OncoHealth

Nplate (romiplostim)

Effective Date: 09/01/2022
Revision Date(s):
Review Date: 06/21/2022
Policy type: Medical Necessity

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

Initial Approval Criteria

Coverage is provided for the following conditions:

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

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.

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 06/30/2022
2. Hematopoietic Growth Factors Version 1.2022 – December 22,2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf Accessed 06/30/2022.
3. Myelodysplatic Syndromes Version 3.2022 – January 13,2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf Accessed 06/30/2022.
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.