

**Generic Name:** Eltrombopag

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

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

**GPI Code:** 8240503010

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 7/14/2014

**Date Last Reviewed / Revised:** 2/6/2019

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when ONE of criteria I through III are met)

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

IV. Documented diagnosis of Refractory Severe Aplastic Anemia AND all of criteria A through D are met:

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

#### EXCLUSION CRITERIA

- Patients with myelodysplastic syndrome (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.
  - First-line Severe Aplastic Anemia:
    - Patients age 12 years and up: doses up to 150 mg per day.
    - Pediatric patients age 6 to 11 years: doses up to 75 mg per day.
    - Pediatric patients age 2 to 5 years: doses up to 2.5 mg/kg per day
  - Severe Refractory 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).
  - First-line Severe Aplastic Anemia: 6 months.
  - Severe Refractory 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

<b>Child-Pugh Classification Of Severity Of Liver Disease</b>			
<b>Child-Pugh Classification</b>	<b>Points</b>		
A: well-compensated disease	5 to 6		
B: significant functional compromise	7 to 9		
C: decompensated disease	10 to 15		
<b>Parameter</b>	<b>Points Assigned</b>		
	<b>1</b>	<b>2</b>	<b>3</b>
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

1. <http://www.connecticare.com/provider/PDFs/Pharmacy/Promacta.pdf> .
2. [http://www.tuftshealthplan.com/providers/pdf/pharmacy\\_criteria/promacta.pdf](http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/promacta.pdf) .
3. [http://www.fchp.org/~media/Files/FCHP/Imported/Promacta\\_eltrombopag.pdf.ashx](http://www.fchp.org/~media/Files/FCHP/Imported/Promacta_eltrombopag.pdf.ashx).
4. Medi-Span®.
5. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/promacta.pdf> .

## HISTORICAL TRACKING OF CHANGES MADE TO POLICY

<b>Date</b>	<b>Notes/Changes</b>
2/6/2019	<p>I. <b>Added</b> item III <b>under Prior Authorization Criteria new indication for First-line Severe aplastic anemia</b></p> <p>First-line treatment of documented Severe Aplastic Anemia and criteria A through C are met:</p>

Documented platelet count of less than 30,000/mm<sup>3</sup>.

Patient will receive combination therapy with immunosuppressive agents.

Minimum age requirement: 2 years old.

**Changed under Prior Authorization Criteria**

**From:**

Documented diagnosis of Aplastic Anemia AND all of criteria A through D are met:

**To:**

Documented diagnosis of **Refractory Severe** Aplastic Anemia AND all of criteria A through D are met:

**Added under Quantity/Days Supply Restrictions:**

o **First-line Severe Aplastic Anemia:**

- Patients age 12 years and up: doses up to 150 mg per day.
- Pediatric patients age 6 to 11 years: doses up to 75 mg per day.
- Pediatric patients age 2 to 5 years: doses up to 2.5 mg/kg per day

**Changed under Quantity/Days Supply:**

**From:**

Severe Aplastic Anemia: Doses up to 150 mg per day

**To:**

Severe **Refractory** Aplastic Anemia: Doses up to 150 mg per day

**Added under Approval Length:**

- o **First-line Severe Aplastic Anemia: 6 months.**

**Changed under Approval Length:**

**From:**

Severe Aplastic Anemia: 16 weeks.

**To:**

Severe **Refractory** Aplastic Anemia: 16 weeks.

	<p><b>Deleted</b> obsolete URLs <b>under References</b> item #1 and #3  <a href="http://blue.regence.com/trgmedpol/drugs/dru180.pdf">http://blue.regence.com/trgmedpol/drugs/dru180.pdf</a>  <a href="http://www.bcbsil.com/pdf/pharmacy/rx_criteria/itp.pdf">http://www.bcbsil.com/pdf/pharmacy/rx_criteria/itp.pdf</a> .</p>
1/4/2018	<p>1. <b>Added</b> "Patients with myelodysplastic syndromes (MDS)" <b>under Exclusion Criteria</b>.</p>
10/9/2016	<p>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> "http://www.gsksource.com/gskprm/htdocs/documents/PROMACTA-PI-MG-COMBINED.PDF" <b>to</b> "https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/promacta.pdf" <b>under References</b>.</p>
8/21/2015	<p>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"</p> <p><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".</p>

2. **Changed** "30 tablets per 30 days" to "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" **under Quantity/Days Supply Restrictions.**
3. **Changed Authorization under Approval Length from** "12 weeks" to "Chronic ITP: 12 weeks; Chronic Hepatitis C-associated Thrombocytopenia: Length of interferon-based therapy (up to 48 weeks); Severe Aplastic Anemia: 16 weeks".
4. **Changed Re-Authorization under Approval Length from** "6 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is 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".
5. **Added** "Points Assigned: 1, 2, 3" to corresponding columns on "Child-Pugh Classification Of Severity Of Liver Disease" table under Appendix.
6. **Added**  
"[http://www.fchp.org/~media/Files/FCHP/Imported/Promacta\\_eltrombopag.pdf.ashx](http://www.fchp.org/~media/Files/FCHP/Imported/Promacta_eltrombopag.pdf.ashx)"  
**under References.**

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.