

Nplate (romiplostim)

Effective Date: 5/1/2022

Revision Date(s): 5/1/2022, 10/04/2023

Review Date: 5/1/2022, 10/04/2023

Policy type: Medical Necessity

Line of Business: Commercial

Authorizations are for 4 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Universal Criteria Applied to All Requests:

- 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
- Indication specific criteria should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.
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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.

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. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 10/04/2022
2. Hematopoietic Growth Factors Version 2.2023 — March 6, 2023 Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf Accessed 10/04/2023.
3. Myelodysplastic Syndromes Version 1.2023 — September 12, 2022 Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf Accessed 10/04/2023.
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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Revision History

5/1/2022 –

10/04/2023 – 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.