

SENTARA HEALTH PLANS

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) (J2796) (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 Name/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 Recommendations and Quantity Limits:

[Injection romiplostim, 10 micrograms; 10 mcg = 1 billable unit]

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

- Nplate 125 mcg SDV for injection: 4 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

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

- Immune (idiopathic) thrombocytopenia (ITP): 125 billable units weekly
- Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS): 125 billable units x 1 dose

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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: 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

Diagnosis: Immune (idiopathic) thrombocytopenia (ITP)

- Member is at increased risk for bleeding as indicated by platelet count < $30 \times 10^9/L$
- 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 REAUTHORIZATION CRITERIA**

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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: 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 $50 \times 10^9/L$ (not to exceed $400 \times 10^9/L$) 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 $< 50 \times 10^9/L$: Increase weekly dose by 1 mcg/kg.
- Platelet count $>200 \times 10^9/L$ to $\leq 400 \times 10^9/L$ for two consecutive weeks: Reduce weekly dose by 1 mcg/kg.
- Platelet count $> 400 \times 10^9/L$: Withhold dose; assess platelet count weekly; when platelet count $< 200 \times 10^9/L$, 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

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.****