UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1083-13
Program	Prior Authorization/Notification
Medication	Promacta® (eltrombopag)
P&T Approval Date	1/2012, 2/2013, 2/2014, 2/2015, 2/2016, 12/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 1/2022, 1/2023
Effective Date	4/1/2023; Oxford only: 4/1/2023

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 persistent or 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 to treat patients with severe aplastic anemia and those patients 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]:

A. <u>Chronic immune thrombocytopenia (ITP)</u>

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

   a. Diagnosis of chronic immune thrombocytopenia (ITP)

   -AND-

   b. Patient has had an insufficient response to a previous treatment (e.g., corticosteroids, immunoglobulins, thrombopoietin receptor agonists, splenectomy)

   Authorization will be issued for 6 months.

2. **<u>Reauthorization Criteria</u>**

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

(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 12 months.

C. Aplastic Anemia

1. **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 Criteria**

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

(1) Documentation of positive clinical response to Promacta therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.

4. References:

1. Promacta [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2021.

Program	Prior Authorization/Notification – Promacta (eltrombopag)
Change Control	
2/2014	Annual review. Increased authorization to 60 months for ITP.
9/2014	Administrative change – Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review. Added criteria for new aplastic anemia indication. Updated background and references.
2/2016	Annual review. Revised reauthorization criteria for thrombocytopenia due to chronic hepatitis C. Extended initial authorization to 6 months for chronic hepatitis C and aplastic anemia. Updated background and references.
12/2016	Annual review. Reduced ITP authorization to 6 months and added reauthorization criteria. Updated background and references.
11/2017	Annual review. Updated references.
11/2018	Annual review. Revised coverage rationale to rename idiopathic thrombocytopenic purpura to immune thrombocytopenia. Updated background and references.
11/2019	Annual review. Revised coverage rationale for aplastic anemia. Updated background and references.
11/2020	Annual review. No changes to coverage rationale. Updated reference.
11/2021	Annual review. No changes to coverage criteria. Updated reference.
1/2022	Revised try/fail criteria to insufficient response. Updated reference.
1/2023	Annual review with no changes to coverage criteria. Updated background per label and added state mandate.