Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Promacta (eltrombopag olamine)

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

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

APPROVAL CRITERIA

Requests for initial therapy with Promacta (eltrombopag olamine) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP); **AND**
   A. 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;

Requests for Promacta (eltrombopag olamine) may be approved if the following criteria are met:

I. Individual has a diagnosis of severe aplastic anemia; **AND**
   A. 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;

OR

Market Applicability							
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Applicable	X	X	X	X	X	X	NA

II. Individual has a diagnosis of low risk myelodysplastic syndrome (MDS) (NCCN 2A); **AND**
   A. Individual has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents or immunosuppressive therapy.

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 – 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.

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 concomitantly with other thrombopoietin receptor agonists, such as romiplostim (Nplate).

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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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 N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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    a. Myelodysplastic Syndromes. V2.2019. Revised October 18, 2018.
12. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. *Blood*. 2011; 117(16):4190-4207. Available from: http://www.hematology.org/Clinicians/Guidelines-Quality/Guidelines.aspx. Accessed on: March 21, 2019.
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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.
CRX-ALL-0428-19

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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.
CRX-ALL-0428-19