

Medical Policy Manual

Draft Revision Policy: Do Not Implement

Rituximab Products (Rituxan®, Rituximab-abbs [Truxima®], Rituximab-arxx [Riabni™] and Rituximab-pvvr [Ruxience®])

(Hematologic and Oncology Indications)

Some agents on this policy may require step therapy See “Step Therapy Requirements for Provider Administered Specialty Medications” Document at:

https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Rituxan is indicated for the treatment of pediatric patients aged 6 months and older with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy.

Rituxan, Ruxience, Truxima, and Riabni are indicated for:

- Non-Hodgkin's lymphoma (NHL) in adult patients with:
 - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
 - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy
 - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
 - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
- Chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC), for the treatment of adult patients with previously untreated and previously treated CD20-positive CLL.
- Granulomatosis with polyangiitis (Wegener's Granulomatosis) and microscopic polyangiitis (MPA) in combination with glucocorticoids (Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other medical policy)
- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely active RA who have inadequate response to one or more TNF antagonist therapies. (Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other medical policy)

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Rituxan is also indicated for:

- Rituxan is indicated for moderate to severe pemphigus vulgaris in adult patients
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other medical policy)

Compendial Uses

- Autoimmune hemolytic anemia
- B-cell acute lymphoblastic leukemia (ALL)
- B-cell lymphomas
 - Human Immunodeficiency Virus (HIV) Related B-Cell lymphomas
 - B-cell lymphoblastic lymphoma
 - Burkitt lymphoma
 - Castleman's disease
 - Diffuse Large B-Cell lymphoma
 - Follicular lymphoma
 - High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
 - Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
 - Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
 - Mantle cell lymphoma
 - Marginal zone lymphomas
 - Nodal marginal zone lymphoma
 - Extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue {MALT} lymphoma)
 - Splenic marginal zone lymphoma
 - Post-transplant lymphoproliferative disorder (PTLD)
 - Pediatric Aggressive Mature B-Cell Lymphomas
 - Primary Mediastinal Large B-Cell Lymphoma
- Central nervous system (CNS) cancers
 - Leptomeningeal metastases from lymphomas
 - Primary CNS lymphomas
- Chronic graft-versus-host disease (GVHD)
- CLL/Small lymphocytic lymphoma (SLL)
- Hairy cell leukemia
- Rosai-Dorfman disease
- Hodgkin's lymphoma, nodular lymphocyte-predominant
- Immune checkpoint inhibitor-related toxicities
- Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients
- Primary cutaneous B-cell lymphoma
- Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
- Thrombotic thrombocytopenic purpura
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL) / Bing-Neel syndrome
- Allogeneic transplant conditioning
- For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other medical policy

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

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Submission of the following information is necessary to initiate the prior authorization review: Testing or analysis confirming CD20 protein on the surface of the B-cell (if applicable).

COVERAGE CRITERIA

Oncologic Indications

Authorization of 12 months may be granted for treatment of any of the following oncologic disorders that are CD20-positive as confirmed by testing or analysis:

- B-cell acute lymphoblastic leukemia (ALL)
- B-cell lymphomas:
 - HIV-Related B-Cell Lymphomas
 - B-cell lymphoblastic lymphoma
 - Burkitt lymphoma
 - Castleman's disease
 - Diffuse large B-cell lymphoma
 - Follicular lymphoma
 - High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
 - Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
 - Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
 - Mantle cell lymphoma
 - Marginal zone lymphomas
 - Nodal marginal zone lymphoma
 - Extranodal marginal zone lymphoma (gastric and non-gastric (MALT) lymphoma)
 - Splenic marginal zone lymphoma
 - Post-transplant lymphoproliferative disorder (PTLD)
 - Pediatric Aggressive Mature B-Cell Lymphomas
 - Primary Mediastinal Large B-Cell Lymphoma
- Central nervous system (CNS) cancers:
 - Leptomeningeal metastases from lymphomas
 - Primary CNS lymphoma
- CLL/Small lymphocytic lymphoma (SLL)
- Hairy cell leukemia
- Rosai-Dorfman disease
- Hodgkin's lymphoma, nodular lymphocyte-predominant
- Primary cutaneous B-cell lymphoma
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL) / Bing-Neel Syndrome

Hematologic Indications

Authorization of 12 months may be granted for treatment of any of the following indications:

- Refractory immune or idiopathic thrombocytopenic purpura (ITP)
- Autoimmune hemolytic anemia
- Thrombotic thrombocytopenic purpura
- Chronic graft-versus-host disease (GVHD)
- Prevention of Epstein-Barr virus (EBV)-related PTLD
- As part of a non-myeloablative conditioning regimen for allogeneic transplant



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Immune Checkpoint Inhibitor-Related Toxicities

Authorization of 3 months may be granted for treatment of immune checkpoint inhibitor-related toxicities.

CONTINUATION OF THERAPY

Oncologic indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed in coverage criteria section. when there is no evidence of unacceptable toxicity.

Immune checkpoint inhibitor-related toxicities

Authorization of 3 months may be granted for continued treatment in members requesting reauthorization for treatment of immune checkpoint inhibitor-related toxicities who are experiencing benefit from therapy.

All other indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section. who are experiencing benefit from therapy.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Rituxan (Rituximab) Riabni (Rituximab-arrx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	Allogeneic Transplant Conditioning	Route of Administration: Intravenous 375mg/m ² on the day before transplant and 1,000 mg/m ² on days 1, 8, and 15 after transplant
Rituxan (Rituximab) Riabni (Rituximab-arrx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	Autoimmune Hemolytic Anemia, B-Cell Acute Lymphoblastic Leukemia (B-ALL), B-Cell Lymphomas: Castleman's Disease, B-Cell Lymphomas: Diffuse Large B-Cell Lymphoma, HIV-related Diffuse Large B-cell Lymphoma, High- Grade B-Cell Lymphomas, Primary Mediastinal Large B-Cell Lymphoma, B- Cell Lymphomas: Follicular Lymphoma, B-Cell Lymphomas: Mantle Cell Lymphoma, B-Cell Lymphomas: Marginal Zone Lymphomas [Nodal Marginal Zone Lymphoma, Gastric Mucosa Associated Lymphoid Tissue (GALT) Lymphoma, Nongastric MALT Lymphoma, Splenic Marginal Zone Lymphoma], B-Cell Lymphomas: Post-Transplant Lymphoproliferative Disorders, Chronic Graft Versus-Host Disease (GVHD), Hairy Cell Leukemia, Immune or Idiopathic Thrombocytopenic Purpura (ITP), Thrombotic Thrombocytopenic	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)



	Purpura, Prevention of Epstein-Barr Virus (EBV)-related PTLD in high-risk patients, Rosai-Dorfman Disease, Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma (LPL)	
Rituxan (Rituximab) Riabni (Rituximab-arrx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	B-Cell Lymphomas: Burkitt Lymphoma and HIV-related Burkitt Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days or on Days 1 and 5 of a 21-day cycle)
Rituxan (Rituximab) Riabni (Rituximab-arrx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	B-Cell Lymphomas: Histological Transformation of Indolent Lymphomas to Diffuse Large B-cell Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days)
Rituxan (Rituximab) Riabni (Rituximab-arrx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)	Route of Administration: Intravenous 500mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab) Riabni (Rituximab-arrx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	CNS Cancers: Primary CNS Lymphoma	Route of Administration: Intravenous 750mg/m ² every week
Rituxan (Rituximab) Riabni (Rituximab-arrx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	CNS Cancers: Primary CNS Lymphoma or Leptomeningeal Metastases	Route of Administration: Intrathecal, Intraventricular 25mg (frequency and cycle length varies by regimen; should not be more frequent than twice a week)
Rituxan (Rituximab) Riabni (Rituximab-arrx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	Hodgkin Lymphoma: Nodular Lymphocyte-Predominant	Route of Administration: Intravenous ≥18 Years 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab) Riabni (Rituximab-arrx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Intravenous 375mg/m ² every week OR 500 mg/m ² every 2 weeks OR 1000 mg every 2 weeks
Rituxan (Rituximab)	Pediatric Aggressive Mature B-Cell Lymphomas [Diffuse Large B-cell Lymphoma, Burkitt Lymphoma, Burkitt-	Route of Administration: Intravenous ≤17 Years



	Like Lymphoma (BLL)] or Mature B-cell Acute Leukemia (B-AL)	375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than 2 doses in one week)
Rituxan (Rituximab) Riabni (Rituximab-arxx) Ruxience (Rituximab-pvvr) Truxima (Rituximab-abbs)	Primary Cutaneous B-cell Lymphoma	Route of Administration: Intravenous 375mg/m ² on Days 1, 8, 15, and 22 of a 28-day cycle for 1 cycle
Riabni (Rituximab-arxx)	Allogeneic Transplant Conditioning	Route of Administration: Intravenous 375mg/m ² on the day before transplant and 1000 mg/m ² on days 1, 8, and 15 after transplant
Riabni (Rituximab-arxx)	Autoimmune Hemolytic Anemia	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arxx)	B-Cell Acute Lymphoblastic Leukemia (B-ALL)	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arxx)	B-Cell Lymphomas: Burkitt Lymphoma and HIV-related Burkitt Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days or on Days 1 and 5 of a 21-day cycle)
Riabni (Rituximab-arxx)	B-Cell Lymphomas: Castleman's Disease	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arxx)	B-Cell Lymphomas: Diffuse Large B-Cell Lymphoma, HIV-related Diffuse Large B-cell Lymphoma, High-Grade B-Cell Lymphomas, Primary Mediastinal Large B-Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arxx)	B-Cell Lymphomas: Follicular Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arxx)	B-Cell Lymphomas: Histological Transformation of Indolent Lymphomas to Diffuse Large B-cell Lymphoma or Histological Transformation of Indolent Lymphomas to High-grade B-cell Lymphoma with MYC and BCL6 without BCL2 rearrangements	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days)
Riabni (Rituximab-arxx)	B-Cell Lymphomas: Mantle Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)



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Riabni (Rituximab-arrx)	B-Cell Lymphomas: Marginal Zone Lymphomas [Nodal Marginal Zone Lymphoma, Gastric Mucosa Associated Lymphoid Tissue (GMALT) Lymphoma, Nongastric MALT Lymphoma, Splenic Marginal Zone Lymphoma]	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arrx)	B-Cell Lymphomas: Post-Transplant Lymphoproliferative Disorders	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arrx)	Chronic Graft Versus Host Disease (GVHD)	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arrx)	Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)	Route of Administration: Intravenous 500mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arrx)	CNS Cancers: Primary CNS Lymphoma	Route of Administration: Intravenous 750mg/m ² every week
Riabni (Rituximab-arrx)	CNS Cancers: Primary CNS Lymphoma or Leptomeningeal Metastases	Route of Administration: Intrathecal, Intraventricular 25mg (frequency and cycle length varies by regimen; should not be more frequent than twice a week)
Riabni (Rituximab-arrx)	Cryoglobulinemia	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Riabni (Rituximab-arrx)	Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² every week for 4 weeks, followed by 500 mg every 2 weeks for 2 doses (start no sooner than 16 to 24 weeks after last induction dose), followed by 500 mg every 6 months based on clinical evaluation 1000mg every 2 weeks for 2 doses, followed by 1000 mg every 4 to 6 months
Riabni (Rituximab-arrx)	Hairy Cell Leukemia	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arrx)	Hodgkin Lymphoma: Nodular Lymphocyte-Predominant	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week) <u>≥2 to <18 year(s)</u>



		375mg/m ² every 2 to 3 weeks for 3 doses
Riabni (Rituximab-arrx)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Intravenous 375mg/m ² every week OR 500 mg/m ² every 2 weeks OR 1000 mg every 2 weeks
Riabni (Rituximab-arrx)	Immune or Idiopathic Thrombocytopenic Purpura (ITP), Thrombotic Thrombocytopenic Purpura	Route of Administration: Intravenous 375mg/m ² every week for 4 doses
Riabni (Rituximab-arrx)	Membranous Nephropathy	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Riabni (Rituximab-arrx)	Multiple Sclerosis	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Riabni (Rituximab-arrx)	Myasthenia Gravis	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Riabni (Rituximab-arrx)	Neuromyelitis Optica (i.e. Neuromyelitis Optica Spectrum Disorder, NMOSD, or Devic Disease)	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Riabni (Rituximab-arrx)	Opsoclonus-Myoclonus Ataxia	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Riabni (Rituximab-arrx)	Pediatric Aggressive Mature B-Cell Lymphomas: Diffuse Large B-cell Lymphoma, Burkitt Lymphoma, Burkitt-Like Lymphoma (BLL)] or Mature B-cell Acute Leukemia (B-AL)	Route of Administration: Intravenous <u>≥6 month(s) to <18 year(s)</u> 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than 2 doses in one week)
Riabni (Rituximab-arrx)	Pemphigus Vulgaris (PV) and other Autoimmune Blistering Disease (e.g., Pemphigus Foliaceus, Bullous Pemphigoid, Cicatricial Pemphigoid, Epidermolysis Bullosa Acquisita and Paraneoplastic Pemphigus)	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² every week for 4 doses per treatment course; may repeat treatment after at least 6 months if necessary Initial: 1000mg every 2 weeks for 2 doses Maintenance: 500mg at month 12 and every 6 months thereafter 1000mg on relapse; subsequent infusions no sooner than 16 weeks following previous infusion
Riabni (Rituximab-arrx)	Prevention of Epstein-Barr Virus (EBV)-related PTLD in high risk patients	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arrx)	Primary Cutaneous B-Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² on Days 1, 8, 15, and 22 of a 28-day cycle for 1 cycle



Riabni (Rituximab-arrx)	Rheumatoid Arthritis	Route of Administration: Intravenous <u>≥18 year(s)</u> 1000mg x 2 doses given 2 weeks apart (one course); Subsequent courses may be given every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks
Riabni (Rituximab-arrx)	Rosai-Dorfman Disease	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Riabni (Rituximab-arrx)	Sjögren's Syndrome	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Riabni (Rituximab-arrx)	Solid Organ Transplant	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Riabni (Rituximab-arrx)	Systemic Lupus Erythematosus	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Riabni (Rituximab-arrx)	Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma (LPL)/ Bing-Neel Syndrome	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	Allogeneic Transplant Conditioning	Route of Administration: Intravenous 375mg/m ² on the day before transplant and 1000 mg/m ² on days 1, 8, and 15 after transplant
Rituxan (Rituximab)	Autoimmune Hemolytic Anemia	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	B-Cell Acute Lymphoblastic Leukemia (B- ALL)	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	B-Cell Lymphomas: Burkitt Lymphoma and HIV-related Burkitt Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days or on Days 1 and 5 of a 21-day cycle)
Rituxan (Rituximab)	B-Cell Lymphomas: Castleman's Disease	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	B-Cell Lymphomas: Diffuse Large B-Cell Lymphoma, HIV-related Diffuse Large B- cell Lymphoma, High-Grade B-Cell Lymphomas, Primary Mediastinal Large B-Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)



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Rituxan (Rituximab)	B-Cell Lymphomas: Follicular Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	B-Cell Lymphomas: Histological Transformation of Indolent Lymphomas to Diffuse Large B-cell Lymphoma or Histological Transformation of Indolent Lymphomas to High-grade B-cell Lymphoma with MYC and BCL6 without BCL2 rearrangements	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days)
Rituxan (Rituximab)	B-Cell Lymphomas: Mantle Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	B-Cell Lymphomas: Marginal Zone Lymphomas [Nodal Marginal Zone Lymphoma, Gastric Mucosa Associated Lymphoid Tissue (GMALT) Lymphoma, Nongastric MALT Lymphoma, Splenic Marginal Zone Lymphoma]	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	B-Cell Lymphomas: Post-Transplant Lymphoproliferative Disorders	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	Chronic Graft Versus Host Disease (GVHD)	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)	Route of Administration: Intravenous 500mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	CNS Cancers: Primary CNS Lymphoma	Route of Administration: Intravenous 750mg/m ² every week
Rituxan (Rituximab)	CNS Cancers: Primary CNS Lymphoma or Leptomeningeal Metastases	Route of Administration: Intrathecal, Intraventricular 25mg (frequency and cycle length varies by regimen; should not be more frequent than twice a week)
Rituxan (Rituximab)	Cryoglobulinemia	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every weeks
Rituxan (Rituximab)	Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² every week for 4 weeks, followed by 500 mg every 2 weeks for 2 doses (start no sooner than 16 to 24 weeks after last induction dose), followed by 500 mg every 6 months based on



		clinical evaluation 1000mg every 2 weeks for 2 doses, followed by 1000 mg every 4 to 6 months <u>≥2 to <18 year(s)</u> 375mg/m² every week for 4 weeks, followed by 250 mg/m² every 2 weeks for 2 doses (start no sooner than 16 to 24 weeks after last induction dose), followed by 250 mg/m² every 6 months based on clinical evaluation 750mg/m² (max 1000 mg/dose) every 2 weeks for 2 doses, followed by 750 mg/m² (max 1000 mg/dose) every 4 to 6 months
Rituxan (Rituximab)	Hairy Cell Leukemia	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	Hodgkin Lymphoma: Nodular Lymphocyte-Predominant	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m² (frequency and cycle length varies by regimen; should not be more frequent than once a week) <u>≥2 to <18 year(s)</u> 375mg/m² every 2 to 3 weeks for 3 doses
Rituxan (Rituximab)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Intravenous 375mg/m ² every week OR 500 mg/m ² every 2 weeks OR 1000 mg every 2 weeks
Rituxan (Rituximab)	Immune or Idiopathic Thrombocytopenic Purpura (ITP), Thrombotic Thrombocytopenic Purpura	Route of Administration: Intravenous 375mg/m ² every week for 4 doses
Rituxan (Rituximab)	Membranous Nephropathy	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Rituxan (Rituximab)	Multiple Sclerosis	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Rituxan (Rituximab)	Myasthenia Gravis	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Rituxan (Rituximab)	Neuromyelitis Optica (i.e. Neuromyelitis Optica Spectrum Disorder, NMOSD, or Devic Disease)	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week



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Rituxan (Rituximab)	Opsoclonus-Myoclonus Ataxia	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Rituxan (Rituximab)	Pediatric Aggressive Mature B-Cell Lymphomas: Diffuse Large B-cell Lymphoma, Burkitt Lymphoma, Burkitt-Like Lymphoma (BLL)] or Mature B-cell Acute Leukemia (B-AL)	Route of Administration: Intravenous <u>≥6 month(s) to <18 year(s)</u> 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than 2 doses in one week)
Rituxan (Rituximab)	Pemphigus Vulgaris (PV) and other Autoimmune Blistering Disease (e.g., Pemphigus Foliaceus, Bullous Pemphigoid, Cicatricial Pemphigoid, Epidermolysis Bullosa Acquisita and Paraneoplastic Pemphigus)	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² every week for 4 doses per treatment course; may repeat treatment after at least 6 months if necessary Initial: 1000mg every 2 weeks for 2 doses Maintenance: 500mg at month 12 and every 6 months thereafter 1000mg on relapse; subsequent infusions no sooner than 16 weeks following previous infusion
Rituxan (Rituximab)	Prevention of Epstein-Barr Virus (EBV)-related PTLN in high risk patients	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	Primary Cutaneous B-Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² on Days 1, 8, 15, and 22 of a 28-day cycle for 1 cycle
Rituxan (Rituximab)	Rheumatoid Arthritis	Route of Administration: Intravenous <u>≥18 year(s)</u> 1000mg x 2 doses given 2 weeks apart (one course); Subsequent courses may be given every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks
Rituxan (Rituximab)	Rosai-Dorfman Disease	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan (Rituximab)	Sjögren's Syndrome	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Rituxan (Rituximab)	Solid Organ Transplant	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Rituxan (Rituximab)	Systemic Lupus Erythematosus	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every weeks



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Rituxan (Rituximab)	Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma (LPL)/ Bing-Neel Syndrome	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	B-Cell Lymphomas: Castleman's Disease	Route of Administration: Subcutaneous 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	B-Cell Lymphomas: Diffuse Large B-Cell Lymphoma, High-Grade B-Cell Lymphomas	Route of Administration: Subcutaneous 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	B-Cell Lymphomas: Follicular Lymphoma	Route of Administration: Subcutaneous 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	B-Cell Lymphomas: Histological Transformation of Indolent Lymphomas to Diffuse Large B-cell Lymphoma	Route of Administration: Subcutaneous 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than every 14 days)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	B-Cell Lymphomas: Mantle Cell Lymphoma	Route of Administration: Subcutaneous 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	B-Cell Lymphomas: Marginal Zone Lymphomas [Nodal Marginal Zone Lymphoma, Gastric Mucosa Associated Lymphoid Tissue (GMALT) Lymphoma, Nongastric MALT Lymphoma, Splenic Marginal Zone Lymphoma]	Route of Administration: Subcutaneous 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	B-Cell Lymphomas: Post-Transplant Lymphoproliferative Disorders	Route of Administration: Subcutaneous 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)	Route of Administration: Subcutaneous 1600/26,800mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	Hairy Cell Leukemia	Route of Administration: Subcutaneous 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	Hodgkin Lymphoma: Nodular Lymphocyte-Predominant	Route of Administration: Subcutaneous <u>≥18 year(s)</u> 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Rituxan Hycela (Rituximab- Hyaluronidase Human)	Primary Cutaneous B-Cell Lymphoma	Route of Administration: Subcutaneous 1400/23,400mg-units on Days 8, 15, and 22 of a 28-day cycle for 1 cycle



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Rituxan Hycela (Rituximab-Hyaluronidase Human)	Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma (LPL)	Route of Administration: Subcutaneous 1400/23,400mg-units (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	Allogeneic Transplant Conditioning	Route of Administration: Intravenous 375mg/m ² on the day before transplant and 1000 mg/m ² on days 1, 8, and 15 after transplant
Ruxience (Rituximab-pvvr)	Autoimmune Hemolytic Anemia	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	B-Cell Acute Lymphoblastic Leukemia (B-ALL)	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	B-Cell Lymphomas: Burkitt Lymphoma and HIV-related Burkitt Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days or on Days 1 and 5 of a 21-day cycle)
Ruxience (Rituximab-pvvr)	B-Cell Lymphomas: Castleman's Disease	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	B-Cell Lymphomas: Diffuse Large B-Cell Lymphoma, HIV-related Diffuse Large B- cell Lymphoma, High-Grade B-Cell Lymphomas, Primary Mediastinal Large B-Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	B-Cell Lymphomas: Follicular Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	B-Cell Lymphomas: Histological Transformation of Indolent Lymphomas to Diffuse Large B-cell Lymphoma or Histological Transformation of Indolent Lymphomas to High-grade B-cell Lymphoma with MYC and BCL6 without BCL2 rearrangements	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days)
Ruxience (Rituximab-pvvr)	B-Cell Lymphomas: Mantle Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	B-Cell Lymphomas: Marginal Zone Lymphomas [Nodal Marginal Zone Lymphoma, Gastric Mucosa Associated Lymphoid Tissue (GMALT) Lymphoma,	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)



	Nongastric MALT Lymphoma, Splenic Marginal Zone Lymphoma]	
Ruxience (Rituximab-pvvr)	B-Cell Lymphomas: Post-Transplant Lymphoproliferative Disorders	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	Chronic Graft Versus Host Disease (GVHD)	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)	Route of Administration: Intravenous 500mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	CNS Cancers: Primary CNS Lymphoma	Route of Administration: Intravenous 750mg/m ² every week
Ruxience (Rituximab-pvvr)	CNS Cancers: Primary CNS Lymphoma or Leptomeningeal Metastases	Route of Administration: Intrathecal, Intraventricular 25mg (frequency and cycle length varies by regimen; should not be more frequent than twice a week)
Ruxience (Rituximab-pvvr)	Cryoglobulinemia	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Ruxience (Rituximab-pvvr)	Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² every week for 4 weeks, followed by 500 mg every 2 weeks for 2 doses (start no sooner than 16 to 24 weeks after last induction dose), followed by 500 mg every 6 months based on clinical evaluation 1000mg every 2 weeks for 2 doses, followed by 1000 mg every 4 to 6 months
Ruxience (Rituximab-pvvr)	Hairy Cell Leukemia	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	Hodgkin Lymphoma: Nodular Lymphocyte-Predominant	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week) <u>≥2 to <18 year(s)</u> 375mg/m ² every 2 to 3 weeks for 3 doses
Ruxience (Rituximab-pvvr)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Intravenous



		375mg/m ² every week OR 500 mg/m ² every 2 weeks OR 1000 mg every 2 weeks
Ruxience (Rituximab-pvvr)	Immune or Idiopathic Thrombocytopenic Purpura (ITP), Thrombotic Thrombocytopenic Purpura	Route of Administration: Intravenous 375mg/m ² every week for 4 doses
Ruxience (Rituximab-pvvr)	Membranous Nephropathy	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Ruxience (Rituximab-pvvr)	Multiple Sclerosis	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Ruxience (Rituximab-pvvr)	Myasthenia Gravis	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Ruxience (Rituximab-pvvr)	Neuromyelitis Optica (i.e. Neuromyelitis Optica Spectrum Disorder, NMOSD, or Devic Disease)	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Ruxience (Rituximab-pvvr)	Opsoclonus-Myoclonus Ataxia	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Ruxience (Rituximab-pvvr)	Pediatric Aggressive Mature B-Cell Lymphomas: Diffuse Large B-cell Lymphoma, Burkitt Lymphoma, Burkitt-Like Lymphoma (BLL)] or Mature B-cell Acute Leukemia (B-AL)	Route of Administration: Intravenous <u>≥6 month(s) to <18 year(s)</u> 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than 2 doses in one week)
Ruxience (Rituximab-pvvr)	Pemphigus Vulgaris (PV) and other Autoimmune Blistering Disease (e.g., Pemphigus Foliaceus, Bullous Pemphigoid, Cicatricial Pemphigoid, Epidermolysis Bullosa Acquisita and Paraneoplastic Pemphigus)	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² every week for 4 doses per treatment course; may repeat treatment after at least 6 months if necessary Initial: 1000mg every 2 weeks for 2 doses Maintenance: 500mg at month 12 and every 6 months thereafter 1000mg on relapse; subsequent infusions no sooner than 16 weeks following previous infusion
Ruxience (Rituximab-pvvr)	Prevention of Epstein-Barr Virus (EBV)-related PTLD in high risk patients	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	Primary Cutaneous B-Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² on Days 1, 8, 15, and 22 of a 28-day cycle for 1 cycle
Ruxience (Rituximab-pvvr)	Rheumatoid Arthritis	Route of Administration: Intravenous <u>≥18 year(s)</u> 1000mg x 2 doses given 2 weeks apart (one course);



		Subsequent courses may be given every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks
Ruxience (Rituximab-pvvr)	Rosai-Dorfman Disease	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Ruxience (Rituximab-pvvr)	Sjögren's Syndrome	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Ruxience (Rituximab-pvvr)	Solid Organ Transplant	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Ruxience (Rituximab-pvvr)	Systemic Lupus Erythematosus	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Ruxience (Rituximab-pvvr)	Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma (LPL)/ Bing-Neel Syndrome	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	Allogeneic Transplant Conditioning	Route of Administration: Intravenous 375mg/m ² on the day before transplant and 1000 mg/m ² on days 1, 8, and 15 after transplant
Truxima (Rituximab-abbs)	Autoimmune Hemolytic Anemia	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	B-Cell Acute Lymphoblastic Leukemia (B-ALL)	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	B-Cell Lymphomas: Burkitt Lymphoma and HIV-related Burkitt Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days or on Days 1 and 5 of a 21-day cycle)
Truxima (Rituximab-abbs)	B-Cell Lymphomas: Castleman's Disease	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	B-Cell Lymphomas: Diffuse Large B-Cell Lymphoma, HIV-related Diffuse Large B-cell Lymphoma, High-Grade B-Cell Lymphomas, Primary Mediastinal Large B-Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	B-Cell Lymphomas: Follicular Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)



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Truxima (Rituximab-abbs)	B-Cell Lymphomas: Histological Transformation of Indolent Lymphomas to Diffuse Large B-cell Lymphoma or Histological Transformation of Indolent Lymphomas to High-grade B-cell Lymphoma with MYC and BCL6 without BCL2 rearrangements	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than every 14 days)
Truxima (Rituximab-abbs)	B-Cell Lymphomas: Mantle Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	B-Cell Lymphomas: Marginal Zone Lymphomas [Nodal Marginal Zone Lymphoma, Gastric Mucosa Associated Lymphoid Tissue (GMALT) Lymphoma, Nongastric MALT Lymphoma, Splenic Marginal Zone Lymphoma]	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	B-Cell Lymphomas: Post-Transplant Lymphoproliferative Disorders	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	Chronic Graft Versus Host Disease (GVHD)	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)	Route of Administration: Intravenous 500mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	CNS Cancers: Primary CNS Lymphoma	Route of Administration: Intravenous 750mg/m ² every week
Truxima (Rituximab-abbs)	CNS Cancers: Primary CNS Lymphoma or Leptomeningeal Metastases	Route of Administration: Intrathecal, Intraventricular 25mg (frequency and cycle length varies by regimen; should not be more frequent than twice a week)
Truxima (Rituximab-abbs)	Cryoglobulinemia	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Truxima (Rituximab-abbs)	Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)	Route of Administration: Intravenous ≥18 year(s) 375mg/m ² every week for 4 weeks, followed by 500 mg every 2 weeks for 2 doses (start no sooner than 16 to 24 weeks after last induction dose), followed by 500 mg every 6 months based on clinical evaluation 1000mg every 2 weeks for 2 doses, followed by 1000 mg every 4 to 6 months



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Truxima (Rituximab-abbs)	Hairy Cell Leukemia	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	Hodgkin Lymphoma: Nodular Lymphocyte-Predominant	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week) <u>≥2 to <18 year(s)</u> 375mg/m ² every 2 to 3 weeks for 3 doses
Truxima (Rituximab-abbs)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Intravenous 375mg/m ² every week OR 500 mg/m ² every 2 weeks OR 1000 mg every 2 weeks
Truxima (Rituximab-abbs)	Immune or Idiopathic Thrombocytopenic Purpura (ITP), Thrombotic Thrombocytopenic Purpura	Route of Administration: Intravenous 375mg/m ² every week for 4 doses
Truxima (Rituximab-abbs)	Membranous Nephropathy	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Truxima (Rituximab-abbs)	Multiple Sclerosis	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Truxima (Rituximab-abbs)	Myasthenia Gravis	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Truxima (Rituximab-abbs)	Neuromyelitis Optica (i.e. Neuromyelitis Optica Spectrum Disorder, NMOSD, or Devic Disease)	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Truxima (Rituximab-abbs)	Opsoclonus-Myoclonus Ataxia	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Truxima (Rituximab-abbs)	Pediatric Aggressive Mature B-Cell Lymphomas: Diffuse Large B-cell Lymphoma, Burkitt Lymphoma, Burkitt-Like Lymphoma (BLL)] or Mature B-cell Acute Leukemia (B-AL)	Route of Administration: Intravenous <u>≥6 month(s) to <18 year(s)</u> 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than 2 doses in one week)
Truxima (Rituximab-abbs)	Pemphigus Vulgaris (PV) and other Autoimmune Blistering Disease (e.g., Pemphigus Foliaceus, Bullous Pemphigoid, Cicatricial Pemphigoid, Epidermolysis Bullosa Acquisita and Paraneoplastic Pemphigus)	Route of Administration: Intravenous <u>≥18 year(s)</u> 375mg/m ² every week for 4 doses per treatment course; may repeat treatment after at least 6 months if necessary Initial: 1000mg every 2 weeks for 2 doses Maintenance: 500mg at month 12 and every 6 months thereafter



		1000mg on relapse; subsequent infusions no sooner than 16 weeks following previous infusion
Truxima (Rituximab-abbs)	Prevention of Epstein-Barr Virus (EBV)-related PTLT in high risk patients	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	Primary Cutaneous B-Cell Lymphoma	Route of Administration: Intravenous 375mg/m ² on Days 1, 8, 15, and 22 of a 28-day cycle for 1 cycle
Truxima (Rituximab-abbs)	Rheumatoid Arthritis	Route of Administration: Intravenous <u>≥18 year(s)</u> 1000mg x 2 doses given 2 weeks apart (one course); Subsequent courses may be given every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks
Truxima (Rituximab-abbs)	Rosai-Dorfman Disease	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)
Truxima (Rituximab-abbs)	Sjögren's Syndrome	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Truxima (Rituximab-abbs)	Solid Organ Transplant	Route of Administration: Intravenous 1000mg (frequency should not be more frequent than every 14 days)
Truxima (Rituximab-abbs)	Systemic Lupus Erythematosus	Route of Administration: Intravenous 1000mg every 2 weeks or 375 mg/m ² every week
Truxima (Rituximab-abbs)	Waldenström's Macroglobulinemia/ Lymphoplasmacytic Lymphoma (LPL)/ Bing-Neel Syndrome	Route of Administration: Intravenous 375mg/m ² (frequency and cycle length varies by regimen; should not be more frequent than once a week)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).



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EFFECTIVE DATE

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