Draft Revised Policy: Do Not Implement

Rituximab Products (Rituxan®, Rituximab-abbs [Truxima®], Rituximab-arrx [Riabni™] and Rituximab-pvvr [Ruxience®])

Treatment of Rheumatoid Arthritis and Other Conditions (Non-Oncolgy Indications)

Some agents on this policy may require step therapy See "Step Therapy Requirements for Provider Administered Specialty Medications" Document at:
https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
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. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older* in combination with glucocorticoids (*pediatric indication applies to Rituxan only).
2. Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies.
3. Non-Hodgkin's lymphoma (NHL)
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-Oncology SGM)
4. Chronic lymphocytic leukemia (CLL)
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-Oncology SGM)

Rituxan is also indicated for:
1. Pemphigus Vulgaris (PV)
Rituxan is indicated for the treatment of adult patients with moderate to severe pemphigus vulgaris.
2. Mature B-cell acute leukemia (B-AL)
(Not addressed in this policy - Refer to Rituxan-Ruxience-Truxima-Riabni Oncology SGM)

B. Compendial Uses
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
9. Myasthenia gravis, refractory
10. Membranous nephropathy
11. For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-Oncology SGM

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA)
   1. 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. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Sjögren's syndrome, 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.

III. PRESCRIBER SPECIALITIES

This medication must be prescribed by or in consultation with one of the following:
A. RA, GPA (Wegener's granulomatosis), MPA, Churg-Strauss, pauci-immune glomerulonephritis, SLE: rheumatologist, immunologist, nephrologist
B. Sjogren's syndrome: rheumatologist, ophthalmologist, immunologist
C. Multiple sclerosis, NMOSD, myasthenia gravis, opsoclonus-myoclonus-ataxia: neurologist, immunologist, rheumatologist
D. Autoimmune blistering disease: dermatologist, immunologist
E. Cryoglobulinemia: hematologist, rheumatologist, neurologist, nephrologist
F. Solid organ transplant: immunologist, transplant specialist
G. Membranous nephropathy: nephrologist

IV. 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, Truxima, or Riabni with any other biologics ~~s~~ drug or targeted synthetic drug for RA.
C. Member will not receive Rituxan, Ruxience, Truxima, or Riabni with other multiple sclerosis (MS) drugs excluding Ampyra.
D. Member will not use Rituxan, Ruxience, Truxima, or Riabni concomitantly with other biologics for the treatment of neuromyelitis optica.

V. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adults who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of ~~with~~ moderately to severely active rheumatoid arthritis ~~(RA)~~. The requested medication must be prescribed in combination with methotrexate (MTX) or leflunomide unless the member has a contraindication (see VII. Appendix) or intolerance to MTX or leflunomide ~~and either of the following criteria are met:~~
   ~~i. The member has previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis; or~~
   ~~ii. The member has received at least two full doses of Rituxan, Ruxience, Truxima, or Riabni 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 adults with moderately to severely active RA in combination with MTX or leflunomide unless the member has a contraindication (see VII. Appendix) or intolerance to MTX or leflunomide when all of the following criteria are met:
   i. The member meets either of the following criteria:
      a. 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)
      b. 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)
   ii. The member meets either of the following criteria:
      a. 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
      b. The member had an intolerable adverse effect or contraindication to MTX (see VII. Appendix), and an inadequate response to another conventional drug (e.g., hydroxychloroquine, leflunomide, sulfasalazine).

B. 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.

C. Sjögren's syndrome

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

D. Multiple sclerosis

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

E. 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).

F. 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 acquisita and paraneoplastic pemphigus).

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

H. 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.

I. 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.

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

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

L. Membranous nephropathy
Authorization of 12 months may be granted for treatment of membranous nephropathy when the member is at moderate to high risk for disease progression.

VI. CONTINUATION OF THERAPY

A. Rheumatoid arthritis
Authorization of 12 months may be granted for continued treatment in all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who ~~requesting reauthorization who meet all initial authorization criteria and~~ achieve or maintain a positive clinical response after at least two doses of therapy with Rituxan, Ruxience, Truxima, or Riabni 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 (RRMS) who are experiencing disease stability or improvement while receiving Rituxan, Ruxience, Truxima, or Riabni.

C. 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.

VII. APPENDIX

Examples of clinical reasons to avoid pharmacologic treatment with ~~contraindications to~~ methotrexate or ~~and~~ leflunomide

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Drug Interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. ~~Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)~~
9. ~~Elevated liver transaminases~~
10. History of intolerance or adverse event
11. ~~Interstitial pneumonitis or clinically significant pulmonary fibrosis~~
12. ~~Myelodysplasia~~
13. ~~Pregnancy or currently planning pregnancy~~
14. ~~Renal impairment~~
15. ~~Significant drug interaction~~

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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EFFECTIVE DATE

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