Reference number(s)
1704-A

SPECIALTY GUIDELINE MANAGEMENT

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

Treatment of Rheumatoid Arthritis and Other Conditions

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 combination with glucocorticoids.
2. Non-Hodgkin's lymphoma (NHL)
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-Oncology SGM)
3. Chronic lymphocytic leukemia (CLL)
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-Oncology SGM)

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. 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. 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. 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, 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. 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 other biologics for RA.
C. Member will not receive Rituxan, Ruxience, Truxima, or Riabni with other multiple sclerosis (MS) drugs excluding Ampyra.

IV. CRITERIA FOR INITIAL APPROVAL

A. 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 V. Appendix) or intolerance to MTX and either of the following criteria are met:
   i. 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
   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 moderately to severely active RA in combination with MTX unless the member has a contraindication (see V. Appendix) or intolerance to MTX 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 20 mg/week); or
   b. The member had an intolerable adverse effect or contraindication to MTX (see V. Appendix), and an inadequate response to another conventional DMARD (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 (MS).

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) 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.

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.

V. 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, 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 (MS) 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.

VI. APPENDIX

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

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