Rituximab
[Riabni (rituximab-arrx), Rituxan (rituximab) Truxima (rituximab-abbs), or Ruxience (rituximab-pvvr)]

Override(s)	Approval Duration
Prior Authorization	1 year; unless state regulations require otherwise

Medications	Comments
Riabni (rituximab-arrx)	Preferred
Rituxan (rituximab)	
Ruxience (rituximab-pvvr)	Non-Preferred
Truxima (rituximab-abbs)	

Rituximab Dosing Limit

Drug	Limit Per Indication
Rituxan (rituximab) 100 mg, 500 mg vial; Riabni (rituximab-arrx) 100 mg, 500 mg vial; Truxima (rituximab-abbs) 100 mg, 500 mg vial; Ruxience (rituximab-pvvr) 100 mg, 500 mg vial	**Rheumatoid arthritis (RA):** 1000 mg on days 1 and 15; repeated as frequent as every 16 weeks **Pemphigus Vulgaris & other autoimmune blistering skin diseases; maintenance**: 500 mg as frequently as every 16 weeks* **Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) maintenance:** 1000 mg every 4 months (DP)† **Myasthenia Gravis**: 375 mg/m^2 monthly (DP)^ **Autoimmune Hemolytic Anemia:** 375 mg/m^2 weekly for 4 weeks (DP) **Immune Thrombocytopenia (ITP):** 375 mg/m^2 weekly for up to 4 weeks (DP) **Primary Sjogren's Syndrome:** 1000 mg on days 1 and 15 (2000 mg total) (DP)

Override Criteria

*For initiation of therapy, may approve two 1000mg doses separated by 2 weeks. May also approve one 1000 mg infusion upon relapse.

†For induction treatment, may approve 375 mg/m^2 weekly for 4 weeks (Label) or 1000 mg on days 1 and 15 (DP). After induction (at least 16 weeks after rituximab induction or within 4 weeks after achieving disease control from induction with other standard of care immunosuppressants), may approve two 500mg infusions separated by 2 weeks followed by maintenance therapy.

^May approve 375 mg/m^2 weekly for 4 weeks when initiating therapy or as clinically indicated upon relapse.

APPROVAL CRITERIA

Non-oncologic Indications

All requests require documentation provided for diagnosis.

Requests for Rituxan (rituximab), Riabni (rituximab-arrx), Truxima (rituximab-abbs), or Ruxience (rituximab-pvvr) may be approved for the following:

I. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe (RA);
   AND
   B. Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021);
   OR
   C. If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine);
   AND
   D. Individual had an inadequate response, is intolerant of, or has a contraindication to one or more tumor necrosis factor (TNF) antagonist therapies;

OR

II. Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with GPA and MPA; **AND**
   B. Individual is using concomitantly with glucocorticoids with or without avacopan for induction treatment;
   OR
   C. Individual is using as follow up treatment after achieving disease control with induction treatment;

OR

III. Autoimmune blistering skin diseases (such as but not limited to pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus) (Ahmed 2016, Maley 2016) when either of the following criteria are met:
   A. As first-line treatment in adults with moderate to severe pemphigus vulgaris; **OR**
   B. Disease is treatment-refractory;

OR

IV. Acquired Hemophilia or acquired inhibitors in individuals with hemophilia when used in combination with corticosteroids or in individuals who have had an inadequate response, are intolerant of, or have a contraindication to corticosteroid and cytotoxic therapy (Collins 2009, Tiede 2020);

OR

V. Autoimmune hemolytic anemia (Birgens 2013, Michel 2017, DP B IIb);

OR

VI. Cryoglobulinemia, primary Sjogren Syndrome, or systemic lupus erythematosus refractory to standard therapy (Ramos 2009, DP B IIb) including:
   A. Corticosteroids; **AND**
   B. Two (2) or more immunosuppressive agents (such as but not limited to azathioprine, cyclosporine, mycophenolate, cyclophosphamide, methotrexate, or hydroxychloroquine);

OR

VII. Steroid-refractory Graft-Versus-Host Disease (Cutler 2006, NCCN 2A, DP B IIb);

OR

VIII. Hepatitis C virus infection-related glomerulonephritis in individuals with cryoglobulinemic flare, and rapidly progressing glomerulonephritis, or nephrotic syndrome (KDIGO 2022);

OR

IX. Immunoglobulin G4-related disease when any of the following criteria are met (Khosroshahi 2015):
   A. Failure to respond to prednisone or other corticosteroid agents; **OR**
   B. Unable to tolerate tapering of prednisone or other corticosteroid agents; **OR**
   C. Has a medical contraindication to prednisone or other corticosteroid agents;

OR

X. Relapsing Multiple Sclerosis (AAN 2018, DP B IIb);

OR

XI. Neuromyelitis optica (Nikoo 2017, Tahara 2020, DP B IIa);

OR

XII. Pediatric nephrotic syndrome when each of the following criteria are met (KDIGO 2025, DP B IIb):
   A. Individual 18 years of age or younger; **AND**
   B. Individual has frequently relapsing or steroid-dependent disease; **AND**
   C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to corticosteroids or immunosuppressive agents (such as but not limited to cyclosporine, cyclophosphamide, or mycophenolate);

OR

XIII. Membranous Nephropathy (MN) when each of the following criteria are met (KDIGO 2021):
   A. Individual has moderate to high risk MN as shown by one of the following:
      1. Individual has proteinuria > 3.5 g/d and proteinuria has not decreased > 50% after 6 months of conservative therapy with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs); OR
      2. Individual has an estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73 m^2;

OR

XIV. Renal transplant setting for either of the following indications (Vo 2010, KDIGO 2020):
   A. Pre-transplant to suppress panel reactive anti-human leukocyte antigens (HLA) antibodies in individuals with high panel reactive antibody (PRA or cPRA [corrected PRA]) levels to HLAs **or** in individuals with a history of high levels of donor-specific antibodies (DSAs); **OR**
   B. Post-transplant in individuals with acute rejection who had received rituximab treatment pre-transplant;

OR

XV. Antibody-mediated solid organ transplant rejection (KDIGO 2009, ISHLT 2010);

OR

XVI. Thrombocytopenic purpura, immune or idiopathic (ITP) (ASH 2019);

OR

XVII. Immune mediated thrombotic thrombocytopenic purpura (TTP) when each of the following criteria are met (ISTH 2020):

A. TTP is confirmed by severely reduced baseline activity of ADAMTS 13 (less than 10%), with the presence of an ADAMTS 13 inhibitor or anti-ADAMTS13 IgG;

AND

B. Individual is using in combination with plasma exchange therapy and glucocorticoids for treatment of acute event or relapse;

OR

C. Individual is in remission and using for prevention of relapse;

OR

XVIII. Myasthenia gravis when the following criteria are met (MGFA 2020, DP B I):

A. Individual is 18 years of age or older with myasthenia gravis; **AND**

B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to two or more immunosuppressive drug agents (such as azathioprine, cyclosporine, or methotrexate);

OR

XIX. Systemic Sclerosis-associated skin fibrosis when the following criteria are met (DP BIIa, Del Galdo 2023);

A. Individual has a diagnosis of systemic sclerosis-associated skin fibrosis; **AND**

B. Individual has had a trial and inadequate response to, is intolerant of, or has a contraindication to mycophenolate or methotrexate;

OR

XX. Systemic Autoimmune Rheumatic Disease- associated Interstitial Lung Disease (SARD-ILD) when the following criteria are met (DP BIIa, ATS 2023, ACR 2023):

A. Individual has a diagnosis of Systemic Autoimmune Rheumatic Disease (including systemic sclerosis [SSc], rheumatoid arthritis [RA], idiopathic inflammatory myopathies [IIM including polymyositis, dermatomyositis, antisynthetase syndrome, immune-mediated necrotizing myopathy], mixed connective tissue disease [MCTD], or Sjogren disease [SjD]) - associated Interstitial Lung Disease (SARD-ILD); **AND**

B. Diagnosis has been verified through chest high resolution computed tomography (HRCT) showing characteristic features of ILD in an individual with a known systemic autoimmune rheumatic disease (including SSc, RA, IIM, MCTD, or SjD); **AND**

C. Individual has had a trial and inadequate response to, is intolerant of, or has a contraindication to mycophenolate or cyclophosphamide;

OR

XXI. Immune-mediated encephalitis, including paraneoplastic and autoimmune encephalitis when the following criteria are met (Zuliani 2019, Lancaster 2016):

A. Diagnosis is confirmed by detection of a specific autoantibody associated with encephalitis [including but not limited to: NMDAR, LGI1, Caspr2, AMPAR, GABA-A or GABA-B receptor, IgLON5, DPPX, GlyR, mGluR1, mGluR2, mGluR5, Neurexin 3-alpha, or dopamine-2 receptor (D2R)]; **AND**

B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to first line agent(s) including immunoglobulin therapy or plasma exchange;

OR

XXII. Immune Checkpoint Inhibitor -related toxicities including (NCCN 2A):
   A. Moderate, severe, or life-threatening bullous pemphigoid or bullous dermatitis; **OR**
   B. Hemolytic anemia or thrombocytopenia refractory to corticosteroids; **OR**
   C. Acute kidney injury/elevated serum creatinine if toxicity remains greater than stage 2 after 4-6 weeks of corticosteroids or if creatinine increases during steroid taper (or once off steroids); **OR**
   D. Moderate, severe, or life-threatening myositis for significant dysphagia, life- threatening situations, or cases refractory to corticosteroids; **OR**
   E. Severe myasthenia gravis refractory to prior therapy; **OR**
   F. Encephalitis refractory to prior therapy in individuals positive for autoimmune encephalopathy antibody.

Requests for Truxima (rituximab-abbs) or Ruxience (rituximab-pvvr) for a **non-oncologic indication** must also meet the following criteria:

I. Individual has had a trial of and has an allergy or severe intolerance to an inactive ingredient in Rituxan (rituximab) or Riabni (rituximab-arrx) which interferes with the individual's ability to use the product, and the same allergy/severe intolerance is not expected with the non-preferred products [Truxima (rituximab-abbs) or Ruxience (rituximab-pvvr)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

Requests for Rituxan (rituximab), Riabni (rituximab-arrx),Truxima (rituximab-abbs), or Ruxience (rituximab-pvvr) may not be approved when the above criteria are not met and for all other non-oncologic indications.

<u>Oncologic indications</u>

Requests for Rituxan (rituximab), Truxima (rituximab-abbs), Riabni (rituximab-arrx) or Ruxience (rituximab-pvvr) may be approved for oncologic indications.

Requests for a Truxima (rituximab-abbs) or Ruxience (rituximab-pvvr) for an **oncologic indication** must also meet the following criteria:

I. Individual has had a trial of and has an allergy or severe intolerance to an inactive ingredient in Rituxan (rituximab) or Riabni (rituximab-arrx) which interferes with the individual's ability to use the product, and the same allergy/severe intolerance is not expected with the non-preferred products [Truxima (rituximab-abbs) or Ruxience (rituximab-pvvr)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.

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