Pharmacy Drug Policy

SUBJECT: Immune Thrombocytopenia (ITP) Drug Policy
POLICY NUMBER: PHARMACY-137
EFFECTIVE DATE: 12/1/2025
LAST REVIEW DATE: 10/01/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Immune thrombocytopenia (ITP) is a rare autoimmune bleeding disorder defined as thrombocytopenia (platelet count < 100,000 x 10^9/L) without anemia or leukocytopenia and without another apparent cause of thrombocytopenia. Patients may appear asymptomatic, in which thrombocytopenia is detected through CBC, or symptomatic with signs of bleeding, such as petechiae, purpura, epistaxis, and rarely, major or clinical hemorrhages. ITP can be further categorized based on duration: newly diagnosed (within 3 months), persistent (3-12 months), and chronic ITP (> 12 months).

ITP can affect both children and adults. First line treatment is corticosteroids. For adults with persistent ITP, who are dependent on or unresponsive to corticosteroids, it is recommended to initiate thrombopoietin (TPO) receptor agonists: Nplate (romiplostim), Promacta (eltrombopag olamine), Alvaiz (eltrombopag choline), and Doptelet (avatrombopag). For adults with chronic ITP, who are dependent on or unresponsive to corticosteroids, recommended treatment options include TPO receptor agonists or splenectomy.

For children with persistent ITP, who are unresponsive to corticosteroids or intravenous immune globulin (IVIG), recommended treatment options include TPO receptor agonists and splenectomy.

Intravenous immune globulin (IVIG) is a potent immunomodulating agent that consists of concentrated human immunoglobulin, prepared from pooled plasma collected from human donors. IVIG is indicated for providing antibodies to patients who are susceptible to diseases where there is no immunization available and to treat certain immunodeficiencies. IVIG is recommended for patients who require a rapid increase in platelet count in those unresponsive to corticosteroid. In ITP, IVIG increases platelet count by blocking the Fc receptors on macrophages in the spleen and liver, preventing the uptake of autoantibody-coated platelets.

This policy contains coverage requirements for the following drugs: Nplate (romiplostim), Promacta (eltrombopag olamine), Alvaiz (eltrombopag choline), Doptelet (avatrombopag), Mulpleta (lusutrombopag), Tavalisse (fostamatinib), and Wayrilz (rilzabrutinib). IVIG is addressed in a separate policy (see Intravenous Immune Globulin (IVIG) & Sub-Cutaneous Immune Globulin (SCIG) Therapy Pharmacy-26).

TPO receptor agonists for the treatment of ITP include **Nplate (romiplostim)**, **Promacta (eltrombopag olamine)**, **Alvaiz (eltrombopag choline)**, and **Doptelet (avatrombopag)** which are all indicated after insufficient response to corticosteroids, immunoglobulin, or splenectomy. Nplate is also indicated for increasing the survival in adults and pediatric patients (including term neonates) with hematopoietic syndrome of acute radiation syndrome. Promacta and Alvaiz are also indicated for thrombocytopenia due to chronic hepatitis C and severe aplastic anemia. **Mulpleta (lusutrombopag)** is a TPO receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. Doptelet is also indicated for adult patients with chronic liver disease who are scheduled to undergo a procedure.

Tavalisse (fostamatinib) is a spleen tyrosine kinase (SYK) inhibitor that is only indicated for the treatment of chronic ITP after insufficient response to previous therapies.

Wayrilz (rilzabrutinib) is a Bruton's tyrosine kinase (BTK) inhibitor that is only indicated for the treatment of adults with persistent or chronic ITP who have had insufficient response to previous treatments.

POLICY:

Alvaiz (eltrombopag tablets) - Rx

A. Immune Thrombocytopenia (ITP)

1. Must have a diagnosis of Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP) **AND**
2. Must be prescribed by or in consultation with a hematologist **AND**
3. Member has one of the following within the previous 30 days **(a or b):**
    a. Platelet count < 30 x 10^9/L **OR**
    b. Platelet count < 50 x 10^9/L with significant bleeding symptoms
4. Must have had an insufficient response (defined as a platelet count of < 30 x 10^9/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG)
5. Initial approval will be provided for 6 months.
6. Recertification for 12 months at a time will require the following:
    a. First recertification (after initial approval) will require documentation of the following:
        i. Positive response to treatment as documented by one of the following **(A or B):**
            A. Platelet count ≥ 50 x 10^9/L **OR**
            B. Platelet count ≥ 30 x 10^9/L without evidence of bleeding
    b. Subsequent recertifications (after first recertification) will require documentation of the following:
        i. Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 10^9/L **OR** platelet count ≥ 30 x 10^9/L without evidence of bleeding) **AND**
        ii. Provider attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts

B. Chronic Hepatitis C-associated thrombocytopenia

1. Must have a diagnosis of chronic hepatitis C-associated thrombocytopenia **AND**
2. Must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology or hematology **AND**
3. Must have a platelet level < 75 x 10^9/L within previous 30 days **AND**
4. Eltrombopag is being prescribed to increase platelet count sufficiently to allow the initiation and/or maintenance of interferon-based therapy
5. Initial approval will be provided for 6 months.
6. Recertification for 6 months at a time will require documentation of the following:

a. Documentation of platelet count ≥ 90 x 10^9/L **OR** platelet count has increased sufficiently to initiate or maintain interferon therapy **AND**
b. Patient is continuing to receive interferon-based therapy. Eltrombopag should be discontinued when interferon therapy is discontinued.

C. <u>Severe Aplastic Anemia (SAA)</u>

1. Must have a diagnosis of severe aplastic anemia **AND**
2. Must be prescribed by or in consultation with a hematologist **AND**
3. Diagnosis of severe aplastic anemia must be documented by **(a <u>and</u> b):**
   a. One of the following (i or ii):
      i. A marrow biopsy showing <25 percent of normal cellularity **OR**
      ii. A marrow biopsy showing <50 percent normally cellularity in which <30 percent of the cells are hematopoietic
   b. At least two of the following are present at the time of diagnosis (documentation required):
      i. Absolute reticulocyte count <60,000/microL
      ii. Absolute neutrophil count (ANC) <500/microL
      iii. Platelet count <20,000/microL **AND**
4. Baseline hemoglobin and documentation of RBC transfusion status must be submitted **AND**
5. Must have had an insufficient response to immunosuppressive therapy
6. Alvaiz should not be used to normalize platelet counts.
7. Initial approval will be provided for 6 months.
8. Recertification for 12 months at a time requires the following:
   a. First recertification (after initial approval) will require documentation of positive hematologic response as evidenced by any of the following:
      i. Platelet count ≥ 50 x 10^9/L
      ii. Platelet count increases to 20 x 10^9/L above baseline
      iii. Stable platelet counts with transfusion independence for a minimum of 8 weeks
      iv. Hemoglobin increase by greater than 1.5 g/dL
      v. Reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks
      vi. An ANC increase of 100 %
      vii. An ANC increase greater than 0.5 x 10^9/L
   b. Subsequent recertifications (after first recertification) will require documentation of maintenance of positive hematologic response.

D. <u>Quantity limit for all diagnoses</u>

1. Quantity limit is 30 tablets per 30 days
   a. Approved requests for FDA approved indications that require 108 mg dosing will be approved with a quantity authorization to allow two 54 mg tablets per day
   b. Requests above the quantity limit will be reviewed for medical necessity **AND** reviewed to require the most cost-efficient dose available for the quantity requested

Doptelet and Doptelet Sprinkle (avatrombopag) - Rx

1. Member must have a diagnosis of chronic liver disease and be scheduled to undergo a procedure with date of the procedure provided **AND**
   a. Must be 18 years of age or older
   b. Must also have a diagnosis of thrombocytopenia defined as a platelet count of less than 50 x 10^9/L within 30 days prior to procedure
   c. Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or hematologist
   d. Must be prescribed for the appropriate dose based on platelet count prior to the scheduled procedure:
      i. For patients with a platelet count between 40 and 50 x 10^9/L, Doptelet can be approved at a dose of 40 mg (2 tablets) per day for 5 days

ii. For patients with a platelet count less than 40 x 10^9/L, Doptelet can be approved at a dose of 60 mg (3 tablets) per day for 5 days
e. Patients should begin dosing 10-13 days prior to their procedure and undergo their procedure within 5-8 days after their last dose
f. Approval will be for 14 days
g. Reauthorizations for future peri-procedural treatment must meet initial authorization criteria. Documentation of prior response to therapy is required. Patients will not be eligible for retreatment if considered a non-responder to the initial course of therapy (non-responder defined as requiring a platelet transfusion following avatrombopag therapy) **OR**

2. Member must have a diagnosis of Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP) **AND**
   a. An adult patient with thrombocytopenia lasting more than 12 months (**chronic** ITP) **OR**
   b. Pediatric patient 1 year of age or older with thrombocytopenia lasting 6 months or greater (**persistent or chronic** ITP) **AND**
   c. Must be prescribed by or in consultation with a hematologist **AND**
   d. Member has one of the following within the previous 30 days (**i or ii**):
      i. Platelet count < 30 x 10^9/L **OR**
      ii. Platelet count < 50 x 10^9/L with significant bleeding symptoms
   e. Must have had an insufficient response (defined as a platelet count of <30 x 10^9/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids **OR** immunoglobulins (IVIG)
   f. Initial approval will be provided for 6 months.
   g. Recertification for 12 months at a time will require the following:
      i. First recertification (after initial approval) will require documentation of the following:
         1. Positive clinical response to treatment as documented by one of the following:
            A. Platelet count ≥ 50 x 10^9/L **OR**
            B. Platelet count ≥ 30 x 10^9/L without evidence of bleeding
         2. Subsequent recertifications (after first recertification) will require documentation of the following:
            A. Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 10^9/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) **AND**
            B. Provider attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts
3. Doptelet should not be used to normalize platelet counts
4. Quantity limits:
   a. **Tablets**: 15 tablets per 30 days.
      i. For adult and pediatric patients with a diagnosis of ITP, a quantity of 60 **tablets** per 30 days will be allowed
      ii. **Sprinkle capsules** are only approved for children aged 1 to less than 6 years old with a quantity limit of 60 capsules per 30-day supply for a maximum of 20 mg/day.

Mulpleta (lusutrombopag) - Rx

1. Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or hematologist
2. Member must be at least 18 years old
3. Must have a diagnosis of chronic liver disease and be scheduled to undergo a procedure with date of the procedure provided
4. Must also have a diagnosis of thrombocytopenia defined as a platelet count of less than 50 x 10^9/L within 30 days prior to procedure
5. Patients should begin dosing 8-14 days prior to their procedure and undergo their procedure within 2-8 days after their last dose
6. Approval will be for 14 days

7. Reauthorizations for future peri-procedural treatment must meet initial authorization criteria. Documentation of prior response to therapy is required. Patients will not be eligible for retreatment if considered a non-responder to the initial course of therapy (non-responder defined as requiring a platelet transfusion following lusutrombopag therapy).
8. Quantity limit is 7 tablets per 30 days.

Nplate (romiplostim) - Medical

1. The medication must be used for one of the following (a or b):
   a. The medication must be used to treat **hematopoietic subsyndrome of acute radiation syndrome** to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation
      i. The medication must be given as a single dose of 10 mcg/kg
      ii. Approval will be provided for 1 month and may not be renewed **OR**
   b. The patient must have a diagnosis of **Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura** (ITP) **AND**
      i. The medication must be prescribed by or in consultation with a hematologist **AND**
      ii. Member has one of the following within the previous 30 days (a **OR** b):
         a) Platelet count < 30 x 10^9/L **OR**
         b) Platelet count < 50 x 10^9/L with significant bleeding symptoms **AND**
      iii. Must have had an insufficient response (defined as a platelet count of <30 x 10^9/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids **OR** immunoglobulins (IVIG)
      iv. Initial approval will be provided for 6 months.
      v. Recertification for 12 months at a time will require the following:
         a) First recertification (after initial approval) will require documentation of the following:
            1. Positive response to treatment as documented by one of the following (A **OR** B)
               A. Platelet count ≥ 50 x 10^9/L **OR**
               B. Platelet count ≥ 30 x 10^9/L without evidence of bleeding
         b) Subsequent recertifications (after first recertification) will require documentation of the following:
            1. Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 10^9/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) **AND**
            2. Provider attests continuation of treatment is required to maintain platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts.
      vi. Nplate may be used in combination with other medical ITP therapies such as, corticosteroids, danazol, azathioprine, intravenous immunoglobulin (IVIG), and anti-D immunoglobulin.
      vii. The approved dose is 1 mcg/kg once weekly (subcutaneously). The dose may be adjusted in increments of 1 mcg/kg to achieve platelet counts of ≥ 50 x 10^9/L. Max weekly dose of 10 mcg/kg.

HCPCS: J2802

Promacta and eltrombopag tablet and powder for suspension - Rx

A. **Immune Thrombocyopenia (ITP)**
1. Member must have a diagnosis of Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP) **AND**
2. Must be prescribed by or in consultation with a hematologist **AND**
3. Member has one of the following within previous 30 days **(a or b):**
   a. Platelet count < 30 x 10^9/L **OR**
   b. Platelet count < 50 x 10^9/L with significant bleeding

4. Must have had an insufficient response (defined as a platelet count of less than 30 x 10^9/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG)
5. Initial approval will be for 6 months.
6. Recertification for 12 months at a time will require the following:
   a. First recertification (after initial approval) will require documentation of the following:
      i. Positive response to treatment as documented by one of the following:
         A. Platelet count ≥ 50 x 10^9/L **OR**
         B. Platelet count ≥ 30 x 10^9/L without evidence of bleeding
   b. Subsequent recertifications (after first recertification) will require documentation of the following:
      i. Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 10^9/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) **AND**
      ii. Provider attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts

B. **Chronic Hepatitis C-associated thrombocytopenia**
1. Must have a diagnosis of chronic hepatitis C-associated thrombocytopenia **AND**
2. Must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or hematology **AND**
3. Must have a platelet level < 75 x 10^9/L within previous 30 days **AND**
4. Eltrombopag is being prescribed to increase platelet count sufficiently to allow the initiation (or maintenance) of interferon-based therapy
5. Initial approval will be provided for 6 months.
6. Recertification for 6 months at a time will require documentation of the following:
   a. Documentation of platelet count ≥ 90 x 10^9/L **OR** platelet count has increased sufficiently to initiate or maintain interferon therapy **AND**
   b. Patient is continuing to receive interferon-based therapy. Eltrombopag should be discontinued when interferon therapy is discontinued.

C. **Severe Aplastic Anemia (SAA)**
1. Must have a diagnosis of severe aplastic anemia **AND**
2. Must be prescribed by or in consultation with a hematologist **AND**
3. Diagnosis of severe aplastic anemia must be documented by (**a and b**):
   a. One of the following **(i or ii):**
      i. A marrow biopsy showing <25 percent of normal cellularity **OR**
      ii. A marrow biopsy showing <50 percent normally cellularity in which <30 percent of the cells are hematopoietic
   b. At least two of the following are present at the time of diagnosis (documentation required):
      i. Absolute reticulocyte count <60,000/microL
      ii. Absolute neutrophil count (ANC) <500/microL
      iii. Platelet count <20,000/microL
4. Baseline hemoglobin and documentation of RBC transfusion status must be submitted **AND**
5. Eltrombopag will be prescribed for one of the following **(a or b):**
      i. As first-line therapy in combination with standard immunosuppressive therapy **OR**
      ii. For refractory or second-line treatment as a single agent following insufficient response to immunosuppressive therapy
6. Eltrombopag should not be used to normalize platelet counts
7. Initial approval will be provided for 6 months.
8. Recertification for 12 months at a time requires the following:
   a. First recertification (after initial approval) will require documentation of positive hematologic response as evidenced by any of the following:
      i. Platelet count ≥ 50 x 10^9/L
      ii. Platelet count increases to 20 x 10^9/L above baseline **OR**

iii. Stable platelet counts with transfusion independence for a minimum of 8 weeks **OR**
iv. Hemoglobin increase by greater than 1.5 g/dL **OR**
v. Reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks **OR**
vi. An ANC increase of 100 % **OR**
vii. An ANC increase greater than 0.5 x 10^9/L

b. Subsequent recertifications (after first recertification) will require documentation of maintenance of positive hematologic response

D. **Quantity limit for all diagnoses**

1. Quantity limit is 30 tablets or packets per 30 days
   a. Approved requests for FDA approved indications that require 150 mg dosing will be approved with a quantity authorization to allow two 75 mg tablets per day
   b. Requests above the quantity limit will be reviewed for medical necessity **AND** reviewed to require the most cost-efficient dose available for the quantity requested

Tavalisse (fostamatinib tablet) - Rx

1. Must be prescribed by or in consultation with a hematologist
2. Member must be at least 18 years old
3. Member must have a diagnosis of **chronic** Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP) [thrombocytopenia lasting more than 12 months] **AND**
4. Member has one of the following within the previous 30 days (**a or b**):
   a. Platelet count <30 x 10^9/L **OR**
   b. Platelet count < 50 x 10^9/L with significant bleeding symptoms
5. Must have had an insufficient response (defined as a platelet count of less than 30 x 10^9/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids **OR** immunoglobulins (IVIG)
6. Tavalisse should not be used to normalize platelet counts
7. Initial approval will be provided for 6 months.
8. Recertification for 12 months at a time requires the following:
   a. First recertification (after initial approval) will require documentation of positive response as evidenced by one of the following (i or ii)
      i. Platelet count ≥ 50 x 10^9/L **OR**
      ii. Platelet count ≥ 30 x 10^9/L without evidence of bleeding
   b. Subsequent recertifications (after first recertification) will require documentation of the following:
      i. Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 10^9/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) **AND**
      ii. Prescriber attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts.
9. The starting dose of Tavalisse is 100 mg twice daily. After 4 weeks, the dose can be increased to 150 mg twice daily to achieve a platelet count of at least 50 x 10^9/L to reduce the risk of bleeding.
10. Quantity limit of 60 per 30 days

Wayrilz (rilzabrutinib) - Rx

1. Must be prescribed by or in consultation with a hematologist **AND**
2. Must be 18 years of age or older **AND**
3. Member must have a diagnosis of **persistent or chronic** Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP) **AND**
4. Member has one of the following within the previous 30 days (**a or b**):
   a. Platelet count <30 x 10^9/L **OR**
   b. Platelet count < 50 x 10^9/L with significant bleeding symptoms
5. Must have had an insufficient response (defined as a platelet count of less than 30 x 10^9/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG) **AND**
6. Must have had serious side effects or drug failure with eltrombopag

7. Initial approval will be provided for 6 months.
8. Recertification for 12 months at a time will require the following:
   a. First recertification (after initial approval) will require documentation of positive response as evidenced by one of the following (**i or ii**):
      i. Platelet count ≥ 50 x 109/L **OR**
      ii. Platelet count ≥ 30 x 109/L without evidence of bleeding
   b. Subsequent recertifications (after first recertification) will require documentation of the following:
      i. Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 10^9/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) **AND**
      ii. Provider attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding
9. Recommended dosage of Wayrilz is 400 mg twice daily.
10. Quantity limit is 60 tablets per 30-day supply.

POLICY GUIDELINES:

1. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
   a. Coverage criteria may be dependent on the contract renewal date.
   b. Coverage of drugs listed in this policy are contract dependent.
   c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit.
   d. Not all contracts/benefits cover all medical infusible drugs.
2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in the requirement to trial more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. This policy is applicable to drugs that are included on a specific drug formulary (Pharmacy benefit only). If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
5. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label

Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
6. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
7. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
8. Approval timeframes may be extended to align authorization periods for drugs administered as part of a multidrug regimen, including when regimen components are administered across different benefits. This provision does not apply when the approval timeframe reflects a drug-specific limitation on duration of therapy.
9. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
10. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
11. The requested site of care may impact approval timeframe and subject to review.
12. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
13. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
14. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key:
Experimental/Investigational = (E/I),
Not medically necessary/ appropriate = (NMN).
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HCPCS:

J2802 Nplate (romiplostim)

UPDATES:

Date	Revision
10/01/2026	Revised
09/15/2026	Revised
08/13/2026	P&T Committee Review & Approval
06/01/2026	Revised
02/12/2026	P&T Committee Review & Approval
01/30/2026	Revised
01/01/2026	Effective & Posted
11/13/2025	P&T Committee Review & Approval

REFERENCES:

1. Nplate Prescribing Information. Amgen Inc.; Revised 03/2025.
2. Promacta Prescribing Information. Novartis Pharmaceuticals Corporation; Revised 06/2025.
3. Alvaiz Prescribing Information. Teva Pharmaceuticals, Inc.; Revised 07/2024.
4. Doptelet Prescribing Information. AkaRx, Inc.; Revised 07/2025.
5. Tavalisse Prescribing Information. Rigel Pharmaceuticals, Inc.; Revised 11/2020.
6. Wayrilz Prescribing Information. Sanofi; Issued 08/2025.
7. Neunert C, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv 2019; 3 (23):3829-3866.
8. DeZern A E., Churpek J E. Approach to the diagnosis of aplastic anemia. Blood Adv 2021; 5 (12): 2660–2671.
9. Mulpleta Prescribing Information. Eddingpharm (U.S.) Inc.; Revised 8/2025