

Rituximab (Rituxan[®], Ruxience[®], Truxima[®], Riabni[™])

When requesting a rituximab product (Rituxan[®], Ruxience[®], Truxima[®], Riabni[™]) 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

Rituximab products are indicated for the treatment of:

- Moderately to severely active rheumatoid arthritis
- Granulomatosis with polyangiitis (GPA) [Wegener's granulomatosis]
- Microscopic polyangiitis (MPA)
- Moderate to severe pemphigus vulgaris

Approved Non-oncology Off-label Compendial Uses

- Immune thrombocytopenia (ITP)
- Multiple sclerosis (MS)
- Neuromyelitis optica (NMO) spectrum disorder
- Systemic lupus erythematosus (SLE)
- Graft-versus-host disease (GVHD)

Coverage Guidelines

The individual must meet the following criteria for select indications:

Rheumatoid arthritis

The individual must meet **all** of the following criteria for initial authorization:

- Had a 3-month trial of at least one biologic agent OR at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine);
- Rituximab will not be used concurrently with another biologic or with a targeted synthetic DMARD;
- Rituximab is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- At least 16 weeks will have elapsed between treatment courses;
- Rituximab will not be used concurrently with another biologic or with a targeted synthetic DMARD;
- For an individual who has received at least 2 courses of rituximab therapy, the individual must have experienced an improvement in at least one symptom (e.g.,

decreased joint pain, morning stiffness; improved function or activities of daily living)
OR experienced an improvement in at least one objective measure (e.g., Clinical Disease Activity Index, Simplified Disease Activity Index, Patient Activity Scale-II, Rapid Assessment of Patient Index Data 3, etc.)

Approval duration (initial and renewal): 1 month

Pemphigus vulgaris

The individual must meet **all** of the following criteria for initial authorization:

- Rituximab is being initiated in combination with a corticosteroid, unless contraindicated;
- Rituximab is prescribed by or in consultation with a dermatologist.

The individual must meet **all** of the following criteria for reauthorization:

- At least 16 weeks will have elapsed between treatment course;
- Rituximab 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)

The individual must meet **all** of the following criteria for initial authorization (*for induction treatment*):

- Rituximab will be used in combination with glucocorticoids;
- Rituximab is prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist.

The individual must meet **all** of the following criteria for reauthorization (*for follow up-treatment*):

- Has received induction treatment using a rituximab product or other standard of care immunosuppressants;
- Has achieved disease control with induction treatment;
- For an individual who has previously received a course of rituximab therapy, at least 16 weeks will have elapsed between treatment courses.

Approval duration (initial): 1 month

Approval duration (renewal): 12 months

Immune thrombocytopenia

The individual must meet **all** of the following criteria for initial authorization:

- Has tried at least one other therapy (e.g., intravenous immunoglobulin, corticosteroids, splenectomy);

- Rituximab is prescribed by or in consultation with a hematologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has responded to previous rituximab therapy (e.g., increased platelet counts);
- Has relapsed (e.g., experienced thrombocytopenia after achievement of a remission);
- At least 6 months will have elapsed between treatment courses.

Approval duration (initial and renewal): 1 month

Multiple sclerosis (MS)

The individual must meet **all** of the following criteria for initial authorization:

- Had an inadequate response or intolerance to at least TWO other disease-modifying agent used for MS;
- Rituximab will not be used concurrently with another disease-modifying agent used for MS;
- Rituximab is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS;

The individual must meet **all** of the following criteria for reauthorization:

- Rituximab will not be used concurrently with another disease-modifying agent used for MS;
- Rituximab is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS;
- At least 6 months will have elapsed between treatment courses;
- For an individual who has received rituximab for 12 months or more, the individual has experienced stabilization, slow progression, or improvement in at least one symptom (e.g., motor function, vision, spasticity, pain/numbness/tingling sensation) OR has experienced an improvement in at least one objective measure (e.g., stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging [MRI], stabilization or reduced worsening on the Expanded Disability Status Scale [EDSS] score, reduction or absence of relapses, improvement or maintenance on the 6-minute walk test, etc.)

Approval duration (initial and renewal): 12 months

Neuromyelitis optica spectrum disorder

Rituximab is prescribed by or in consultation with a neurologist.

Approval duration: 1 month

Graft-versus-host disease (GVHD)

The individual must meet **all** of the following criteria for initial authorization:

- Has tried at least one conventional systemic treatment (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, Imbruvica, imatinib, antithymocyte globulin, or Nipent);
- Rituximab is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

The individual must meet **all** the following criteria for reauthorization:

- Has experienced an improvement in at least one symptom compared with baseline (e.g., improvement in skin, oral mucosal, ocular or gastrointestinal symptoms) OR has experienced an improvement in at least one objective measure compared with baseline (e.g., normalization of liver function tests, red blood cell count, or platelet count, or resolution of fever or rash)

Approval duration (initial): 1 month

Approval duration (renewal): 12 months

Systemic lupus erythematosus (SLE)

The individual must meet **all** of the following criteria for initial authorization:

- Has tried at least one standard immunomodulating or immunosuppressant agent (e.g., hydroxychloroquine, corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, or cyclophosphamide);
- Rituximab is prescribed by or in consultation with a rheumatologist, nephrologist, or neurologist.

For reauthorization, at least 6 months will have elapsed between treatment courses.

Approval duration (initial and renewal): 1 month

Dosing Recommendations

Rheumatoid arthritis

The recommended dose is two-1000 mg intravenous infusion separated by 2 weeks.

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

For adult patients:

The recommended induction dose is 375 mg/m² intravenous infusion once weekly for 4 weeks. The recommended follow-up dose is two-500 mg intravenous infusions separated by two weeks, followed by a 500 mg intravenous infusion every 6 months thereafter based on clinical evaluation. Initiate follow-up treatment no sooner than 16 weeks after the last induction infusion.

For pediatric patients:

The recommended induction dose is 375 mg/m² intravenous infusion once weekly for 4 weeks. The recommended follow-up dose is two-250 mg/m² intravenous infusions separated by two weeks, followed by a 250 mg/m² intravenous infusion every 6 months thereafter based on clinical evaluation. Initiate follow-up treatment no sooner than 16 weeks after the last induction infusion.

Pemphigus vulgaris

The recommended dose is two 1,000 mg intravenous infusions separated by 2 weeks. The recommended maintenance dose is 500 mg intravenous infusion at Month 12 and every 6 months thereafter or based on clinical evaluation. The recommended dose for relapse is 1000 mg intravenous infusion on relapse, and consider resuming or increasing the glucocorticoid dose based on clinical evaluation.

Neuromyelitis optica (NMO) spectrum disorder

The recommended dose is 375 mg/m² administered intravenously once a week for 4 weeks OR two-1,000 mg doses administered as an intravenous infusion separated by at least 2 weeks.

Multiple sclerosis

The recommended dose is up to 2000 mg (total) administered as one or two intravenous infusion administered over 1 month.

Immune thrombocytopenia (ITP)/Graft-versus-host disease (GVHD)

The recommended dose is 375 mg/m² administered intravenously once a week for 4 weeks.

References

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