Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Promacta (eltrombopag)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***October 2008***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Promacta (eltrombopag).

Promacta (eltrombopag) is indicated for:

- Treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.
- Treatment of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy.

DEFINITIONS

ALT – aspartate aminotransferase

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes

appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Promacta (eltrombopag), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Chronic immune (idiopathic) thrombocytopenic purpura:**
   - Must be prescribed by a hematologist or an oncologist
   - Must be age 1 year or older
   - Must have a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP)
   - Must have a previous inadequate response or intolerance to corticosteroids as documented through platelet response
   - Must have, prior to initiation, a platelet count <30 x 10^9/L prior to initiation

2. **Chronic hepatitis C:**
   - Must be prescribed by a gastroenterologist or a hematologist
   - Must be age 18 years or older
   - Must have a diagnosis of chronic hepatitis C
   - Must currently be treated with or anticipating hepatitis C treatment with an interferon agent
   - Must have a platelet count <75 x 10^9/L prior to initiation

3. **Severe aplastic anemia:**
   - Must be prescribed by a hematologist or an oncologist
   - Must be 18 years or older
   - Must have a diagnosis of severe aplastic anemia
   - Must have a previous inadequate response or intolerance to antithymocyte globulin-based immunosuppressive therapy (Atgam®, Thymoglobulin®)
   - Must have a platelet count <30 x 10^9/L prior to initiation

Reauthorization Criteria:

All prior authorization renewals are reviewed on a 3 to 4 month basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 3 to 4 month intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy. In addition, the below criteria must be met, based upon diagnosis:

1. **For All Diagnosis:**
   - Must not have ALT levels increase to ≥3X upper limit of normal (ULN) and that also are:
     - Progressive
     - Persistent for ≥4 weeks
     - Accompanied by increased direct bilirubin
     - Accompanied by clinical symptoms of liver injury or evidence for hepatic decompensation
   - Must not have platelet count >400 x 10^9/L, [Eltrombopag (Promacta) should be stopped if platelet count is >400 x 10^9/L and should be discontinued permanently if platelet count is >400 x 10^9/L after 2 weeks of therapy at the lowest dose of eltrombopag (Promacta).

2. **Chronic immune (idiopathic) thrombocytopenic purpura:**
   - Must provide documentation showing that platelet count has normalized or that dose increase is planned if not already on a dose of 75 mg. [Eltrombopag (Promacta) should be discontinued if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy at the maximum daily dose of 75mg.]

3. **Chronic hepatitis C:**
   - Must provide documentation that member continues on antiviral therapy [Eltrombopag (Promacta) should be discontinued when antiviral therapy is discontinued.]

4. **Severe aplastic anemia:**

- Must provide documentation showing the member has had a hematologic response (increase in platelet count, increase in hemoglobin, increase in absolute neutrophil count, reduction in frequency of platelet or RBC transfusions). [Eltrombopag (Promacta) should be discontinued after 12 weeks of therapy if there is no hematologic response at the maximum daily dose of 150mg.]

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Chronic immune thrombocytopenia purpura: Up to 3 months • Chronic hepatitis C: up to 3 months • Aplastic anemia: Up to 4 months
Reauthorization	Same as initial
Quantity Level Limit	
12.5mg, 25mg	30 tablets per 30 days
50mg, 75mg	60 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/17, 02/18*