MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
01/18/2013	02/18/2017	03/09/2016

Policy Name	Policy Number
Immune (Idiopathic) Thrombocytopenia Purpura (ITP)	SRx-0018

Policy Type		
☒ Medical	☐ Administrative	☐ Payment

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A. SUBJECT

Immune (Idiopathic) Thrombocytopenia Purpura (ITP)

- Eltrombopag (Promacta)
- Romiplostim (NPlate)

B. BACKGROUND

The CareSource medication policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The medication policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of thrombopoiesis stimulating agents such as Promacta, NPlate program is to encourage appropriate selection of therapy for patients according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A

D. POLICY

CareSource will approve the use of Eltrombopag (Promacta) and romiplostim (NPlate), and consider their use as medically necessary when the following criteria have been met for:

- Thrombocytopenia due to chronic immune (idiopathic) thrombocytopenic purpura (ITP)
- Thrombocytopenia associated with Hepatitis C infection to allow the initiation and maintenance of interferon-based therapy; (Promacta ONLY)

- Severe aplastic anemia in patients that have had insufficient response to immunosuppressive therapy (Promacta ONLY)

I. **Romiplostim (NPlate)** is indicated for the treatment of thrombocytopenia in adults with chronic immune (idiopathic) thrombocytopenic purpura (ITP) whose degree of thrombocytopenia and clinical condition increases the risk for bleeding, and have not responded to treatment with corticosteroids, immunoglobulins or splenectomy.
   A. **Prior Authorization Criteria ITP:**
      1. Documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) made by a hematologist
      2. Platelet count less than 20,000/mm^3 or platelet count less than 30,000/mm^3 accompanied by symptoms of bleeding
      3. Patient has documented insufficient response to corticosteroids, immunoglobulins or splenectomy or has **1 (one)** of the following exceptions:
         3.1 Unable to tolerate or has a medical contraindication to corticosteroids or immunoglobulins
         3.2 Have a contraindication to splenectomy
      4. Patient is 18 years or older

II. **Eltombopag (Promacta)** is indicated for the treatment when criteria are met for **1 (one)** of the following:
   A. **Thrombocytopenia in patients with Chronic Immune (Idiopathic) Thrombocytopenic Purpura (ITP)**
      1. Documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) made by a hematologist
      2. Patient is greater than **1 (one)** year of age.
      3. Platelet count less than 20,000/mm^3 or Platelet count less than 30,000/mm^3 accompanied by symptoms of bleeding
      4. Patient has documented insufficient response to corticosteroids, immunoglobulins or splenectomy or **1 (one)** of the following exceptions:
         4.1 Unable to tolerate or has a medical contraindication to corticosteroids or immunoglobulins
         4.2 Have a contraindication to splenectomy
      5. Patient has documented baseline serum ALT, AST, and bilirubin levels from provider
   B. **Thrombocytopenia in Patients with Chronic Hepatitis C**
      1. Documented diagnosis of Thrombocytopenia made by, or in consultation with a hematologist
      2. Documented diagnosis of chronic hepatitis C
      3. Patient is 18 years of age or older
      4. Patient unable to initiate or maintain interferon (IFN) therapy due to platelet count less than 75,000/mm^3, and a Child-Pugh level A (score 5-6)
      5. Patient has documented baseline serum ALT, AST, and bilirubin levels from provider
   C. **Severe Refractory Aplastic Anemia**
      1. Documented diagnosis of Severe Refractory Aplastic Anemia made by, or in consultation with a hematologist
      2. Documentation of a baseline severe cytopenia (severe aplastic anemia), with at least **2 (two)** of the following three criteria:
         2.1 Reticulocyte count less than 20,000/mm^3
         2.2 Platelet count less than 20,000/mm^3
         2.3 Absolute neutrophil count (ANC) less than 500/mm^3
      3. Baseline platelet count of less than 30,000/mm^3
      4. Patient is 18 years of age or older

5. Documented failure of **4 (four) months or more** of immunosuppressive therapy
6. Patient has documented baseline serum ALT, AST, and bilirubin levels from provider

NOTE: These agents are not indicated and should not be used in an attempt to normalize platelet counts.

NOTE: Aspirin is contraindicated for members diagnosed with ITP. If a member has chronic hepatitis C and takes eltrombopag with medications for hepatitis C, called interferon (Peginterferon, Pegintron, others) and ribavirin, there is an increased risk they will develop serious liver damage.

NOTE: Pregnant women require special consideration for delivery:

a. If the platelet count is greater than 50×10^9/L ($>50 \times 10^3$/µL), the risk of serious hemorrhage is low, but beginning oral prednisone a week before delivery is a reasonable precaution.
b. If the platelet count is less than 50×10^9/L (50×10^3/µL) before delivery, treatment with oral prednisone and IVIG is recommended. The safety of thrombopoietin mimetics in pregnancy and breastfeeding has not been established.
c. The standard dose of IV RhIG for ITP contains approximately 10-fold the concentration of anti-D that is in the standard antepartum dose of intramuscular RhIG for Rh immunoprophylaxis. Although the effects on an Rh(D)-positive fetus are unknown, avoiding the use of IV RhIG in this situation until safety data are available is advisable.
d. Rarely, splenectomy may be required to manage acute hemorrhage

NOTE: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes. **ALL** other uses of Promacta, NPlate are considered experimental/investigational and therefore, will follow CareSource's Off-Label policy.

Refer to the product package insert for dosing, administration and safety guidelines.

CONDITIONS OF COVERAGE

HCPCS J8999 Promacta
J2796 NPlate

CPT

Step Therapy

Under some plans, including plans that use an open or closed formulary, some of the medications in this policy may be subject to step-therapy. Refer to the CareSource formulary tool or PDL for further guidance.

PLACE OF SERVICE

Promacta: Preferred place of service: *Home*
Nplate: Preferred place of service: *Office, Outpatient*

NOTE: CareSource supports administering injectable medications in various setting, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical

condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

AUTHORIZATION PERIOD
Coverage may be approved for up to 12 weeks and should be discontinued if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after weeks of therapy at the maximum dose.

Reauthorization requirements are as follows:
For ITP Continued authorization or re-authorization (after the initial 12 week period) shall be reviewed at least every **3 (three)** months to confirm that current medical necessity criteria are met and that the medication is effective:

1. The patient's recent (within the last 30 days) platelet count is either: Equal to or greater than 30,000/mm^3 but not more than 150,000/mm^3 OR Less than 30,000/mm^3 but platelet counts have increased from baseline accompanied with a resolution of previous bleeding

For Thrombocytopenia in Patients with Chronic Hepatitis C continued authorization or re-authorization (after the initial 4 week period) shall be reviewed at least every **3 (three)** months to confirm that current medical necessity criteria are met and that the medication is effective:

1. The patient remains on interferon/ribavirin therapy and platelet count is less than 400,000/mm^3

For Severe Aplastic anemia continued authorization or re-authorization (after the initial **4 (four)** week period) shall be reviewed at least every **3 (three)** months to confirm that current medical necessity criteria are met and that the medication is effective: The patient has a documented hematologic response, based on blood counts AND/OR a reduced need for blood products and **1 (one)** of the following:

1. Platelet count equal to or greater than 30,000/mm^3 but not more than 150,000/mm^3
2. Platelet count less than 30,000/mm^3 but 20,000/mm^3 more than baseline.
3. Reduction in RBC transfusions (of at least 4 units) or hemoglobin increase of at least 1.5 g/dL from baseline.
4. Absolute neutrophil count (ANC) increase of 100% from baseline or an ANC increase greater than 500/mm^3.

Appendix A – Child-Pugh Classification of Severity of Liver Disease

Child-Pugh Classification	**Points**		
A: well-compensated disease	**5 to 6**		
B: significant functional compromise	**7 to 9**		
C: decompensated disease	**10 to 15**		
	Points Assigned		
Parameter	1	2	3
Ascites	**Absent**	**Slight**	**Moderate**
Bilirubin (mg/dl)	<2	2 to 3	>3
Albumin (g/dl)	>3.5	2.8 to 3.5	<2.8
Protrombin Time			

Seconds over control	1 to 3	4 to 6	>6
INR	<1.7	1.8 to 2.3	>2.3
Encephalopathy	None	Grade 1 to 2	Grade 3 to 4

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued: 01/18/2013
Date Reviewed: 01/18/2013, 01/18/2014, 09/08/2015, 03/09/2016
Date Revised: 01/18/2014 – Changed platelet criteria, added Hep C indications, added values for reauth period, change auth period
02/18/2015 – Revision to current policy to include aspirin contraindication, pregnancy special considerations, and updated references.
9/08/2015 – Added age change for ITP and Promacta, added indication for severe aplastic anemia
03/09/2016 – Criteria added to Promacta

G. REFERENCES

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The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 11/19/2012