ITP (Immune Thrombocytopenic Purpura) Prior Authorization (with Quantity Limit) program summary

OBJECTIVE

The intent of the prior authorization (PA) requirement for Promacta® is to encourage appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines and according to dosing recommended in product labeling. The PA criteria for Promacta direct their use to the FDA-approved indications for the treatment of chronic immune (idiopathic) thrombocytopenic purpura (ITP) in those who have had an insufficient response to corticosteroids, immunoglobulins (IVIg or anti-D), or splenectomy and for Promacta in chronic hepatitis C patients whose degree of thrombocytopenia prevents the initiation of interferon therapy or limits the ability to maintain optimal interferon-based therapy. Criteria will limit the approved dose to at or below the maximum FDA labeled dose. Renewal criteria will require improvement in platelet counts sufficient to avoid clinically significant bleeding.

TARGET DRUGS

Promacta® (eltrombopag)

QUANTITY LIMIT TARGET DRUGS- RECOMMENDED LIMITS

Brand (generic)	GPI	Multisource Code	Quantity per Day Limit
Promacta® (eltrombopag) oral tablet			
12.5 mg tablet	82405030100310	M, N, O, or Y	1 tablet
25 mg tablet	82405030100320	M, N, O, or Y	4 tablets
50 mg tablet	82405030100330	M, N, O, or Y	2 tablet
75 mg tablet	82405030100340	M, N, O, or Y	1 tablet

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

Promacta will be approved when the following are met:

1. The patient has an FDA labeled diagnosis for the requested agent
   AND
2. The patient does not have any FDA labeled contraindications to therapy
   AND
3. ONE of the following:
   a. If the diagnosis is **chronic idiopathic thrombocytopenia (ITP)**, ONE of the following:
      i. The patient has a history of trial and failure of; or a documented intolerance, FDA labeled contraindication, or hypersensitivity to ONE of the following treatments: corticosteroids, immunoglobulins (IVIg or anti-D) **OR**
      ii. The patient has had an insufficient response to or is not a candidate for splenectomy

   OR

b. If diagnosis is **hepatitis C associated thrombocytopenia,** ONE of the following:
    i. The patient's platelet count is <100 x10^9/L AND the intent is to increase platelet counts sufficiently to initiate interferon therapy **OR**
    ii. The patient is on concurrent therapy with a pegylated interferon and ribavirin AND is at risk for discontinuing HCV therapy due to thrombocytopenia

AND

4. ONE of the following:
    a. The quantity requested is less than or equal to the program quantity limit **OR**
    b. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist.

Length of Approval: Promacta for ITP. 12 weeks for Promacta for hepatitis C associated thrombocytopenia.

Renewal Evaluation

Promacta will be renewed for ITP when the following are met:

1. The patient has been previously approved for therapy through Prime Therapeutics PA process.

AND

2. The patient does not have any FDA labeled contraindications to therapy

AND

3. ONE of the following:
    a. The patient's platelet count is ≥50 x 10^9/L **OR**
    b. The patient's platelet count has increased sufficiently to avoid clinically important bleeding

AND

4. ONE of the following:
    a. The quantity requested is less than or equal to the program quantity limit **OR**
    b. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist.

Promacta will be renewed for hepatits C associated thrombocytopenia when the following are met:

1. The patient has been previously approved for therapy through Prime Therapeutics PA process.

AND

2. The patient does not have any FDA labeled contraindications to therapy

AND

3. ONE of the following:
    a. The patient will be initiating hepatitis C therapy with interferon and ribavirin **OR**
    b. The patient will be maintaining hepatitis C therapy with interferon and ribavirin at the same time as eltrombopag

AND

4. ONE of the following:
    a. The patients platelet count is ≥90 x 10^9/L **OR**

b. The patients platelet count has increased sufficiently to initiate or maintain interferon based therapy for the treatment of hepatitis C

AND

5. ONE of the following:
   a. The quantity requested is less than or equal to the program quantity limit **OR**
   b. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist.

Length of approval: 12 months for ITP. 48 weeks for HCV genotype 1,4,6 and 24 weeks for HCV genotype 2,3.

Promacta should be discontinued when antiviral therapy is discontinued

Agent	Contraindication(s)
Promacta (eltrombopag)	None