meets BOTH of the following (i, ii, and iii):

i. According to the prescriber, the patient demonstrates a beneficial clinical response; AND
Note: A beneficial response can include increased platelet counts, maintenance of platelet counts, and/or a decreased frequency of bleeding episodes.

ii. Patient remains at risk for bleeding complications; AND

iii. The patient meets ONE of the following conditions (a or b):
- a. The patient is less than 18 years of age; OR
- b. The patient has tried Doptelet or Doptelet is contraindicated.

3. Thrombocytopenia in a Patient with Chronic Hepatitis C. Approve for 6 months if the patient meets ALL of the following (A, B, C, and D):

A) The patient is ≥ 18 years old; AND

B) Patient has low platelet counts at baseline (pretreatment); AND
Note: An example of a low platelet count is < 75 x 109/L (< 75,000/mcL).

C) Patient will be receiving interferon-based therapy for chronic hepatitis C; AND
Note: Examples of therapies are pegylated interferon (Pegasys [peginterferon alfa-2a injection], PegIntron [peginterferon alfa-2b injection]), and Intron A (interferon alfa-2b).

D) The medication is prescribed by or in consultation with a gastroenterologist, a hepatologist, or a physician who specializes in infectious diseases.

Other Uses with Supportive Evidence

1. Thrombocytopenia in a Patient with Myelodysplastic Syndrome. Approve if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, and, iv):

i. The patient is ≥18 years old; AND

ii. Patient has low- to intermediate-risk myelodysplastic syndrome; AND

iii. Patient meets ONE of the following (a or b):

a. Patient has a platelet count < 30 x 109/L (< 30,000/mcL); OR
b. Patient meets BOTH of the following [(1) and (2)]:
(1) Patient has a platelet count < 50 x 109/L (< 50,000/mcL); AND
(2) According to the prescriber, the patient is at an increased risk for bleeding; AND

iv. The medication is prescribed by or in consultation with a hematologist or oncologist; OR

B) Patient is Currently Receiving Eltrombopag. Approve for 6 months if the patient meets BOTH of the following (i and ii):
i. According to the prescriber, the patient demonstrates a beneficial clinical response; AND
Note: A beneficial response can include increased platelet counts, maintenance of platelet counts, and/or decreased frequency of bleeding episodes.
ii. Patient remains at risk for bleeding complications.

2. **Thrombocytopenia in a Patient Post-Allogeneic Transplantation**. Approve Promacta or Alvaiz if the patient meets ONE of the following (A or B):
A) Initial Therapy. Approve for 3 months if the patient meets ALL the following (i, ii, and, iii):
i. According to the prescriber, the patient has poor graft function; AND
ii. The patient is ≥18 years old; AND
iii. Patient has a platelet count < 50 x 10^9/L (< 50,000/mcL); AND
iv. The medication is prescribed by or in consultation with a hematologist, an oncologist, or a stem cell transplant specialist physician; OR
B) Patient is Currently Receiving Eltrombopag. Approve for 6 months if according to the prescriber, the patient demonstrated a beneficial clinical response.
Note: A beneficial response can include increased platelet counts, maintenance of platelet counts, and/or decreased frequency of bleeding episodes.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

eltrombopag products has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Use in combination with other thrombopoietin (TPO) receptor agonists.** TPO receptor agonists include Alvaiz, Doptelet, Nplate, and Promacta.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical

necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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