

STANDARD MEDICARE PART B MANAGEMENT

RITUXAN (rituximab)
RUXIENCE (rituximab-pvvr)
TRUXIMA (rituximab-abbs)
RIABNI (rituximab-arrx)

POLICY

I. INDICATIONS

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

A. FDA-Approved Indications

Rituxan, Ruxience, Truxima, and Riabni are indicated for:

1. Non-Hodgkin's Lymphoma (NHL) in adult patients with:
 - i. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
 - ii. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy
 - iii. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
 - iv. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
2. Chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC), for the treatment of adult patients with previously untreated and previously treated CD20-positive CLL.
3. Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis, in combination with glucocorticoids.

Rituxan and Truxima are also indicated for:

Rheumatoid Arthritis (RA)

Rituxan or Truxima, in combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Rituxan is also indicated for:

Pemphigus Vulgaris (PV)

Rituxan is indicated for the treatment of adult patients with moderate to severe pemphigus vulgaris.

B. Compendial Uses

1. B-cell lymphoma
 - i. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
 - ii. Burkitt lymphoma

- iii. Castleman's disease
- iv. Diffuse large B-cell lymphoma
- v. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
- vi. Histological transformation from follicular lymphoma to diffuse large B-cell lymphoma
- vii. Histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma
- viii. Follicular lymphoma
- ix. Mantle cell lymphoma
- x. Marginal zone lymphoma (nodal, splenic, gastric/non-gastric MALT)
- xi. Post-transplant lymphoproliferative disorder (PTLD)
- xii. Pediatric aggressive mature B-cell lymphomas
- xiii. B-cell lymphoblastic lymphoma
- 2. Malignant ascites, in advanced low-grade non-Hodgkin lymphoma
- 3. B-cell acute lymphoblastic leukemia (ALL)
- 4. CLL/small lymphocytic lymphoma (SLL)
- 5. Hairy cell leukemia
- 6. Rosai-Dorfman disease
- 7. Hodgkin's lymphoma, lymphocyte-predominant
- 8. Hodgkin's lymphoma, CD20-positive, relapsed or progressive
- 9. Primary cutaneous B-cell lymphoma
- 10. Central nervous system (CNS) cancers
 - i. Leptomeningeal metastases from lymphomas
 - ii. Primary CNS lymphoma
- 11. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
- 12. Rheumatoid arthritis, moderate or high disease activity despite disease-modifying anti-rheumatic drug (DMARD) monotherapy
- 13. Autoimmune hemolytic anemia
- 14. Immune or idiopathic thrombocytopenic purpura (ITP), as initial therapy
- 15. Immune or idiopathic thrombocytopenic purpura (ITP), relapsed/refractory to standard therapy (e.g., corticosteroids, immune globulin)
- 16. Thrombotic thrombocytopenic purpura
- 17. Relapsing-remitting multiple sclerosis
- 18. Primary progressive multiple sclerosis
- 19. Myasthenia gravis, refractory to standard therapy (e.g., corticosteroids, immunosuppressants)
- 20. Systemic lupus erythematosus, refractory to standard therapy (e.g., corticosteroids, immunosuppressants)
- 21. Sjögren's syndrome
- 22. Chronic graft-versus-host disease (GVHD)
- 23. Prevention of Epstein-Barr virus (EBV)-related PTLD in hematopoietic stem cell transplant in (HSCT) recipients
- 24. Evans syndrome
- 25. Nephrotic syndrome, refractory to standard therapy (e.g., corticosteroids, immunosuppressants)⁴
- 26. Acquired factor VIII deficiency (acquired hemophilia A)
- 27. Idiopathic inflammatory myopathy, refractory
- 28. Immune checkpoint inhibitor-related toxicities

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. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis

Authorization of 12 months may be granted for treatment of rheumatoid arthritis when any of the following criteria are met.

1. The member has previously received treatment with a biologic or targeted synthetic DMARD (e.g., TNF inhibitor, Xeljanz) for the treatment of rheumatoid arthritis.
2. The member has had an inadequate response to methotrexate or there is a clinical reason to avoid treatment with methotrexate (e.g., renal or hepatic impairment).

B. Oncologic indications

Oncologic disorders must be CD20-positive as confirmed by testing or analysis to identify the CD20 protein on the surface of the B-cell.

1. B-cell lymphoma

Authorization of 12 months may be granted for treatment of any of the following indications:

- i. AIDS-related B-cell lymphoma
- ii. Burkitt lymphoma
- iii. Castleman's disease
- iv. Diffuse large B-cell lymphoma
- v. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
- vi. Histological transformation from follicular lymphoma to diffuse large B-cell lymphoma
- vii. Histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma
- viii. Follicular lymphoma
- ix. Mantle cell lymphoma
- x. Marginal zone lymphoma (nodal, splenic, gastric MALT, nongastric MALT)
- xi. Post-transplant lymphoproliferative disorder
- xii. Pediatric aggressive mature B-cell lymphomas
- xiii. B-cell lymphoblastic lymphoma

2. Malignant ascites

Authorization of 12 months may be granted for treatment of malignant ascites in patients with advanced low-grade non-Hodgkin lymphoma.

3. B-cell acute lymphoblastic leukemia (ALL)

Authorization of 12 months may be granted for treatment of B-cell ALL.

4. Chronic lymphocytic leukemia/small lymphocytic lymphoma

Authorization of 12 months may be granted for treatment of CLL/SLL.

5. Hairy cell leukemia

Authorization of 12 months may be granted for treatment of hairy cell leukemia.

6. Hodgkin's lymphoma

Authorization of 12 months may be granted for treatment of any of the following indications:

- i. Lymphocyte-predominant Hodgkin's lymphoma
- ii. CD20-positive relapsed or progressive Hodgkin's lymphoma

7. Primary cutaneous B-cell lymphoma

Authorization of 12 months may be granted for treatment of primary cutaneous B-cell lymphoma.

8. Central nervous system (CNS) cancers

Authorization of 12 months may be granted for treatment of any of the following indications:

- i. Leptomeningeal metastases from lymphomas
- ii. Primary CNS lymphoma

9. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma

Authorization of 12 months may be granted for treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma.

10. Rosai-Dorfman disease

Authorization of 12 months may be granted for the treatment of Rosai-Dorfman disease.

C. Hematologic indications

Authorization of 12 months may be granted for treatment of any of the following indications:

1. Autoimmune hemolytic anemia
2. Immune or idiopathic thrombocytopenic purpura
3. Thrombotic thrombocytopenic purpura
4. Evans syndrome
5. Acquired factor VIII deficiency (acquired hemophilia A)

D. Multiple sclerosis

Authorization of 12 months may be granted for treatment of relapsing-remitting multiple sclerosis and primary progressive multiple sclerosis.

E. Myasthenia gravis

Authorization of 12 months may be granted for treatment of myasthenia gravis that is refractory to standard therapy (e.g., corticosteroids, immunosuppressants) or if there is a clinical reason to avoid standard therapy.

F. Systemic lupus erythematosus

Authorization of 12 months may be granted for treatment of systemic lupus erythematosus that is refractory to standard therapy (e.g., corticosteroids, immunosuppressants) or if there is a clinical reason to avoid standard therapy.

G. Granulomatosis with polyangiitis (Wegener's granulomatosis) and microscopic polyangiitis

Authorization of 12 months may be granted for treatment of granulomatosis with polyangiitis and microscopic polyangiitis.

H. Sjögren's syndrome

Authorization of 12 months may be granted for treatment of Sjögren's syndrome.

I. Nephrotic syndrome

Authorization of 12 months may be granted for treatment of nephrotic syndrome that is refractory to standard therapy (e.g., corticosteroids, immunosuppressants) or if there is a clinical reason to avoid standard therapy.

J. Idiopathic inflammatory myopathy

Authorization of 12 months may be granted for treatment of refractory idiopathic inflammatory myopathy.

Reference number(s)
2501-A

K. Immune checkpoint inhibitor-related toxicities

Authorization of 3 months may be granted for treatment of immune checkpoint inhibitor-related toxicities.

L. Other indications

Authorization of 12 months may be granted for treatment of any of the following indications:

1. Chronic GVHD
2. Prevention of EBV-related PTLD in HSCT recipients
3. Pemphigus vulgaris

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

- A. Authorization for 3 months may be granted for the diagnosis of immune checkpoint inhibitor-related toxicities when all of the following criteria are met:
 1. The member is currently receiving therapy with Rituxan, Ruxience, Truxima, or Riabni.
 2. Rituxan, Ruxience, Truxima, or Riabni is being used to treat an indication enumerated in Section II.
 3. The member is receiving benefit from therapy.
- B. Authorization for 12 months may be granted for all diagnoses (except immune checkpoint inhibitor-related toxicities) when all of the following criteria are met:
 1. The member is currently receiving therapy with Rituxan, Ruxience, Truxima, or Riabni.
 2. Rituxan, Ruxience, Truxima, or Riabni is being used to treat an indication enumerated in Section II.
 3. The member is receiving benefit from therapy.

IV. REFERENCES

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