THROMBOPOIETIN MIMETIC AGENTS FOR TREATMENT OF THROMBOCYTOPENIA

Description: Immune thrombocytopenic purpura (ITP) is an autoimmune disorder in which patients produce antiplatelet autoantibodies and specialized white blood cells that destroy their blood platelets and, in some cases, damage their megakaryocytes (the cells that produce platelets in the bone marrow), causing a decrease in platelet production. This results in a low blood platelet count (thrombocytopenia) that may produce bruising or excessive bleeding. Immune thrombocytopenic purpura is classified as primary or as secondary to an underlying disorder and as acute (of six months or less in duration) or chronic.

Adult-onset and childhood-onset ITP are strikingly different. Affected children are young (peak age, approximately five years) and previously healthy, and they typically present with the sudden onset of petechiae or purpura a few days or weeks after an infectious illness. Boys and girls are equally affected. In more than 70 percent of children, the illness resolves within six months, irrespective of whether they receive therapy. By contrast, ITP in adults is generally chronic and the onset is often insidious. Approximately twice as many women as men are affected. Therapies for symptomatic chronic ITP include corticosteroids, IVIG, splenectomy, rituximab and cyclophosphamide.

Romiplostim (Nplate®) and eltrombopag (Promacta®) are thrombopoietin receptor agonists with FDA approval for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. The FDA has also approved eltrombopag for treatment of thrombocytopenia in patients with chronic hepatitis C virus (HCV) infection to help them qualify for interferon-based therapy.
Policy:

I. Thrombopoietin mimetic agents (e.g., romiplostim and eltrombopag) may be considered **MEDICALLY NECESSARY** for treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who meet **ALL** of the following criteria:
   A. Disease duration greater than six (6) months; **AND**
   B. Insufficient response to corticosteroids, immunoglobulins, or splenectomy. An insufficient response is defined as a platelet count of less than 30,000 per microliter OR a platelet count less than 50,000 per microliter and at increased risk of bleeds due to concomitant disease states or occupation.

II. Eltrombopag may be considered **MEDICALLY NECESSARY** for treatment of thrombocytopenia in patients with chronic hepatitis C virus (HCV) infection for patients whose level of thrombocytopenia prevents the start or maintenance of interferon-based therapy.

III. Romiplostim is considered **INVESTIGATIVE** to increase platelet counts and facilitate treatment for hepatitis C virus infection in patients with thrombocytopenia associated with HCV-related cirrhosis due to the lack of clinical evidence demonstrating its impact on improved health outcomes.

IV. All other uses of thrombopoietin mimetic agents (e.g., romiplostim and eltrombopag) are considered **INVESTIGATIVE** including, but not limited to, the following due to the lack of clinical evidence demonstrating their impact on improved health outcomes:
   A. Initial therapy for chronic ITP;
   B. Acute ITP;
   C. Normalization of platelet counts in patients with chronic ITP in the absence of increased risk for bleeding;
   D. Thrombocytopenia due to myelodysplastic syndrome;
   E. Thrombocytopenia due to chronic liver disease;
   F. Chemotherapy-induced thrombocytopenia.

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member’s summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.
For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

**Coding:**

*The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

**HCPCS:**

J2796 Injection, romiplostim, 10 mcg

**Policy History:**

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*Most recent history:*

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**Cross Reference:**

Rituximab, II-47

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