



Prior Authorization Approval Criteria

- Generic name:** Romiplostim
- Brand name:** Nplate
- Medication class:** Thrombopoietin receptor agonist
- FDA-approved uses:** Idiopathic thrombocytopenic purpura (ITP), chronic
- Available dosage forms:** Lyophilized white powder for solution:
- 250 mcg, 500 mcg
- Usual dose:**
- Initial dose: 1 mcg/kg (actual body weight) subcutaneously once a week to achieve a platelet count of $> 50 \times 10^9/L$
 - Increase at increments of 1 mcg/kg
 - Maximum: 10 mcg/kg
- Approximate yearly cost:** (based on AWP 2009) \$17,851.98
- Duration of therapy:** Indeterminate
- Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):
- Only prescribers and patients enrolled in Nplate NEXUS program can receive, prescribe, or administer romiplostim
 - ≥ 18 years old
 - Insufficient response to corticosteroids, immunoglobulins, or splenectomy
 - Platelet count $< 30 \times 10^9/L$ (as seen in clinical trials)
- Criteria for discontinuation of therapy:**
- If platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of romiplostim therapy at the maximum dose of 10 mcg/kg
- Caution:**
- Antibody development to romiplostim
 - Bone marrow formation
 - Bone marrow reticulin formation
 - Failure to respond or maintain response: possible due to neutralizing antibodies or bone marrow fibrosis
 - Thrombotic and thromboembolic complications
 - Worsened thrombocytopenia after cessation of romiplostim
 - Malignancies and progression to malignancies

Monitoring:

- CBC, including platelet count and peripheral blood smear, prior to initiation, weekly during dose adjustments, monthly after stable platelet count of $> 50 \times 10^9/L$ for at least 4 weeks without dose adjustment, and for at least 2 weeks after discontinuation
- Lack of response: formation of antibodies or bone marrow fibrosis
- Increase in platelet counts and resolution of thrombocytopenia
- New or worsening morphological abnormalities of Red and White blood cells or cytopenia
- Signs and symptoms of thrombotic/thromboembolic complications

Contraindication:

- Not yet determined

Not approved if:

- Used to normalize platelet counts

Special considerations:

- Pregnancy category C
 - Pregnancy registry has been established
- Nursing mothers: Safety data has not been established but infant risk cannot be ruled out.
- Pediatrics: Safety and efficacy data has not been established.
- Geriatrics: greater sensitivity cannot be ruled out. Dose adjust with caution.
- Renal and hepatic impairment: No clinical studies were conducted.
- May be used with other ITP therapies

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 03/11/09