

Rituxan® (rituximab)



When requesting Rituxan® (rituximab) for non-oncology indications, the individual requiring treatment must be diagnosed with an FDA-approved indication or an off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Non-Oncology Indications

Rituxan 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 tumor necrosis factor (TNF) antagonist therapies.

Rituxan, in combination with glucocorticoids, is indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA).

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

Approved Non-Oncology Off-Label Compendial Use

Myasthenia gravis

Coverage Guidelines

For all approved indications, the individual must meet **all** of the following criteria for approval:

- Does not have severe, active infection
- Rituxan (rituximab) will not be used in combination with another biologic agent (e.g., IL-inhibitor, TNF-inhibitor, T-cell costimulation modulator)
- Prior to initiating Rituxan (rituximab), an individual has been screened for hepatitis B virus (HBV) infection

For rheumatoid arthritis initial authorization:

- Had an inadequate response or intolerance to prior biologic agent or targeted synthetic DMARD (i.e., tofacitinib) OR
- Has moderately to severely active disease AND
- Had an inadequate response to at least 3 months of methotrexate therapy unless contraindicated or intolerant to methotrexate OR
- Had an inadequate response to at least 3 months of leflunomide or sulfasalazine unless contraindicated or intolerant to leflunomide or sulfasalazine

For pemphigus vulgaris initial authorization:

- Disease is moderate to severe

For rheumatoid arthritis and pemphigus vulgaris re-authorization:

- An individual's condition has improved or stabilized with Rituxan (rituximab) therapy
- At least 16 weeks have elapsed since last Rituxan (rituximab) infusion

For granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA):

- Rituxan (rituximab) will be used in combination with glucocorticoids

For myasthenia gravis:

- Disease is refractory

Approval duration (initial and renewal): 12 months**Dosing Recommendations****Rheumatoid arthritis:**

The recommended dose is two-1000 mg intravenous infusion separated by 2 weeks (one course) every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks.

Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA):

The recommended dose is 375 mg/m² intravenously once weekly for 4 weeks.

Pemphigus vulgaris:

The recommended dose is two-1000 mg intravenous infusion separated by 2 weeks, then a 500 mg at month 12 and every 6 months thereafter or based on clinical evaluation. Dose upon relapse is a 1000 mg intravenous infusion with considerations to resume or increase the glucocorticoid dose based on clinical evaluation. Subsequent infusions may be no sooner than 16 weeks after the previous infusion.

References

1. Rituxan prescribing information. South San Francisco, CA; Genentech, Inc. June 2018.
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed April 20, 2018.
3. Singh JA, Saag KG, Bridges JR SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2015.
4. Smolen JS, Landewe R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis* Published Online First: [March 6, 2017] doi:10.1136/annrheumdis-2016-210715