UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Rituximab Intravenous Products Utilization Management Medical Policy
- Riabni™ (rituximab-arrx intravenous infusion – Amgen)
- Rituxan® (rituximab intravenous infusion – Genentech)
- Ruxience® (rituximab-pvvr intravenous infusion – Pfizer)
- Truxima® (rituximab-abbs intravenous infusion – Celltrion/Teva)

REVIEW DATE: 08/26/2026; selected revision 09/16/2026

OVERVIEW

Rituximab products are CD20-directed cytolytic antibodies. All approved rituximab intravenous products are indicated for treatment of the following conditions:[1-3,22]

- **Chronic lymphocytic leukemia** (CLL), in combination with fludarabine and cyclophosphamide (FC) for the treatment of patients with previously untreated and previously treated CD20-positive disease.
- **Granulomatosis with polyangiitis** (Wegener's granulomatosis) and **microscopic polyangiitis** in adults, in combination with glucocorticoids.
- **Non-Hodgkin lymphoma** (NHL), for the following uses:
  - previously untreated follicular, CD20-positive disease, in combination with first-line chemotherapy, and in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as a single-agent maintenance therapy.
  - for relapsed or refractory, low-grade or follicular, CD20-positive, B-cell disease.
  - for non-progressing (including stable disease) low-grade, CD20-positive, B-cell disease as a single agent after first-line cyclophosphamide/vincristine/prednisone (CVP) chemotherapy.
  - for previously untreated diffuse large B-cell, CD20-positive disease, in combination with cyclophosphamide/doxorubicin/vincristine/prednisone (CHOP) or other anthracycline-based chemotherapy regimens.
- **Pemphigus vulgaris**, for adults with moderate to severe disease.
- **Rheumatoid arthritis**, in adult patients with moderately to severely active disease, in combination with methotrexate for patients who have had an inadequate response to one or more tumor necrosis factor inhibitors.

In addition to the above indications, Rituxan intravenous is also indicated for treatment of the following conditions:[1]

- **Granulomatosis with polyangiitis** (Wegener's granulomatosis) and **microscopic polyangiitis** in patients ≥ 2 years of age, in combination with glucocorticoids.
- **B-cell lymphoma,** in patients ≥ 6 months of age with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia in combination with chemotherapy.

Riabni, Ruxience, and Truxima are approved as biosimilars to Rituxan intravenous, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Rituxan intravenous. However, minor differences in clinically inactive components are allowed. At this time, biosimilars have not demonstrated interchangeability.

Guidelines

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The use of rituximab is supported in clinical guidelines in numerous situations, both as first-line therapy and in patients who have refractory disease or have relapsed following treatment with other therapies.[4-21]

- **Antineutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis:** Guidelines from the American College of Rheumatology (ACR) [2021] list rituximab among the alternatives for induction or maintenance of remission.
- **Autoimmune Hemolytic Anemia (AIHA):** AIHA is divided serologically into warm type (65% of cases), cold type (29% of cases are cold hemagglutinin disease [CHAD]), paroxysmal cold hemoglobinuria (1% of cases), or mixed AIHA (5% of cases).[30] For primary warm AIHA, prednisolone is recommended first-line by the British Society for Haematology (BSH) with rituximab as second-line if no response or if patient relapses. For CHAD, rituximab is considered a first-line therapy. Mixed AIHA is treated as warm AIHA. Supportive care is recommended for paroxysmal cold hemoglobinuria.
- **Immune Thrombocytopenia (ITP):** Guidelines from the American Society of Hematology for ITP (2019) mention rituximab as an alternative for children and adults with ITP who do not respond to first-line treatment, and for adults who are corticosteroid-dependent.[17]
- **Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitors:** NCCN (version 1.2026 – October 23, 2025) and the American Society of Clinical Oncology guidelines (2021) recommend rituximab as an option for corticosteroid-refractory dermatologic and hematologic immune mediated adverse events, as well as for myasthenia gravis, immune-mediated encephalitis, myositis, and stage 3 acute kidney injury/elevated serum creatinine.[26,27]
- **Interstitial Lung Disease Associated with Systemic Autoimmune Rheumatic Disease (SARD-ILD):** The American College of Rheumatology (ACR) and the American College of Chest Physicians (CHEST) [2023] conditionally recommend rituximab as a first-line ILD treatment option for adults with SARD-ILD.[48] Other first-line options include mycophenolate, azathioprine, and cyclophosphamide. In addition, rituximab is conditionally recommended for people with SARD-ILD progression despite first ILD treatment. Rituximab is also conditionally recommended for people with SARD and rapidly progressive ILD as a first-line treatment option. Other first-line treatment options include cyclophosphamide, intravenous immune globulin, mycophenolate, a calcineurin inhibitor, and Janus kinases inhibitors.
- **Lupus Nephritis:** European League Against Rheumatism recommendations for systemic lupus erythematosus with kidney involvement (2025), the Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guideline for the management of lupus nephritis (2024) and ACR guidelines for screening, treatment and management of lupus nephritis (2024) mention rituximab as a treatment option for patients who are refractory to standard immunosuppressive therapies.[21, 52-54]
- **Membranous Nephropathy:** KDIGO Clinical Practice Guideline for the Management of Glomerular Diseases (2021) list rituximab as a therapeutic option for membranous nephropathy in patients at moderate risk or high risk for progressive loss of kidney function.[31] In patients who relapse, initial therapy can be repeated or treatment may be switched to rituximab if the initial treatment was a calcineurin inhibitor or cyclophosphamide.
- **Minimal Change Disease (MCD):** The KDIGO Clinical Practice Guideline for the Management of Glomerular Diseases (2021) list rituximab as a therapeutic option for adults with frequently relapsing or steroid-dependent MCD.[31]
- **Multiple Sclerosis (MS):** In June 2019, a consensus paper was updated by the MS Coalition that discusses the use of disease-modifying therapies in MS.[18] Rituximab is listed among various options, involving different mechanisms of action and modes of administration, which have shown benefits in patients with MS. The American Academy of Neurology has practice guidelines regarding disease-modifying therapies for adults with MS.[19] The guidelines mention rituximab for use in MS.

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- **Myasthenia Gravis (MG):** An international consensus guidance for the management of MG was published in 2016.[35] The consensus guidance recommends pyridostigmine for the initial treatment in most patients with MG. The ability to discontinue pyridostigmine can indicate that the patient has met treatment goals and may guide the tapering of other therapies. Corticosteroids or immunosuppressant therapy should be used in all patients with MG who have not met treatment goals after an adequate trial of pyridostigmine. Nonsteroidal immunosuppressant agents used in MG include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, and tacrolimus. It is usually necessary to maintain some immunosuppression for many years, sometimes for life. Plasma exchange and intravenous immunoglobulin can be used as short-term treatments for certain patients. An update to an international consensus guidance for the management of MG was published in 2020.[36] Rituximab should be considered as an early therapeutic option in patients with muscle specific kinase antibody-positive MG who have an unsatisfactory response to initial immunotherapy. While the efficacy of rituximab in acetylcholine receptor antibody-positive MG is uncertain, it is an option if patients fail or do not tolerate other immunosuppressive agents.
- **Neuromyelitis Optica Spectrum Disorders (NMOSD):** The Neuromyelitis Optica Study Group (NEMOS) published revised recommendations for the treatment of NMOSD in 2023 and recommend rituximab as a treatment option for aquaporin-4 (AQP4)-immunoglobulin G (IgG) positive NMOSD and double-negative NMOSD.[20]
- **Oncology indications**: The use of Rituximab is recommended across multiple National Comprehensive Cancer Network (NCCN) guidelines and the NCCN Compendium.[6-15, 24-26, 28-29, 50] Recommendations with a category of evidence of 2B or higher support the approval criteria outlined below.
- **Pediatric Nephrotic Syndrome:** The KDIGO Clinical Practice Guideline for the Management of Nephrotic Syndrome in Children (2025) recommends rituximab as a treatment option for steroid-sensitive nephrotic syndrome in children who have frequent relapses despite optimal combinations of prednisone and glucocorticoid-sparing oral agents.[32] For steroid-resistant nephrotic syndrome, KDIGO recommends cyclosporine or tacrolimus as initial second-line therapy. A potential role was suggested for the use of rituximab in patients with calcineurin inhibitor-resistant, steroid-resistant nephrotic syndrome.
- **Pemphigus Vulgaris:** British guidelines (2017) list rituximab in combination with corticosteroids as a first-line therapy.[23]
- **Rheumatoid Arthritis:** Guidelines from ACR (2021) recommend the addition of a biologic (which includes rituximab) or a targeted synthetic disease modifying antirheumatic drug (DMARD) for a patient taking the maximum tolerated dose of methotrexate who is not at target.[16]
- **Solid Organ Transplantation:** Various transplant center protocols and clinical practice guidelines discuss the use of rituximab for highly sensitized patients as part of desensitization protocols and for acute antibody-mediated rejection following transplantation.[37-44]
- **Systemic Lupus Erythematosus (SLE):** EULAR recommendations for the management of SLE (2025) and ACR Guidelines for the Treatment of SLE (2025) mention rituximab as a therapeutic option for patients who are refractory to standard immunosuppressive therapies.[21, 51]
- **Thrombotic Thrombocytopenic Purpura (TTP):** The International Society on Thrombosis and Haemostasis (ISTH) [2025] recommends the addition of rituximab to corticosteroids and therapeutic plasma exchange for patients experiencing their first acute event or relapses of immune-mediated TTP.[33-34] This is a conditional recommendation in the context of very low certainty of evidence.

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Clinical Efficacy

- **Gene Therapy Pretreatment:** Waskyra (etuvetidigene autotemcel) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of pediatric patients ≥ 6 months of age and adults with Wiskott-Aldrich Syndrome (WAS) who have a mutation in the WAS gene for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available.[49] Prior to infusion of Waskyra, patients undergo an extensive preparation process including mobilization/apheresis procedures, pretreatment and conditioning, and premedication. In the clinical studies, during the pre-treatment and conditioning phase, patients received rituximab and a conditioning regimen with busulfan and fludarabine. Rituximab was administered as a single dose of 375 mg/m² approximately 22 days before Waskyra administration to deplete autoreactive B-cells and provide pre-emptive treatment for potential lymphoproliferative disorder due to Epstein Barr Virus infection which is a risk factor in WAS patients.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of rituximab IV products. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with rituximab products as well as the monitoring required for adverse events and long-term efficacy, initial approval requires rituximab to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of rituximab intravenous products is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Antineutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   Note: Examples of ANCA-associated vasculitis include granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis.
   - **A)** Induction Therapy. Approve for 1 month if the patient meets BOTH of the following (i and ii):
     - **i.** The medication is being administered in combination with glucocorticoids; AND
     - **ii.** The medication is prescribed by or in consultation with a rheumatologist, nephrologist, pulmonologist, or immunologist; OR
   - **B)** Follow-Up Treatment of a Patient Who Has Received Induction Therapy. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     Note: This includes a patient who received induction treatment using a rituximab product or other standard of care immunosuppressants.
     - **i.** According to the prescriber, the patient achieved disease control with induction treatment; AND

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ii. If the patient previously received a course of therapy, at least 16 weeks will elapse between courses.

Dosing. Approve ONE of the following (A or B):

A) Induction Therapy. Approve ONE of the following (i or ii):
- **A)** 375 mg/m^2 per dose administered intravenously for 4 doses separated by at least 7 days; OR
- **B)** Up to two 1,000 mg intravenous doses separated by at least 2 weeks; OR

B) Follow-Up Treatment of a Patient Who Has Received Induction Therapy. Approve ONE of the following (i or ii):
- **i.** ≥ 18 years of age: Up to 1,000 mg administered by intravenous infusion for 6 doses; OR
- **ii.** < 18 Years of age: Up to 250 mg/m^2 administered by intravenous infusion for 2 doses.

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2. B-Cell Lymphoma. Approve for 1 year if prescribed by or in consultation with an oncologist or hematologist.

Note: Examples of B-cell lymphomas include Burkitt lymphoma, classic follicular lymphoma, diffuse large B-cell lymphoma, extranodal marginal zone lymphoma of non-gastric sites (non-cutaneous), extranodal marginal zone lymphoma of the stomach, high-grade B-cell lymphoma, histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma, lymphoblastic lymphoma, mantle cell lymphoma, nodal marginal zone lymphoma, post-transplant lymphoproliferative disorders, primary mediastinal large B-cell lymphoma, and splenic marginal zone lymphoma.

Dosing. Approve ONE of the following regimens (A or B):

A) Approve up to 500 mg/m^2 per dose administered intravenously with doses separated by at least 7 days; OR

B) Approve up to 500 mg/m^2 on two days of each cycle.

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3. Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma. Approve for 1 year if prescribed by or in consultation with an oncologist or hematologist.

Dosing. Approve up to 500 mg/m^2 administered as an intravenous infusion on 1 day of each cycle.

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4. Pemphigus Vulgaris. Approve for the duration noted if the patient meets ONE of the following (A, B, or C):

A) Initial Therapy. Approve for 1 month (which is adequate duration to administer one course of therapy) if the patient meets BOTH of the following (i and ii):
- **i.** Therapy is initiated in combination with a systemic corticosteroid unless contraindicated; AND
  Note: An example of a systemic corticosteroid is prednisone.
- **ii.** The medication is prescribed by or in consultation with a dermatologist; OR

B) Patient is Being Treated for a Relapse of Pemphigus Vulgaris. Approve for 1 month (which is adequate duration to administer one course of therapy) if the patient meets BOTH of the following (i and ii):
- **i.** Subsequent infusions will be administered no sooner than 16 weeks following the previous infusion of a rituximab product; AND
  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.
- **ii.** The medication is prescribed by or in consultation with a dermatologist; OR

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C) Patient is Being Treated for Maintenance of Pemphigus Vulgaris. Approve for 1 year if the patient meets BOTH of the following (i and ii):
- **i.** Subsequent infusions will be administered no sooner than 16 weeks following the previous infusion of a rituximab product; AND
  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.
- **ii.** The medication is prescribed by or in consultation with a dermatologist.

Dosing. Approve ONE of the following (A or B):

A) Initial Therapy or Treatment of a Relapse. Approve one course of therapy, which consists of up to two 1,000 mg doses administered as an intravenous infusion separated by at least 2 weeks; OR

B) Maintenance Therapy. Approve up to 500 mg per dose administered intravenously every 6 months.

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5. Rheumatoid Arthritis. Approve for the duration noted if the patient meets ONE of the following (A, B, or C):

A) Initial Therapy. Approve for 1 month (which is adequate duration to administer one course of therapy) if the patient meets ALL of the following (i, ii, and iii):
- **i.** Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND
  Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient already has a 3-month trial of at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix A for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic is not required to "step back" and try a conventional synthetic DMARD.
- **ii.** The medication will not be used concurrently with another biologic or with a targeted synthetic DMARD; AND
  Note: Refer to Appendix A for examples of biologics and targeted synthetic DMARDs.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist; OR

B) Patient Has Already Received One Course of a Rituximab Product. Approve for 1 month (which is adequate duration to administer one course of therapy) if the patient meets BOTH of the following (i and ii):
- **i.** 16 weeks or greater will elapse between treatment courses; AND
  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.
- **ii.** The medication will not be used concurrently with another biologic or with a targeted synthetic DMARD; OR
  Note: Refer to Appendix A for examples of biologics and targeted synthetic DMARDs.

C) Patient Has Already Received Two or More Courses of a Rituximab Product. Approve for 1 month (which is adequate duration to administer one course of therapy) if the patient meets ALL of the following (i, ii, and iii):
- **i.** 16 weeks or greater will elapse between treatment courses; AND
  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.
- **ii.** The medication will not be used concurrently with another biologic or with a targeted synthetic DMARD; AND
  Note: Refer to Appendix A for examples of biologics and targeted synthetic DMARDs.
- **iii.** Patient meets at least ONE of the following (a or b):

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a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
b) Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

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

Other Uses with Supportive Evidence

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6. Acute Lymphoblastic Leukemia. Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient has CD20-positive disease; AND
B) The medication is prescribed by or in consultation with an oncologist or hematologist.

Dosing. Approve up to 375 mg/m^2 administered intravenously with doses separated by at least 7 days.

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7. Autoimmune Hemolytic Anemia. Approve for 1 month if the medication is prescribed by or in consultation with a hematologist.

Dosing. Approve one course of therapy (4 doses), which consists of ONE the following (A or B):
A) 375 mg/m^2 administered intravenously with doses separated by at least 7 days; OR
B) 100 mg administered intravenously with doses separated by at least 7 days.

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8. Castleman Disease. Approve for 1 year if prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following regimens (A or B):
A) Approve up to 375 mg/m^2 per dose administered intravenously with doses separated by at least 7 days; OR
B) Approve up to 375 mg/m^2 on two days of each cycle.

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9. Central Nervous System Lymphoma. Approve for 1 year if patient meets BOTH of the following (A and B):
A) Patient meets ONE of the following (i or ii):
i. Patient has primary central nervous system lymphoma; OR
ii. Patient has leptomeningeal metastases; AND
B) The medication is prescribed by or in consultation with an oncologist or hematologist.

Dosing. Approve up to 375 mg/m^2 administered intravenously with doses separated by at least 7 days.

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10. Gene Therapy Pretreatment. Approve a single dose if the medication will be used as a pretreatment for gene therapy.

Dosing. Approve requested dose.

11. Graft-Versus-Host Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 1 month if the patient meets ALL of the following (i, ii, and iii):

i. Patient has chronic graft-versus-host disease; AND

ii. Patient has tried at least one systemic medication for graft versus host disease; AND
Note: Examples of systemic medications include systemic corticosteroids (methylprednisolone, prednisone), Jakafi (ruxolitinib), Rezurock (belumosudil), Niktimvo (axatilimab-csfr),Orencia (abatacept intravenous infusion), cyclosporine, tacrolimus, mycophenolate mofetil, Imbruvica (ibrutinib), imatinib, hydroxychloroquine, methotrexate, Nipent (pentostatin), interleukin-2 (e.g., Proleukin [aldesleukin]), sirolimus, an alemtuzumab product or an etanercept product.

iii. The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center; OR

B) Patient has Already Received a Course of a Rituximab Product. Approve for 1 year if the patient meets at least ONE of the following (i or ii):

i. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating a rituximab product); OR
Note: Examples of objective measures include normalization of liver function tests, red blood cell count, or platelet count; or resolution of fever or rash.

ii. Compared with baseline (prior to initiating a rituximab product), patient experienced an improvement in at least one symptom, such as improvement in skin, oral mucosal, ocular, or gastrointestinal symptoms (e.g., nausea, vomiting, anorexia).

Dosing. Approve up to 375 mg/m^2 administered intravenously with doses separated by at least 7 days.

12. Hairy Cell Leukemia. Approve for 1 year if the medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 375 mg/m^2 administered intravenously with doses separated by at least 7 days.

13. Hematopoietic Cell Transplantation. Approve for 1 month (which is adequate duration to administer one course of therapy) if the patient meets BOTH of the following (A and B):

A) The medication will be used as part of a conditioning regimen for allogeneic transplant; AND

B) The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

Dosing. Approve one course of therapy, which consists of one dose of 375 mg/m^2 administered intravenously before transplant and three doses of 1,000 mg/m^2 administered intravenously separated by at least 7 days after transplant.

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14. Hodgkin Lymphoma. Approve for 1 year if the patient meets BOTH of the following (A and B):
- **A)** Patient has nodular lymphocyte-predominant disease; AND
- **B)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 375 mg/m^2 administered intravenously with doses separated by at least 7 days.

15. Immune Thrombocytopenia (ITP). Approve for 1 month if the patient meets ONE of the following (A or B):
- **A)** Initial Therapy. Approve if the patient meets BOTH of the following (i and ii):
  - **i.** Patient has tried one other therapy; AND
    Note: Examples of therapies for ITP include intravenous immunoglobulin (IVIG), anti-D (RHO) immunoglobulin, corticosteroids, Alvaiz (eltrombopag), Doptelet (avatrombopag), Nplate (romiplostim), Promacta (eltrombopag), Tavalisse (fostamatinib), and splenectomy.
  - **ii.** The medication is prescribed by or in consultation with a hematologist; OR
- **B)** Patient has Already Received a Course of a Rituximab Product. Approve if the patient meets ALL of the following (i, ii, and iii):
  - **i.** At least 6 months will elapse between treatment courses; AND
    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.
  - **ii.** According to the prescriber, the patient responded to therapy; AND
    Note: Examples of response include a platelet count increase from baseline following treatment with a rituximab product.
  - **iii.** According to the prescriber, the patient has relapsed.
    Note: Examples of relapse include the patient experiences thrombocytopenia after achievement of a remission.

Dosing. Approve up to 375 mg/m^2 administered intravenously with doses separated by at least 7 days.

16. Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitors. Approve for 1 month if the patient meets ONE of the following (A or B):
- **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
  - **i.** According to the prescriber, patient developed an immunotherapy-related toxicity; AND
  - **ii.** Patient developed this immunotherapy-related toxicity while receiving a checkpoint inhibitor; AND
  - **iii.** Patient is symptomatic despite a trial of at least ONE systemic corticosteroid; AND
    Note: Examples of a systemic corticosteroid include methylprednisolone and prednisone.
  - **iv.** The medication is prescribed by or in consultation with an oncologist, hematologist, nephrologist, neurologist, rheumatologist, or dermatologist; OR
- **B)** Patient has Already Received a Course of a Rituximab Product. Approve if prescribed by or in consultation with an oncologist, hematologist, nephrologist, neurologist, rheumatologist, or dermatologist.

Dosing. Approve dosing that meets ONE of the following (A or B):
- **A)** Approve up to 500 mg/m^2 or up to 1,000 mg administered intravenously for 2 doses separated by at least 14 days; OR
- **B)** Approve up to 375 mg/m^2 administered intravenously for 4 doses separated by at least 7 days.

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17. Interstitial Lung Disease Associated with Systemic Autoimmune Rheumatic Disease. Approve for 1 month if the patient meets ONE of the following (A or B):
Note: Examples of systemic autoimmune rheumatic diseases include systemic sclerosis, myositis, mixed connective tissue disease, rheumatoid arthritis, and Sjögren's disease.

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Diagnosis is confirmed by high-resolution computed tomography; AND
- **iii.** The medication is prescribed by or in consultation with a pulmonologist or a rheumatologist; OR

B) Patient Has Already Received a Course of a Rituximab Product. Approve if the patient meets ALL of the following (i, ii, and iii):
- **i.** 24 weeks or greater will elapse between treatment courses; AND
  Note: For example, there will be a minimum of 24 weeks since the first dose of the previous course and the first dose of the next course of a rituximab product.
- **ii.** Patient has experienced a beneficial response to therapy with rituximab; AND
  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.
- **iii.** The medication is prescribed by or in consultation with a pulmonologist or a rheumatologist.

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

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18. Kaposi Sarcoma. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient has Kaposi sarcoma-associated herpesvirus (KSHV)-associated inflammatory cytokine syndrome; AND
Note: KSHV-associated inflammatory cytokine syndrome is also known as Kaposi sarcoma inflammatory cytokine syndrome (KICS).Patient has refractory/progressive disease;

B) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 375 mg/m^2 administered intravenously with doses separated by at least 7 days.

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19. Lupus Nephritis. Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):
- **i.** Diagnosis of lupus nephritis has been confirmed on biopsy; AND
  Note: For example, World Health Organization Class III, IV or V lupus nephritis.
- **ii.** The medication is being used concurrently with an immunosuppressive regimen; AND
  Note: Examples of an immunosuppressive regimen include azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil, and/or a systemic corticosteroid.
- **iii.** The medication is prescribed by or in consultation with a nephrologist or rheumatologist; OR

B) Patient Has Already Received a Course of Rituximab. Approve if the patient meets ALL of the following (i, ii, and iii):
- **i.** The medication is being used concurrently with an immunosuppressive regimen; AND
  Note: Examples of an immunosuppressive regimen include azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil, and/or a systemic corticosteroid.
- **ii.** The medication is prescribed by or in consultation with a nephrologist or rheumatologist; AND
- **iii.** According to the prescriber, patient has responded to the medication.

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Note: Examples of a response include improvement in organ dysfunction, reduction in flares, reduction in corticosteroid dose, decrease of anti-double-stranded DNA (anti-dsDNA) titer, and improvement in complement levels (i.e., C3, C4).

Dosing. Approve ONE of the following (A or B):
A) 375 mg/m^2 per dose administered intravenously for 4 doses separated by at least 7 days; OR
B) Up to two 1,000 mg intravenous doses separated by at least 2 weeks.

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20. Membranous Nephropathy. Approve for 1 year if the patient meets ONE of the following (A or B):
A) Initial Therapy. Approve if the patient meets BOTH of the following (i and ii):
i. According to the prescriber, the patient is at moderate risk or high risk for the progressive loss of kidney function; AND
ii. The medication is prescribed by or in consultation with a nephrologist; OR
B) Patient has Already Received a Course of a Rituximab Product. Approve if prescribed by or in consultation with a nephrologist.

Dosing. Approve dosing that meets ONE of the following (A or B):
A) Approve 1,000 mg administered intravenously for 2 doses separated by at least 14 days; OR
B) Approve 375 mg/m^2 administered intravenously for up to 4 doses separated by at least 7 days.

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21. Minimal Change Disease. Approve for 1 year if the patient meets ONE of the following (A or B):
A) Initial Therapy. Approve if the patient meets BOTH of the following (i and ii):
i. The medication is being used for frequently relapsing or steroid-dependent disease; AND
ii. The medication is prescribed by or in consultation with a nephrologist; OR
B) Patient Has Already Received a Course of a Rituximab Product. Approve if prescribed by or in consultation with a nephrologist.

Dosing. Approve dosing that meets ONE of the following (A or B):
A) Approve 1,000 mg administered intravenously for up to 2 doses separated by at least 14 days; OR
B) Approve 375 mg/m^2 administered intravenously for up to 4 doses separated by at least 7 days.

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22. Multiple Sclerosis. Approve for 1 year if the patient meets ONE of the following (A or B):
A) Initial Therapy. Approve if the patient meets ALL the following (i, ii, iii, and iv):
i. According to the prescriber, the patient has experienced inadequate efficacy or significant intolerance to at least TWO other disease-modifying agents for multiple sclerosis; AND
Note: See Appendix B for examples of disease-modifying agents used for multiple sclerosis.
ii. Medication will not be used concurrently with another disease-modifying agent used for multiple sclerosis; AND
Note: See Appendix B for examples of disease-modifying agents used for multiple sclerosis.
iii. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; AND
iv. At least 6 months will elapse between treatment courses; OR
Note: For example, if the patient has already received a course of therapy 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 therapy.
B) Patient is Currently Receiving Rituximab. Approve if the patient meets ONE of the following (i or ii):

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i. Patient Has Been Receiving Rituximab For < 1 year. Approve if the patient meets ALL of the following (a, b, and c):
- **a)** Medication will not be used concurrently with another disease-modifying agent used for multiple sclerosis; AND
  Note: See Appendix B for examples of disease-modifying agents used for multiple sclerosis.
- **b)** At least 6 months will elapse between treatment courses; AND
  Note: For example, if the patient has already received a course of therapy 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 therapy.
- **c)** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR

ii. Patient Has Been Receiving Rituximab For ≥ 1 year. Approve for 1 year if the patient meets ALL of the following (a, b, c, and d):
- **a)** Medication will not be used concurrently with another disease-modifying agent used for multiple sclerosis; AND
  Note: See Appendix B for examples of disease-modifying agents used for multiple sclerosis.
- **b)** At least 6 months will elapse between treatment courses; AND
  Note: For example, if the patient has already received a course of therapy 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 therapy.
- **c)** Patient meets ONE of the following [(1) or (2)]:
  - **(1)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
    Note: Examples of a beneficial clinical response include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]; stabilization or reduced worsening on the Expanded Disability Status Scale (EDSS) score; achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4; improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale; reduction or absence of relapses; improvement or maintenance on the six-minute walk test or 12-Items Multiple Sclerosis Walking Scale; improvement on the Multiple Sclerosis Functional Composite (MSFC) score; and or attenuation of brain volume loss.
  - **(2)** Patient experienced stabilization, slow progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation; AND
- **d)** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.

Dosing. Approve up to 2,000 mg (total) administered as one or two intravenous infusions administered over 1 month.

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23. Myasthenia Gravis. Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient meets ONE of the following (a, b, or c):
- **a)** Patient has received or is currently receiving pyridostigmine; OR
- **b)** Patient has a contraindication to pyridostigmine; OR

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c) Patient has an anti-muscle-specific tyrosine kinase (MuSK) antibody-positive generalized myasthenia gravis; AND

ii. Patient has tried at least one immunosuppressant therapy; AND
Note: Examples of immunosuppressant therapies include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus, and cyclophosphamide. A trial of Imaavy (nipocalimab-aahu intravenous infusion) or Rystiggo (rozanolixizumab-noli subcutaneous infusion) also counts.

iii. Patient has evidence of unresolved symptoms of myasthenia gravis; AND
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, talking, impairment of mobility).

iv. The medication is prescribed by or in consultation with a neurologist; OR

B) Patient Has Already Received a Course of a Rituximab Product. Approve if the patient meets BOTH of the following (i and ii):

i. According to the prescriber, patient is continuing to derive benefit from the rituximab product; AND
Note: Examples of benefit include reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, and respiratory function.

ii. The medication is prescribed by or in consultation with a neurologist.

Dosing. Approve one course of therapy that meets ONE of the following (A, B, or C):

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

B) 375 mg/m^2 administered intravenously for 4 doses separated by at least 7 days with or without an additional 375 mg/m^2 administered monthly for 2 doses (up to 6 doses total); OR

C) 750 mg/m^2 administered intravenously for 2 doses separated by at least 14 days.

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24. Neuromyelitis Optica Spectrum Disorder. Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. Diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody; AND

iii. The medication is prescribed by or in consultation with a neurologist; OR

B) Patient is Currently Receiving a Rituximab Product. Approve if the patient meets ALL of the following criteria (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody; AND

iii. According to the prescriber, patient has had clinical benefit from the use of rituximab; AND
Note Examples of clinical benefit include reduction in relapse rate, reduction in symptoms (e.g., pain, fatigue, motor function) and a slowing progression in symptoms.

iv. The medication is prescribed by or in consultation with a neurologist.

Dosing. Approve ONE of the following (A or B):

A) Up to 375 mg/m^2 administered intravenously for 4 doses separated by at least 7 days; OR

B) Up to two 1,000 mg doses administered as an intravenous infusion separated by at least 2 weeks.

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25. Pediatric Nephrotic Syndrome. Approve for 1 year if the patient meets ONE of the following (A or B):

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A) Initial Therapy. Approve if the patient meets BOTH of the following (i, and ii):
- **i.** Patient meets ONE of the following (a or b):
  - **a)** Patient has tried at least one systemic corticosteroid; OR
    Note: Examples of systemic corticosteroids include prednisone or prednisolone.
  - **b)** Patient has tried at least one glucocorticoid-sparing agent for nephrotic syndrome; AND
    Note: Examples of glucocorticoid-sparing agents for nephrotic syndrome include oral calcineurin inhibitors (e.g., tacrolimus, cyclosporine), cyclophosphamide, or mycophenolate mofetil.
- **ii.** The medication is prescribed by or in consultation with a nephrologist; OR

B) Patient has Already Received a Course of a Rituximab. Approve if prescribed by or in consultation with a nephrologist.

Dosing. Approve 375 mg/m^2 administered intravenously for up to 4 doses separated by at least 7 days.

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26. Rosai-Dorfman Disease. Approve for 1 year if the patient meets BOTH of the following (A and B)
- **A)** Patient has IgG 4 related disease; AND
- **B)** The medication is prescribed by or in consultation with an oncologist or hematologist.

Dosing. Approve the requested dose.

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27. Solid Organ Transplantation. Approve for 1 year if the patients BOTH of the following (A and B):
- **A)** Patient meets ONE of the following (i or ii):
  - **i.** The medication will be used for desensitization therapy prior to or immediately after transplantation; OR
  - **ii.** The medication will be used for antibody-mediated rejection; AND
- **B)** The medication will be prescribed by or in consultation with a physician affiliated with a transplant center.

Dosing. Approve if the requested dosage is based on a transplant center's protocol.

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28. Systemic Lupus Erythematosus (SLE) . Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii and iii):
- **i.** Patient has autoantibody-positive SLE, defined as positive for at least one of the following: antinuclear antibodies (ANA), anti-double-stranded DNA (antids-DNA) antibodies, anti-Smith (anti-Sm) antibodies; AND
  Note: Not all patients with SLE are positive for anti-dsDNA, but most will be positive for ANA.
- **i.** Patient meets ONE of the following (a or b):
  - **a)** The medication is being used concurrently with at least one other standard therapy for SLE; OR
    Note: Examples of standard therapies for SLE include an antimalarial (e.g., hydroxychloroquine), systemic corticosteroid (e.g., prednisone), and other immunosuppressants (e.g., azathioprine, mycophenolate mofetil, methotrexate).
  - **b)** According to the prescriber, patient is determined to be intolerant to standard therapy due to a significant toxicity; AND

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ii. The medication is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist; OR

B) Patient is Currently Receiving Rituximab Intravenous. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient meets ONE of the following (a or b):

a) The medication is being used concurrently with at least one other standard therapy for SLE; OR

Note: Examples of standard therapies for SLE include an antimalarial (e.g., hydroxychloroquine), systemic corticosteroid (e.g., prednisone) and other immunosuppressants (e.g., azathioprine, mycophenolate mofetil, methotrexate).

b) According to the prescriber, patient is determined to be intolerant to standard therapy due to a significant toxicity; AND

ii. The medication is prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist; AND

iii. According to the prescriber, patient has responded to rituximab product.

Dosing. Approve ONE of the following (A or B):

A) 375 mg/m^2 per dose administered intravenously for 4 doses separated by at least 7 days; OR

B) Up to two 1,000 mg intravenous doses separated by at least 2 weeks;

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29. Thrombotic Thrombocytopenic Purpura. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) The medication will be used in combination with systemic corticosteroids; AND

Note: Examples of systemic corticosteroids include prednisone and methylprednisolone.

B) The medication will be used in combination with therapeutic plasma exchange; AND

C) The medication is prescribed by or in consultation with a hematologist.

Dosing. Approve up to 375 mg/m^2 administered intravenously for up to 4 doses separated by at least 7 days.

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30. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. Approve for 1 year if prescribed by or in consultation with an oncologist.

Dosing. Approve up to 375 mg/m^2 administered intravenously with doses separated by at least 7 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of rituximab intravenous products is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/14/2024
Annual Revision	**Antineutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis:** Pulmonologist was added as an accepted specialist to the specialist requirement. **B-Cell Lymphoma:** The nomenclature acquired immune deficiency (AIDS)-related B-cell lymphoma was updated to human immunodeficiency virus (HIV)-related B-cell lymphoma. **Rheumatoid Arthritis:** The requirements for a patient who has already received one or more courses of therapy were modified to a patient has already received one course of a rituximab product and a patient has already received two or more courses of a rituximab product. For patients already receiving one course, the requirements are 16 weeks or greater will lapse between treatment courses and the medication will not be used concurrently with another biologic or with a targeted synthetic DMARD. In addition to these requirements, a patient who has already received two or more courses will either experience a beneficial clinical response when assessed by at least one objective measure or experience an improvement in at least one symptom. **Graft-Versus-Host-Disease (GVHD):** A requirement was added that patient has chronic GVHD. The requirement patient has tried at least one conventional systemic treatment was modified to at least one systemic medication. Jakafi (ruxolitinib), Rezurock (belumosudil), Niktimvo (axatilimab-csfr), hydroxychloroquine, methotrexate, interleukin-2, sirolimus, and etanercept were added, and antithymocyte globulin and infliximab were removed from the Note of examples of systemic medications. **Hematopoietic Cell Transplantation:** This was added as a new condition of approval. **Immune Thrombocytopenia (ITP):** Alvaiz (eltrombopag), Doptelet (avatrombopag), Nplate (romiplostim), Promacta (eltrombopag), Tavalisse (fostamatinib) were added to the Note of examples of therapies for ITP. **Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitors:** Requirements were added that, according to the prescriber, the patient developed an immunotherapy-related toxicity and developed this immunotherapy-related toxicity while receiving a checkpoint inhibitor. Hematologist and nephrologist were added as accepted specialists to the specialist requirement. An additional dosing regimen of up to 1,000 mg administered intravenously for 2 doses separated by at least 14 days was added. **Rosai-Dorfman Disease:** This was added as a new condition of approval.	08/13/2025
Selected Revision	**Pemphigus Vulgaris:** For a patient being treated for a relapse, the approval duration was changed from 1 year to 1 month. For maintenance therapy dosing, added a frequency of every 6 months.	09/03/2025
Selected Revision	**Autoimmune Hemolytic Anemia:** This was added as a new condition of approval. **Immune Thrombocytopenia (ITP):** For a patient that has already received a course of a rituximab product for ITP, the requirements that the patient has responded to therapy and that the patient has relapsed were modified from "as determined by the prescriber" to "according to the prescriber". **Membranous Nephropathy:** This was added as a new condition of approval. **Minimal Change Disease:** This was added as a new condition of approval. **Myasthenia Gravis:** This was added as a new condition of approval. **Pediatric Nephrotic Syndrome:** This was added as a new condition of approval. **Solid Organ Transplantation:** This was added as a new condition of approval. **Thrombotic Thrombocytopenic Purpura:** This was added as a new condition of approval. **Appendix:** Otezla XR (apremilast extended-release tablet) was added under the Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs.	12/03/2025
Selected Revision	**Interstitial Lung Disease Associated with Systemic Autoimmune Rheumatic Disease:** This was added as a new condition of approval.	12/10/2025
Annual Revision	No criteria changes	08/26/2026
Selected Revision	**Acute Lymphoblastic Leukemia:** A hematologist was added to the specialist requirement. **Antineutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis:** A note was added giving examples of ANCA associated vasculitis and the criterion requiring the patient to have ANCA associated vasculitis was removed.	09/16/2026

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	B-Cell Lymphomas: The note listing examples was updated to add extranodal marginal zone lymphoma of nongastric sites (noncutaneous), extranodal marginal zone lymphoma of the stomach, histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, lymphoblastic lymphoma, nodal marginal zone lymphoma, post-transplant lymphoproliferative disorders, and splenic marginal zone lymphoma. Follicular lymphoma was clarified to be classic follicular lymphoma. The following examples were removed: Castleman disease, marginal zone lymphoma (e.g., extranodal or MALT [gastric or nongastric], nodal, or splenic marginal zone lymphoma), post-transplant lymphoproliferative disorders, gray-zone lymphoma, primary cutaneous B-cell lymphoma, and pediatric aggressive mature B-cell lymphoma. **Castleman Disease:** This was added as a new condition of approval. **Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma:** A hematologist was added to the specialist requirement. **Gene Therapy Pretreatment.** This was added as a new condition of approval. **Graft-Versus-Host-Disease:** The note containing examples of systemic medications was updated to include Orencia (abatacept intravenous infusion) and an alemtuzumab product. **Immunotherapy Related Toxicities Associated with Checkpoint Inhibitors:** The note of examples of checkpoint inhibitors was removed. The note listing examples of corticosteroids was updated to clarify these are systemic corticosteroids. **Kaposi Sarcoma:** This was added as a new condition of approval. **Lupus Nephritis:** This was moved from under Systemic Lupus Erythematosus to its own indication. **Membranous Nephropathy:** The approval duration was changed from 1 month to 1 year. **Minimal Change Disease:** The approval duration was changed from 1 month to 1 year. **Myasthenia Gravis:** The approval duration was changed from 6 months to 1 year. The requirement that the patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine was changed to require a contraindication to pyridostigmine. An exception was added for a patient who has anti-muscle-specific tyrosine kinase (MuSK) antibody-positive generalized myasthenia gravis who is not required to try pyridostigmine. **Neuromyelitis Optica Spectrum Disorder:** The duration of approval was changed from 1 month to 1 year. Requirements were added that the patient is ≥ 18 years of age, and that the diagnosis was confirmed by a positive blood serum test for anti-aquaporin-4 antibody. For a patient who is currently receiving a rituximab product, a requirement was added that, according to the prescriber, the patient has had clinical benefit from the use of rituximab; a Note was added listing examples of clinical benefit. **Pediatric Nephrotic Syndrome:** The approval duration was changed from 1 month to 1 year and the criterion for < 18 years of age was removed. **Pemphigus Vulgaris:** The requirement that the patient has tried a corticosteroid and corresponding note was clarified to indicate this is a systemic corticosteroid. **Central Nervous System Lymphoma:** This was changed to as listed; previously was Primary Central Nervous System Lymphoma. A requirement was added that the patient has primary central nervous system lymphoma or leptomeningeal metastases. A hematologist was added to the specialist requirement. **Rosai-Dorfman Disease:** A requirement that the patient has IgG4-related disease was added. The requirement that the patient is ≥ 18 years of age was removed. **Systemic Lupus Erythematosus:** The approval duration was changed from 1 month to 1 year. A dermatologist was added to the specialist requirement. For initial therapy, a requirement was added that the patient has autoantibody-positive SLE, defined as positive for at least one of the following (with a corresponding note): antinuclear antibodies, anti-double-stranded DNA antibodies, anti-Smith antibodies. The requirement that the patient has tried at least one other standard immunomodulating or immunosuppressive agent was changed to require that the medication is being used concurrently with at least one other standard therapy for SLE. The corresponding Note listing examples of immunomodulating or immunosuppressive agents was updated to include examples of standard therapies and clarify that the corticosteroid is a systemic corticosteroid. The criteria that apply to a patient who has already received a course of a rituximab product was updated to be for a patient who is currently receiving rituximab intravenous. The requirement that there is a minimum of at least 6 months separating the first dose of the previous rituximab course and the first dose of the requested course of rituximab was removed. For a patient currently receiving rituximab intravenous, a requirement was added that the medication is being used concurrently with at least one other standard therapy for SLE, unless, according to the	

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	prescriber, the patient is determined to be intolerant to standard therapy to do a significant toxicity, and that according to the prescriber, the patient has responded to rituximab. **Thrombotic Thrombocytopenia Purpura:** The approval duration was changed from 1 month to 1 year. **Appendix A:** Icotyde (icotrokinra tablets) were added. Generics were added to Xeljanz and Xeljanz XR.	

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APPENDIX A

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, HS, PJIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, PJIA, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, PJIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	RA
Tocilizumab Products (Actemra® IV, biosimilars; Actemra SC, biosimilars)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	PJIA, RA
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, HS, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	AS, HS, nr-axSpA, PsO, PsA
Ustekinumab Products (Stelara® IV, biosimilars; Stelara SC, biosimilars)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Skyrizi® (risankizumab-rzaa SC injection, IV infusion)	Inhibition of IL-23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, IV infusion)	Inhibition of IL-23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, SC injection)	Integrin receptor antagonist	CD, UC
Orencia® (abatacept IV infusion, SC injection)	T-cell costimulation modulator	SC formulation: PJIA, PsA, RA
		IV formulation: PJIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed antibody	RA
Oral Therapies/ Targeted Synthetic Oral Small Molecule Drugs		
Icotyde® (icotrokinra tablets)	Inhibition of IL-23 receptor	PsO
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Otezla® XR (apremilast extended-release tablets)	Inhibition of PDE4	PsO, PsA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	AA, RA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA
Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, CD, nr-axSpA, PJIA, PsA, RA, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Tofacitinib tablets/oral solution (Xeljanz®, generics)	Inhibition of JAK pathways	Tablets: AS, PsA, RA, UC
		Oral solution: PJIA, PsA
Tofacitinib XR extended-release tablets (Xeljanz XR, generics)	Inhibition of JAK pathways	AS, PsA, RA, UC
Zeposia® (ozanimod tablets)	S1PRM	UC
Velsipity® (etrasimod tablets)	S1PRM	UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; HS – Hidradenitis Suppurativa; PJIA – Polyarticular juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ERA – Enthesitis-related arthritis; PDE4 – Phosphodiesterase 4; TYK2 – Tyrosine kinase 2; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; S1PRM – Sphingosine-1 phosphate receptor modulator.

APPENDIX B

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Medication	Mode of Administration
Aubagio® (teriflunomide tablets, generic)	Oral
Avonex® (interferon beta-1a intramuscular injection)	Injection (self-administered)
Bafiertam® (monomethyl fumarate delayed-release capsules)	Oral
Betaseron® (interferon beta-1b subcutaneous injection)	Injection (self-administered)
Briumvi™ (ublituximab-xiiy intravenous infusion)	Injection
Copaxone® (glatiramer acetate subcutaneous injection, generic)	Injection (self-administered)
Gilenya® (fingolimod capsules, generic)	Oral
Glatopa® (glatiramer acetate subcutaneous injection)	Injection (self-administered)
Kesimpta® (ofatumumab subcutaneous injection)	Injection (self-administered)
Lemtrada® (alemtuzumab intravenous infusion)	Intravenous infusion
Mavenclad® (cladribine tablets)	Oral
Mayzent® (siponimod tablets)	Oral
Ocrevus® (ocrelizumab intravenous infusion)	Intravenous infusion
Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq subcutaneous injection)	Subcutaneous injection (not self-administered)
Plegridy® (peginterferon beta-1a subcutaneous or intramuscular injection)	Injection (self-administered)
Ponvory™ (ponesimod tablets)	Oral
Rebif® (interferon beta-1a subcutaneous injection)	Injection (self-administered)
Tascenso ODT™ (fingolimod orally disintegrating tablets)	Oral
Tecfidera® (dimethyl fumarate delayed-release capsules, generic)	Oral
Tyruko® (natalizumab-sztn intravenous infusion)	Intravenous infusion
Tysabri® (natalizumab intravenous infusion)	Intravenous infusion
Vumerity® (diroximel fumarate delayed-release capsules)	Oral
Zeposia® (ozanimod capsules)	Oral

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