

Rituximab Intravenous Products

When requesting a rituximab product (Rituxan®, Ruxience®, Truxima®, Riabni™) for non-oncology indications, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or one of the following off-label compendial uses 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)
- Autoimmune hemolytic anemia
- Interstitial lung disease associated with systemic autoimmune rheumatic disease
- Membranous nephropathy
- Minimal change disease
- Myasthenia gravis
- Pediatric nephrotic syndrome
- Solid organ transplantation
- Thrombotic thrombocytopenic purpura

Coverage Guidelines

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 the following criteria for reauthorization if they have received one course of rituximab therapy:

- 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.

The individual must meet the following criteria for reauthorization if they have received two or more courses of rituximab therapy:

- Subsequent infusions will be administered no sooner than 16 weeks following the previous infusion of a rituximab product;
- Rituximab will not be used concurrently with another biologic or with a targeted synthetic DMARD;
- 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 both 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 both of the following criteria for reauthorization:

- At least 16 weeks will have elapsed between treatment courses;
Note: For example, there will be a minimum of 16 weeks since the first dose of the previous course and the first dose of the next course of a rituximab product.
- Rituximab is prescribed by or in consultation with a dermatologist.

Approval duration (initial and renewal): 1 month

Antineutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis

Note: Examples of ANCA-associated vasculitis include granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA)

The individual must meet both 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, pulmonologist, 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;
- At least 16 weeks will have elapsed between treatment courses.

Approval duration (initial): 1 month

Approval duration (renewal): 12 months

Immune thrombocytopenia (ITP)

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

- Has tried at least one other therapy;
Note: Examples of therapies for ITP include intravenous immunoglobulin, corticosteroids, anti-D (RHO) immunoglobulin, Alvaiz (eltrombopag), Doptelet (avatrombopag), Nplate (romiplostim), Promacta (eltrombopag), Tavalisse (fostamatinib) and 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.
Note: For example, there will be a minimum of 6 months separating 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 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, 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

The individual must meet the following criterion for authorization:

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

Approval duration: 1 month

Graft-versus-host disease (GVHD)

The individual must meet the following criteria for initial authorization:

- Has chronic graft-versus host disease;
- Has tried at least one systemic treatment;
Note: Examples of systemic medications include corticosteroids (methylprednisolone, prednisone), Jakafi (ruxolitinib), Rezurock (belumosudil), Niktimvo (axatilimab-csfr), cyclosporine, tacrolimus, mycophenolate mofetil, Imbruvica (ibrutinib), imatinib, hydroxychloroquine, methotrexate, Nipent (pentostatin), interleukin-2 (Proleukin), sirolimus, or an etanercept product.
- Rituximab is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

The individual must meet the following criterion 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 both 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.

The individual must meet the following criterion for reauthorization:

- At least 6 months will have elapsed between treatment courses.

Approval duration (initial and renewal): 1 month

Autoimmune hemolytic anemia

The individual must meet the following for authorization:

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

Approval duration: 1 month

Interstitial lung disease associated with systemic autoimmune rheumatic disease

Note: Examples of systemic autoimmune rheumatic diseases include systemic sclerosis, myositis, mixed connective tissue disease, rheumatoid arthritis, and Sjogren's disease.

The individual must meet the following criteria for initial authorization:

- Individual is at least 18 years of age or older;
- Diagnosis is confirmed by high-resolution computed tomography;
- Rituximab is prescribed by or in consultation with a pulmonologist or a rheumatologist.

The individual must meet the following criteria for re-authorization:

- At least 24 weeks will have elapsed between treatment courses;
Note: There should be a minimum of 24 weeks from the first dose of the previous course and the first dose of the next course of rituximab.
- Has experienced a beneficial response to therapy with rituximab;
Note: Examples of a beneficial response include a reduction in the anticipated decline in forced vital capacity, improvement in 6-minute walk distance, and/or reduction in the number or severity of disease-related exacerbations.
- Rituximab is prescribed by or in consultation with a pulmonologist or a rheumatologist.

Approval duration (initial and renewal): 1 month

Membranous nephropathy

The individual must meet the following for initial authorization:

- Individual is at moderate or high risk for the progressive loss of kidney function;
- Rituximab is prescribed by or in consultation with a nephrologist.

The individual must meet the following for re-authorization:

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

Approval duration (initial and renewal): 1 month

Minimal change disease

The individual must meet the following criteria for initial authorization:

- Rituximab is being used for frequently relapsing or steroid-dependent disease;
- Rituximab is prescribed by or in consultation with a nephrologist.

The individual must meet the following criteria for re-authorization:

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

Approval duration (initial and renewal): 1 month

Myasthenia gravis

The individual must meet the following criteria for initial authorization:

- Has confirmed anti-muscle-specific tyrosine kinase antibody-positive myasthenia gravis;
- Has previously received or is currently receiving pyridostigmine OR has had inadequate efficacy, contraindication, or significant intolerance to pyridostigmine;
- Has tried at least one immunosuppressant therapy;
Note: Examples of immunosuppressant therapies include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus, cyclophosphamide, Imaavy (nipocalimab-aahu), and Rystiggo (rozanolixizumab-noli).
- Has evidence of unresolved symptoms of myasthenia gravis;
Note: evidence of unresolved symptoms of myasthenia gravis includes difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, trouble talking, impairment of mobility).

The individual must meet the following criteria for reauthorization:

- Individual is continuing to derive benefit from the rituximab product;
- Rituximab is prescribed by or in consultation with a neurologist.

Approval duration (initial and renewal): 6 months

Pediatric nephrotic syndrome

The individual must meet the following criteria for initial authorization:

- Individual is 18 years of age or less;
- Rituximab is prescribed by or in consultation with a nephrologist;
- Has tried at least one systemic corticosteroid OR has tried at least one glucocorticoid-sparing agent for nephrotic syndrome (e.g., tacrolimus, cyclosporine, cyclophosphamide, or mycophenolate mofetil).

The individual must meet the following criteria for reauthorization:

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

Approval duration (initial and renewal): 1 month

Solid organ transplantation

The individual must meet the following criteria for authorization:

- Rituximab is prescribed by or in consultation with a physician affiliated with a transplant center;
- Rituximab will be used for antibody-mediated rejection OR be used as desensitization therapy prior to or immediately after transplantation.

Approval duration: 1 year

Thrombotic thrombocytopenic purpura

The individual must meet the following criteria for authorization:

- Rituximab will be used in combination with systemic corticosteroids;
- Rituximab will be used in combination with therapeutic plasma exchange;
- Rituximab is prescribed by or in consultation with a hematologist.

Approval duration: 1 month

Dosing Recommendations

Rheumatoid arthritis

The recommended dose is two 1,000 mg intravenous infusion separated by at least 2 weeks.

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

For adult patients:

The recommended induction dose can be one of the following:

375 mg/m² intravenous infusion once weekly for 4 weeks separated by at least 7 days;

Up to 1,000 mg intravenous doses separated by at least 2 weeks.

The recommended follow-up dose is 1,000 mg intravenous infusion for 6 doses.

For pediatric patients:

The recommended induction dose can be one of the following:

375 mg/m² intravenous infusion once weekly for 4 weeks separated by at least 7 days;

Up to 1,000 mg intravenous doses separated by at least 2 weeks.

The recommended follow-up dose is 250 mg/ m² administered by intravenous infusion for 2 doses.

Pemphigus vulgaris

The recommended dose for initial treatment or treatment of relapse is two 1,000 mg doses administered as an intravenous infusions separated by 2 weeks.

The recommended maintenance dose is 500 mg administered as an intravenous infusion every 6 months.

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 2,000 mg (total) administered as one or two intravenous infusions 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.

Graft-Versus-Host Disease

The recommended dose is 375 mg/m² administered intravenously with doses separated by at least 7 days.

Hematopoietic cell transplantation

The recommended dose is 375 mg/m² administered intravenously before transplant and three doses of 1,000 mg/m² administered intravenously separated by at least 7 days after the transplant.

Interstitial lung disease associated with systemic autoimmune rheumatic disease

The recommended dose is up to two 1,000 mg intravenous doses separated by at least 2 weeks.

Membranous nephropathy

The recommended dose can be one of the following:

1,000 mg administered intravenously for 2 doses separated by at least 14 days;

375 mg/m² administered intravenously for up to 4 doses separated by at least 7 days;

Minimal change disease

The recommended dose can be one of the following:

- 1,000 mg administered intravenously for 2 doses separated by at least 14 days;
- 375 mg/m² administered intravenously for up to 4 doses separated by at least 7 days;

Myasthenia gravis

The recommended dose can be one of the following:

- 1,000 mg administered intravenously for 2 doses separated by at least 14 days;
- 375 mg/m² administered intravenously for up to 4 doses separated by at least 7 days;
- 750 mg/m² administered intravenously for 2 doses separated by at least 14 days.

Pediatric nephrotic syndrome

The recommended dose is 375 mg/m² administered intravenously for up to 4 doses separated by at least 7 days.

Solid organ transplantation

Dosing is based on transplant center's protocol

Thrombotic thrombocytopenic purpura

The recommended dose is 375 mg/m² administered intravenously for up to 4 doses separated by at least 7 days.

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