Drug Policy:

Promacta™, Alvaiz™ (eltrombopag)

POLICY NUMBER UM ONC_1244	SUBJECT Promacta™, Alvaiz™ (eltrombopag)		DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 07/10/13, 07/22/14, 12/18/15, 12/21/16, 11/08/17, 10/05/18, 07/10/19, 12/11/19, 08/12/20, 09/09/20, 08/11/21, 11/15/21, 05/11/22, 07/13/22, 06/14/23, 06/12/24, 01/08/25	APPROVAL DATE January 08, 2025	EFFECTIVE DATE January 31, 2025	COMMITTEE APPROVAL DATES 07/10/13, 07/22/14, 12/18/15, 12/21/16, 11/08/17, 10/05/18, 07/10/19, 12/11/19, 08/12/20, 09/09/20, 08/11/21, 11/15/21, 05/11/22, 07/13/22, 06/14/23, 06/12/24, 01/08/25	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

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. A list of 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.

I. 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.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

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

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Aplastic Anemia

1. 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.
2. Alvaiz (eltrombopag) may be used in adult members with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

C. Chronic Idiopathic Thrombocytopenic Purpura (ITP)

1. 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.
2. 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.

D. Thrombocytopenia in Chronic Hepatitis C Infection

1. 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.
2. Alvaiz (eltrombopag) may be used adult members with thrombocytopenia related to chronic hepatitis C infection and that have a platelet count of less than 50 x 10^9/L.

III. EXCLUSION CRITERIA

A. Concurrent use with other TPO receptor agonist such as Nplate (romiplostim) or Doptelet (avatrombopag).

B. 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).

C. Treatment exceeds the maximum limit of Promacta (eltrombopag) 30 (12.5 mg), 90 (25 mg), 90 (50 mg), and 60 (75 mg) tablets/month.

D. 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).

E. Treatment exceeds the maximum limit of Alvaiz (eltrombopag) 28 (9 mg), 28 (18 mg), 56 (36 mg), and 56 (54 mg) tablets/month.

F. 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:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. 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.
4. 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).
5. 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.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. 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.

IV. CODING INFORMATION

HCPCS Code	Description
J8499	Promacta (eltrombopag)
J8499	Alvaiz (eltrombopag)

V. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

VI. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

A. None

VIII. REFERENCES

A. Peffault de Latour R, et al. RACE Clinical Trial. Severe Aplastic Anemia Working Party of the European Society for Blood and Marrow Transplantation. Eltrombopag Added to Immunosuppression in Severe Aplastic Anemia. N Engl J Med. 2022 Jan 6;386(1):11-23.

B. Bussel JB, et al. Eltrombopag for the treatment of chronic idiopathic thrombocytopenic purpura. N Engl J Med. 2007 Nov 29;357(22):2237-47. doi: 10.1056/NEJMoa073275

C. Grainger JD, et al. Eltrombopag for children with chronic immune thrombocytopenia (PETIT2): a randomised, multicentre, placebo-controlled trial. Lancet. 2015 Oct 24;386(10004):1649-58. doi: 10.1016/S0140-6736(15)61107-2

D. Afdhal NH, et al. Eltrombopag increases platelet numbers in thrombocytopenic patients with HCV infection and cirrhosis, allowing for effective antiviral therapy. Gastroenterology. 2014 Feb;146(2):442-52.e1. doi: 10.1053/j.gastro.2013.10.012

E. Olnes MJ, et al. Eltrombopag and improved hematopoiesis in refractory aplastic anemia. N Engl J Med. 2012 Jul 5;367(1):11-9. doi: 10.1056/NEJMoa1200931

F. Promacta prescribing information 2023. Novartis Pharmaceuticals Corporation, East Hanover, NJ

G. Alvaiz prescribing information 2023. Teva Pharmaceuticals, Parsippany, NJ

H. Clinical Pharmacology Elsevier Gold Standard 2025.

I. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2025.

J. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.

K. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.

L. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

M. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.