Evolent Clinical Guideline 3256 for Promacta™, Alvaiz™ (eltrombopag)

Guideline Number:	Applicable Codes	
Evolent_CG_3256		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
July 2013	January 2026	January 2026

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STATEMENT

Purpose

To define and describe the accepted indications for Promacta and Alvaiz (eltrombopag) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Aplastic Anemia

- Promacta (eltrombopag) may be used as a single agent or in combination with immunosuppression (e.g., ATG, cyclosporine, or other immunosuppression) in adult and pediatric members 2 years of age and older with severe aplastic anemia defined as an ANC count less than 500 /mcL, platelet count less than 20 x 10^9/L, and an absolute reticulocyte count less than 60 x 10^9/L.
- Alvaiz (eltrombopag) may be used in adult members with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Chronic Idiopathic Thrombocytopenic Purpura (ITP)

- Promacta (eltrombopag) may be used in adult and pediatric members 1 year of age and older with a diagnosis of relapsed/refractory chronic ITP with an insufficient response to previous therapies including corticosteroids AND the member has a platelet count of less than 30 x 10^9/L.
- Alvaiz (eltrombopag) may be used in adult and pediatric members 6 years of age and older with a diagnosis of relapsed/refractory chronic ITP with an insufficient response to previous therapies including corticosteroids AND the member has a platelet count of less than 30 x 10^9/L.

Thrombocytopenia in Chronic Hepatitis C Infection

- Promacta (eltrombopag) may be used in members with thrombocytopenia related to chronic hepatitis C infection and that have a platelet count of less than 50 x 10^9/L.
- Alvaiz (eltrombopag) may be used in adult members with thrombocytopenia related to chronic hepatitis C infection and that have a platelet count of less than 50 x 10^9/L.

CONTRAINDICATIONS/WARNINGS

- US Boxed Warning
  - Hepatotoxicity
    - In patients with chronic hepatitis C, eltrombopag in combination with interferon and ribavirin may increase the risk of hepatic decompensation.
    - Eltrombopag may increase the risk of severe and potentially life-threatening hepatotoxicity. Monitor hepatic function and discontinue dosing as recommended.

EXCLUSION CRITERIA

- Concurrent use with other TPO receptor agonist such as Nplate (romiplostim) or Doptelet (avatrombopag).
- Dosing exceeds single dose limit of Promacta (eltrombopag) 75 mg (for ITP), 150 mg (for aplastic anemia), or 100 mg (for thrombocytopenia in chronic hepatitis C).
- Treatment exceeds the maximum limit of Promacta (eltrombopag) 30 (12.5 mg), 90 (25 mg), 60 (50 mg), and 60 (75 mg) tablets/month.
- Dosing exceeds single dose limit of Alvaiz (eltrombopag) 54 mg (for ITP), 108 mg (for aplastic anemia), or 72 mg (for thrombocytopenia in chronic hepatitis C).
- Treatment exceeds the maximum limit of Alvaiz (eltrombopag) 28 (9 mg), 84 (18 mg), 56 (36 mg), and 56 (54 mg) tablets/month.
- Investigational use of Promacta and Alvaiz (eltrombopag) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

- Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
- That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J8499 - Promacta, Alvaiz (eltrombopag)

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
January 2026	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1244 Promacta, Alvaiz (eltrombopag) • Updated maximum dosage form quantities in exclusion criteria • Updated references
January 2025	• Added other brand product “Alvaiz” to policy • Added Evolent disclaimer language • Added Coding Information section with HCPCS code • Updated indication section • Updated dosing limits in exclusion criteria • Added new references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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