Rituximab

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Rituximab policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies for Rituxan (rituximab), Truxima (rituximab-abbs), Riabni (rituximab-arrx) and Ruxience (rituximab-pvvr). For this program, Truxima, Ruxience, and Riabni are the preferred products. Coverage for non-preferred products, Rituxan and Rituxan Hycela, is provided based on clinical circumstances that would exclude the use of the preferred product(s) and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

FDA-Approved Indications

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

1. Non-Hodgkin's lymphoma (NHL) in adult patients with:
    a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
    b. 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
    c. 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
    d. 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 (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids

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4. Rheumatoid arthritis, in combination with methotrexate, 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.

Compendial Use

1. Sjögren's syndrome
2. Multiple sclerosis, relapsing remitting
3. Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder, NMOSD, Devic disease)
4. Autoimmune blistering disease
5. Cryoglobulinemia
6. Solid organ transplant
7. Opsoclonus-myoclonus ataxia
8. Systemic lupus erythematosus (SLE)
9. B-cell acute lymphoblastic leukemia (ALL)
10. B-cell lymphomas
    a. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
    b. B-cell lymphoblastic lymphoma
    c. Burkitt lymphoma
    d. Primary cutaneous B-cell lymphoma
    e. Castleman's disease
    f. High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma)
    g. High-grade B-cell lymphoma, not otherwise specified
    h. Histological transformation from follicular lymphoma to diffuse large B-cell lymphoma
    i. Histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma
    j. Mantle cell lymphoma
    k. Marginal zone lymphomas
        i. Nodal marginal zone lymphoma
        ii. Gastric mucosa associated lymphoid tissue (MALT) lymphoma
        iii. Nongastric MALT lymphoma
        iv. Splenic marginal zone lymphoma
    l. Post-transplant lymphoproliferative disorder (PTLD)
    m. Pediatric Aggressive Mature B-Cell Lymphomas
11. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
12. Autoimmune hemolytic anemia
13. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
14. Thrombotic thrombocytopenic purpura
15. Central nervous system (CNS) cancers
    a. Leptomeningeal metastases from lymphomas
    b. Primary CNS lymphomas
16. Chronic graft-versus-host disease (GVHD)
17. CLL/Small lymphocytic lymphoma (SLL)
18. Hairy cell leukemia
19. Rosai-Dorfman disease
20. Hodgkin's lymphoma, nodular lymphocyte-predominant
21. Immune checkpoint inhibitor-related toxicities
22. Myasthenia gravis, refractory
23. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients

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24. Membranous Nephropathy

POLICY

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

Coverage for a non-preferred product is provided when the following criteria is met:

- The member has had a documented intolerable adverse event to all the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

Table. Rituximab Products

Medication	Generic Name
Preferred Products:	
Ruxience	rituximab-pvvr
Truxima	rituximab-abbs
Riabni	rituximab-arrx
Targeted Products:	
Rituxan	rituximab
Rituxan Hycela	rituximab and hyaluronidase human

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Rheumatoid arthritis (RA)
   1. For initial requests:
      i. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
      ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
   2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Sjögren's syndrome, neuromyelitis optica, autoimmune blistering disease, cryoglobulinemia, opsoclonus-myoclonus-ataxia, and systemic lupus erythematosus (initial requests only): Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

C. Hematologic/Oncologic indications:Testing or analysis confirming CD20 protein on the surface of the B cell (if applicable)

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Exclusions

A. Coverage will not be provided for requests for the treatment of rheumatoid arthritis (RA) when planned date of administration is less than 16 weeks since date of last dose received.
B. Member will not receive Rituxan, Ruxience, Riabni, or Truxima with other biologics for RA.
C. Member will not receive Rituxan, Ruxience, Riabni, or Truxima with other multiple sclerosis (MS) drugs excluding Ampyra

Criteria for Initial Approval

A. Hematologic indications

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

1. Refractory immune or idiopathic thrombocytopenic purpura (ITP)
2. Autoimmune hemolytic anemia
3. Thrombotic thrombocytopenic purpura
4. Chronic graft-versus-host disease (GVHD)
5. Prevention of Epstein-Barr virus (EBV)-related PTLD

B. Oncologic indications

Authorization of 12 months may be granted for treatment of any of the following oncologic disorders that are CD20-positive as confirmed by testing or analysis:

1. B-cell acute lymphoblastic leukemia (ALL)
2. B-cell lymphomas:
    a) Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
    b) B-cell lymphoblastic lymphoma
    c) Burkitt lymphoma
    d) Castleman's disease
    e) Diffuse large B-cell lymphoma
    f) Follicular lymphoma
    g) High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma)
    h) High-grade B-cell lymphoma, not otherwise specified
    i) Histological transformation from follicular lymphoma to diffuse large B-cell lymphoma
    j) Histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma
    k) Mantle cell lymphoma
    l) Marginal zone lymphomas
        i. Nodal marginal zone lymphoma
        ii. Gastric mucosa associated lymphoid tissue (MALT) lymphoma
        iii. Nongastric MALT lymphoma
        iv. Splenic marginal zone lymphoma
    m) Post-transplant lymphoproliferative disorder (PTLD)
    n) Pediatric Aggressive Mature B-Cell Lymphomas
3. Central nervous system (CNS) cancers:
    a) Leptomeningeal metastases from lymphomas
    b) Primary CNS lymphoma
4. CLL/Small lymphocytic lymphoma (SLL)
5. Hairy cell leukemia
6. Rosai-Dorfman disease
7. Hodgkin's lymphoma, nodular lymphocyte-predominant
8. Primary cutaneous B-cell lymphoma
9. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)

C. Myasthenia gravis

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Authorization of 12 months may be granted for treatment of refractory myasthenia gravis.

D. Immune checkpoint inhibitor-related toxicities

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

E. Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for the treatment of moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX) unless the member has a contraindication (see Appendix A) or intolerance to MTX and either of the following criteria are met:
   a) The member has previously received any biologic disease-modifying antirheumatic drug (DMARD) or targeted synthetic DMARD (e.g., Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis; or
   b) The member has received at least two full doses of Rituxan, Ruxience, Riabni, or Truxima for the treatment of RA, where the most recent dose was given within 6 months of the request.
2. Authorization of 12 months may be granted for treatment of moderately to severely active RA in combination with MTX unless the member has a contraindication (see Appendix A) or intolerance to MTX when all of the following criteria are met:
   a) The member meets either of the following criteria:
      i. The member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      ii. The member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   b) The member meets either of the following criteria:
      i. The member has experienced an inadequate response to at least a 3-month trial of MTX despite adequate dosing (i.e., titrated to at least 15 mg/week); or
      ii. The member had an intolerable adverse effect or contraindication to MTX (see Appendix A), and an inadequate response to another conventional DMARD (e.g., hydroxychloroquine, leflunomide, sulfasalazine).

F. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA) and Churg-Strauss and pauci-immune glomerulonephritis

Authorization of 12 months may be granted for treatment of GPA, MPA, Churg-Strauss or pauci-immune glomerulonephritis.

G. Autoimmune blistering disease

Authorization of 12 months may be granted for treatment of autoimmune blistering disease (e.g., pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquista and paraneoplastic pemphigus).

H. Cryoglobulinemia

Authorization of 12 months may be granted for treatment of cryoglobulinemia when corticosteroids and other immunosuppressive agents were ineffective

I. Sjögren's syndrome

Authorization of 12 months may be granted for treatment of Sjögren's syndrome when corticosteroids and other immunosuppressive agents were ineffective.

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J. Multiple sclerosis

Authorization of 12 months may be granted for treatment of relapsing remitting multiple sclerosis.

K. Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder; NMOSD, Devic disease)

Authorization of 12 months may be granted for treatment of neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder, NMOSD, Devic disease) when both of the following criteria are met:

1. When at least one other immunotherapy was ineffective.
2. The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

L. Solid organ transplant

Authorization of 3 months may be granted for treatment of solid organ transplant and prevention of antibody-mediated rejection in solid organ transplant.

M. Opsoclonus-myoclonus-ataxia

Authorization of 12 months may be granted for treatment of opsoclonus-myoclonus-ataxia associated with neuroblastoma when the member is refractory to steroids and chemotherapy.

N. Systemic Lupus Erythematosus

Authorization of 12 months may be granted for the treatment of systemic lupus erythematosus that is refractory to immunosuppressive therapy.

O. Membranous Nephropathy

Authorization of 6 months may be granted for the treatment of membranous nephropathy when the following criteria are met:

1. Member has a diagnosis of membranous nephropathy
2. Member is at moderate or high risk for progressive disease

Continuation of Therapy

A. Rheumatoid arthritis

Authorization of 12 months may be granted for continued treatment in all members (including new members) requesting reauthorization who meet all initial authorization criteria and achieve or maintain positive clinical response after at least two doses of therapy with Rituxan, Ruxience, Riabni, or Truxima as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B. Multiple Sclerosis

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for relapsing remitting multiple sclerosis (MS) who are experiencing disease stability or improvement while receiving Rituxan, Ruxience, Riabni, or Truxima.

C. Oncologic indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed in Section B who have not experienced an unacceptable toxicity.

D. Immune checkoint inhibitor-related toxicities

Authorization of 3 months may be granted for continued treatment in members requesting reauthorization for treatment of immune checkpoint inhibitor-related toxicities who are experiencing benefit from therapy.

E. Membranous Nephropathy

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Authorization of an additional 3 months may be granted for continued treatment in members with the presence of anti-phospholipase A2 receptor (PLA2R) antibodies.

F. Other indications

Authorization of 12 months may be granted for continued treatment in all members (including new members) requesting reauthorization who meet all initial authorization criteria and are receiving benefit from therapy.

Dosage and Administration

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

Appendices

Appendix A: Examples of contraindications to methotrexate

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9312 Rituxan, Injection, rituximab, 10 mg (effective 1/1/2019)
- Q5115 Injection, rituximab-abbs, biosimilar, (truxima), 10 mg (effective 7/1/2019)
- Q5119 Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg (effective 7/1/2020)
- J9999 Injection, Not otherwise classified, antineoplatic drugs (rituximab-arrx, biosimilar [riabni])
- Q5123 Injection, rituximab-arrx, biosimilar, (riabni), 10 mg (effective 7/1/2021)

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