MEDICAL MUTUAL®

Drug Policy

Policy:	Promacta® (eltrombopag tablets)	Annual Review Date: 07/20/2023 Last Revised Date: 10/19/2023

OVERVIEW

Promacta, a thrombopoietin receptor agonist, has three indications. Promacta is indicated for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta is indicated for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. Promacta is also indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C (CHC) to allow initiation and maintenance of interferon-based therapy. Promacta should only be used in those with ITP whose degree of thrombocytopenia and clinical condition increase the bleeding risk. Promacta should be used only in patients with CHC whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. The safety and efficacy of Promacta have not been established in combination with direct-acting antiviral agents indicated for the treatment of CHC genotype 1 infection. Promacta has a boxed warning regarding the risk for hepatic decompensation in patients with CHC. It is important to note, that Promacta should not be used to normalize platelet counts for any approved indication.

POLICY STATEMENT

This policy involves the use of Promacta. Prior authorization is recommended for pharmacy benefit coverage of Promacta. 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 Promacta as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Promacta 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 Promacta is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Treatment of Thrombocytopenia in Patients with Immune Thrombocytopenia Purpura (ITP).** Approve Promacta if the patient meets the following criteria (a, b, c, d, e and f):

   a. The agent is prescribed by, or in consultation with a hematologist; AND
   b. The patient has a low platelet count at baseline (pretreatment) [e.g., <50,000 mm^3] at risk of, or currently bleeding; AND
   c. Not using Promacta in combination with Nplate; AND
   d. Dose does not exceed 75 mg/day; AND
   e. The Patient meets ONE of the following conditions (i or ii):
      i. The patient has tried corticosteroids or IVIG, unless contraindicated; OR
      ii. The patient has undergone splenectomy; AND
   f. The patient meets ONE of the following conditions (i or ii):
      i. The patient is less than 18 years of age; OR
      ii. The patient has tried Doptelet or Doptelet is contraindicated;

2. **Treatment of Thrombocytopenia in Patients with Chronic Hepatitis C.** Approve Promacta if the patient meets the following criteria (a, b, c, d, e, and f):

   a. Promacta is prescribed by, or after consultation with, either a gastroenterologist, a hepatologist, or a physician that specializes in infectious disease; AND
   b. The patient is ≥ 18 years old; AND
   c. The patient has thrombocytopenia with a low platelet count at baseline (pretreatment) [e.g., < 75,000 mm^3]; AND
   d. The patient will be receiving Promacta to allow the initiation and maintenance of concurrent interferon-based therapy for chronic hepatitis C (e.g., pegylated interferon [Pegasys® {peginterferon alfa-2a injection}, PegIntron® {peginterferon alfa-2b injection], or Intron A® [interferon alfa-2b]);AND
   e. Not using Promacta in combination with Nplate.
   f. Dose does not exceed 100 mg/day.

3. **Aplastic Anemia.** Approve Promacta if the patient meets the following criteria (a, b, c, d, e, and f):

   a. The patient has low platelet counts at baseline (pretreatment) [e.g., < 30,000 mm^3]; AND
   b. Promacta is prescribed by, or after consultation with, a hematologist; AND
   c. The patient is concurrently using or had tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus, Atgam® [lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution for intravenous use only]); AND
   d. The patient is ≥ 2 years of age; AND
   e. Not using Promacta in combination with Nplate; AND
   f. Dose does not exceed 150 mg/day.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months

B) *Extended Approval:* 6 months

Other Uses with Supportive Evidence

1. **Thrombocytopenia in Myelodysplastic Syndrome (MDS).** Approve Promacta for 6 months if the patient meets the following criteria (a, b, c, d and e):
   - **a.** The agent is prescribed by, or in consultation with, a hematologist or an oncologist; AND
   - **b.** The patient is ≥18 years old; AND
   - **c.** The patient has low- to intermediate-risk MDS; AND
   - **d.** According to the prescribing physician the patient has clinically significant thrombocytopenia (e.g., low platelet counts [< 30,000 mm^3 {pretreatment}]; is platelet transfusion-dependent; active bleeding, and/or a history of bleeding at low platelet counts); AND
   - **e.** Patient is not using Promacta in combination with Nplate

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 6 months

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Promacta 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. 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.

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