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: 2/24/2025

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of one of the following diagnoses A through C AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Documented diagnosis of thrombocytopenia in patients with persistent or chronic immune (idiopathic) thrombocytopenia purpura (ITP):

1. Documentation of ITP duration > 3 months.
2. Documentation that patient is at risk of spontaneous bleeding as demonstrated by one of the following 1 or 2:
   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.
3. 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.
4. Minimum Age Requirement: 1 year old.
5. Treatment must be prescribed by or in consultation with a hematologist.

B. Documented diagnosis of thrombocytopenia associated with chronic hepatitis C infection:

1. Patient is unable to initiate or maintain interferon-based therapy due to thrombocytopenia.
2. Documented platelet count of less than 75,000/mm3.
3. Documented Child-Pugh level A (score 5-6) - see Appendix.
4. Minimum age requirement: 18 years old.
5. Treatment must be prescribed by or in consultation with a gastroenterologist, infectious disease specialist, or hepatologist.

C. Aplastic anemia

1. Documented platelet count of less than 30,000/mm^3.
2. Documentation of severe aplastic anemia and the patient meets one of the following criteria a or b:
   a) Used for first-line treatment in combination with immunosuppressive agents.
      (1) Minimum age requirement: 2 years old.
   b) Documented insufficient response or intolerance to at least one immunosuppressive therapy.
      (1) Minimum age requirement: 18 years old.
3. Treatment is prescribed by or in consultation with a hematologist.

Other Uses With Supportive Evidence

D. Myelodysplastic syndrome

E. Post-allogenic transplantation

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

III. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Patient is on a 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 12 years and older: 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

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

APPROVAL LENGTH

- **Authorization:**
  - Persistent or 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:**
  - Persistent or 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

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2. Neunert C, Terrell Dr, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Advances.* 2019;3(23):3829-3858. DOI: 10.1182/bloodadvances.2019000966.
3. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Advances.* 2019;3(22):3780-3817.
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Hematopoietic Growth Factors. Version 1.2025. Updated October 11, 2024. Accessed January 12, 2025. www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. Version 1.2025. Updated November, 2024. Accessed January 12, 2025. www.nccn.org/professionals/physician_gls/pdf/mds.pdf