Romiplostim (Nplate®)

Prior Authorization Drug Coverage Policy

Effective Date: 3/1/2021
Revision Date: 7/22/2020
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Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of Romiplostim. 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.

Drug Description[1]

Romiplostim increases platelet production through binding and activation of the thrombopoietin (TPO) receptor, a mechanism analogous to endogenous TPO.

NCCN Compendium Supported Recommendations[2]

- Chemotherapy-induced thrombocytopenia (CIT)
- Myelodysplastic Syndrome

Coverage Determinations[1,2]

Romiplostim will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Chemotherapy-induced thrombocytopenia (CIT)

- May be considered for the treatment of chemotherapy-induced thrombocytopenia (CIT) (platelets <100,000/mcL for ≥3-4 weeks following last chemotherapy administration and/or following delays in chemotherapy initiation related to thrombocytopenia

Recommended dosage: 1 mcg/kg once weekly as a subcutaneous injection. Adjust dose based on platelet response. Maximum dose: 10 mcg/kg/week

Myelodysplastic Syndromes (MDS)

- The member has a diagnosis of lower risk MDS [Lower risk defined as IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)] **AND**
- The member has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents, immunosuppressive therapy, or clinical trial

Recommended dosage: 1 mcg/kg once weekly as a subcutaneous injection. Adjust dose based on platelet response. Maximum dose: 10 mcg/kg/week

All indications:

- Romiplostim will be approved through clinical review for up to a 12-month duration.

Coverage Limitations

Treatment with Romiplostim is not considered medically necessary for members with the following concomitant conditions:

- Romiplostim should not be used in an attempt to normalize platelet counts
- Lack or loss of response (after four weeks at max dose), patient should be assessed for other possible etiologies (e.g., antibodies to romiplostim and bone marrow fibrosis) and romiplostim discontinued
- Concomitant use with other thrombopoitein receptor agonists (e.g., eltrombopag, avotrombopag, lusutrombopag)
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/precautions:
    - In some patients with MDS, Romiplostim increases blast cell counts and increases the risk of progression to acute myelogenous leukemia.
    - Thrombotic/thromboembolic complications may result from increases in platelet counts with Romiplostim use. Portal vein thrombosis has been reported in patients with chronic liver disease receiving Romiplostim.
    - If severe thrombocytopenia develops during Romiplostim treatment, assess patients for the formation of neutralizing antibodies.

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: injection, romiplostim, 10 mcg

- J2796

Disclaimer

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 Oncology Analytics, Inc.

References

1. Nplate [package insert]. Amgen, Inc., Thousand Oaks, CA. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/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. Kuter DJ, Bussel JB, Lyons RM, et al, "Efficacy of Romiplostim in Patients With Chronic Immune Thrombocytopenic Purpura: A Double-Blind Randomised Controlled Trial," Lancet, 2008, 371(9610):395-403.
4. Kuter DJ, Rummel M, Boccia R, et al, "Romiplostim or Standard of Care in Patients With Immune Thrombocytopenia," N Engl J Med, 2010, 363(20):1889-99.
5. Giagounidis A, Mufti GJ, Fenaux P, et al. Results of a randomized, double-blind study of romiplostim versus placebo in patients with low/intermediate-1-risk myelodysplastic syndrome and thrombocytopenia. Cancer. 2014;120(12):1838-1846.