Clinical Policy: Romiplostim (Nplate)

Reference Number:LA.PHAR.179
Effective Date:
Last Review Date: 06.21 — **Coding Implications**
Line of Business: Medicaid — **Revision Log**

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Romiplostim (Nplate®) is a thrombopoietin receptor agonist.

FDA Approved Indication(s)

Nplate is indicated for the treatment of thrombocytopenia in:

- **Adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy;**
- **Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.**

Limitation(s) of use:

- **Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome or any cause of thrombocytopenia other than ITP.**
- **Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding.**
- **Nplate should not be used in an attempt to normalize platelet counts.**

Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Nplate is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Immune Thrombocytopenia (must meet all):

1. **Diagnosis of ITP;**
2. **Prescribed by or in consultation with a hematologist;**
3. **Age ≥ 1 year;**
4. **Current (within 30 days) platelet count is < 30,000/µL or member has an active bleed;**
5. **Member meets one of the following (a or b):**
   a. **Failure of a systemic corticosteroid;**
   b. **Member has intolerance or contraindication to systemic corticosteroids, and failure of an immune globulin, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);**

Prior authorization may be required for immune globulins

6. **Nplate is not prescribed concurrently with rituximab or another thrombopoietin receptor agonist (e.g., Promacta®, Doptelet®);**
7. **Dose does not exceed 10 mcg/kg per week.**

Approval duration: 6 months

B. Myelodysplastic Syndromes (off-label) (must meet all):

1. **Diagnosis of myelodysplastic syndromes (MDS);**
2. **Prescribed by or in consultation with an oncologist or hematologist;**
3. **Member has lower-risk MDS (IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate);**
4. **Member has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents (e.g., azacitadine, decitabine), immunosuppressive therapy (e.g., Atgam®, cyclosporine), or clinical trial;**
5. **Request meets one of the following (a or b):***
   a. **Dose does not exceed 10 mcg/kg per week;**
   b. **Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 6 months

C. Other diagnoses/indications

1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

A. Immune Thrombocytopenia (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
2. **Member is responding positively to therapy (e.g., increase in platelet count from baseline, reduction in bleeding events);**
3. **Current (within the last 90 days) platelet count is < 400,000/µL;**
4. **Nplate is not prescribed concurrently with rituximab or another thrombopoietin receptor agonist (e.g., Promacta, Doptelet);**
5. **If request is for a dose increase, new dose does not exceed 10 mcg/kg per week.**

Approval duration: 12 months

B. Myelodysplastic Syndromes (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Nplate for MDS and has received this medication for at least 30 days;**
2. **Member is responding positively to therapy;**
3. **If request is for a dose increase, request meets one of the following (a or b):***

a. **New dose does not exceed 10 mcg/kg per week;**
b. **New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 12 months

C. **Other diagnoses/indications (must meet 1 or 2):**
1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
Approval duration: Duration of request or 6 months (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

III. Diagnoses/Indications for which coverage is NOT authorized:

A. **Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy –LA.PMN.53 for Medicaid, or evidence of coverage documents.**

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
IPSS: International Prognostic Scoring System
IPSS-R: Revised International Prognostic Scoring System
ITP: chronic immune thrombocytopenia
MDS: myelodysplastic syndromes
WPSS: WHO Classification-based Prognostic Scoring System

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Corticosteroids*		
dexamethasone	**ITP** **Oral dosage:** ***Adults*: Initially, 0.75 to 9 mg/day PO, given in 2 to 4 divided doses. Adjust according to patient response.** ***Children and adolescents*: 0.02 to 0.3 mg/kg/day PO or 0.6 to 9 mg/m^2/day PO, given in 3 to 4 divided doses** **Intramuscular or intravenous dosage:** ***Adults:* Initially, 0.5 to 9 mg/day IV or IM, given in 2 to 4 divided doses.**	**Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.**

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Adjust according to patient response. *Children:* 0.02 to 0.3 mg/kg/day or 0.6 to 9 mg/m^2/day IV or IM given in 3-4 divided doses. Adjust according to patient response.	
methylprednisolone	ITP Oral dosage: *Adults:* 4 to 48 mg/day PO in 4 divided doses. Adjust according to patient response. *Children:* 0.5 to 1.7 mg/kg/day PO in divided doses every 6 to 12 hrs Intravenous dosage: *Adults:* 10 to 40 mg IV every 4 to 6 hours for up to 72 hours *Children:* 0.11 to 1.6 mg/kg/day IV in 3 or 4 divided doses.	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.
prednisone	ITP *Adults:* Initially, 1 mg/kg PO once daily; however, lower doses of 5 mg/day to 10 mg/day PO are preferable for long-term treatment.	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.
Immune globulins		
immune globulins (Carimune® NF, Flebogamma® DIF 10%, Gammagard® S/D, Gammaked™, Gamunex®-C, Gammaplex®, Octagam® 10%, Privigen®)	ITP Refer to prescribing information	Refer to prescribing information

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Examples of corticosteroids/immunosuppressive agents provided are not all inclusive*

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- **MDS prognostic scoring system online calculators are available below:**
  - **IPSS-R: https://qxmd.com/calculate/calculator_109/mds-revised-international-prognostic-scoring-system-ipss-r**
  - **IPSS: https://qxmd.com/calculate/calculator_123/mds-intnl-prognostic-scoring-sys-ipss**
  - **WPSS: https://qxmd.com/calculate/calculator_143/mds-who-classification-based-prognostic-scoring-system-wpss**

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ITP	The initial dose is 1 mcg/kg SC once weekly based on actual body weight. Adjust weekly dose by increments of 1 mcg/kg to achieve and maintain a platelet count ≥ 50,000/µL as necessary to reduce the risk for bleeding. Do not dose if platelet count is > 400,000/µL.	10 mcg/kg/week

VI. Product Availability

Lyophilized powder in single-dose vials for injection: 125 mcg, 250 mcg, 500 mcg

VII. References

1. Nplate Prescribing Information. Thousand Oaks, CA: Amgen Inc.; October 2019. Available at https://www.nplate.com/. Accessed November 17, 2020.
2. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011; 117(16): 4190-4207.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/.
4. National Comprehensive Cancer Network. Myelodysplastic Syndromes Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed November 17, 2020.
5. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 17, 2020.
6. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv (2019) 3 (23): 3829–3866.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2796	Injection, romiplostim, 10 mcg

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	6.2021

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.