

Prior Authorization Criteria Rituxan (rituximab)

All requests for Rituximab (rituximab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Rituxan (rituximab), all of the following criteria must be met in addition to the diagnosis-specific criteria below:

- Medication must be prescribed by or in association with a Hematologist, Oncologist, Immunologist, Ophthalmologist, Neurologist, Dermatologist, or Rheumatologist
- Must have a therapeutic failure, contraindication, or intolerance to the biosimilar agent(s) approved or medically accepted for the member's diagnosis
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines

For <u>oncology indications</u> (not otherwise listed below), refer to the Oncology Agents, IV/Injectable policy.

Coverage may be provided with a <u>diagnosis</u> of Granulomatosis with Polyangiitis (GPA or Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) and the following criteria is met:

- Must be used in combination with glucocorticoids.
- Initial Duration of Approval: 1 month
- Reauthorization Criteria Improvement with prior courses of treatment.
- Reauthorization Duration of approval: 1 month

Coverage may be provided with a <u>diagnosis</u> of Rheumatoid Arthritis and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with methotrexate or another DMARD.
- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with a tumor necrosis factor (TNF) inhibitor.
- Medication will be used in combination with Methotrexate (if not contraindicated or member does not have intolerance to methotrexate).
- Initial Duration of Approval: 6 months
- Reauthorization Criteria:
 - o There must be documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of approval:** 6 months

Coverage may be provided with a diagnosis of Pemphigus Vulgaris and the following criteria is met:

- Member must have mucosal involvement and diagnosis confirmed by ONE of the following:
- o Lesional skin or mucosal biopsy for routine hematoxylin and eosin (H&E) staining.
- o A perilesional skin or mucosal biopsy for direct immunofluorescence (DIF)
- Serum collection for enzyme-linked immunosorbent assay (ELISA) and indirect immunofluorescence (DIF)



- Initial Duration of Approval: 1 month
- Reauthorization Criteria
- o There must be documented, significant improvement with prior course of treatment.
- o A time period of 6 months has passed since previous treatment.
- Reauthorization Duration of Approval: 1 month

Coverage may be provided with a <u>diagnosis</u> of Neuromyelitis Optica (NMO) and the following criteria is met:

- Documentation of at least 1 attack during the last year or at least 2 attacks during the last 2 years
- Initial Duration of Approval: 1 month
- Reauthorization Criteria:
 - o There must be documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of approval:** 6 months

Coverage may be provided with a <u>diagnosis</u> of Relapsing forms of Multiple Sclerosis (relapsing-remitting, secondary-progressive, or progressive-relapsing multiple sclerosis) and the following criteria is met:

- Member must have a medical history of one of the following:
 - One clinical relapse documented (e.g. functional disability, hospitalization, acute steroid therapy, etc.) during the prior year
 - o Two relapses within the prior two years
 - o A single clinical demyelinating event and 2 or more brain lesions characteristic of MS
- If coverage is provided for situations in which there is functional status that can be preserved, ONE of the following must be met:
 - o Member must still be able to walk at least a few steps
 - Member must have some functional arm/hand use consistent with performing activities of daily living
- Must provide documentation showing the member has tried and failed another MS treatment for at least 90 days
- Initial Duration of Approval: 6 months
- Reauthorization criteria
 - O Documentation of clinical response defined as:
 - Member continues to receive benefit from treatment by having the ability to walk at least a few steps or alternatively have some functional arm/hand use consistent with performing activities of daily living.
 - Member did not experience 1 or more relapses
 - Member does not have 2 or more unequivocally new MRI-detected lesions

Reauthorization Duration of approval: 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.



WHOLECARE
When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.



RITUXAN (RITUXIMAB) PRIOR AUTHORIZATION FORM – PAGE 1 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. FAX: (888) 245-2049

	armacy Services. FAX: (888) 245-2049			
If needed, you may call to speak to a Pharmacy Services Represen	` ' /			
PROVIDER INI	<u> </u>			
Requesting Provider:	Provider NPI:			
Provider Specialty:	Office Contact:			
State license #:	Office NPI:			
Office Address:	Office Phone:			
	Office Fax:			
MEMBER INF	ORMATION			
Member Name:	DOB:			
Member ID:	Member weight: Height:			
REQUESTED DRUG	GINFORMATION			
Medication: Strength:				
Directions:	Quantity: Refills:			
Is the member currently receiving requested medication? Yes	No Date Medication Initiated:			
Billing Information				
This medication will be billed: at a pharmacy OR medically, JCODE:				
Place of Service: Hospital Provider's office Member's home Other				
Place of Service Information				
Name:	NPI:			
Address:	Phone:			
MEDICAL HISTORY (Complete for ALL requests)				
WEDICHE HISTORY (CO.	inflete for ALL requests)			
· ·	ICD Code:			
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Diagnosis:	ICD Code:			
Diagnosis: For Rheumatoid Arthritis: Which of the following have been tried for at least 3 month Methotrexate or another DMARD	ICD Code:			
Diagnosis: For Rheumatoid Arthritis: Which of the following have been tried for at least 3 month Methotrexate or another DMARD TNF Inhibitor	ICD Code: s:			
Diagnosis: For Rheumatoid Arthritis: Which of the following have been tried for at least 3 month Methotrexate or another DMARD	ICD Code: s:			
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Diagnosis: For Rheumatoid Arthritis: • Which of the following have been tried for at least 3 month Methotrexate or another DMARD TNF Inhibitor • Will the medication be used in combination with methotrex For Granulomatosis with Polyangiitis (GPA or Wegener's Granulom • Will the medication be used in combination with glucocort For Pemphigus Vulgaris: • How was the diagnosis confirmed? Please check all that ap Lesional skin or mucosal biopsy for routine he A perilesional skin or mucosal biopsy for direct Serum collection for enzyme-linked immunoso For Neuromyelitis Optica: • Which of the following apply?	s: tate?			
Diagnosis: For Rheumatoid Arthritis: • Which of the following have been tried for at least 3 month Methotrexate or another DMARD TNF Inhibitor • Will the medication be used in combination with methotrex For Granulomatosis with Polyangiitis (GPA or Wegener's Granulor • Will the medication be used in combination with glucocort For Pemphigus Vulgaris: • How was the diagnosis confirmed? Please check all that ap Lesional skin or mucosal biopsy for routine he A perilesional skin or mucosal biopsy for direct Serum collection for enzyme-linked immunoso For Neuromyelitis Optica: • Which of the following apply? There has been 1 attack within the past year	ICD Code: s: tate?			



RITUXAN (RITUXIMAB) PRIOR AUTHORIZATION FORM (CONTINUED)- PAGE 2 of 2

	d information below including the ble to Highmark Wholecare I		aboratory test results, or chart documentation	
If needed, you may call to speak to a Pharmacy Services Representative. PHONE : (800) 392-1147 Mon – Fri 8:30am to 5:00pm MEMBER INFORMATION				
Member Name:		DOB:		
Member ID:		Member weight:	Height:	
	MEDICAL HISTORY (Complete for ALL req	uests)	
For Relapsing forms of Multiple Scl				
Which of the following appl	•			
○ One clinical relapse within the past year ☐ Yes ☐ No				
○ Two relapses within the past two years ☐ Yes ☐ No				
○ A single clinical demyelinating event and 2 or more brain lesions characteristic of MS ☐ Yes ☐ No				
• If member is using for situations in which functional status can be preserved, which of the following apply:				
 Member is able to walk at least a few steps Yes No Member has some functional arm/hand use consistent with performing activities of daily living Yes No 				
	not apply to member Y		activities of daily living \(\subseteq \text{Yes} \) \(\subseteq \text{No} \)	
O This situation does	not apply to member 1	23 🔲 110		
	CURRENT or PR	EVIOUS THERAPY		
Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)	
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REAUTHORIZATION				
Has the member experienced an improvement with treatment? Yes No				
For relapsing forms of Multiple Sclerosis, indicate which of the following currently apply: Member continues to receive benefit from treatment by having the ability to walk at least a few steps or alternatively have some functional arm/hand use consistent with performing activities of daily living				
Member did not experience 1 or more relapses				
Member does not have 2 or more unequivocally new MRI-detected lesions				
	more unequivocally new M	IRI-detected lesions		
SUI	PPORTING INFORMATI		TIONALE	
SUI			TIONALE	
SUI			TIONALE	
	PPORTING INFORMATI			
SUI Prescribing Provide	PPORTING INFORMATI		TIONALE Date	