HIGHMARK WHOLECARE

Updated: 03/2024
PARP Approved: 04/2024

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 oncology indications (not otherwise listed below), refer to the Oncology Agents, IV/Injectable 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 documented, significant improvement with prior course of treatment.
  - A time period of 6 months has passed since previous 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 serologic testing for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies has been performed
- Previous history of (if AQP4-IgG/NMO-IgG positive- one of the following, if negative- two of the following):
  - Optic neuritis
  - Acute myelitis
  - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
  - Acute brainstem syndrome
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
- 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
- **Initial Duration of Approval:** 1 month
- **Reauthorization Criteria:**
  - Documentation the member has experienced a decrease from baseline in the number of NMOSD relapse(s) **or**
  - The member has experienced a decrease in the severity of relapses or improvement in the EDSS score
- **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)
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
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
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:	

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:

For 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

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

For 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)

For Neuromyelitis Optica:
Has serologic testing for AQP4-IgG/NMO-IgG antibodies been completed? ☐ Yes ☐ No
Is the member AQP4-IgG/NMO-IgG positive or negative? ☐ Positive ☐ Negative
Check all that applies to the member:
☐ Optic neuritis
☐ Acute myelitis
☐ Acute brainstem syndrome
☐ Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
☐ Symptomatic cerebral syndrome with NMOSD-typical brain lesions
☐ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
How many relapses occurred in the past year? _____
What is the EDSS score? ☐ ≤ 7 ☐ > 7

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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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049
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 requests)

For Relapsing forms of Multiple Sclerosis:

- Which of the following apply?
  - 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
  - This situation does not apply to member ☐ Yes ☐ No

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 NMO, which of the following apply:

☐ There has been a decrease from baseline in the number of relapses
☐ There has been a decrease in severity of relapses
☐ Improvement in EDSS score

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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date