Sample Letter of Medical Necessity

(Practice Letterhead)

(Date)

(Insurer Name)
(Insurer Company Name)
(City, State ZIP)
Attn: **(Name, Department Name)**

RE: Treatment authorization request for **(Patient Name)**
(Policy Number/Group Number/Patient ID #)
(Date of Birth)

To Whom It May Concern:

I am writing on behalf of my patient, **(patient's name)**, to document the medical necessity of Nplate® (romiplostim) therapy for adult chronic ITP.

(Mr./Mrs./Ms.) (patient's last name)'s medical history and treatment pathway are as follows:

- **List previous regimen(s) and outcome(s)**

Nplate® was approved for marketing by the FDA on August 22, 2008. Attached is the full prescribing information and medication guide for Nplate®. **(Mr./Mrs./Ms.) (patient's last name)** should receive Nplate® for the following reasons:

- **List reasons**

Nplate® 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® should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. Nplate® should not be used in an attempt to normalize platelet counts.

IMPORTANT SAFETY INFORMATION
Serious adverse reactions associated with Nplate® in clinical studies were bone marrow reticulin deposition and worsening thrombocytopenia after Nplate® discontinuation. Additional risks include Bone Marrow Fibrosis, Thrombotic/Thromboembolic Complications, Lack or Loss of Response to Nplate®, and Hematological Malignancies and Progression of Malignancy in Patients with a Pre-existing Hematological Malignancy or Myelodysplastic Syndrome (MDS).

Nplate® is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than chronic ITP.

Monitor CBC's, including platelet counts and peripheral blood smears, prior to initiation, throughout, and following discontinuation of Nplate® therapy.

Nplate® is available only through a restricted distribution program called Nplate® NEXUS (Network of Experts Understanding and Supporting Nplate and Patients) Program.

In the placebo-controlled studies, headache was the most commonly reported adverse drug reaction.

In summary, Nplate® therapy is necessary and reasonable for **(Mr./Mrs./Ms.) (patient's last name)**'s medical condition. Please contact me if any additional information is required to ensure the prompt approval of this therapy.

Sincerely,

(Physician Name)

encl.