STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELTROMBOPAG OLAMINE	PROMACTA	35989		GPI-10 (8240503010)	

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
   - Therapy is prescribed by or given in consultation with a hematologist or immunologist
   - The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to splenectomy

   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 or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg tablet: #1 per day.**
   - **Promacta 25mg tablet: #1 per day.**
   - **Promacta 50mg tablet: #1 per day.**
   - **Promacta 75mg tablet: #1 per day.**

   APPROVAL TEXT: Renewal requires a clinical response, as defined by an increase in platelet count to at least 50X10(9)/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 or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg packets: #1 per day.**
   - **Promacta 25mg packets: #3 per day.**

   APPROVAL TEXT: Renewal requires a clinical response as defined by an increase in platelet count to at least 50X10(9)/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 had a trial of Promacta tablets
   - The patient has a medical need for powder packets

   If yes, **approve for 2 months by GPID or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg packets: #1 per day.**
   - **Promacta 25mg packets: #3 per day.**

   APPROVAL TEXT: Renewal requires a clinical response as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter).

   If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 2 months by GPID or GPI-14 as follows:**
   - **Promacta 12.5mg tablet: #1 per day.**
   - **Promacta 25mg tablet: #1 per day.**
   - **Promacta 50mg tablet: #1 per day.**
   - **Promacta 75mg tablet: #1 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 or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg tablet: #1 per day.**
   - **Promacta 25mg tablet: #1 per day.**
   - **Promacta 50mg tablet: #2 per day.**
   - **Promacta 75mg tablet: #1 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 or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg packets: #1 per day.**
   - **Promacta 25mg packets: #4 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 had a trial of Promacta tablets
   - The patient has a medical need for powder packets

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg packets: #1 per day.**
   - **Promacta 25mg packets: #4 per day.**

   If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 12 months by GPID or GPI-14 as follows:**
   - **Promacta 12.5mg tablet: #1 per day.**
   - **Promacta 25mg tablet: #1 per day.**
   - **Promacta 50mg tablet: #2 per day.**
   - **Promacta 75mg tablet: #1 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.

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INITIAL CRITERIA (CONTINUED)

10. Is the request for Promacta tablets?

    If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
    - **Promacta 12.5mg tablet: #3 per day.**
    - **Promacta 25mg tablet: #1 per day.**
    - **Promacta 50mg tablet: #2 per day.**
    - **Promacta 75mg tablet: #2 per day.**

    If no, continue to #11.

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 or GPI-14 for all strengths as follows:**
    - **Promacta 12.5mg packets: #3 per day.**
    - **Promacta 25mg packets: #6 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 had a trial of Promacta tablets
    - The patient has a medical need for powder packets

    If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
    - **Promacta 12.5mg packets: #3 per day.**
    - **Promacta 25mg packets: #6 per day.**

    If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 12 months by GPID or GPI-14 as follows:**
    - **Promacta 12.5mg tablet: #3 per day.**
    - **Promacta 25mg tablet: #1 per day.**
    - **Promacta 50mg tablet: #2 per day.**
    - **Promacta 75mg tablet: #2 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 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.

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INITIAL CRITERIA (CONTINUED)

14. Is the request for Promacta tablets?

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg tablet: #1 per day.**
- **Promacta 25mg tablet: #1 per day.**
- **Promacta 50mg tablet: #2 per day.**
- **Promacta 75mg tablet: #2 per day.**

If no, continue to #15.

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 or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg packets: #1 per day.**
- **Promacta 25mg packets: #6 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 had a trial of Promacta tablets
- The patient has a medical need for powder packets

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg packets: #1 per day.**
- **Promacta 25mg packets: #6 per day.**

If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 12 months by GPID or GPI-14 as follows:**

- **Promacta 12.5mg tablet: #1 per day.**
- **Promacta 25mg tablet: #1 per day.**
- **Promacta 50mg tablet: #2 per day.**
- **Promacta 75mg tablet: #2 per day.**

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

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELTROMBOPAG (Promacta)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
   2. Thrombocytopenia (low blood platelet count) due to chronic hepatitis C
   3. Severe aplastic anemia (type of blood disorder)

B. **If you are greater than 12 years of age and the request is for Promacta packets, approval also requires:**
   1. You previously had a trial of Promacta tablets
   2. You have a medical need for powder packets

C. **If you have chronic immune (idiopathic) thrombocytopenia, approval also requires:**
   1. You are 1 year of age or older
   2. You have tried corticosteroids or immunoglobulins, or did not have a good enough response to a splenectomy (removal of spleen) - unless there is a medical reason why you cannot (contraindication)
   3. The medication is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)

D. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
   1. Your thrombocytopenia does not allow you to start interferon-based therapy (type of drug for hepatitis) or limits your ability to maintain interferon-based therapy

E. **If you have severe aplastic anemia, approval also requires ONE of the following:**
   1. You are 2 years of age or older and Promacta will be used in combination with standard immunosuppressive therapy (treatment that prevents activity from your immune system) as first-line treatment
   2. You did not have a good enough response to immunosuppressive therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

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

1. 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 $50X10^9$/L (at least 50,000 per microliter)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths and formulations as follows:**
   - **Promacta 12.5mg tablet: #1 per day.**
   - **Promacta 25mg tablet: #1 per day.**
   - **Promacta 50mg tablet: #1 per day.**
   - **Promacta 75mg tablet: #1 per day.**
   - **Promacta 12.5mg packets: #1 per day.**
   - **Promacta 25mg packets: #3 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG (Promacta) requires the following rules be met for renewal:**
   A. You have chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
   B. You have a clinical response, as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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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; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/20/20
Created: 01/09
Client Approval: 04/20
P&T Approval: 07/19