

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
- Had a 3-month trial of at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine); AND
- The medication will not be used concurrently with another biologic or with a targeted synthetic DMARD; AND
- The medication 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 elapse between treatment courses (e.g., a minimum of 16 weeks will separate the first dose of the previous course and the first dose of the next course of a rituximab product); AND
- For an individual who has received at least 2 courses of rituximab therapy, the individual must have responded to rituximab therapy (e.g., less joint pain, less morning stiffness, improved function, decreased soft tissue swelling in joints, etc.).

Approval duration (initial and renewal): 1 month

Pemphigus vulgaris

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

- Therapy is initiated in combination with a corticosteroid, unless contraindicated; AND
- The rituximab product is prescribed by or in consultation with a dermatologist.

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

- At least 16 weeks have elapsed since the previous infusion of a rituximab product; AND
- The rituximab product 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:

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

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

- Has achieved disease control with induction treatment (e.g., induction treatment using a rituximab product or other standard of care immunosuppressants); AND
- For an individual who has received a course of rituximab for induction treatment, at least 16 weeks have elapsed since last rituximab treatment course.

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 previous therapy (e.g., intravenous immunoglobulin, corticosteroids, splenectomy); AND
- The medication is prescribed by or in consultation with a hematologist.

The individual must meet the following criteria for reauthorization:

- Has responded to therapy with a rituximab product (e.g., increased platelet counts);
- Has relapsed (e.g., experienced thrombocytopenia after achievement of a remission); AND
- At least 6 months will elapse between treatment courses (e.g., a minimum of 6 months will separate the first dose of the previous course and the first dose of the requested course of a rituximab product).

Approval duration (initial and renewal): 1 month

Multiple sclerosis (MS)

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

- Had an inadequate response or intolerance to at least ONE other disease-modifying agent used for MS;
- The rituximab product will not be used concurrently with another disease-modifying agent;
- The rituximab product is prescribed by or in consultation with a physician who specializes in the treatment of MS and/or a neurologist; AND
- At least 6 months will elapse between treatment courses (e.g., a minimum of 6 months will separate the first dose of the previous course and the first dose of the subsequent course of therapy).

Approval duration: 12 months

Neuromyelitis optica spectrum disorder

The rituximab product 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 authorization:

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

Approval duration: 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); AND
- The rituximab product is prescribed by or in consultation with a rheumatologist, nephrologist, or neurologist.

For reauthorization, at least 6 months will elapse between treatment courses (e.g., a minimum of 6 months will separate the first dose of the previous course and the first dose of the requested course of therapy).

Approval duration (initial and renewal): 1 month

Dosing Recommendations

Rheumatoid arthritis

Approve one course of therapy, which consists of up to two 1,000 mg intravenous doses separated by at least 2 weeks.

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

The recommended induction dose is 375 mg/m² administered intravenously no more frequently than once weekly. The follow-up dose is two 500 mg intravenous infusions separated by 2 weeks, followed by a 1,000 mg intravenous infusion no more frequently than once every 6 months.

Pemphigus vulgaris

The recommended dose is two 1,000 mg intravenous infusions separated by 2 weeks (one course) for initial treatment or treatment of relapse. For maintenance therapy, approve up to 500 mg per dose administered intravenously.

Neuromyelitis optica (NMO) spectrum disorder

Each single dose must not exceed 375 mg/m² administered as an intravenous infusion not more frequently than once weekly OR up to two 1,000 mg doses administered as an intravenous infusion separated by at least 2 weeks.

Multiple sclerosis

Each course is up to 2,000 mg (total) and each course is administered as one or two intravenous infusions over 1 month

Immune thrombocytopenia (ITP)

Approve up to 375 mg/m² administered intravenously with doses separated by at least 7 days.

Graft-versus-host disease (GVHD)

Each single dose must not exceed 375 mg/m² administered as an intravenous infusion with doses separated by at least 7 days.

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