Promacta (eltrombopag olamine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 6 months Maintenance requests: 1 year

Medications	Quantity Limit
Promacta (eltrombopag olamine)	May be subject to quantity limits

APPROVAL CRITERIA

Initial requests for Promacta (eltrombopag olamine) for **ITP** may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP); **AND**
   A. Documentation is provided that individual has a platelet count of less than 30 x 10^9/L or active bleeding (ASH, 2011; Hicks et al., 2014); **AND**
   B. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and insufficient response to **one** of the following:
      1. Corticosteroids; **OR**
      2. Immunoglobulins (for example IVIg, anti-D); **OR**
      3. Splenectomy.

Initial requests for Promacta (eltrombopag olamine) for **severe aplastic anemia** may be approved if the following criteria are met:

I. Individual has a diagnosis of severe aplastic anemia; **AND**
   A. Documentation is provided that individual has a platelet count of less than or equal to 30 x 10^9/L (Olnes et al., 2012; Desmond et al., 2014); **AND**
   B. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and insufficient response to an immunosuppressive therapy [such as, anti-thymocyte globulin (ATG)];
   OR
   C. Individual is using as first-line treatment in combination with standard immunosuppressive therapy.

Continuation requests for Promacta (eltrombopag) for **ITP** *or* **severe aplastic anemia** may be approved if the following criteria is met:

I. Documentation is provided that individual has demonstrated a response to therapy as evidenced by increased platelet counts; **AND**
II. Continuation of treatment is to maintain an adequate platelet count (50 – 100 X 10^9/L)* to decrease the risk of bleeding.

*Note: If platelet count is greater than 100 X 10^9/L, adjust the dose using a cut-off platelet level of 100 X10^9/L as a substitute for 200 X 10^9/L in the US food and Drug Administration (FDA) dosage and administration recommendations.

Initial requests for Promacta (eltrombopag olamine) for **MDS** may be approved if the following criteria are met:

I. Documentation is provided that individual has a diagnosis of lower risk myelodysplastic syndrome (MDS) [Lower risk defined as IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very low, low, intermediate)] (NCCN 2A); **AND**
II. Individual has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents or immunosuppressive therapy.

Continuation requests for Promacta (eltrombopag olamine) for **MDS** may be approved if the following criteria are met (NCCN MDS V3.2021):

I. Documentation is provided that individual has demonstrated a clinically significant response to therapy, such as an increase in platelet counts, decrease in bleeding events, or reduction in need for platelet transfusions.

Promacta (eltrombopag olamine) may **not** be approved for the following:

I. Used to normalize platelet counts*; **OR**
II. Individual is requesting for the treatment of ITP whose degree of thrombocytopenia and clinical condition (for example, platelet count greater than 30 x 10^9/L or absence of bleeding) do not increase the risk of bleeding; **OR**
III. Used in individuals with chronic hepatitis C whose degree of thrombocytopenia does not prevent the initiation of interferon therapy or limit the ability to maintain an optimal peginterferon-based therapy; **OR**
IV. Used in individuals with chronic hepatitis C who are no longer on a peginterferon and ribavirin-based regimen; **OR**
V. Used in individuals taking in combination with a direct-acting antiviral agent without concomitant use of a peginterferon agent for treatment of thrombocytopenia associated with chronic hepatitis C infection; **OR**
VI. Used in combination with other thrombopoietin receptor agonists, such as romiplostim (Nplate) or eltrombopag choline (Alvaiz).

*Note: Promacta is recommended for use to increase or maintain a platelet count necessary to reduce the risk of bleeding, it is not recommended as therapy to increase or maintain platelet counts at normal levels.

Note:
Promacta (eltrombopag olamine) has black box warnings for risk of hepatic decompensation in individuals with chronic hepatitis C and risk of hepatotoxicity. The concomitant use with peginterferon and ribavirin may increase the risk of hepatic decompensation in individuals with

chronic hepatitis C. Promacta therapy should be discontinued if the peginterferon and ribavirin-based regimen is discontinued. Promacta may increase the risk of severe and potentially life-threatening hepatotoxicity. Hepatic function should be monitored with therapy discontinued as appropriate.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
3. Desmond R, Townsley DM, Dumitriu B, et al. Eltrombopag restores trilineage hematopoiesis in refractory severe aplastic anemia that can be sustained on discontinuation of drug. *Blood*. 2014; 123(12):1818-1825. Available from: http://www.bloodjournal.org/content/bloodjournal/123/12/1818.full.pdf.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Fenaux P, Muus P, Kantarjian H, et al. Romiplostim monotherapy in thrombocytopenia patients with myelodysplastic syndromes: long-term safety and efficacy. Br J Haematol. 2017; 178:906-913.
6. Giagounidis A. Mufti GJ, Fenaux P, et al. Results of a randomized, double-blind study of romiplostim versus placebo in patients with low/intermediate-1-risk myelodysplastic syndrome and thrombocytopenia. Cancer 2014;120:1838-1846. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4298760/ .
7. Greenberg PL, Garcia-Manero G, Moore M, et al. A randomized controlled trial of romiplostim in patients with low- or intermediate-risk myelodysplastic syndrome receiving decitabine. Leuk Lymphoma. 2013; 54(2):321-328.
8. Hicks LK, Bering H, Carson KR, et al. Five hematologic tests and treatments to question. *Blood*. 2014; 124(24):3524-3528. Available from: http://www.bloodjournal.org/content/bloodjournal/124/24/3524.full.pdf?sso-checked=true. Accessed on: March 21, 2019.
9. Jurczak W, Chojnowski K, Mayer J, Phase 3 randomised study of avatrombopag, a novel thrombopoietin receptor agonist for the treatment of chronic immune thrombocytopenia. Br J Haematol. 2018 Nov;183(3):479-490. doi: 10.1111/bjh.15573. Available from: https://onlinelibrary.wiley.com/doi/epdf/10.1111/bjh.15573
10. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
11. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 5, 2023.
12. Myelodysplastic Syndromes. V3.2023. Revised November 10, 2023.

Neunert C, Terrell DR, Arnold DM, et al. The American Society of Hematology (ASH) 2019 evidence-based practice guideline for immune thrombocytopenia. *Blood Adv*. 2019; 3(23):3829-3866. Available from: