Reference number(s)
4452-A

JURISDICTION SPECIFIC MEDICARE PART B

RITUXIMAB AND BIOSIMILARS
RITUXAN (rituximab)
RIABNI (rituximab-arrx)
RUXIENCE (rituximab-pvvr)
TRUXIMA (rituximab-abbs)

POLICY

I. **COVERED USES**

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Non-Hodgkin's lymphoma (NHL)
B. Chronic lymphocytic leukemia (CLL)
C. Rheumatoid arthritis
D. Granulomatosis with polyangiitis (GPA)
E. Microscopic polyangiitis (MPA)
F. Pemphigus vulgaris (PV)
G. Prior to autologous stem cell rescue
H. Immune or idiopathic thrombocytopenia purpura
I. Evans' syndrome
J. Waldenstrom's macroglobulinemia
K. Thrombotic thrombocytic purpura (TTP)
L. Autoimmune hemolytic anemia
M. Multifocal motor neuropathy (MMN)
N. Relapsing-remitting multiple sclerosis
O. Neuromyelitis optica
P. Polymyositis
Q. Myasthenia gravis
R. Anti-myelin associated glycoprotein (anti-MAG) polyneuropathy
S. Graft-versus-host disease (GVHD)
T. Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis
U. Cryoglobulinemia and cryoglobulinemia-induced renal disease
V. Post-transplant lymphoproliferative disorder (PTLD)

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W. Epstein-Barr viremia
X. Autoimmune encephalitis

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. The medical record must substantiate the medical need for the use of these chemotherapy drugs by clearly indicating the diagnoses for which the drugs are being used. The Medicare Administrative Contractor (MAC) would expect the disease, type of malignancy (if cancer is the diagnosis), the staging (if applicable), and all prior therapy and the member's response to that therapy. For the diagnosis of lymphoma, an explanation of lymphoma type and previous treatment(s) should be maintained in the medical record.
B. If the provider is other than the ordering/referring physician, that provider must maintain copies of the ordering/referring physician's order for the chemotherapy drug. The ordering physician must state the clinical indication/medical need for using the chemotherapy drug in the order.
C. For autoimmune hemolytic anemia, in addition to the diagnosis and prior therapy requirements, other documentation required in the medical record includes hemoglobin, hematocrit, reticulocyte count, bilirubin, liver function tests, and subjective complaints.

III. CRITERIA FOR APPROVAL

A. **Non-Hodgkin's lymphoma**

Authorization of 12 months may be granted for treatment of non-Hodgkin's lymphoma (NHL) when any of the following criteria is met:

1. Member has relapsed or refractory low-grade or follicular CD20-positive B-cell NHL and rituximab will be used as a single agent
2. Member has previously untreated follicular CD20-positive B-cell NHL in combination with first-line chemotherapy
3. Single-agent maintenance therapy in members who achieved a complete or partial response to rituximab in combination with chemotherapy
4. Member has non-progressing (including stable disease), low-grade, CD20-positive NHL and rituximab will be used in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) or other anthracycline-based chemotherapy regimens
5. Rituxan will be used a re-induction treatment appropriate for responders and members with stable low-grade or follicular CD20-positive B-cell NHL
6. Member has intermediate or high-grade NHL and rituximab will be used in one of the following regimens:
   i. Single agent

ii. In combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone)
iii. In combination with other agents active against the disease

B. **Chronic lymphocytic leukemia**
Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia (CLL) when both of the following criteria are met:
1. Member has either previously untreated or previously treated CD20-positive CLL
2. Rituximab will be used in combination with fludarabine and cyclophosphamide

C. **Rheumatoid arthritis**
Authorization of 12 months may be granted for treatment of adults with moderate to severely active rheumatoid arthritis when both of the following criteria are met:
1. Rituximab will be used in combination with methotrexate
2. Member has tried and had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies

D. **Granulomatosis with polyangiitis and microscopic polyangiitis**
Authorization of 12 months may be granted for treatment of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA) when rituximab will be used in combination with glucocorticoids.

E. **Pemphigus vulgaris**
Authorization of 12 months may be granted for treatment of moderate to severe pemphigus vulgaris.

F. **Prior to autologous stem cell rescue**
Authorization of 12 months may be granted prior to autologous stem cell rescue when both of the following criteria are met:
1. Rituximab will be used as second-line or salvage therapy for progressive or relapsed disease with or without radiation therapy
2. Member was initially treated with chemotherapy with or without radiation therapy in combination with bendamustine

G. **Immune or idiopathic thrombocytopenia purpura**
Authorization of 12 months may be granted for treatment of immune or idiopathic thrombocytopenia purpura.

H. **Evans' syndrome**
Authorization of 12 months may be granted for treatment of Evans' syndrome.

I. **Waldenstrom's macroglobulinemia**
Authorization of 12 months may be granted for treatment of Waldenstrom's macroglobulinemia.

J. **Thrombotic thrombocytopenic purpura (TTP)**

Authorization of 12 months may be granted for treatment of refractory thrombotic thrombocytopenic purpura if the member did not respond to plasmapheresis.

K. **Autoimmune hemolytic anemia**
Authorization of 12 months may be granted for treatment of autoimmune hemolytic anemia when the disease is refractory to conventional treatment (e.g., corticosteroid treatment and splenectomy).

L. **Multifocal motor neuropathy**
Authorization of 12 months may be granted for treatment of multifocal motor neuropathy (MMN) when rituximab will be used as a second-line therapy.

M. **Multiple sclerosis**
Authorization of 12 months may be granted for treatment of relapsing-remitting multiple sclerosis (RRMS) when rituximab will be used as a third-line therapy.

N. **Neuromyelitis optica**
Authorization of 12 months may be granted for treatment of neuromyelitis optica.

O. **Polymyositis**
Authorization of 12 months may be granted for treatment of polymyositis when rituximab will be used as a second- or third-line therapy.

P. **Myasthenia gravis**
Authorization of 12 months may be granted for treatment of myasthenia gravis.

Q. **Anti-myelin associated glycoprotein (anti-MAG) polyneuropathy**
Authorization of 12 months may be granted for treatment of anti-myelin associated glycoprotein (anti-MAG) polyneuropathy.

R. **Graft-versus-host disease**
Authorization of 12 months may be granted for treatment of graft-versus-host disease when rituximab will be used as third-line therapy or greater.

S. **Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis**
Authorization of 12 months may be granted for treatment of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis.

T. **Cryoglobulinemia**
Authorization of 12 months may be granted for treatment of cryoglobulinemia and cryoglobulinemia-induced renal disease.

U. **Post-transplant lymphoproliferative disorder**
Authorization of 12 months may be granted for treatment of post-transplant lymphoproliferative disorder (PTLD).

V. **Epstein-Barr viremia**

Authorization of 12 months may be granted for the prevention of Epstein-Barr viremia when all of the following criteria are met:

1. The member is at high risk for post-transplant lymphoproliferative disease
2. The member has undergone an allogenic bone marrow transplant and will have prolonged T-cell impairment
3. Member must have received one of the following treatments:
   i. Cord blood units or ex vivo CD34 selected or T-cell depleted hematopoietic cell grafts
   ii. Anti T-cell antibodies (alemtuzumab)
   iii. High-dose steroids for treatment of severe acute graft-versus-host disease

W. **Autoimmune encephalitis**

Authorization of 12 months may be granted for treatment of autoimmune encephalitis in bone marrow transplant patients.

IV. **REFERENCES**

1. Rituximab LCD (L35026) Version R26. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed April 22, 2021.
2. Billing and Coding: Rituximab (A56380) Version R9. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed January 11, 2022.
3. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc; June 2021.