

SPECIALTY GUIDELINE MANAGEMENT

RITUXAN (rituximab) Treatment of Rheumatoid Arthritis

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

1. Moderately to severely active rheumatoid arthritis (RA)
 - a. In combination with methotrexate in patients who have inadequate response to one or more TNF antagonist therapies
2. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)
 - a. In combination with glucocorticoids
3. Other FDA-approved indications (not addressed in this policy – Refer to Rituxan–Oncology SGM)
 - a. Non-Hodgkin's lymphoma (NHL)
 - b. Chronic lymphocytic leukemia (CLL)

B. Compendial Uses

1. Sjögren's syndrome
2. Multiple sclerosis, relapsing remitting
3. For other compendial uses, refer to Rituxan–Oncology SGM

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage will not be provided for requests for the treatment of rheumatoid arthritis when planned date of administration is less than 16 weeks since date of last dose received.

III. CRITERIA FOR INITIAL APPROVAL

Prior to initiating therapy, all members must be screened for hepatitis B virus infection with serologic assays, in addition to meeting the indication-specific criteria listed below.

A. **Moderately to severely active rheumatoid arthritis (RA)**

1. Authorization of 24 months may be granted to members who have previously received any biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis OR have received at least two full doses of Rituxan for the treatment of RA, where the most recent dose was given within 6 months of the request. Rituxan must be prescribed in combination with methotrexate (MTX) unless the member has a contraindication or intolerance to MTX (see Appendix A).

2. Authorization of 24 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
 - a. Member is prescribed Rituxan in combination with MTX or has a contraindication or intolerance to MTX.
 - b. Member meets any of the following criteria:
 - i. 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)
 - ii. Member has an intolerance or contraindication to MTX (see Appendix A)

B. Granulomatosis with Polyangiitis (GPA) (Wegener’s Granulomatosis) and Microscopic Polyangiitis (MPA)¹

Authorization of 12 months may be granted for treatment of GPA or MPA.

C. Sjögren’s syndrome

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

D. Multiple sclerosis

Authorization of 12 months may be granted for treatment of multiple sclerosis (MS) when both of the following criteria are met:

1. Member has a diagnosis of relapsing remitting MS
2. Member has had an inadequate response to two or more disease-modifying drugs indicated for MS despite adequate duration of treatment (see Appendix B)

IV. CONTINUATION OF THERAPY

A. Rheumatoid Arthritis

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least two doses of therapy with Rituximab as evidenced by low disease activity or improvement in signs and symptoms of the condition.

B. Other indications

Authorization of 12 months may be granted for all members (including new members) who meet all initial authorization criteria.

V. APPENDICES

Appendix A: Examples of contraindications to methotrexate

1. Alcoholism, 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 planning pregnancy (male or female)
10. Renal impairment

Reference number(s)
1704-A

11. Significant drug interaction

Appendix B: Disease-modifying drugs indicated for multiple sclerosis

1. Aubagio (teriflunomide)
2. Avonex (interferon beta-1a)
3. Betaseron (interferon beta-1a)
4. Copaxone/Glatopa (glatiramer acetate)
5. Extavia (interferon beta-1a)
6. Gilenya (fingolimod)
7. Tecfidera (dimethyl fumarate)
8. Plegridy (peginterferon beta-1a)
9. Rebif (interferon beta-1a)
10. Tysabri (natalizumab)

VI. REFERENCES

1. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; April 2016.
2. DRUGDEX® System [Internet database]. Ann Arbor, MI: Truven Health Analytics. Updated periodically. Accessed August 30, 2017.
3. Dass S, Bowman SJ, Vital EM, et al. Reduction of fatigue in Sjögren syndrome with rituximab: results of a double blind, placebo-controlled study. *Ann Rheum Dis.* 2008;67:1541-1544.
4. Meijer JM, Meiners PM, Vissink A, et al. Effectiveness of rituximab treatment in primary Sjögren's syndrome: a randomized, double-blind, placebo-controlled trial. *Arthritis Rheum.* 2010;62(4):960-8.
5. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis.* 2017;0:1-18.
6. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1)1-26.
7. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* 2008;59(6):762-784.
8. Hauser SL, Waubant E, Arnold DL, et al. B-cell depletion with rituximab in relapsing-remitting multiple sclerosis. *N Engl J Med.* 2008;358:676-688.