Gateway Health℠ It's Wholecare.

Updated: 01/2021
PARP Approved: 03/2021

Prior Authorization Criteria

Rituxan and rituximab biosimilars

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 and rituximab biosimilars include Rituxan (rituximab), Truxima (rituximab-abbs), and Ruxience (rituximab-pvvr). New products with this classification will require the same documentation.

For all requests for Rituxan and rituximab biosimilars 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
- Member should not have active HBV liver disease.
- 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

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:

- Member is age 2 years or older.
- Must be used in combination with glucocorticoids.
- **Initial Duration of Approval:** 1 month
- **Reauthorization Criteria:** If 6 months or greater have elapsed since the first dose of the previous rituximab product regimen and there is documented, significant 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:

- The member is age 18 years or older
- 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:

- The member is age 18 years or older
- 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:

- The member is age 18 years or older.
- 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:

- The member is age 18 years or older
- 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 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 Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 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:	
Gateway 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:

Does the member have active HBV liver disease? ☐ Yes ☐ No

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:

- Which of the following apply?
  - ☐ There has been 1 attack within the past year
  - ☐ There have been at least 2 attacks within the past 2 years

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RITUXAN AND RITUXIMAB BIOSIMILARS
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 Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:	
Gateway 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 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