# 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:** 10/9/16

**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/$mm^3$.
   b. Documented platelet count of less than 30,000/$mm^3$ 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/$mm^3$.
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/$mm^3$.
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:**

- N/A

**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/$mm^3$ but not more than 200,000/$mm^3$ is also required.
  - Chronic Hepatitis C-associated Thrombocytopenia: N/A

**Appendix:**

| *Child-Pugh Classification Of Severity Of Liver Disease* | | | |
|---|---|---|---|
| **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:**


1. http://blue.regence.com/trgmedpol/drugs/dru180.pdf.
2. http://www.connecticare.com/provider/PDFs/Pharmacy/Promacta.pdf.
3. http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/promacta.pdf.
4. http://www.bcbsil.com/pdf/pharmacy/rx_criteria/itp.pdf.
5. http://www.fchp.org/~/media/Files/FCHP/Imported/Promacta_eltrombopag.pdf.ashx.
6. Medi-Span.
7. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/promacta.pdf.

# MEDICATION POLICY

| *Historical Tracking Of Changes Made To Policy* | |
|---|---|
| *10/9/2016* | 1. **Changed** "I. A. 3. Minimum Age Requirement: 6 years old" **to** "I. A. 3. Minimum Age Requirement: 1 year old" **under Prior Authorization Criteria**.<br>2. **Updated** "http://www.gsksource.com/gskprm/htdocs/documents/PROMACTA-PI-MG-COMBINED.PDF" **to** "https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/promacta.pdf" **under References**. |
| *8/21/2015* | 1. **Changed Prior Authorization Criteria from:**<br>"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/mm3; b. Platelet count less than 30,000/mm3 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/mm3; 2. Documented Child-Pugh level A (score 5-6) - see Appendix; II. Minimum age requirement: 18 years old"<br>**to:**<br>"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/$mm^3$; b. Documented platelet count of less than 30,000/$mm^3$ 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/$mm^3$; 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/$mm^3$; 2. Documented insufficient response or intolerance to at least one immunosuppressive therapy; 3. Minimum age requirement: 18 years old; 4. Prescriber is a hematologist".<br>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**.<br>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".<br>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 |

| *Historical Tracking Of Changes Made To Policy* | |
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| | platelet count is either a or b listed below: a. At least 30,000/mm3 but not more than 150,000/mm3; b. Less than 30,000/mm3 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/ mm3" **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/$mm^3$ but not more than 200,000/$mm^3$ is also required; Chronic Hepatitis C-associated Thrombocytopenia: N/A".<br>5. **Added** "Points Assigned: 1, 2, 3" **to corresponding columns on "Child-Pugh Classification Of Severity Of Liver Disease" table under Appendix**.<br>6. **Added** "http://www.fchp.org/~/media/Files/FCHP/Imported/Promacta_eltrombopag.pdf.ashx" **under References**. |