Drug Policy:

Promacta™ (eltrombopag)

POLICY NUMBER UM ONC_1244	SUBJECT Promacta™ (eltrombopag)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
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	APPROVAL DATE July 13, 2022	EFFECTIVE DATE July 29, 2022	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	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

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

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways (http://pathways.newcenturyhealth.com/) when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs AND
6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a Preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendia or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

B. Chronic Idiopathic Thrombocytopenic Purpura (ITP)

1. The member is an adult or pediatric member 1 year of age and older with a diagnosis of relapsed/refractory chronic ITP with an insufficient response to previous therapies including corticosteroids, immunoglobulins (IVIG), and Rituxan (rituximab)/splenectomy AND
2. The member has a platelet count of < 30 x 10^9/L.

C. Thrombocytopenia in Chronic Hepatitis C Infection

1. Promacta (eltrombopag) may be used in a member with thrombocytopenia related to chronic hepatitis C infection and has a platelet count of < 50 x 10^9/L.

D. Aplastic Anemia

1. The member is an adult or pediatric member 2 years of age and older with severe aplastic anemia defined as an ANC count <500 /mcL, platelet count < 20 x 10^9/L, and an absolute reticulocyte count <60 x 10^9/L AND
2. Promacta (eltrombopag) may be used as a single agent or in combination with immunosuppression (e.g., ATG, cyclosporine, or other immunosuppression)

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 30 (12.5 mg), 30 (25 mg), 90 (50 mg), 60 (75 mg) tablets/month.

D. Investigational use of Promacta (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 definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of 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. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. RACE trial. Latour et al. N Engl J Med 2022;386:11-23. DOI: 10.1056/NEJMoa2109965

B. Promacta prescribing information. Novartis Pharmaceuticals Corporation Hanover, NJ 2022.

C. Clinical Pharmacology Elsevier Gold Standard 2021.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.

F. 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.

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

H. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.