Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, revised, or archived.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
Background Information, continued:

Definitions

- Idiopathic thrombocytopenic purpura (ITP) is an auto-immune disorder characterized by immune-mediated platelet destruction and decreased platelet production.

Medication Summary

- Romiplostim (Nplate®) is an injectable thrombopoietin receptor agonist produced by recombinant DNA technology in Escherichia coli. Romiplostim stimulates the thrombopoietin receptor (TPO) to increase platelet production, similar to endogenous TPO. The unique peptide sequence of romiplostim significantly limits, but does not completely remove, the risk for developing thrombopoietin autoantibodies. It is indicated for treatment of thrombocytopenia in members with **chronic** immune (idiopathic) thrombocytopenic purpura (ITP) who have had insufficient response to corticosteroids, immunoglobulins, or splenectomy.

- Romiplostim should not be used in an attempt to normalize platelet counts and should only be used in members with ITP whose degree of thrombocytopenia and clinical condition increases the risk of bleeding.

- Romiplostim initial dosing is 1 mcg/kg subcutaneous injection based on actual body weight. The weekly dose should be adjusted by 1 mcg/kg increments until the member achieves a platelet count ≥ 50 X 10^9/L (≥ 50,000 /mm^3). The weekly dose should not exceed a maximum of 10 mcg/kg.

- Romiplostim should be discontinued if the platelet count has not increased above 50 X 10^9/L (> 50,000 /mm^3) or to a level that will prevent spontaneous bleeding after four (4) weeks of therapy at the maximum weekly dose of 10 mcg/kg.

- Romiplostim is supplied in a single-use vial containing 250 mcg and 500 mcg deliverable romiplostim.

- Romiplostim is available only through a restricted distribution program called the Nplate NEXUS Program. Under this program, only prescribers and Members registered with the program are able to prescribe, administer, and receive product.
Background Information, continued:

Coverage Guidelines

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Member less than 18 years of age, as safety and efficacy have not been established.
- Thrombocytopenia from any other causes except chronic ITP, including thrombocytopenia due to myelodysplastic syndrome.
- Do not use if the platelet count is > 400 x 10^9/L (≥ 400,000 /mm^3).
- Concomitant use with eltrombopag (Promacta).

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.

Procedure:

1.0 Request for initial therapy for chronic idiopathic thrombocytopenia purpura requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying ALL of the following:

1.1 Member must be at least 18 years of age;

1.2 Member must have a diagnosis of chronic immune idiopathic thrombocytopenia purpura (ITP);

1.3 Member must have a current platelet count of less than 30 x 10^9/L (<30,000/mm^3);
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Procedure:

1.0 Request for initial therapy for chronic idiopathic thrombocytopenia purpura requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying ALL of the following, continued:

1.4 Member must have had an inadequate response to corticosteroids with intravenous immune globulin (IVIG or IGIV), anti-Rho(D) immune globulin (WinRho, Rhophylac), OR rituximab, OR must have been splenectomized;

1.5 Prescribing physician must be a hematologist/oncologist;

1.6 Member has failure or contraindication (hepatic disease) to Promacta (eltrombopag) therapy prior to Nplate utilization;

1.7 If criteria is met, may approve for three (3) months:

1.7.1 Initial dose is 1 mcg/kg per week up to a maximum dose of 10mcg/kg per week:
1.7.1.1 Dose should be adjusted weekly by increments of 1 mcg/kg to achieve and maintain platelet count ≥ 50 x 10^9/L (≥ 50,000 /mm^3) as necessary to reduce the risk for bleeding.

2.0 Request for continuation therapy beyond the initial authorization period requires documentation from the member’s medical records maintained by the requesting independent practitioner verifying ALL of the following:

2.1 Member must have experienced an increase in platelet count over baseline, counts should be greater than 50 x 10^9/L (>50,000 /mm^3) and less than 400 x 10^9/L (≤400,000 /mm^3);

2.2 Absence of any intolerable side effects or any new or worsening morphological abnormalities;

2.3 If criteria are met, may approve up a maximum of 10mcg/kg per week for an additional six (6) months.
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**References:**


