MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
1/2013	2/2016	2/2015
Policy Name		**Policy Number**
Immune (Idiopathic) Thrombocytopenia Purpura (ITP)		**SRx-0018**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

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

D. POLICY

CareSource will approved 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)**

Eltrombopag (Promacta) and romiplostim (NPlate) are indicated for the treatment of thrombocytopenia in adults (18 years and older) 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.

Prior Authorization Criteria ITP:

- Documented diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) made by, or in consultation with a hematologist
- Platelet count less than 20,000/mm3
  OR
- Platelet count less than 30,000/mm3 accompanied by symptoms of bleeding
  AND
- Insufficient response to corticosteroids, immunoglobulins or splenectomy
  OR
- Unable to tolerate or has a medical contraindication to corticosteroids or immunoglobulins
  OR
- Have a contraindication to splenectomy

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

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

Continued authorization or re-authorization (after the initial 4 week period) shall be reviewed at least every three months to confirm that current medical necessity criteria are met and that the medication is effective:

- The patient's recent (within the last 30 days) platelet count is either:
  - Equal to or greater than 30,000/mm3 but not more than 150,000/mm3
    OR
  - Less than 30,000/mm3 but platelet counts have increased from baseline accompanied with a resolution of previous bleeding

Prior Authorization Criteria Thrombocytopenia associated with Hepatitis C:

- Documented diagnosis of Hepatitis C with thrombocytopenia and is unable to initiate interferon therapy with **ALL** the following criteria:
  - Platelet count less than 75,000/mm3
  - Child-Pugh level A (score 5-6) (See Appendix A)
    OR
- Documented diagnosis of Hepatitis C with thrombocytopenia and is unable to maintain interferon therapy with **ALL** of the following criteria:
  - Platelet count less than 75,000/mm3
  - Child-Push level A (score 5-6) (See Appendix A)
  - Reduced interferon dose for platelet count < 30,000/mm3 or discontinued interferon therapy if <20,000mm3

Pregnant women require special consideration for delivery:

- If the platelet count is greater than 50 × 10^9/L (>50 × 10^3/µL), the risk of serious hemorrhage is low, but beginning oral prednisone a week before delivery is a reasonable precaution.
- 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.
- 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.
- Rarely, splenectomy may be required to manage acute hemorrhage

Continued authorization or re-authorization (after the initial 4 week period) shall be reviewed at least every three months to confirm that current medical necessity criteria are met and that the medication is effective:

- The patient remains on interferon/ribavirin therapy and platelet count is less than 400,000/ mm3

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.

For Medicare Plan members, refer to the CareSource policy and Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD).

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

NOTE: Eltrombopag (Promacta) is available only through a restricted distribution program called PROMACTA*CARES*. Under the PROMACTA*CARES* Program, only prescribers, pharmacies, and patients registered with the program are able to prescribe, dispense, and receive eltrombopag (Promacta). To enroll in the PROMACTA*CARES* Program call: 1-877-9- PROMACTA.

NOTE: Romiplostim (Nplate) is available only through a restricted distribution program called Nplate NEXUS (Network of Experts Understanding and Supporting Nplate and Patients) Program. Under the Nplate NEXUS Program, only prescribers and patients registered with the program are able to prescribe, administer, and receive romiplostim Nplate).

CONDITIONS OF COVERAGE

HCPCS J8999 Promacta
J2796 NPlate

CPT

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 4 weeks and should be discontinued if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks of therapy at the maximum dose. Reauthorization period is up to 6 months.

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. REVIEW/REVISION HISTORY

1/2013
1/2014 – Changed platelet criteria, added Hep C indications, added values for reauth period, change auth period
2/2015 – Revision to current policy to include aspirin contraindication, pregnancy special considerations, and updated references.

F. REFERENCES

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2. Amgen, Inc. Nplate (romiplostim) Prescribing Information. Thousand Oaks, CA: Amgen, Inc. August 2008.
3. Facts and Comparison. http://online.factsandcomparisons.com/index.aspx
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14. Eltrombopag. (2015, January 1). Retrieved January 1, 215, from http://www.nlm.nih.gov/medlineplus/druginfo/meds/a609011.html

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

Independent medical review – 11/2012