UM-CDG-074 Rituximab	Approved By: Director, Health Services	Effective Date: 10/20/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address rituximab, a genetically engineered chimeric murine/human monoclonal immunoglobulin G1 (IgG1) kappa antibody directed against the CD20 antigen. It binds specifically to the antigen CD20, a hydrophobic transmembrane protein with a molecular weight of approximately 35 kD located on pre-B and mature B lymphocytes. The antigen is expressed on greater than 90% of B-cell-non-Hodgkin's lymphomas (NHL), but the antigen is not found on hematopoietic stem cells, pro-B cells, normal plasma cells, or other tissues. In non-Hodgkin's lymphoma members, administration of rituximab resulted in depletion of circulating and tissue based B-cells.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

None

POLICY

SECUR Health Plan recognizes the following indications for US Food and Drug Administration (FDA) approved uses of rituximab as medically necessary:

1. Non-Hodgkin's Lymphoma
   - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
   - Previously untreated follicular, CD-20-positive, B-cell NHL in combination with first line chemotherapy and, in members achieving a complete or partial response to rituximab in combination with chemotherapy, as a single-agent maintenance therapy
   - Non-progressing chemotherapy
   - Previously untreated diffuse large B-cell, CD-20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
2. Chronic lymphocytic leukemia (CLL)
   - Rituximab is indicated, in combination with fludarabine and cyclophosphamide (FC), for the treatment of members with previously untreated and previously treated CD20-positive CLL.
3. Rheumatoid Arthritis

- Rituximab in combination with methotrexate is indicated for the treatment of members with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

4. Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA)
   - Rituximab in combination with glucocorticoids is indicated for the treatment of GPA and MPA

Accepted Off-Label Uses

- Second line or salvage therapy with or without radiation therapy (RT) prior to autologous stem cell rescue for progressive disease or for relapsed disease in members initially treated with chemotherapy with or without RT in combination with bendamustine
- Low grade or follicular CD20-positive, B-cell NHL
- Intermediate and high-grade NHL when used as a single agent, in combination with CHOP chemotherapy regimen, or in combination with other agents active in the disease
- Immune or idiopathic thrombocytopenia purpura
- Evans' syndrome
- Waldenstrom's macroglobulinemia
- Treatment of refractory thrombotic thrombocytopenic purpura (TTP) for members who do not respond to plasmapheresis
- Autoimmune hemolytic anemia - rituximab is covered for those patients with autoimmune hemolytic anemia condition that is refractory to conventional treatment (e.g., corticosteroid treatment and splenectomy)
- Multifocal motor neuropathy (MMN) as a second line therapy
- Multiple sclerosis, relapsing, remitting (RRMS) as a third line therapy
- Neuromyelitis optica
- Polymyositis as a second or third line therapy
- Myasthenia gravis
- Anti-myelin associated glycoprotein (anti-MAG) polyneuropathy
- Graft-Versus-Host Disease (GVHD) as third line of therapy or greater
- Antineutrophil cytoplasmic antibody (ANCA) associated vasculitis
- Rituximab has been shown to be an effective therapy for cryoglobulinemia and cryoglobulinemia induced renal disease with less complications than the standard therapy with cyclophosphamide and plasmapheresis
- Post-transplant lymphoproliferative disorder (PTLD)
- Epstein-Barr viremia (EBV) in members at high risk for PTLD – allogenic bone marrow transplant member with prolonged T-cell immune impairment
- Autoimmune encephalitis in bone marrow transplant members

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