OncoHealth

Nplate (romiplostim)

Effective Date: 5/1/2022
Revision Date(s): 5/1/2022, 10/04/2023, 4/25/2024
Review Date: 4/25/2024
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Universal Criteria:

- Patient is at least 18 years old age; **AND**
- Patient is not receiving any other thrombopoietin receptor agonist (eltrombopag, lusutrombopag etc.) or fostamatinib; **AND**
- Romiplostim is not being used to normalize platelet counts; **AND**
- Laboratory values for platelet count are within 30 days of request; **AND**
- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature; **AND**
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event, the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Indication Specific Approval Criteria:

Chemotherapy-induced thrombocytopenia

- The patient is receiving active treatment with chemotherapy; **AND**
    - The patient has a platelet count < 100,000/mcL for ≥3 weeks following the last chemotherapy administration; **OR**
    - The patient has had delays in chemotherapy initiation related to thrombocytopenia

Myelodysplastic Syndrome

- Patient has severe or refractory disease; **AND**
- The patient must have a platelet count ≤ 50,000/mcL; **AND**
- The patient must be diagnosed with lower risk MDS (Lower risk defined as IPSS-R (Very Low, Low, Intermediate); **AND**
- Patient has failed prior therapy with one of the following: hypomethylating agents, immunosuppressive therapy, or clinical trial.

Universal Approval Criteria:

Unless otherwise noted above the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
  - Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
- NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
- Clinical Pharmacology (Strong For)
- American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
- Thompson Micromedex DrugDex® (Class I and IIa)
- Wolters Kluwer Lexi-Drugs® (Level A)
  - Other use of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals
- American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology
- **Meeting abstracts and case reports are excluded from consideration.**
  - Non-standard protocols may be approved based on unique clinical circumstances.

Billing

Drug Name	HCPCS Code	Description
Romiplostim	J2796	Injection, romiplostim, 10 mcg

References

1. Romiplostim [package insert]. Amgen, Inc., Thousand Oaks, CA. Available at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Nplate/nplate_pi_hcp_english.pdf
2. Romiplostim. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed April 25th, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.
4. Kantarjian H, Fenaux P, Sekeres MA, Becker PS, Boruchov A, Bowen D, Hellstrom-Lindberg E, Larson RA, Lyons RM, Muus P, Shammo J, Siegel R, Hu K, Franklin J, Berger DP. Safety and efficacy of

romiplostim in patients with lower-risk myelodysplastic syndrome and thrombocytopenia. J Clin Oncol. 2010 Jan 20;28(3):437-44. doi: 10.1200/JCO.2009.24.7999. Epub 2009 Dec 14. PMID: 20008626.

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

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Date	Updates
5/1/2022	Policy approved at P&T
10/4/2023	Updated references to align with most up to date version of NCCN. Additional verbiage added under universal criteria and approval criteria. Headings updated for indication specific approval criteria.
4/25/2024	Annual Review. Updated Universal Criteria and References