UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Promacta

Program	Prior Authorization
Medication	Promacta® (eltrombopag)
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

Promacta (eltrombopag) is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have experienced an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta is indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Promacta is also approved to treat patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.[1]

Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.[1]

Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon therapy or limits the ability to maintain interferon-based therapy. Safety and efficacy have not been established in combination with direct acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.[1]

Members will be required to meet the coverage criteria below.

2. Coverage Criteria:

A. <u>Chronic idiopathic thrombocytopenic purpura (ITP)</u>

1. **Promacta** will be approved based on **<u>both</u>** of the following criteria:

   a. Diagnosis of chronic idiopathic thrombocytopenic purpura (ITP)

   -AND-

   b. History of failure, contraindication, or intolerance to at least **<u>one</u>** of the following:

(1) Corticosteroids

(2) Immunoglobulins

(3) Splenectomy

Authorization will be issued for 12 months.

2. **Reauthorization Criteria**

a. **Promacta** will be approved based on the following criteria:

(1) Documentation of positive clinical response to Promacta therapy

Authorization will be issued for 12 months.

B. Chronic hepatitis C-associated thrombocytopenia

1. **Initial Therapy**

a. Promacta will be approved based on **both** of the following criteria:

(1) Diagnosis of chronic hepatitis C-associated thrombocytopenia

-AND-

(2) **One** of the following:

(a) Planning to initiate and maintain interferon-based treatment

-OR-

(b) Currently receiving interferon-based treatment

Authorization will be issued for 6 months.

2. **Reauthorization Criteria**

a. **Promacta** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Promacta therapy

-AND-

(2) Patient is currently on antiviral interferon therapy for treatment of chronic

hepatitis C

Authorization will be issued for 6 months.

C. Aplastic Anemia

1. **Promacta** will be approved based on **both** of the following criteria:

   a. Diagnosis of severe aplastic anemia

   -AND-

   b. History of failure, contraindication, or intolerance to at least one course of immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine], Thymoglobulin [antithymocyte globulin rabbit], cyclosporine)

Authorization will be issued for 6 months.

2. **Reauthorization Criteria**

   a. **Promacta** will be approved based on the following criteria:

      (1) Documentation of positive clinical response to Promacta therapy

Authorization will be issued for 12 months.

3. References:

1. Promacta [Package Insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2017.

Program	Prior Authorization- Promacta (eltrombopag)
Change Control	
3/2013	New policy.
10/2016	Updated to align with Employer & Individual criteria. Updated policy template.
12/2016	Added reauthorization criteria for ITP. Updated background and references.
3/2017	Changed reauthorization duration for chronic hepatitis C-associated thrombocytopenia from 12 months to 6 months.
11/2017	Annual Review. Updated References.