HIGHMARK HEALTH OPTIONS

Updated: 02/2024
Approved: 03/2024

Request for Prior Authorization for Rituxan (rituximab)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Rituxan (rituximab) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Rituxan (rituximab) Prior Authorization Criteria:

For all requests for Rituxan (rituximab) all of the following criteria must be met:

- Medication must be prescribed by or in consultation with a Hematologist, Oncologist, Immunologist, Ophthalmologist, Neurologist, Dermatologist or Rheumatologist.
- Must have a therapeutic failure, contraindication, or intolerance to the biosimilar agent(s) FDA-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

Coverage may be provided for oncology indications (not otherwise listed below):

- **Initial Duration of Approval:** as requested with a maximum of 12 months.
- **Reauthorization Criteria:**
  - Documentation of a positive clinical response
- **Reauthorization Duration of Approval:** as requested with a maximum of 12 months

Coverage may be provided with a diagnosis 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 conventional DMARD (cDMARD)**.**
- 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:**
  - Documentation of a positive clinical response
- **Reauthorization Duration of approval:** 6 months

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

- Documentation of a positive test for AQP4-IgG antibodies
- The prescriber submits documentation of baseline number of relapse(s), which occurred over the last year.
- Documentation of an Expanded Disability Status Scale (EDSS) score of ≤ 7

- If using concurrent corticosteroids, dose is less than or equal to the equivalent of prednisone 20 mg per day
- **Initial Duration of Approval:** 1 month
- **Reauthorization Criteria:**
  - Documentation the member has experienced a decrease from baseline in the number of NMOSD relapse(s)
- **Reauthorization Duration of approval:** 6 months

Coverage may be provided with a diagnosis 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
  - Two relapses within the prior two years
  - A single clinical demyelinating event and 2 or more brain lesions characteristic of MS
- Member must have documented Expanded Disability Status Scale (EDSS) score of 6.5 or lower
- Must provide documentation showing the member has tried and failed another MS treatment for at least 90 days
- The drug will not be given in combination with other disease modifying therapies approved for the treatment of MS
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria:**
  - Documentation of clinical response defined as:
    - No increase in their Expanded Disability Status Scale (EDSS) score
    - 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 with a diagnosis 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:**
  - Documentation of a positive clinical response
- **Reauthorization Duration of approval:** 1 month

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:
  - Lesional skin or mucosal biopsy for routine hematoxylin and eosin (H&E) staining.
  - 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:**
  - Documentation of a positive clinical response
- **Reauthorization Duration of Approval:** 1 month

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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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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 Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon- Fri 8 am to 7 pm

PROVIDER INFORMATION	
Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION		
Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION		
Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

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)	
Diagnosis:	ICD Code:
Has a biosimilar agent been tried? ☐ Yes, please list all below ☐ No	

Rheumatoid Arthritis:
Which of the following have been tried for at least 3 months:
- ☐ Methotrexate or another DMARD
- ☐ TNF Inhibitor

Will the medication be used in combination with methotrexate? ☐ Yes ☐ No

Granulomatosis with Polyangiitis (GPA or Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA):
Will the medication be used in combination with glucocorticoids? ☐ Yes ☐ No

Pemphigus Vulgaris:
How was the diagnosis confirmed? Please check all that apply:
- ☐ Lesional skin or mucosal biopsy for routine hematoxylin and eosin (H&E) staining
- ☐ A perilesional skin or mucosal biopsy for direct immunofluorescence (DIF)
- ☐ Serum collection for enzyme-linked immunosorbent assay (ELISA) and indirect immunofluorescence (DIF)

Neuromyelitis Optica (NMO):
Is the member AQP4-IgG/NMO-IgG positive or negative? ☐ Positive ☐ Negative ☐ Unknown/has not been tested
How many relapses have occurred over the past year? _____
What is the EDSS score? ☐ ≤ 7.0 ☐ > 7.0
If using corticosteroids, what is the daily dose? ☐ ≤ equivalent of prednisone 20 mg ☐ > equivalent of prednisone 20 mg ☐ N/A

Relapsing forms of Multiple Sclerosis:
Which of the following apply?
- ☐ One clinical relapse within the past year
- ☐ Two relapses within the past two years
- ☐ A single clinical demyelinating event and 2 or more brain lesions characteristic of MS

What is the EDSS score? ☐ ≤ 6.5 ☐ > 6.5
Will this be used in combination with other disease modifying therapies for MS? ☐ Yes ☐ No

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RITUXAN (RITUXIMAB)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8 am to 7 pm

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced an improvement with treatment? ☐ Yes ☐ No

For Neuromyelitis Optica (NMO):
Have there been fewer relapses since starting this treatment? ☐ Yes ☐ No

For relapsing forms of Multiple Sclerosis, has the member experienced any of the following?

- Increase in EDSS score ☐ Yes ☐ No
- 1 or more relapses ☐ Yes ☐ No
- 2 or more unequivocally new MRI-detected lesions ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date