UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2348-1
Program	Prior Authorization/Medical Necessity
Medication	*Promacta® (eltrombopag) for oral suspension *This program applies to the formulation for oral suspension
P&T Approval Date	8/2024
Effective Date	1/1/2025

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 with severe aplastic anemia and for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

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

Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based 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.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

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

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

a. **Promacta for oral suspension** will be approved based on **all** of the following criteria:

(1) Diagnosis of chronic immune thrombocytopenia (ITP)

-AND-

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

splenectomy)

-AND-

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

(a) Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

i. age

ii. oral/motor difficulties

iii. dysphagia

-OR-

(b) Patient utilizes a feeding tube for medication administration

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Promacta for oral suspension therapy

Authorization will be issued for 12 months.

B. Chronic hepatitis C-associated thrombocytopenia

1. **Initial Authorization**

a. **Promacta for oral suspension** will be approved based on **all** 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

-AND-

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

(a) Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

i. age

ii. oral/motor difficulties

iii. dysphagia

-OR-

(b) Patient utilizes a feeding tube for medication administration

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Promacta oral suspension

-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. **Initial Authorization**

a. **Promacta for oral suspension** will be approved based on **all** of the following criteria:

(1) Diagnosis of severe aplastic anemia

-AND-

(2) **One** of the following

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

-OR-

(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)

-AND-

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

(a) Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:

i. age

ii. oral/motor difficulties

iii. dysphagia

-OR-

(b) Patient utilizes a feeding tube for medication administration

Authorization will be issued for 6 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Promacta for oral suspension 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; March 2023.

Program	Prior Authorization/Medical Necessity – Promacta for oral suspension (eltrombopag)
Change Control	
8/2024	New program.