UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Promacta

Program	Prior Authorization
Medication	Promacta® (eltrombopag)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

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 thrombocytopenia (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 in combination with standard immunosuppressive therapy for the first line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia and for the treatment of 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 Immune Thrombocytopenia (ITP)</u>

1. **<u>Initial Authorization</u>**

   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 **one** of the following:

(1) Corticosteroids

(2) Immunoglobulins

(3) Splenectomy

Authorization will be issued for 12 months.

2. **Reauthorization**

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 Authorization**

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**

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. **Initial Authorization**

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

a. Diagnosis of severe aplastic anemia

-AND-

b. **One** of the following:

(1) Used in combination with standard immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine], Thymoglobulin [antithymocyte globulin rabbit], cyclosporine)

-OR-

(2) 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**

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. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-

10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place

4. References:

1. Promacta [Package Insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2020.

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.
11/2018	Renamed idiopathic thrombocytopenic purpura to immune thrombocytopenia throughout policy. Updated references.
11/2019	Revised coverage criteria for aplastic anemia. Updated background and references.
11/2020	Annual review. No changes to coverage rationale. Updated reference. Added Additional Clinical Rules section.