

Drug Policy:

Nplate™ (romiplostim)

POLICY NUMBER UM ONC_1243	SUBJECT Nplate™ (romiplostim)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 07/10/13, 07/24/14, 12/18/15, 12/20/16, 10/31/17, 10/05/18, 07/10/19, 12/11/19, 08/12/20, 08/11/21	APPROVAL DATE August 11, 2021	EFFECTIVE DATE August 27, 2021	COMMITTEE APPROVAL DATES 07/10/13, 07/24/14, 12/18/15, 12/20/16, 10/31/17, 10/05/18, 07/10/19, 12/11/19, 08/12/20, 08/11/21	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 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 Nplate (romiplostim) 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 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.

B. Chronic Idiopathic Thrombocytopenic Purpura (ITP)

1. The member has a diagnosis of relapsed/refractory chronic ITP AND the member has had an insufficient therapeutic response (defined by failure of platelet count to increase and stay above 30,000/mm³) OR intolerance to OR contraindications to corticosteroids AND/OR immunoglobulin (IVIG), AND/OR rituximab, AND/OR splenectomy.
2. The recommended dosing guidelines for Nplate (romiplostim) need to be followed, e.g., a starting dose of 1 mcg/kg, and subsequent increments by 1 mcg/kg, if the platelet count remains below 50,000/mm³ on the previous lower dose.

III. EXCLUSION CRITERIA

- A. Concurrent use with other TPO receptor agonist such as Promacta (eltrombopag) or Doptelet (avatrombopag).
- B. Dosing exceeds single dose limit of Nplate (romiplostim) 10mcg/kg.
- C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

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. Nplate prescribing information. Amgen Inc. Thousand Oaks, CA 2021.
- B. Clinical Pharmacology Elsevier Gold Standard 2021.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.
- E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.