AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Nplate® (romiplostim) **(J2802) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

A. Quantity Limit (max daily dose) [NDC Unit]:

- Nplate 125 mcg SDV for injection: 40 vials per 28 days
- Nplate 250 mcg SDV for injection: 20 vials per 28 days
- Nplate 500 mcg SDV for injection: 12 vials per 28 days

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B. Max Units (per dose and over time) [HCPCS Unit]:

- Immune (idiopathic) thrombocytopenia (ITP): 1250 billable units weekly
- Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS): 1250 billable units x 1 dose
- Injection, romiplostim, 1 microgram; 1 billable unit = 1 mcg

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Prescribed by a hematologist
- ❑ Member is not on any other thrombopoietin receptor agonist or mimetic (e.g., Doptelet, Mulpleta, Promacta) or Tavalisse
- ❑ Provider attests the requested medication will **NOT** be used as an attempt to normalize platelet counts
- ❑ Platelet count has been drawn within the previous 28 days **(please submit labs)**
- ❑ Applicable diagnosis criteria below has been completed

❑ Diagnosis: Myelodysplastic Syndromes (MDS)

- ❑ Member is at least 18 years of age
- ❑ Member has lower risk disease [i.e., IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate)]
- ❑ Member has severe or refractory thrombocytopenia (i.e., platelet count < 20 x 10^9/L or higher with a history of bleeding)
- ❑ Member progressed or had no response to hypomethylating agents (e.g., azacitidine, decitabine), immunosuppressive therapy, or clinical trial

❑ Diagnosis: Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)

- ❑ Member has suspected or confirmed exposure to radiation levels > 2 gray (Gy)
- ❑ Dosed for one-time administration at 10 mcg/kg subcutaneously

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❑ Diagnosis: Immune (idiopathic) thrombocytopenia (ITP)

- ❑ Member is at increased risk for bleeding as indicated by platelet count < 30×10^9/L
- ❑ **FOR** acute immune (idiopathic) thrombocytopenia (ITP)
  - ❑ Member is at least 18 years of age
  - ❑ Member has previously failed **ONE** of the following treatments for ITP:
    - ❑ Corticosteroids (prednisone 0.5-2.0 mg/kg/day, or dexamethasone 40 mg/day for 4 days)
    - ❑ IVIG
    - ❑ Splenectomy
    - ❑ Other: _____
- ❑ **FOR** chronic ITP lasting at least 6 months
  - ❑ Member is 1 year of age or older
  - ❑ Member has previously failed **ONE** of the following treatments for ITP:
    - ❑ Corticosteroids (defined as not having a response to at least a 3-month trial or is corticosteroid-dependent)
    - ❑ IVIG
    - ❑ Splenectomy
- ❑ **FOR** members currently established on therapy:
  - ❑ Past medical history and laboratory documentation has been provided to show platelet level monitoring and procedural records – PROCEED TO RENEWAL AUTHORIZATION CRITERIA

Reauthorization: 12 months. (All indications) Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ Diagnosis: Myelodysplastic Syndromes (MDS)

- ❑ Member is not experiencing unacceptable toxicity from the drug (e.g., thrombotic/thromboembolic complications, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia)
- ❑ Member has not developed acute myeloid leukemia (AML) (**NOTE:** Nplate induces an increase in immature white blood cells and peripheral blasts which is not indicative of development of AML)
- ❑ Member has experienced disease response indicated by an increase in platelet count compared to pretreatment baseline (not to exceed 450 x 10^9/L), reduction in bleeding events, or reduction in platelet transfusion requirements

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- ❑ Provider will adhere to the following dosage reduction recommendations **(platelet count drawn with the previous 28 days must be submitted)**:

  Adjust dose in 250 mcg increments (from 250 mcg every other week up to 1000 mcg weekly) based on platelet count response:
  - Platelet count < 50 x 10^9/L for three consecutive weeks: Increase to the next highest dose level
  - Platelet count > 450 x 10^9/L: Withhold the dose, reinitiate at a reduced dose when platelet count is <200 x 10^9/L

❑ Diagnosis: Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)

- ❖ **Coverage cannot be renewed**

❑ Diagnosis: Immune (idiopathic) thrombocytopenia (ITP)

- ❑ Member is not experiencing unacceptable toxicity from the drug (e.g., thrombotic/thromboembolic complications, risk of progression of myelodysplastic syndromes to acute myelogenous leukemia)
- ❑ Member has experienced disease response indicated by the achievement and maintenance of a platelet count of at least 50 × 10^9/L (not to exceed 400 x 10^9/L) as necessary to reduce the risk for bleeding
- ❑ Provider will adhere to the following dosage reduction recommendations **(platelet count drawn with the previous 28 days must be submitted)**:

  Adjust dose based on platelet count response:
  - Platelet count < 50 × 10^9/L: Increase weekly dose by 1 mcg/kg.
  - Platelet count >200 ×10^9/L to ≤ 400 ×10^9/L for two consecutive weeks: Reduce weekly dose by 1 mcg/kg.
  - Platelet count > 400 ×10^9/L: Withhold dose; assess platelet count weekly; when platelet count < 200 ×10^9/L, resume with the weekly dose reduced by 1 mcg/kg.
  - DISCONTINUE, if platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the maximum recommended dose of 10 mcg/kg/week.

Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

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For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: **9/16/2021**
REVISED/UPDATED/REFORMATTED: ~~12/9/2021; 12/23/2021; 12/20/2024,~~ **01/16/2025**