



Prior Authorization Approval Criteria

Promacta (eltrombopag)

Generic name:	Eltrombopag
Brand name:	Promacta
Medication class:	Thrombopoietin receptor agonist
FDA-approved uses:	Treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
Available dosage forms:	25 mg and 50 mg tablets
Usual dose:	<ul style="list-style-type: none">• 50 mg once daily for most patients.• For patients of East Asian ancestry or patients with moderate or severe hepatic insufficiency, the starting dose is 25 mg once daily.• Adjust the daily dose to achieve and maintain a platelet count $\geq 50 \times 10^9/L$ in order to reduce the risk for bleeding.• Do not exceed a daily dose of 75 mg/day.
Approximate monthly cost:	\$4,125.00/month based on 50 mg/day. (based on AWP 2009)

Duration of therapy: Indefinite

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

If approved, Promacta will be approved for 6 months at a time.

- Confirmed diagnosis of chronic immune (idiopathic) thrombocytopenic purpura.
- Required information is needed to complete review which includes: clinical notes from the patient's medical records including any applicable labs and / or tests, supporting the diagnosis.
- Patient must have tried and failed corticosteroids, immunoglobulins or splenectomy. (failure defined as platelets not increased to at least 50,000/mcl)
- Must be prescribed by a hematologist.
- Platelet count must be less than 30,000/mcL.
- Patients' degree of thrombocytopenia and clinical condition place patient at an increased risk for bleeding.
- Patient and prescriber must be enrolled in PROMACTA CARES*
- Initial approval will be for 1 month.

Criteria for continuation of therapy:

- Patient must show a response to treatment with a platelet count of at least 50,000/mcL but less than 200,000/mcL. (response rates should be seen at least 1 week after initiation of treatment with a maximum response seen at 2 weeks)

Caution:

- Hepatotoxicity
- Bone marrow reticulin formation and risk for bone marrow fibrosis

- Worsened thrombocytopenia after cessation of Promacta leading to serious hemorrhage
- Thrombotic/thromboembolic complications.
- Increased risk of hematological malignancies and progression of malignancy in patients with pre-existing hematological malignancy or myelodysplastic syndrome (MDS)

Monitoring:

- Liver function tests
- CBC'S including platelet counts and peripheral blood smears weekly during the dose adjustment and then monthly once on a stable dose.

Contraindication:

- None reported at this time.

Not approved if:

- Promacta is being used in an attempt to normalize platelet counts. (The goal of treatment is to prevent bleeding and to achieve a safe, but not necessarily normal, platelet count.)

Special considerations:

- Promacta will be distributed as a "drop-ship" only product.
- Discontinuation may result in worsened thrombocytopenia than was present prior to therapy.

*PROMACTA CARES is a program that consists of a patient registry and a requirement for prescribers to complete and report baseline and periodic safety information for every patient. Pharmacies must be authorized and agree to terms of use of Promacta before ordering.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 03/11/09