

# EVH Clinical Guideline 5029.CC for Rituximab Products

<b>Guideline Number:</b> EVH_CG_5029.CC	<b><u>Applicable Codes</u></b>	
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# STATEMENT

## General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to the Medical Director for review, if required for the plan and level of request.*

## Purpose

The purpose of this guideline is to define the prior authorization process for the rituximab products.

## Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan’s medical benefit.

## Special Notes

Additional uses are included in this policy based on being supported by one or more compendia (e.g., Merative Micromedex®, UpToDate®, Lexidrug™, Elsevier Clinical Pharmacology).

**NCH reviews prior authorization requests for all oncology related indications for rituximab products.**

## Plan Design Summary

Requests for rituximab products are subject to the preferred medical drug list program. This program applies to the products specified in this guideline. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product. The coverage review process will ascertain situations where a clinical exception can be made.

Preferred Product Table	
<b>Preferred</b>	Ruxience (rituximab-pvvr, Q5119) Riabni (rituximab-arrr, Q5123) Truxima (rituximab-abbs, Q5115)
<b>Non-Preferred</b>	Rituxan (rituximab, J9312) Rituxan Hycela (rituximab and hyaluronidase human, J9311)

## INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the diagnosis-specific sections below.

### **Autoimmune Blistering Disease** (*off-label supported indication*)

- Must be prescribed by a dermatologist or immunologist
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have a trial and failure of steroids or immunosuppressive agents OR have a contraindication to all therapies
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Autoimmune Hemolytic Anemia (AHA)** (*off-label supported indication*)

- Must be prescribed by or in consultation with a hematologist, oncologist, neurologist, immunologist, or genetic specialist
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Allogeneic Transplant Conditioning** (*off-label supported indication*)

- Must have documentation of Hepatitis B virus (HBV) screening

- NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Cryoglobulinemia (*off-label supported indication*)**

- Must be prescribed by a hematologist, rheumatologist, neurologist, or nephrologist
- Must have an adequate trial and failure of BOTH the following OR an intolerance or contraindication to all therapies:
  - Corticosteroids
  - Other immunosuppressive agents (e.g., cyclophosphamide)
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Eosinophilic Granulomatosis with Polyangiitis (EGPA) (*off-label supported indication*)**

- Must be prescribed by a rheumatologist, immunologist, or nephrologist
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML

- Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Epstein-Barr Virus (EBV), PTLD** (*off-label supported indication*)

- Must be used to prevent development of post-transplant lymphoproliferative disorders (PTLD) in the setting of Epstein-Barr virus
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Graft-Versus-Host Disease (GVHD)** (*off-label supported indication*)

- Must be prescribed by or in consultation with a transplant specialist, hematologist or oncologist
- Must be an allogeneic hematopoietic stem cell transplant (HSCT) recipient and have a documented diagnosis of chronic graft-versus-host disease
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## Granulomatosis with Polyangiitis (GPA)/Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)

- Must be prescribed by a rheumatologist, immunologist, or nephrologist
- Must be 2 years or older
- Must have a diagnosis of Granulomatosis with Polyangiitis/Wegener's Granulomatosis or Microscopic Polyangiitis
- For induction therapy, must be on concomitant therapy with glucocorticoids
- For maintenance therapy, must have an adequate trial (of at least 3 months) of azathioprine or methotrexate with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## Immune Checkpoint-Inhibitor Related Toxicities (*off-label supported indication*)

- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## **Immune/Idiopathic Thrombocytopenic Purpura (ITP), Relapsed/Refractory (*off-label supported indication*)**

- Must be prescribed by a hematologist or oncologist
- For children *ONLY*, must have ONE of the following:
  - Active bleeding AND platelet count <30,000
  - Upcoming invasive surgery AND either platelet level below threshold designated for procedure (threshold must be provided with request) OR blood loss is expected
  - Non-life-threatening mucosal bleeding and/or diminished quality of life AND documented previous inadequate response or intolerance to corticosteroids
- For non-pregnant adults *ONLY*, must have one of the following:
  - Active bleeding AND platelet count <30,000
  - Upcoming invasive surgery AND platelet level below threshold designated for procedure (threshold must be provided with request)
  - Platelet count <30,000 AND documented previous inadequate response or intolerance to corticosteroids
- For pregnant adults *ONLY*, must have one of the following:
  - Platelet count <50,000
  - Upcoming invasive surgery/procedure
  - History of splenectomy
  - Previously delivered infants with autoimmune thrombocytopenia
- Must have a trial and failure of immune globulin (e.g., IVIG, SCIG) or have a contraindication or intolerance to this therapy
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## **Membranous Nephropathy (*off-label supported indication*)**

- Must be prescribed by a rheumatologist or nephrologist

- Must have documentation that the member is at moderate-to-high risk of disease progression
- Must have no evidence of severe, active infection
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Multiple Sclerosis** (*off-label supported indication*)

- Must have relapsing-remitting form of multiple sclerosis
- Must be prescribed by a rheumatologist, immunologist, or neurologist
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have previously had an inadequate response to at least ONE of the following preferred multiple sclerosis therapies (or have a contraindication or intolerance to all):
  - Betaseron (interferon beta-1b)
  - Copaxone (glatiramer acetate)
  - Gilenya (fingolimod), Rebif (interferon beta-1a)
  - Tecfidera (dimethyl fumarate)
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
- Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Myasthenia Gravis** (*off-label supported indication*)

- Must be prescribed by a rheumatologist, immunologist, or neurologist
- Must have a trial and failure, contraindication, or intolerance to at least ONE corticosteroid (e.g., prednisone)
- Must have a trial and failure or contraindication to at least ONE of the following (or

intolerance of all):

- At least TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
- At least ONE non-steroidal immunosuppressive therapy while on chronic plasmapheresis or plasma exchange
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Neuromyelitis Optica (NMOSD) (*off-label supported indication*)**

- Must be prescribed by a rheumatologist, immunologist, or neurologist
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Opsoclonus-Myoclonus-Ataxia (*off-label supported indication*)**

- Must be prescribed by a rheumatologist, immunologist, or neurologist
- Must have opsoclonus-myoclonus-ataxia associated with neuroblastoma
- Must have tried and failed steroids and chemotherapy
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy

- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## Pemphigus Vulgaris (PV)

- Must have a diagnosis of biopsy-proven moderate to severe pemphigus vulgaris
- Must be prescribed by a dermatologist
- Must be 18 years or older
- Must have an adequate trial of at least one of the following with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies:
  - Immunosuppressants (such as azathioprine or methotrexate)
  - Corticosteroids
  - *EXCEPTION:* In rapidly progressive, extensive, or debilitating cases (i.e., Stevens Johnson Syndrome), rituximab may be approved along with corticosteroids or immunosuppressive agents
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## Renal and/or Pancreatic Transplant Desensitization

- Must be prescribed by a transplant specialist
- Must be 18 years or older
- Must be awaiting kidney and/or pancreas transplant requiring desensitization as defined by:
  - For deceased donor transplants, must have one of the following:

- Panel reactive antibody (PRA) level >30%
- PRA <30% with a previous kidney and/or pancreas transplant
- For living donor transplants, must have the following:
  - Positive crossmatch
  - Positive donor-specific antibody using Luminex® assay
- Must be using the requested product in combination with immune globulin (e.g., IVIG)
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## Rheumatoid Arthritis

- Must be prescribed by or in consultation with a rheumatologist
- Must be 18 years or older
- Must have a diagnosis of moderately to severely active rheumatoid arthritis
- Must have documentation of testing of the following:
  - Rheumatoid factor (RF)
  - Anti-cyclic citrullinated peptide (anti-CCP)
  - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR) – *not required if RF & anti-CCP are positive*
- Must have documentation showing ONE of the following:
  - Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week)
  - Member has an intolerance or contraindication to methotrexate (**see Appendix 1**) and an inadequate response to another conventional drug (e.g., hydroxychloroquine, leflunomide, sulfasalazine)
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
  - An adalimumab product

- Cimzia
- Enbrel
- Xeljanz
- Must be prescribed the requested medication in combination with methotrexate or leflunomide or has a clinical reason not to use methotrexate or leflunomide (see **Appendix 1**)
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not be using a TNF-blocking agent or other biologic agents in combination with rituximab
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Sjogren's Syndrome** (*off-label supported indication*)

- Must be prescribed by a rheumatologist, immunologist, or ophthalmologist
- Must have an adequate trial and failure of BOTH the following OR an intolerance or contraindication to all therapies:
  - Corticosteroids
  - Other immunosuppressive agents (e.g., hydroxychloroquine, methotrexate, leflunomide, azathioprine, sulfasalazine, mycophenolic acid, cyclosporine)
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or

contraindication to at least TWO of the preferred products

### **Solid Organ Transplant Rejection** (*off-label supported indication*)

- Must be prescribed by an immunologist or transplant specialist
- Must be used for the treatment or prevention of antibody-mediated rejection
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Susac Syndrome** (*off-label supported indication*)

- Must be prescribed by a rheumatologist, immunologist, or neurologist
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Systemic Lupus Erythematosus (SLE)** (*off-label supported indication*)

- Must be prescribed by a rheumatologist, immunologist, or nephrologist
- Must have an adequate trial (of at least 3 months) of the following with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies:
  - Hydroxychloroquine **AND**

- Azathioprine **OR** Methotrexate **OR** Mycophenolate
- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

### **Thrombotic Thrombocytopenic Purpura (*off-label supported indication*)**

- Must have documentation of Hepatitis B virus (HBV) screening
  - NOTE: If screening is positive for prior hepatitis B infection, must have documentation showing consultation with specialists for monitoring and consideration for HBV antiviral therapy
- Must have documentation or an attestation from the prescriber of all the following:
  - Must not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
  - Must have no evidence of severe, active infection
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## **REAUTHORIZATION CRITERIA**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed under the diagnosis-specific sections below.

### **Granulomatosis with Polyangiitis/Wegener's Granulomatosis and Microscopic Polyangiitis**

- Must have recent chart note documentation from the prescriber showing that the member's condition has improved or stabilized as a result of therapy
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## Pemphigus Vulgaris (PV)

- Must have recent chart note documentation from the prescriber showing that the member's condition has improved or stabilized as a result of therapy
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
  - *Initial reauthorizations:* A second course will not be granted until 12 months have passed since the initial course
  - *Subsequent reauthorizations:* Additional courses will not be granted until 6 months have passed after the prior course
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## Rheumatoid Arthritis

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by disease activity or improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
  - Additional courses will not be granted until 16 weeks have passed since the previous course
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## Renal and/or Pancreatic Desensitization Candidates

- Must still be awaiting a renal and/or pancreatic transplant
- Must be requesting another course of therapy after at least 6 months have passed since the initial course
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## All Other Diagnoses

- Must have recent chart note documentation from the prescriber showing that the member's condition has improved or stabilized as a result of therapy
- **For non-preferred rituximab products:** Must have a trial and failure, intolerance, or contraindication to at least TWO of the preferred products

## APPROVAL DURATIONS

<b>Initial Authorization</b>	<ul style="list-style-type: none"> <li>• Transplant Desensitization: Up to 6 months</li> <li>• All other diagnoses: 1 year</li> </ul>
<b>Reauthorization</b>	Same as initial

## APPENDICES

### Appendix 1 - Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

## CODING AND STANDARDS

### Codes

Code	Brand	Description
J9311	Rituxan Hycela	Injection, rituximab 10 mg and hyaluronidase
J9312	Rituxan	Injection, rituximab, 10 mg
Q5115	Truxima	Injection, rituximab-abbs, biosimilar, (truxima), 10 mg
Q5119	Ruxience	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg

Code	Brand	Description
Q5123	Riabni	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg

## Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input type="checkbox"/>	Commercial
<input type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

## BACKGROUND

Rituxan (rituximab) is indicated for the treatment of patients with:

- Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell Non-Hodgkin’s Lymphoma (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 Rituxan® (rituximab) 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 chemotherapy
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimens
- In combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive Chronic Lymphocytic Leukemia (CLL)
- In combination with methotrexate, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies
- In combination with glucocorticoids, for the treatment of adult and pediatric patients 2 years of age and older with Wegener’s Granulomatosis (WG) and Microscopic Polyangiitis (MPA)
- Moderate to severe pemphigus vulgaris in adults

## POLICY HISTORY

Date	Summary
March 2026	<ul style="list-style-type: none"> <li>Updated non-preferred criterion to only require a trial of 2 preferred biosimilars; brand Rituximab moved to non-preferred status</li> </ul>
January 2026	<ul style="list-style-type: none"> <li>Added 19 new indications</li> <li>Updated initial and reauthorization criteria for existing indications to include dosing criterion and hepatitis B screening</li> </ul>
February 2023	<ul style="list-style-type: none"> <li>Updated authorization durations to 1 year for applicable diagnoses</li> <li>Added Riabni</li> <li>Updated preferred &amp; non-preferred products</li> </ul>
March 2022	<ul style="list-style-type: none"> <li>New Guideline</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

#### Disclaimer

*Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.*

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