Nplate®
romiplostim injection

ELECTRONIC MEDICAL RECORD SYSTEM TIP SHEET

Finding patients with immune thrombocytopenia (ITP) who are being treated with steroids or IVIG can be an overwhelming process. EMR capabilities can help identify patients with ITP for follow-up evaluation and engagement. This tool provides a few examples of queries on electronic medical records systems that may be helpful in identifying appropriate patients for Nplate® (romiplostim) and should not be used for coding or reimbursement.*

*These examples are not intended to be instructive with respect to clinical decision-making or billing and coding. Healthcare providers are solely responsible for clinical decisions and ensuring the accuracy and validity of all billing and claims. This is not a guarantee of coverage or reimbursement for any product or service.

IVIG = Intravenous immunoglobulin; EMR = Electronic medical record.

INDICATIONS

Nplate® is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Nplate® is indicated for the treatment of thrombocytopenia in pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Nplate® is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP. Nplate® should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate® should not be used in an attempt to normalize platelet counts.

Please see additional Important Safety Information on page 7.

2019 ITP CLINICAL GUIDELINES RECOMMEND LIMITING STEROID USE TO ≤ 6 WEEKS TO MAXIMUM OF 8 WEEKS IN ADULTS BEFORE STARTING A SECOND-LINE THERAPY, SUCH AS NPLATE®[1-3]

In 2019 the American Society of Hematology (ASH) and the International Consensus Report (ICR) released updates to their guidelines for ITP.[1,2] These updates are based on a critical review of relevant articles published over the last 10 years.[1]

ASH recommendations[2]	ICR recommendations[1]
• **≤ 6 weeks of steroid treatment is** preferred vs prolonged, continuous use - Prolonged course defined as > 6 weeks, including **treatment and taper** • **Delay splenectomy** until after 1 year	• **6 weeks of steroid treatment** (8 weeks max) in patients who achieve a response* • **Defer splenectomy** until ≥ 1 year to 2 years

*Response defined as platelet count > 50 x 10^9/L.[1]

Scan here or visit **Nplatehcp.com/guidelines** to access the full ASH and ICR Guidelines

ASH ITP guidelines suggest a TPO-RA, including Nplate®, as a second-line therapy over rituximab[2,3,†]

[†]Rituximab is not FDA-approved for use in ITP.[4]

FDA = The United States Food and Drug Administration; ITP = immune thrombocytopenia; TPO-RA = thrombopoietin receptor agonist

IMPORTANT SAFETY INFORMATION

Risk of Progression of Myelodysplastic Syndromes to Acute Myelogenous Leukemia

- In Nplate® (romiplostim) clinical trials of patients with myelodysplastic syndromes (MDS) and severe thrombocytopenia, progression from MDS to acute myelogenous leukemia (AML) has been observed.
- Nplate® is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than ITP.

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Clinical studies demonstrated

RAPID EFFICACY THAT LASTS[3,5]

Nplate® has proven rapid onset and lasting platelet stability; and offers an **opportunity for treatment-free remission.**[3,5]

93% OF PATIENTS	**~1/3** OF PATIENTS	as early as **7** DAYS
93% of patients achieved any platelet response* (n = 70/75)[3]	**~1/3** of patients achieved treatment-free remission (n = 32%)[3,5]	responses seen as early as 7 days with **median of 2.1 weeks**[3,6,†]

ASH ITP guidelines suggest Nplate® as a second-line option over non-TPO-RAs like rituximab[2,3]

Primary endpoint: 61% patients achieved a response for ≥ 11 months[5]

*A platelet response was defined as a ≥ 50 x 10^9/L platelet count during the 12-month treatment period.

†Time to response: 5.56%, 47.22%, and 61.11% of patients responded by weeks 1,2, and 3. 95% CI: 1.1 to 3.0 weeks.

ESTABLISHED SAFETY PROFILE WITHOUT FOOD RESTRICTION[3,7]

Nplate® is the **once-weekly in-office subcutaneous injection** that offers[3]

No new safety signals observed up to 5 years of continuous treatment[7]	**No** need to remember to take a **pill every day**[3,8-10]	**No liver monitoring**, no **known drug interactions** or **dietary restrictions**[3,11]

STUDY DESIGN

Nplate® was studied in a 52-week, open-label, single-arm, phase 2 trial of 75 adults with ITP for ≤ 6 months who had an insufficient response to first-line ITP treatment.[5]

The primary endpoint of the study was the cumulative number of months in which patients achieved a platelet response: 61% of patients sustained platelet counts ≥ 50 x 10^9/L for ≥ 11 months (n = 46/75).[5]

Treatment-free remission was a secondary endpoint defined as maintaining every platelet count at ≥ 50 x 10^9/L for at least 6 months in the absence of any ITP treatment, and occurred in 32% (n = 24/75) of patients.[5]

Platelet response was defined as a platelet count ≥ 50 x 10^9/L. In this study, 5.56%, 47.22%, and 61.11% of patients responded by weeks 1, 2, and 3, respectively.[3,6]

SAFETY DATA

Based on an open-label, single arm, extension study of 291 adults with Chronic ITP who had at least one dose of Nplate®. Subjects could enter any time during the 277-week period.

Mean treatment duration was 110 weeks.[7]

Study results: AEs did not increase in frequency or type with longer Nplate® drug exposure.[7]

AE = adverse events; CI = confidence interval.

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Considerations for Using Your EMR to Search for ITP Patients

When using search capabilities within your EMR system, the ICD-10 code for ITP and the list of HCPCS codes below for steroid and IVIG therapies can help identify patients that may be appropriate for Nplate®

PATIENT TYPES	SEARCH CRITERIA TO CONSIDER	HELPFUL SEARCH TIPS
Patients with ITP who are treated with steroids, steroid rechallengers, or steroid switchers	• ICD-10-CM code for ITP (D69.3) **AND** • **One OR two** of the following HCPCS codes for steroid therapy, » J1100 for Dexamethasone Sodium Phosphate or, » J1030 for Methylprednisolone Acetate or, » J2930 for Methylprednisolone Sodium Succinate or, » J1040 for Methylprednisolone Acetate or, » J2920 for Methylprednisolone Sodium Succinate or, » J8540 for Dexamethasone Oral or, » J1020 for Methylprednisolone Acetate or, » J1094 for Dexamethasone Acetate or, » 82627 for Dehydroepiandrosterone–Sulfate	• ICD-10-CM codes may be used to identify patients with ITP: » D69.3 for ITP • Use **two different** J-Codes to identify patients that are steroid switchers • For steroid rechallengers, search one J-code for multiple instances
Patients with ITP who are treated with IVIG	• ICD-10-CM code for ITP (D69.3) **AND** • **One** of the following HCPCS codes for IVIG therapy » J1569 for Immune Globulin » J1568 for Immune Globulin » J1561 for Immune Globulin » J1459 for Immune Globulin » J3590 for Sutimlimab-Jome » J1559 for Immune Globulin » J1566 for Immune Globulin » J1575 for Immune Globulin/Hyaluronidase » J1557 for Immune Globulin » J1572 for Immune Globulin, (Flebogamma/Flebogamma Dif)	• ICD-10-CM codes may be used to identify patients with ITP: » D69.3 for ITP

HCPCS = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification; IVIG = Intravenous immunoglobulin.

Amgen is committed to protecting patient privacy, and the Amgen field force is not permitted to access any protected health information. Therefore, any report with patient-specific data must not be handled by, shared with, or discussed by a healthcare professional with any agent of Amgen for any reason.

Important Safety Information

- Thrombotic/thromboembolic complications may result from increases in platelet counts with Nplate® use. Portal vein thrombosis has been reported in patients with chronic liver disease receiving Nplate®.
- To minimize the risk for thrombotic/thromboembolic complications, do not use Nplate® in an attempt to normalize platelet counts. Follow the dose adjustment guidelines to achieve and maintain a platelet count of ≥ 50 x 10^9/L.

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As you work to implement an ITP EMR initiative, consider the following for ITP assessment:

1. Who in your practice may find value in taking on and adopting an ITP EMR initiative?
2. Who is the appropriate individual(s) that can successfully run the list in your EMR system?
3. Once run and potential ITP patients have been identified, who are the appropriate individuals to share the list with?
4. Now that you've identified your patients, what might patient outreach look like for your clinic? As you are thinking about patient outreach, here might be some things to consider:
    - **a.** Mailings can be created to reach patients with a customized resource (letter, folder, brochure, etc)
    - **b.** Patients with an email address on file can receive an electronic message
    - **c.** Patients enrolled in patient portals can receive patient portal messages
    - **d.** Patients with phone numbers on file can receive a phone message
    - **e.** Selected patients can be managed by a care coordinator or engaged by a nurse or other staff member
    - **f.** A reminder, an alert, or an order can be created in the EMR for selected patients

To learn more about Nplate® or if you have questions, please reach out to your Nplate® representative for patient education materials, patient support services, or production information.

Please see additional Important Safety Information on page 7.

✓ *After the clinical decision has been made, consider the broad coverage and $0 potential OOP costs of Nplate®[4,12]*

NPLATE® HAS A HIGHER % OF PATIENT CLAIMS WITH $0 OOP COSTS VS ORAL AGENTS* AND BROAD COVERAGE[4,12]

74% of Nplate® claims have $0 OOP costs for the patient vs **54%** for oral agents[4,*]

86% broad overage[12]

*Based on an analysis from 2020 to 2021 for Commercial and Medicare patient claims combined. Oral OOP percent is a weighted average claim for eltrombopag, avatrombopag, and fostamatinib disodium hexahydrate.

OOP = out-of-pocket.

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Loss of Response to Nplate®

- Hyporesponsiveness or failure to maintain a platelet response with Nplate® should prompt a search for causative factors, including neutralizing antibodies to Nplate®.
- To detect antibody formation, submit blood samples to Amgen (1-800-772-6436). Amgen will assay these samples for antibodies to Nplate® and thrombopoietin (TPO).
- Discontinue Nplate® if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the highest weekly dose of 10 mcg/kg.

Adverse Reactions

Adult ITP

- In the placebo-controlled trials of adult ITP patients, headache was the most commonly reported adverse drug reaction, occurring in 35% of patients receiving Nplate® and 32% of patients receiving placebo. Adverse drug reactions in adults with a ≥ 5% higher patient incidence in Nplate® versus placebo were Arthralgia (26%, 20%), Dizziness (17%, 0%), Insomnia (16%, 7%), Myalgia (14%, 2%), Pain in Extremity (13%, 5%), Abdominal Pain (11%, 0%), Shoulder Pain (8%, 0%), Dyspepsia (7%, 0%), and Paresthesia (6%, 0%).
- The safety profile of Nplate® was similar across patients, regardless of ITP duration. The following adverse reactions (at least 5% incidence and at least 5% more frequent with Nplate® compared with placebo or standard of care) occurred in Nplate® patients with ITP duration up to 12 months: bronchitis, sinusitis, vomiting, arthralgia, myalgia, headache, dizziness, diarrhea, upper respiratory tract infection, cough, nausea and oropharyngeal pain. The adverse reaction of thrombocytosis occurred with an incidence of 2% in adults with ITP duration up to 12 months.

Pediatric ITP

- The most common adverse reactions experienced by ≥ 5% of patients receiving Nplate® with ≥ 5% higher incidence in the Nplate® arm across the two placebo-controlled trials were contusion (41%), upper respiratory tract infection (31%), oropharyngeal pain (25%), pyrexia (24%), diarrhea (20%), rash (15%), and upper abdominal pain (14%).
- In pediatric patients of age ≥ 1 year receiving Nplate® for ITP, adverse reactions with an incidence of ≥ 25% in the two randomized trials were: contusion (41%), upper respiratory tract infection (31%), and oropharyngeal pain (25%).
- In a long term, single arm, open label pediatric safety study, headache occurred in 78/203 patients (38%); the incidence rates of other adverse reactions were similar to those reported in the placebo-controlled studies.

Nplate® administration may increase the risk for development or progression of reticulin fiber formation within the bone marrow. This formation may improve upon discontinuation of Nplate®. In a clinical trial, one patient with ITP and hemolytic anemia developed marrow fibrosis with collagen during Nplate® therapy.

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Please see full Prescribing Information and Medication Guide.

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