JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP027
		Effective Date	10/01/2006
		Review Date	01/15/2020
	Subject **Nplate (Romiplostim)**	*Revision Date*	11/10/2021
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Nplate

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I. POLICY

A. Romiplostim (Nplate®) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Nplate may be approved for patients who meet the following criteria:
   1. 18 years of age or older and one of the following:
      a. Documented diagnosis of chronic immune idiopathic thrombocytopenia(ITP) with platelet count less than 30 x 10^9/L AND insufficient response to corticosteroids, immunoglobulin, or splenectomy **OR**
      b. Documented diagnosis of chronic (ITP) with platelet count between 30 x 10^9/L and 50 x 10^9/L AND insufficient response to corticosteroids or immunoglobulin with significant mucous membrane bleeding **OR**
      c. Documented diagnosis of chronic (ITP) with platelet count between 30 x 10^9/L and 50 x 10^9/L AND insufficient response to corticosteroids or immunoglobulin with risk factors for bleeding (such as but no limited to, hypertension, peptic ulcer disease, anticoagulation, recent surgery, etc.)

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval for Nplate will be restricted to 1 month of therapy at dose less than or equal to the maximum recommended dose.
B. Approval for continuation of therapy can be extended at six month intervals at dose less than or equal to the maximum recommended dose with clinical documentation supporting one of the following:
   1. Patient's platelet count has increased to ≥50 x 10^9/L in response to Nplate

2. Patient's platelet count has not increased to ≥50 x 10^9/L, but is expected to achieve platelet count to ≥50 x 10^9/L with an additional 6-week course of therapy.

IV. EXCLUSIONS

A. Nplate® will not be approved for:
1. Treatment in order to normalize platelet counts
2. Treatment of myelodysplastic syndrome(MDS)Low platelet count associated with any other cause other than chronic ITP
3. Concomitant therapy with any other thrombopoietin receptor agonists
4. Initial therapy for patients chronic ITP without a clinical condition and whose degree of thrombocytopenia does not increase the risk for bleeding (platelet count ≥50 x 10^9/L)
5. Patients who have failed to achieve platelet count to ≥50 x 10^9/L after 8 weeks of therapy

V. RECOMMENDED DOSAGE

All FDA approved dosage(s) and dosing interval(s) for the FDA approved indication(s).

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Nplate 250 MCG SOLR Injection, romiplostim, 10 micrograms	J2796

VII. REFERENCES

1. Product Information: Nplate® (romiplostim). Amgen, Inc. Thousand Oaks, CA, April 2016.
2. Stasi R, Provan D. Management of immune thrombocytopenia purpura in adults. *Mayo Clin Proc.* 2004; 79:504-522.
3. George JN, Woolf SH, Raskob GE, et al. Idiopathic thrombocytopenic purpura: a practice guideline developed by explicit methods for the American Society of Hematology. *Blood*. 1996; 88(1):3-40.
4. George JN. Immune thrombocytopenia (ITP) in adults: Initial treatment and prognosis. In: UpToDate, Leung LLK (Ed), UpToDate, Waltham, MA, 2016.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE

07/20/2016	Removed background information, updated indications for Promacta, updated exclusion criteria, clarified authorization criteria, and made minor criteria edits
07/21/2017	Promacta indication update to include new approved age range for treatment
07/27/2017	Updated Exclusions section regarding physician samples
07/18/2018	Added clinical criteria for Tavalisse
10/17/2018	Added clinical criteria for Doptelet
01/16/2019	Removed references to pharmacy-benefit covered agents
06/05/2019	Converted from MEDS to MMDP policy
01/15/2020	No policy changes- presented polivy for USFHP adoption effective 3/1/2020
11/10/2021	Removed Priority Partners as an applicable LOB

Review/Revision Dates: 01/16/2008, 1/13/2009, 11/1/2009, 3/1/2014, 7/20/2016, 07/21/2017, 07/27/2017, 07/18/2018, 10/17/2018, 01/16/2019, 06/05/2019, 07/17/2019, 01/15/2020, 11/10/2021