Updated: 01/2019
PARP Approved: 02/2019

Prior Authorization Criteria

**Rituxan (rituximab) and rituximab biosimilars (Truxima™)**

All requests for Rituxan (rituximab) and rituximab biosimiliars (Truxima™) 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:

- The member is age 18 years or older
- Medication must be prescribed by or in association with a Hematologist, Oncologist, Immunologist, Ophthalmologist, Neurologist, or Rheumatologist
- Member should not have active HBV liver disease.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of Non-Hodgkin's Lymphoma (NHL) and the following criteria is met:

- Member must meet one of the following:
  - Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent.
  - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy.
  - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens. (Rituxan™ only)
- **Initial Duration of Approval:** 12 months
- **Reauthorization Criteria**
  - Member must meet ONE of the following:
    - Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent.
    - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy.
    - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
    - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and

prednisone) (CHOP) or other anthracycline-based chemotherapy regimens. (Rituxan™ only)

- **Reauthorization Duration of Approval: 12 months**

Coverage may be provided with a diagnosis of Chronic Lymphocytic Leukemia (CLL) and the following criteria is met:

- Medication is Rituxan™
- Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).
- **Initial Duration of Approval:** 12 months
- **Reauthorization Criteria**
  - Member must have previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).
- **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:

- Medication is Rituxan™
- Must be used in combination with glucocorticoids.
- Member must have a history of trial and failure, contraindication, or intolerance to oral cyclophosphamide for at least 3 months.
- **Initial Duration of Approval:** 1 month
- **Reauthorization Criteria:** If 6 months or greater have elapsed since the first dose of the previous rituximab 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:

- Medication is Rituxan™
- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with methotrexate or another DMARD**.**
- 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:

- Medication is Rituxan™
- 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)
- Member must have a history of trial and failure, contraindication, or intolerance with corticosteroids, and ONE of the following:
  - Azathioprine.
  - Mycophenolate Mofetil
- Cyclophosphamide**Initial Duration of Approval:** 4 weeks
- **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:** 4 weeks

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

- Medication is Rituxan™
- Member must have a history of trial and failure, contraindication, or intolerance with ONE of the following immunosuppressive agents for at least 1 month:
  - Azathioprine.
  - Mycophenolate Mofetil
- **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 scleroiss) and the following criteria is met:

- Medication is Rituxan™
- 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
- Member must have positive serology to JC virus

- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication for a time period of at least 90 days with injection therapy with interferon beta-1a, interferon beta 1-b, or glatiramer.
- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication for a time period of at least 90 days with oral therapy with dimethyl fumerate, teriflunomide, or fingolimod.
- **Initial Duration of Approval:** 24 weeks
- **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.

Gateway Health

Updated: 01/2019
PARP Approved: 02/2019

**RITUXAN (rituximab) and rituximab biosimilars (Truxima™)**
**PRIOR AUTHORIZATION FORM**

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:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
**PHONE**: (844) 325-6253 Monday through Friday 8:30am to 5:00pm

**PROVIDER INFORMATION**

| | |
|---|---|
| Requesting Provider: | NPI: |
| Provider Specialty: | Office Contact: |
| Office Address: | Office Phone: |
| | Office Fax: |

**MEMBER INFORMATION**

| | |
|---|---|
| Member Name: | DOB: |
| Gateway ID: | Member weight: _____pounds or _____kg |

**REQUESTED DRUG INFORMATION**

| | |
|---|---|
| Medication: | Strength: |
| Frequency: | Duration: |
| 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 (if medically please provide a 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)**

· Is the member 18 years of age or older?
☐ Yes ☐ No

· Is the prescribing physician a Hematologist, Oncologist, Immunologist or Rheumatologist?
☐ Yes ☐ No

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

· Which of the following diagnoses will the medication be used for?

☐ Non-Hodgkin's Lymphoma. If selected, please answer the following questions:

a. Does the member meet one of the following:

i. Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent.
☐ Yes ☐ No

ii. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy.
☐ Yes ☐ No

iii. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
☐ Yes ☐ No

iv. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens.
☐ Yes ☐ No

☐ Chronic Lymphocytic Leukemia (CLL). If selected, please answer the following question:

a. Has the member experienced previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC)?
☐ Yes ☐ No

☐ Granulomatosis with Polyangiitis (GPA or Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA). If selected, please answer the following question:

a. Will the medication be used in combination with glucocorticoids?
☐ Yes ☐ No

b. Does the member have a history of trial and failure, contraindication, or intolerance to oral cyclophosphamide for at least 3 months?
☐ Yes ☐ No

☐ Rheumatoid Arthritis. If selected, please answer the following question:

a. Does the member have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with methotrexate or another DMARD?
☐ Yes ☐ No

b. Will the medication be used in combination with methotrexate unless contraindicated or member does not have an intolerance to methotrexate?
☐ Yes ☐ No

☐ Pemphigus Vulgaris. If selected, please answer the following question:

· Does the member must have mucosal involvement and diagnosis confirmed by ONE of the following:

i. Lesional skin or mucosal biopsy for routine hematoxylin and eosin (H&E) staining.
☐ Yes ☐ No

ii. A perilesional skin or mucosal biopsy for direct immunofluorescence (DIF)

☐ Yes ☐ No

iii. Serum collection for enzyme-linked immunosorbent assay (ELISA) and indirect immunofluorescence (DIF)
☐ Yes ☐ No

· Does the member have a history of trial and failure, contraindication, or intolerance with corticosteroids, and ONE of the following:

i. Azathioprine
☐ Yes ☐ No

ii. Mycophenolate Mofetil
☐ Yes ☐ No

iii. Cyclophosphamide
☐ Yes ☐ No

☐ Yes ☐ No

☐ Neuromyelitis Optica. If selected, please answer the following question:

· Does the member have a history of trial and failure, contraindication, or intolerance with ONE of the following for at least 1 month:

iv. Azathioprine
☐ Yes ☐ No

v. Mycophenolate Mofetil
☐ Yes ☐ No

☐ Relapsing form of Multiple Sclerosis. If selected, please answer the following question:

· Does the member have a medical history of ONE of the following:

iv. One clinical relapse documented (e.g. functional disability, hospitalization, acute steroid therapy, etc) during the prior year
☐ Yes ☐ No

v. Two relapses within the prior two years
☐ Yes ☐ No

vi. 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, does any of the following apply:

vii. Member is able to walk at least a few steps
☐ Yes ☐ No

viii. Member has some functional arm/hand uses consistent with performing activities of daily living
☐ Yes ☐ No

· This situation does not apply to member
☐ Yes ☐ No

- Does the member have positive serology to JC virus?
  ☐ Yes ☐ No

- Is there documentation showing that the member has tried and failed or had an intolerance or contraindication for a time period of at least 90 days with injection therapy with interferon beta-1a, interferon beta 1-b, or glatiramer?
  ☐ Yes ☐ No

- Is there documentation showing that the member has tried and failed or had an intolerance or contraindication for a time period of at least 90 days with oral therapy with dimethyl fumerate, teriflunomide, or fingolimod?
  ☐ Yes ☐ No

- Is there documentation showing that the member has tried and failed or had an intolerance or contraindication for a time period of at least 12 weeks with infusion therapy with natalizumab or ocrelizumab?
  ☐ Yes ☐ No

☐ Other Diagnosis: _____

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

**REAUTHORIZATION**

1) Which of the following diagnoses will the medication be used for?

☐ Non-Hodgkin's Lymphoma. If selected, please answer the following questions:

a. Does the member meet ONE of the following:

i. Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent.
☐ Yes ☐ No

ii. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy.
☐ Yes ☐ No

iii. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
☐ Yes ☐ No

☐ Granulomatosis with Polyangiitis (GPA or Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA). If selected, please answer the following question:

a. Has 6 months or more elapsed since the first dose of the previous rituximab regimen and there is documented, significant improvement with prior courses of treatment?
☐ Yes ☐ No

☐ Rheumatoid Arthritis. If selected, please answer the following question:

a. Is there documented, significant improvement with prior courses of treatment?
☐ Yes ☐ No

☐ Pemphigus Vulgaris. If selected, please answer the following question:

a. Is there documented, significant improvement with prior courses of treatment?
☐ Yes ☐ No

b. Has 6 months or more elapsed since the first dose of the previous rituximab regimen and there is documented, significant improvement with prior courses of treatment?
☐ Yes ☐ No

Neuromyelitis Optica. If selected, please answer the following question:

a. Is there documented, significant improvement with prior courses of treatment?
☐ Yes ☐ No

☐ Relapsing forms of Multiple Scleroiss

b. Is there documented, significant improvement with prior courses defined by the following?
i. 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.
☐ Yes ☐ No

ii. Member did not experience 1 or more relapses
☐ Yes ☐ No

iii. Member does not have 2 or more unequivocally new MRI-detected lesions
☐ Yes ☐ No

| **SUPPORTING INFORMATION or CLINICAL RATIONALE** |
|---|
| |
| |
| |

| **Prescribing Provider Signature** | Date |
|---|---|
| | |