POLICY AND PROCEDURE

POLICY TITLE: **Nplate (Romiplostim)**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***October 2008 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Nplate (romiplostim).

Nplate (Romiplostim) is indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Nplate (Romiplostim) should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. Nplate (Romiplostim) should not be used in an attempt to normalize platelet counts.

DEFINITIONS

N/A

POLICY
It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Nplate (Romiplostim), is subject to the prior authorization process.

PROCEDURE
Initial Authorization Criteria:

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Must meet all of the criteria listed below:

- Must be prescribed by a hematologist or oncologist
- Must be administered by or under the direction of the prescriber or a healthcare provider
- Must be age > 18 years
- Must have a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP)
- Must have a previous inadequate response or intolerance to corticosteroids as documented through platelet response
- Must have, prior to initiation, a platelet count < 30 x 109/L

Continuation/Discontinuation Criteria:

- Discontinue romiplostim (Nplate) if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy at the maximum weekly dose of 10 mcg/kg
- Utilize the lowest dose of romiplostim (Nplate) to achieve and maintain platelet count ≥ 50 x 109/L
    - If platelet count is > 200 x 109/L for 2 consecutive weeks, reduce the dose by 1 mcg/kg.
    - If the platelet count is > 400 x 109/L, do not dose. Continue to assess the platelet count weekly. After the platelet count has fallen to <200 x 109/L, resume at a dose reduced by 1 mcg/kg.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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8. Tiu RV, Sekeres MA. The role of AMG-531 in the treatment of thrombocytopenia in idiopathic thrombocytopenic purpura and myelodysplastic syndromes. Expert Opinion on Biological Therapy. 2008: 8(7); 1021-1030.

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/17, 02/18*

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