

## Your Input Needed to Continue Access to New ITP Treatment

**September 22, 2008** - As many of you know, the U.S. Food and Drug Administration recently approved Nplate (romiplostim), the first product that directly stimulates the bone marrow to produce needed platelets in splenectomized (spleen removed) and non-splenectomized adults with chronic immune thrombocytopenic purpura (ITP).

On July 31, 2008, the Centers for Medicare and Medicaid Services (CMS), a federal agency responsible for administering health-related programs including Medicare and Medicaid, released a list of 20 topics that the agency is considering for future National Coverage Determinations (NCDs). CMS included Nplate as a topic for a potential NCD by specifically listing "thrombopoiesis stimulating agents (platelet growth factors, e.g. romiplostim)".

### What could an NCD mean for patients and providers?

- Through an NCD, CMS could decide not to cover Nplate at all or for only certain uses, which may be less than the indications listed in the FDA-approved labeling.
- CMS has the ability to dictate the dosage amount of a product and time as to when it can be provided to a patient under a NCD which ultimately results in the elimination of medical judgment on the behalf of a medical professional.
- Implementation of a NCD could require additional physician and staff time to ensure proper documentation of the guidelines included in a NCD.

As a policy, the PDSA does not take a formal position on the recommendation of any specific treatment, however, we are concerned that an NCD would affect many ITP patients by excluding or restricting coverage of Nplate for Medicare and Medicaid recipients and may influence commercial or private payer coverage decisions.

To help ensure access to Nplate and continued coverage of this drug, we encourage individuals to share any thoughts/experiences about how ITP has impacted their life and the need for additional treatment options.

CMS is accepting comments through their website [here](#). **The deadline for submissions is Friday, September 26, 2008 at 5 PM.**

For questions or more information about NCDs, you can contact Dr. Leslye Fitterman, in the agency's Coverage and Analysis Group at (410) 786-3669 or [Leslye.Fitterman@cms.hhs.gov](mailto:Leslye.Fitterman@cms.hhs.gov)

You can search on Nplate or romiplostim for more information about this drug, clinical trial results, and safety data.

Thank you for your input.

Craig Conway  
Executive Director

### About ITP

ITP, immune (idiopathic) thrombocytopenic purpura, is an autoimmune disease. In autoimmune diseases, the body mounts an immune attack toward one or more seemingly normal organ systems. In ITP, platelets are the target. They are marked as foreign by the immune system and eliminated in the spleen and sometimes, the liver. In addition to increased platelet destruction, some people with ITP also have impaired platelet production. Without a sufficient number of platelets, a person with ITP is subject to spontaneous bleeding or bruising.

About PDSA

The Platelet Disorder Support Association is dedicated to enhancing the lives of people with immune thrombocytopenic purpura (ITP) and other platelet disorders through education, advocacy and research. For more information, please contact us at 1-87-PLATELET or visit our Web site at [www.pdsa.org](http://www.pdsa.org).

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