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 Uses

- Immune thrombocytopenia (ITP)
- Multiple sclerosis (MS)
- Neuromyelitis optica (NMO)
- Systemic lupus erythematous (SLE)
- Graft-versus-Host Disease (GVHD)

Coverage Guidelines

Rheumatoid arthritis
For** an **initial authorization:

- Had a 3-month trial of at least one biologic agent OR
- Has tried at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate, leflunomide, hydroxychloroquine) **AND**
- Rituxan is prescribed by or in consultation with a rheumatologist

For a re-authorization:

- At least 16 weeks have elapsed since last Rituxan treatment course AND
- For an individual who have received at least 2 courses of Rituxan therapy must have responded to Rituxan therapy (e.g., less join pain, less morning stiffness, improved function, decreased soft tissue swelling in joints, etc.)

Approval duration (initial and renewal): 1 month

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Pemphigus vulgaris
For an initial authorization:
- Rituxan is being initiated in combination with a corticosteroid, unless contraindicated AND
- Rituxan is prescribed by or in consultation with a dermatologist

For a re-authorization:
- At least 16 weeks have elapsed since last Rituxan treatment course AND
- Rituxan is prescribed by or in consultation with a dermatologist

Approval duration (initial): 1 month
Approval duration (renewal): 12 months

Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA):
For an initial authorization:
- Rituxan will be used in combination with glucocorticoids AND
- Rituxan is prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist

For a re-authorization:
- Has achieved disease control with induction treatment (e.g., induction treatment using Rituxan infusion or other standard of care immunosuppressant) AND
- For an individual who has received a course of Rituxan for induction treatment, at least 16 weeks have elapsed since last Rituxan treatment course

Approval duration (initial): 1 month
Approval duration (renewal): 12 months

Immune thrombocytopenia purpura
For an initial authorization:
- Has tried one other therapy (e.g., intravenous immunoglobulin, corticosteroids, splenectomy) AND
- Rituxan is prescribed by or in consultation with a hematologist

For a re-authorization:
- An individual has responded to previous Rituxan therapy (e.g., increased platelet counts) AND
- An individual had a relapse (e.g., experienced thrombocytopenia after achievement of a remission) AND
- At least 6 months have elapsed since last Rituxan treatment course

Approval duration (initial and renewal): 1 month

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Multiple sclerosis (MS)

- Had an inadequate response or intolerance to at least ONE other disease modifying agent for MS AND
- Rituxan is prescribed by or in consultation with a physician who specializes in the treatment of MS and/or a neurologist

Approval duration: 12 months

Neuromyelitis optica

- Rituxan is prescribed by or in consultation with a neurologist

Approval duration: 12 months

Graft-versus-Host Disease

- Rituxan is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center AND
- Has tried at least one immunosuppressant OR
- Is currently receiving at least one of the following medications in combination with Rituxan:
    - Corticosteroids (e.g., methylprednisolone)
    - Antithymocyte globulin
    - Cyclosporine
    - Tacrolimus
    - Mycophenolate mofetil
    - Sirolimus
    - Thalomid
    - Nipent
    - Imatinib
    - Methotrexate

Approval duration: 12 months

Systemic lupus erythematous (SLE)

For an initial authorization:

- Rituxan is prescribed by or in consultation with a rheumatologist, nephrologist, or neurologist AND
- Has neuropsychiatric manifestations of SLE AND has tried at least one other therapy (e.g., antidepressant, antipsychotic, corticosteroids, immunosuppressant, or plasma exchange) OR
- Has lupus nephritis AND has tried at least one immunosuppressant (e.g., mycophenolate mofetil, cyclophosphamide, azathioprine)

For a re-authorization:

- At least 6 months have elapsed since last Rituxan treatment course

Approval duration (initial and renewal): 1 month

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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 induction dose is 375 mg/m^2 intravenously once weekly for 4 weeks. The follow up dose is two 500 mg intravenous infusions separated by 2 weeks, followed by a 500 mg intravenous infusion every 6 months thereafter based on clinical evaluation.

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.

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