HIGHMARK HEALTH OPTIONS

Updated: 07/2024
Approved: 07/2024

Request for Prior Authorization for Rituxan and Rituximab Biosimilars
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

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

Rituxan (rituximab) and rituximab biosimilar Prior Authorization Criteria:

For all requests, all of the following criteria must be met:

- Medication must be prescribed by or in association with a Hematologist, Oncologist, Immunologist, Ophthalmologist, Neurologist, Dermatologist or Rheumatologist
- 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 oncology indications (not otherwise listed below), refer to the Oncology Agents policy.

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:** Improvement with prior courses of treatment.
- **Reauthorization Duration of approval:** 1 month

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 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:**
    - 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:
    - 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**
  - There must be improvement with prior course of treatment.
- **Reauthorization Duration of Approval:** 1 month

Coverage may be provided with a diagnosis 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:**
  - 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 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
- If coverage is provided for situations in which there is functional status that can be preserved, ONE of the following must be met:
  - 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**
  - 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.

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.

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RITUXAN (RITUXIMAB) AND RITUXIMAB BIOSIMILARS
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: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: 1-844-325-6251 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:

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) AND RITUXIMAB BIOSIMILARS
PRIOR AUTHORIZATION FORM – 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: (833)-547-2030.**
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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