OncoHealth

Nplate (romiplostim)

Original Effective Date: 5/1/2022
Revision Date(s): 5/1/2022, 10/04/2023, 4/25/2024, 11/22/2024
Review Date: 11/22/2024
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are issued for 6 (six) months, unless the ordering physician requests a different timespan or the patients' unique circumstance or condition supports the medical necessity for a different authorization timeframe. Reauthorization requests are reviewed for efficacy, safety and tolerability.

Indication Specific Approval Criteria:

Chemotherapy-induced thrombocytopenia

- 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**
- 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 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**
- 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, the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- National Comprehensive Cancer Network® (NCCN) - use consistent with NCCN recommendations carrying a Category 1 or 2A level of evidence; **OR**
- United States Food and Drug Administration (FDA) labeling - new drugs or regimens (combinations of drugs) consistent with all components of the product labeling; **OR**
- Indications not included in the official FDA labeling or recommended by NCCN (Category 1 or 2A level of evidence) may be considered if determined to be medically necessary per one or more of the following compendia:
    - Clinical Pharmacology (Strong For); **OR**
    - Wolters Kluwer Lexi-Drugs® (Level A); **OR**
- Other uses of drugs and biologics may be considered medically necessary 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;
- Dose and frequency should be consistent with United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature;
- 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 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).

Billing

Drug Name	HCPCS Code	Description
Romiplostim	J2802	Injection, romiplostim, 1 microgram

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 November 22, 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

Drug Coverage Policies are developed as needed, reviewed and 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 utilizing this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice nor 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.

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
11/22/2024	For 1/1/2025 – Update to HCPCS code for 1/1/2025; template update; universal criteria update