

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	NA

*FHK- Florida Healthy Kids

Promacta (eltrombopag olamine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial and Maintenance: 1 year

Medications	Quantity Limit
Promacta (eltrombopag olamine) tablets and oral suspension	May be subject to quantity limits

APPROVAL CRITERIA

Initial therapy requests for Promacta (eltrombopag olamine) tablets and oral suspension may be approved for individuals who meet all of the following criteria:

- I. Individual has a diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP); **AND**
- II. Individual has a platelet count of less than $30 \times 10^9/L$ or active bleeding (ASH, 2011; Hicks et al., 2014); **AND**
- III. 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:
 - A. Corticosteroids; **OR**
 - B. Immunoglobulins (for example intravenous, anti-D); **OR**
 - C. Splenectomy.
- OR**
- IV. Individual has a diagnosis of severe aplastic anemia; **AND**
- V. Individual has a platelet count of less than or equal to $30 \times 10^9/L$ (Olnes et al., 2012; Desmond et al., 2014); **AND**
- VI. 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)].

Maintenance therapy requests for Promacta (eltrombopag) may be approved if the following criteria is met:

- I. 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 ($50 - 200 \times 10^9/L$) to decrease the risk of bleeding.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Promacta (eltrombopag olamine) tablets and oral suspension 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 $30 \times 10^9/L$ 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 concomitantly with other thrombopoietin receptor agonists, such as romiplostim (Nplate); **OR**
- VII. Used in individuals with myelodysplastic syndrome (MDS).

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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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