



## MEDICATION POLICY

**Generic Name:** Eltrombopag

**Therapeutic Class or Brand Name:** Promacta®

**Applicable Drugs (if Therapeutic Class):** N/A

**Date of Origin:** 7/14/14

**Date Last Reviewed/Revised:** 1/4/18

**GPI Code:** 8240503010

### **Prior Authorization Criteria (may be considered medically necessary when criterion I is met):**

- I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:
  - A. Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura (ITP) AND all of criteria 1 through 4 are met:
    1. Documentation that patient is at risk of spontaneous bleeding as demonstrated by one of the following a or b:
      - a. Documented platelet count of less than 20,000/mm<sup>3</sup>.
      - b. Documented platelet count of less than 30,000/mm<sup>3</sup> accompanied by symptoms of bleeding.
    2. Documentation of one of the following a, b, or c:
      - a. Failure or intolerance to systemic corticosteroids.
      - b. Failure or intolerance to immunoglobulin therapy.
      - c. Insufficient response to a splenectomy.
    3. Minimum Age Requirement: 1 year old.
    4. Prescriber is a hematologist.
  - B. Thrombocytopenia associated with chronic hepatitis C infection AND all of criteria 1 through 5 are met:
    1. Patient is unable to initiate or maintain interferon-based therapy due to thrombocytopenia.
    2. Documented platelet count of less than 75,000/mm<sup>3</sup>.
    3. Documented Child-Pugh level A (score 5-6) - see Appendix.
    4. Minimum age requirement: 18 years old.
    5. Prescriber is a gastroenterologist, infectious disease specialist, or hepatologist.
  - C. Severe aplastic anemia AND all of criteria 1 through 4 are met:

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1. Documented platelet count of less than 30,000/mm<sup>3</sup>.
2. Documented insufficient response or intolerance to at least one immunosuppressive therapy.
3. Minimum age requirement: 18 years old.
4. Prescriber is a hematologist.

### Exclusion Criteria:

- Patients with myelodysplastic syndromes (MDS).

### Other Criteria:

- N/A

### Quantity/Days Supply Restrictions:

- The quantity is limited to a maximum of a 30 day supply per fill:
  - Chronic ITP: Doses up to 75 mg per day.
  - Chronic Hepatitis C-associated Thrombocytopenia: Doses up to 100 mg per day.
  - Severe Aplastic Anemia: Doses up to 150 mg per day.

### Approval Length:

- **Authorization:**
  - Chronic ITP: 12 weeks.
  - Chronic Hepatitis C-associated Thrombocytopenia: Length of interferon-based therapy (up to 48 weeks).
  - Severe Aplastic Anemia: 16 weeks.
- **Re-Authorization:**
  - Chronic ITP/ Severe Aplastic Anemia: Up to 6 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective. Documentation of a platelet count of at least 50,000/mm<sup>3</sup> but not more than 200,000/mm<sup>3</sup> is also required.
  - Chronic Hepatitis C-associated Thrombocytopenia: N/A

### Appendix:

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<i>Child-Pugh Classification Of Severity Of Liver Disease</i>			
Child-Pugh Classification	Points		
A: well-compensated disease	5 to 6		
B: significant functional compromise	7 to 9		
C: decompensated disease	10 to 15		
Points Assigned			
Parameter	1	2	3
Ascites	Absent	Slight	Moderate
Bilirubin (mg/dL)	< 2	2 to 3	> 3
Albumin (g/dL)	> 3.5	2.8 to 3.5	< 2.8
Prothrombin Time			
Seconds over control	1 to 3	4 to 6	>6
INR	< 1.7	1.8 to 2.3	> 2.3
Encephalopathy	None	Grade 1 to 2	Grade 3 to 4

### References:

- <http://blue.regence.com/trgmedpol/drugs/dru180.pdf>.
- <http://www.connecticare.com/provider/PDFs/Pharmacy/Promacta.pdf>.
- [http://www.tuftshealthplan.com/providers/pdf/pharmacy\\_criteria/promacta.pdf](http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/promacta.pdf).
- [http://www.bcbsil.com/pdf/pharmacy/rx\\_criteria/itp.pdf](http://www.bcbsil.com/pdf/pharmacy/rx_criteria/itp.pdf).
- [http://www.fchp.org/~media/Files/FCHP/Imported/Promacta\\_eltrombopag.pdf.ashx](http://www.fchp.org/~media/Files/FCHP/Imported/Promacta_eltrombopag.pdf.ashx).
- [Medi-Span](#).
- <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/promacta.pdf>.

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<b>Historical Tracking Of Changes Made To Policy</b>	
1/4/2018	1. <b>Added</b> “Patients with myelodysplastic syndromes (MDS)” <b>under Exclusion Criteria.</b>
10/9/2016	1. <b>Changed</b> “I. A. 3. Minimum Age Requirement: 6 years old” <b>to</b> “I. A. 3. Minimum Age Requirement: 1 year old” <b>under Prior Authorization Criteria.</b> 2. <b>Updated</b> “ <a href="http://www.gsksource.com/gskprm/htdocs/documents/PROMACTA-PI-MG-COMBINED.PDF">http://www.gsksource.com/gskprm/htdocs/documents/PROMACTA-PI-MG-COMBINED.PDF</a> ” <b>to</b> “ <a href="https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/promacta.pdf">https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/promacta.pdf</a> ” <b>under References.</b>
8/21/2015	1. <b>Changed Prior Authorization Criteria from:</b> “Prior Authorization Criteria (may be considered medically necessary when criteria I through II are met): I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis: A. Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia (ITP) and criteria 1 and 2 are met: 1. Documentation that patient is at risk of spontaneous bleeding as demonstrated by one of the following a or b: a. Platelet count less than 20,000/mm <sup>3</sup> ; b. Platelet count less than 30,000/mm <sup>3</sup> accompanied by symptoms of bleeding; 2. Documentation of one of the following a, b, or c: a. Failure or intolerance to systemic corticosteroids (i.e. prednisone 1 to 2 mg/kg for 2 to 4 weeks, or pulse dexamethasone 40 mg daily for 4 days); b. Failure or intolerance to immunoglobulin therapy; c. Insufficient response to a splenectomy; B. Thrombocytopenia associated with chronic hepatitis C and criteria 1 through 2 are met: 1. Patient is unable to initiate or maintain interferon-based therapy due to platelet count less than 75,000/mm <sup>3</sup> ; 2. Documented Child-Pugh level A (score 5-6) - see Appendix; II. Minimum age requirement: 18 years old” <b>to:</b> “Prior Authorization Criteria (may be considered medically necessary when criterion I is met): I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis: A. Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura (ITP) AND all of criteria 1 through 4 are met: 1. Documentation that patient is at risk of spontaneous bleeding as demonstrated by one of the following a or b: a. Documented platelet count of less than 20,000/mm <sup>3</sup> ; b. Documented platelet count of less than 30,000/mm <sup>3</sup> accompanied by symptoms of bleeding; 2. Documentation of one of the following a, b, or c: a. Failure or intolerance to systemic corticosteroids; b. Failure or intolerance to immunoglobulin therapy; c. Insufficient response to a splenectomy; 3. Minimum Age Requirement: 6 years old; 4. Prescriber is a hematologist; B. Thrombocytopenia associated with chronic hepatitis C infection AND all of criteria 1 through 5 are met: 1. Patient is unable to initiate or maintain interferon-based therapy due to thrombocytopenia; 2. Documented platelet count of less than 75,000/mm <sup>3</sup> ; 3. Documented Child-Pugh level A (score 5-6) - see Appendix; 4. Minimum age requirement: 18 years old; 5. Prescriber is a gastroenterologist, infectious disease specialist, or hepatologist; C. Severe aplastic anemia AND all of criteria 1 through 4 are met: 1. Documented platelet count of less than 30,000/mm <sup>3</sup> ; 2. Documented insufficient response or intolerance to at least one immunosuppressive therapy; 3. Minimum age requirement: 18 years old; 4. Prescriber is a hematologist”. 2. <b>Changed</b> “30 tablets per 30 days” <b>to</b> “The quantity is limited to a maximum of a 30 day supply per fill: Chronic ITP: Doses up to 75 mg per day; Chronic Hepatitis C-associated Thrombocytopenia: Doses up to 100 mg per day; Severe Aplastic Anemia: Doses up to 150 mg per day” <b>under Quantity/Days Supply Restrictions.</b> 3. <b>Changed Authorization under Approval Length from</b> “12 weeks” <b>to</b> “Chronic ITP: 12 weeks; Chronic Hepatitis C-associated Thrombocytopenia: Length of interferon-based therapy (up to 48 weeks); Severe Aplastic Anemia: 16 weeks”. 4. <b>Changed Re-Authorization under Approval Length from</b> “6 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is

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	<p>effective as shown by documentation of one of the following 1 or 2: 1. For Chronic ITP: the patient's platelet count is either a or b listed below: a. At least 30,000/mm<sup>3</sup> but not more than 150,000/mm<sup>3</sup>; b. Less than 30,000/mm<sup>3</sup> but platelet counts have increased from baseline accompanied with a resolution of previous bleeding; 2. For Chronic Hepatitis C: The patient remains on interferon-based therapy and platelet count is less than 400,000/ mm<sup>3</sup>" to "Chronic ITP/ Severe Aplastic Anemia: Up to 6 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective. Documentation of a platelet count of at least 50,000/mm<sup>3</sup> but not more than 200,000/mm<sup>3</sup> is also required; Chronic Hepatitis C-associated Thrombocytopenia: N/A".</p> <p>5. <b>Added</b> "Points Assigned: 1, 2, 3" to corresponding columns on "Child-Pugh Classification Of Severity Of Liver Disease" table under Appendix.</p> <p>6. <b>Added</b> "<a href="http://www.fchp.org/~media/Files/FCHP/Imported/Promacta_eltrombopag.pdf.ashx">http://www.fchp.org/~media/Files/FCHP/Imported/Promacta_eltrombopag.pdf.ashx</a>" under References.</p>

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