

JURISDICTION SPECIFIC MEDICARE PART B

RITUXIMAB AND BIOSIMILARS

RITUXAN (rituximab)

RIABNI (rituximab-arrrx)

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
- B. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
- C. Rheumatoid arthritis
- D. Granulomatosis with polyangiitis (GPA)
- E. Microscopic polyangiitis (MPA)
- F. Pemphigus vulgaris
- G. Acquired hemophilia
- H. Autoimmune hemolytic anemia
- I. Diffuse large B-cell lymphoma
- J. Burkitt's lymphoma
- K. Prevention of Epstein-Barr virus-related post-transplant lymphoproliferative disorders
- L. Evans syndrome
- M. Chronic graft-versus-host disease
- N. Hairy cell leukemia
- O. Hodgkin's lymphoma
- P. Refractory idiopathic myopathy
- Q. Idiopathic thrombocytopenic purpura (ITP)
- R. Immune thrombocytopenia
- S. Lymphoproliferative disorder following transplantation
- T. Malignant ascites associated with non-Hodgkin's lymphoma
- U. Mantle cell lymphoma
- V. Refractory minimal change disease
- W. Refractory myasthenia gravis
- X. Acute lymphoblastic leukemia

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Reference number(s)
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Y.	Primary cutaneous B-cell lymphoma
Z.	Primary progressive multiple sclerosis
AA.	Relapsing remitting multiple sclerosis
BB.	Primary Sjogren's syndrome
CC.	Systemic lupus erythematosus
DD.	Thrombotic thrombocytopenic purpura
EE.	Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma
FF.	Follicular lymphoma
GG.	Gastric MALT lymphoma
HH.	Nongastric MALT lymphoma (noncutaneous)
II.	Nodal marginal zone lymphoma
JJ.	Splenic marginal zone lymphoma
KK.	Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
LL.	High-grade B-cell lymphoma
MM.	AIDS-related B-cell lymphoma
NN.	AIDS-related diffuse large B-cell lymphoma
OO.	Primary effusion lymphoma
PP.	HHV8-positive diffuse large B-cell lymphoma, not otherwise specified
QQ.	Monomorphic (B-cell type) or polymorphic (B-cell type) post-transplant lymphoproliferative disorder
RR.	Primary central nervous system (CNS) post-transplant lymphoproliferative disorder
SS.	Unicentric Castleman's disease
TT.	Multicentric Castleman's disease
UU.	Primary cutaneous marginal zone lymphoma
VV.	Follicle center lymphoma
WW.	Management of immunotherapy-related toxicities
XX.	Pediatric aggressive mature B-cell lymphoma
YY.	Nodular lymphocyte-predominant Hodgkin lymphoma
ZZ.	Primary central nervous system (CNS) lymphoma
AAA.	Leptomeningeal metastases from lymphomas
BBB.	Suppression of panel-reactive HLA antibodies
CCC.	Neuromyelitis optica
DDD.	Dermatomyositis
EEE.	Polymyositis
FFF.	Grave's disease/ophthalmopathy

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:

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- A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
- B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

III. CRITERIA FOR APPROVAL

- A. **Non-Hodgkin's Lymphoma**
Authorization of 12 months may be granted for treatment of non-Hodgkin's lymphoma.
- B. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma**
Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma.
- C. **Rheumatoid Arthritis**
Authorization of 12 months may be granted for treatment of rheumatoid arthritis.
- D. **Granulomatosis with Polyangiitis (GPA)**
Authorization of 12 months may be granted for treatment of granulomatosis with polyangiitis.
- E. **Microscopic Polyarteritis (MPA)**
Authorization of 12 months may be granted for treatment of granulomatosis with polyangiitis.
- F. **Pemphigus Vulgaris**
Authorization of 12 months may be granted for treatment of pemphigus vulgaris.
- G. **Suppression of Panel Reactive Anti-HLA Antibodies**
Authorization of 12 months may be granted for pre-transplant suppression of panel reactive anti-human leukocyte antigens (HLA) when the member has high panel reactive antibody (PRA) levels to human leukocyte antigens.
- H. **Dermatomyositis and Polymyositis**
Authorization of 12 months may be granted for treatment of dermatomyositis or polymyositis when the member is refractory to other standard therapies.
- I. **Grave's Disease/Ophthalmopathy**
Authorization of 12 months may be granted for treatment of Grave's disease/ophthalmopathy when the member is refractory to the standard therapies.
- J. **Compendial Uses**
Authorization of 12 months may be granted for the following indications:
 - 1. Acquired hemophilia
 - 2. Autoimmune hemolytic anemia
 - 3. Diffuse large B-cell lymphoma
 - 4. Burkitt's lymphoma
 - 5. Prevention of Epstein-Barr virus-related post-transplant lymphoproliferative disorders

6. Evans syndrome
7. Chronic graft-versus-host disease
8. Hairy cell leukemia
9. Hodgkin's lymphoma
10. Refractory idiopathic myopathy
11. Idiopathic thrombocytopenic purpura (ITP)
12. Immune thrombocytopenia
13. Lymphoproliferative disorder following transplantation
14. Malignant ascites associated with non-Hodgkin's lymphoma
15. Mantle cell lymphoma
16. Refractory minimal change disease
17. Refractory myasthenia gravis
18. Acute lymphoblastic leukemia
19. Primary cutaneous B-cell lymphoma
20. Primary progressive multiple sclerosis
21. Relapsing remitting multiple sclerosis
22. Primary Sjogren's syndrome
23. Systemic lupus erythematosus
24. Thrombotic thrombocytopenic purpura
25. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma
26. Follicular lymphoma
27. Gastric MALT lymphoma
28. Nongastric MALT lymphoma (noncutaneous)
29. Nodal marginal zone lymphoma
30. Splenic marginal zone lymphoma
31. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
32. High-grade B-cell lymphoma
33. AIDS-related B-cell lymphoma
34. AIDS-related diffuse large B-cell lymphoma
35. Primary effusion lymphoma
36. HHV8-positive diffuse large B-cell lymphoma, not otherwise specified
37. Monomorphic (B-cell type) or polymorphic (B-cell type) post-transplant lymphoproliferative disorder
38. Primary central nervous system (CNS) post-transplant lymphoproliferative disorder
39. Unicentric Castleman's disease
40. Multicentric Castleman's disease
41. Primary cutaneous marginal zone lymphoma
42. Follicle center lymphoma
43. Management of immunotherapy-related toxicities
44. Pediatric aggressive mature B-cell lymphoma
45. Nodular lymphocyte-predominant Hodgkin lymphoma
46. Primary CNS lymphoma
47. Leptomeningeal metastases from lymphomas
48. Neuromyelitis optica

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IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed April 22, 2021.
2. Billing and Coding: Rituximab, Biosimilars and Rituximab and Hyaluronidase Human (A52452) Version R23. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed April 22, 2021.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R7. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed April 22, 2021.
4. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; March 2020.
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6. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; July 2019.
7. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed April 22, 2021.
8. Clinical Pharmacology [database online]. Atlanta, GA: Elsevier, Inc.; 2020. <https://www.clinicalkey.com/pharmacology>. Accessed April 22, 2021.