Generic Name: Eltrombopag

Therapeutic Class or Brand Name: Promacta®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 7/14/2014

Date Last Reviewed / Revised: 2/14/2023

PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of Thrombocytopenia in patients with persistent or chronic immune (idiopathic) thrombocytopenia purpura (ITP) AND all of criteria A through F are met:
   A. Documentation that patient is at risk of spontaneous bleeding as demonstrated by one of the following 1 or 2:
   B. Documented platelet count of less than 20,000/mm^3.
   C. Documented platelet count of less than 30,000/mm^3 accompanied by symptoms of bleeding.
   D. 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.
   E. Minimum Age Requirement: 1 year old.
   F. Prescribed by or in consultation with a hematologist or oncologist.

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/mm3.
   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 D are met:
   A. Documented platelet count of less than 30,000/mm^3.
   B. Patient will receive combination therapy with immunosuppressive agents.
   C. Minimum age requirement: 2 years old.
   D. Prescribed by or on consultation with a hematologist or oncologist.

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^3.
   B. Documented insufficient response or intolerance to at least one immunosuppressive therapy.
   C. Minimum age requirement: 18 years old.
   D. Prescribed by or in consultation with a hematologist or oncologist.

V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

Exclusion Criteria

- Patients with myelodysplastic syndrome(MDS).
- Patient is on regimen containing direct-acting antiviral agent used without interferon for the treatment of chronic hepatitis C infection

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 to150 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/mm3 but not more than 200,000/mm3 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. Promacta®. Prescribing information. East Hanover, NJ: Novartis; October 2021. Accessed February 14, 2023. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/promacta.pdf .
2. National Comprehensive Cancer Network. Myelodysplastic Syndrome (Version 1.2023) https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed February 14, 2023.