



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG

Generic	Brand	HICL	GCN	Exception/Other
ELTROMBOPAG OLAMINE	PROMACTA	35989		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune (idiopathic) thrombocytopenia (cITP) and meet **ALL** of the following criteria?
 - The patient is 1 year of age or older
 - The patient has had a trial of, or contraindication to corticosteroids or immunoglobulins, or has had an insufficient response to splenectomy
 - The medication is prescribed by or given in consultation with a hematologist or immunologist

If yes, continue to #2.

If no, continue to #5.

2. Is the request for Promacta tablets?

If yes, **approve for 2 months by GPID for the requested drug as follows:**

- **Promacta 12.5mg tablet (GPID 31176): #1 tablet per day.**
- **Promacta 25mg tablet (GPID 15994): #1 tablet per day.**
- **Promacta 50mg tablet (GPID 15995): #1 tablet per day.**
- **Promacta 75mg tablet (GPID 28344): #1 tablet per day.**

APPROVAL TEXT: Renewal requires a clinical response, as defined by an increase in platelet count to at least 50X10⁹/L (at least 50,000 per microliter).

If no, continue to #3.

3. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

If yes, **approve for 2 months by GPID for Promacta 12.5mg packets for oral suspension (GPID 45875) with a quantity limit of #6 packets per day.**

APPROVAL TEXT: Renewal requires a clinical response as defined by an increase in platelet count to at least 50X10⁹/L (at least 50,000 per microliter).

If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?
- The patient is greater than 12 years of age
 - The patient has had a trial of Promacta tablets
 - Physician attestation of medical need for powder packets

If yes, **approve for 2 months by GPID for Promacta 12.5mg packets for oral suspension (GPID 45875) with a quantity limit of #6 packets per day.**

APPROVAL TEXT: Renewal requires a clinical response as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter).

If no, do not approve for Promacta packets. **Please enter proactive approvals for Promacta tablets for 2 months by GPID as follows:**

- **Promacta 12.5mg tablet (GPID 31176): #1 tablet per day.**
 - **Promacta 25mg tablet (GPID 15994): #1 tablet per day.**
 - **Promacta 50mg tablet (GPID 15995): #1 tablet per day.**
 - **Promacta 75mg tablet (GPID 28344): #1 tablet per day.**
- DENIAL TEXT:** See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C **AND** meet the following criterion?
- The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

If yes, continue to #6.

If no, continue to #9.

6. Is the request for Promacta tablets?

If yes, **approve for 12 months by GPID for the requested drug as follows:**

- **Promacta 12.5mg tablet (GPID 31176): #1 tablet per day.**
- **Promacta 25mg tablet (GPID 15994): #1 tablet per day.**
- **Promacta 50mg tablet (GPID 15995): #2 tablets per day.**
- **Promacta 75mg tablet (GPID 28344): #1 tablet per day.**

If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

7. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

If yes, **approve for 12 months by GPID for Promacta 12.5mg packets for oral suspension (GPID 45875) with a quantity limit of #8 packets per day.**

If no, continue to #8.

8. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?

- The patient is greater than 12 years of age
- The patient has had a trial of Promacta tablets
- Physician attestation of medical need for powder packets

If yes, **approve for 12 months by GPID for Promacta 12.5mg packets for oral suspension (GPID 45875) with a quantity limit of #8 packets per day.**

If no, do not approve for Promacta packets. **Please enter proactive approvals for Promacta tablets for 12 months by GPID as follows:**

- **Promacta 12.5mg tablet (GPID 31176): #1 tablet per day.**
- **Promacta 25mg tablet (GPID 15994): #1 tablet per day.**
- **Promacta 50mg tablet (GPID 15995): #2 tablets per day.**
- **Promacta 75mg tablet (GPID 28344): #1 tablet per day.**

DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of severe aplastic anemia and meet **ALL** of the following criteria?

- The patient is 2 years of age or older
- Promacta will be used in combination with standard immunosuppressive therapy as first-line treatment

If yes, continue to #10.

If no, continue to #13.

10. Is the request for Promacta tablets?

If yes, **approve for 12 months by GPID for the requested drug as follows:**

- **Promacta 12.5mg tablet (GPID 31176): #3 tablets per day.**
- **Promacta 25mg tablet (GPID 15994): #1 tablet per day.**
- **Promacta 50mg tablet (GPID 15995): #2 tablets per day.**
- **Promacta 75mg tablet (GPID 28344): #2 tablets per day.**

If no, continue to #11.

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INITIAL CRITERIA (CONTINUED)

11. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

If yes, **approve for 12 months by GPID for Promacta 12.5mg packets for oral suspension (GPID 45875) with a quantity limit of #12 packets per day.**

If no, continue to #12.

12. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?

- The patient is greater than 12 years of age
- The patient has had a trial of Promacta tablets
- Physician attestation of medical need for powder packets

If yes, **approve for 12 months by GPID for Promacta 12.5mg packets for oral suspension (GPID 45875) with a quantity limit of #12 packets per day.**

If no, do not approve for Promacta packets. **Please enter proactive approvals for Promacta tablets for 12 months by GPID as follows:**

- **Promacta 12.5mg tablet (GPID 31176): #3 tablets per day.**
- **Promacta 25mg tablet (GPID 15994): #1 tablet per day.**
- **Promacta 50mg tablet (GPID 15995): #2 tablets per day.**
- **Promacta 75mg tablet (GPID 28344): #2 tablets per day.**

DENIAL TEXT: See the initial denial text at the end of the guideline.

13. Does the patient have a diagnosis of severe aplastic anemia **AND** meet the following criterion?

- The patient has had an insufficient response to immunosuppressive therapy

If yes, continue to #14.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

14. Is the request for Promacta tablets?

If yes, **approve for 12 months by GPID for the requested drug as follows:**

- **Promacta 12.5mg tablet (GPID 31176): #1 tablet per day.**
- **Promacta 25mg tablet (GPID 15994): #1 tablet per day.**
- **Promacta 50mg tablet (GPID 15995): #2 tablets per day.**
- **Promacta 75mg tablet (GPID 28344): #2 tablets per day.**

If no, continue to #15.

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INITIAL CRITERIA (CONTINUED)

15. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

If yes, **approve for 12 months by GPID for Promacta 12.5mg packets for oral suspension (GPID 45875) with a quantity limit of #12 packets per day.**

If no, continue to #16.

16. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?

- The patient is greater than 12 years of age
- The patient has had a trial of Promacta tablets
- Physician attestation of medical need for powder packets

If yes, **approve for 12 months by GPID for Promacta 12.5mg packets for oral suspension (GPID 45875) with a quantity limit of #12 packets per day.**

If no, do not approve for Promacta packets. **Please enter proactive approvals for Promacta tablets for 12 months by GPID as follows:**

- **Promacta 12.5mg tablet (GPID 31176): #1 tablet per day.**
- **Promacta 25mg tablet (GPID 15994): #1 tablet per day.**
- **Promacta 50mg tablet (GPID 15995): #2 tablets per day.**
- **Promacta 75mg tablet (GPID 28344): #2 tablets per day.**

DENIAL TEXT: See the initial denial text at the end of the guideline.

INITIAL DENIAL TEXT: The guideline named **ELTROMBOPAG (Promacta)** requires a diagnosis of chronic immune (idiopathic) thrombocytopenia (cITP), thrombocytopenia due to chronic hepatitis C or severe aplastic anemia. In addition the following must be met:

For requests of Promacta packets for patients greater than 12 years old, approval requires:

- The patient has had a trial of Promacta tablets
- Physician attestation of medical need for powder packets

For the diagnosis of chronic immune (idiopathic) thrombocytopenia (cITP), approval requires:

- The patient is 1 year of age or older
- The patient has had a trial of, or contraindication to corticosteroids or immunoglobulins, or has had an insufficient response to splenectomy

For the diagnosis of thrombocytopenia due to chronic hepatitis C, approval requires:

- The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

For the diagnosis of severe aplastic anemia, approval requires ONE of the following:

- The patient is 2 years of age or older and Promacta will be used in combination with standard immunosuppressive therapy as first-line treatment
- The patient has had an insufficient response to immunosuppressive therapy

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GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C treatment or severe aplastic anemia, please refer to the Initial Criteria section.

- Does the patient have a diagnosis of chronic immune (idiopathic) thrombocytopenia (ciTP), **AND** meet the following criterion?
 - The patient has a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter)

If yes, **approve for 12 months by GPID for the requested drug as follows:**

- Promacta 12.5mg tablet (GPID 31176): #1 tablet per day.**
- Promacta 25mg tablet (GPID 15994): #1 tablet per day.**
- Promacta 50mg tablet (GPID 15995): #1 tablet per day.**
- Promacta 75mg tablet (GPID 28344): #1 tablet per day.**
- Promacta 12.5mg packets for oral suspension (GPID 45875): #6 packets per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ELTROMBOPAG (Promacta)** requires a diagnosis of chronic immune (idiopathic) thrombocytopenia (ciTP). In addition, the following must be met for renewal:

- The patient has a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Promacta.

REFERENCES

- Promacta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 01/09

Client Approval: 08/19

P&T Approval: 07/19