

Rituximab

Drugs:

Rituxan (rituximab)

Rituxan Hycela (rituximab/hyaluronidase human, recombinant)

Truxima (rituximab-abbs)

Ruxience (rituximab-pvvr)

Riabni (rituximab-arrx)

RITUXIMAB WILL BE APPROVED IF THE FOLLOWING PRIOR AUTHORIZATION CRITERIA IS MET:

MULTIPLE SCLEROSIS:

Initial Authorization

- The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- **The medication is being prescribed by a neurologist**
- Attestation that the patient has been screened for and does not have active hepatitis B virus (HBV)
- **For requests for Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS), Secondary Progressive MS (SPMS): documented trial of at least two preferred agents or a documented medical reason (e.g. contraindication, intolerance, hypersensitivity, etc.) for not utilizing preferred multiple sclerosis disease-modifying agents**
 - **For patients with “highly active” MS, a prior trial with Gilenya (fingolimod), Lemtrada (alemtuzumab), or Tysabri (natalizumab) will be acceptable.**
- **For requests for Primary Progressive MS (PPMS) approve if all other criteria have been met**
- **If the request is for any medication other than Ruxience (rituximab-pvvr), there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) it cannot be used**
- If the request is for Rituxan Hycela (rituximab/hyaluronidase), all of the above AND documented medical reason why the patient cannot use Rituxan (rituximab).

If all of the above conditions are met, the request will be approved for up to a 1 ~~month~~ **year** duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
- The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

If all of the above conditions are met, the request will be approved for up to a 1 ~~month~~ **year** duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NEUORMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):

Initial Authorization

- Member has a diagnosis of NMOSD
- Documentation indicating that the patient has been screened for HBV (hepatitis B virus) prior to initiation of treatment
- Dosing is supported by compendia or standard of care guidelines
- If the request is for any medication other than Ruxience (rituximab-pvvr), there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) it cannot be used

If all of the above conditions are met, the request will be approved for up to a 1 ~~month~~ **year** duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
- Request is for an FDA approved/medically accepted dose

If all of the above conditions are met, the request will be approved for up to a 1 ~~month~~ **year** duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

RHEUMATOID ARTHRITIS:

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist.
- The patient is an adult (≥ 18 y/o) and has a documented clinical diagnosis of rheumatoid arthritis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates and doses) of 3 months or more of therapy with one conventional (non-biologic) DMARD (e.g. methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) or has a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing any of these therapies to manage their medical condition.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) ~~3-month trial~~ **adequate trial** (including dates, doses) of 2 preferred biologics indicated for rheumatoid arthritis, or has documented medical reason (intolerance, hypersensitivity, etc.) for not taking **the preferred** ~~ALL of these~~ therapies to manage their medical condition.
- Documentation indicating that rituximab is being used concurrently with methotrexate.
- Documentation indicating that the patient has been screened for Hepatitis B Virus (HBV) prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the request is for any medication other than ~~Truxima (rituximab-abbs)~~ **Ruxience (rituximab-pvvr)** there is a documented trial and failure of **Ruxience (rituximab-pvvr)** ~~Truxima (rituximab-abbs)~~, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) **Ruxience (rituximab-pvvr)** ~~Truxima (rituximab-abbs)~~ cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- The member has been receiving rituximab and documentation is provided that a rheumatologist has reevaluated the member and recommends continuation of therapy.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.

- At least 16 weeks (4 months) has elapsed since the previous course of rituximab therapy.
- Documentation indicating that rituximab is being used concurrently with methotrexate.
- Rituximab is being prescribed at an FDA approved dosage.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

PEMPHIGUS VULGARIS

Initial Authorization

- The medication is being recommended and prescribed by a rheumatologist or dermatologist
- The patient is ≥ 18 years with a diagnosis of moderate to severe pemphigus vulgaris
- Documentation the patient will be receiving P. jirovecii pneumonia (PJP) prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment
- Rituximab is being prescribed at an FDA approved dose/frequency
- Rituximab is being used in combination with a tapering course of glucocorticoids

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- Documentation of clinical benefits (e.g., absence of new lesions) with rituximab therapy was provided by a rheumatologist or dermatologist
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Rituximab is being prescribed at an FDA approved dose/frequency

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

ONCOLOGY INDICATIONS

Initial Authorization:

- The medication is being recommended and prescribed by an oncologist.
- The medication is being requested for a labeled indication or the an indication supported by a NCCN category 1 or 2A level of evidence
- ~~The requested indication is CD20 positive~~ **Documentation of CD20 positive disease**
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or the National Comprehensive Cancer Network (NCCN) or American Society of Clinical Oncology (ASCO) standard of care guidelines.
- If the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.
- If the request is for Rituxan Hycela (rituximab/hyaluronidase human, recombinant):
 - **T**he patient has received at least one full dose of a rituximab product by intravenous infusion
 - **T**he medication is being requested for a malignant condition
 - **T**here is a medical reason why the alternative rituximab product cannot be continued

If all of the above conditions are met, the request will be approved for up to a 3 month duration;
if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Reauthorization

- The medication is being recommended and prescribed by an oncologist.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or per the NCCN or ASCO standard of care guidelines.

If all of the above conditions are met, the request will be approved for up to a 3 month duration;
if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

GRANULOMATOSIS WITH POLYANGIITIS (GPA) (WEGENER'S GRANULOMATOSIS) AND MICROSCOPIC POLYANGIITIS (MPA):

Initial Authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- The patient is 2 years of age or older and has a documented clinical diagnosis of GPA (Wegener's Granulomatosis) or MPA.
- **For non-severe disease** ~~The~~ the patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial of three months (including dates, doses) of glucocorticoid (i.e. prednisone) AND methotrexate, **or** ~~OR~~ glucocorticoid AND cyclophosphamide (Cytosan) documentation includes a medical reason (intolerance, hypersensitivity, etc.) why patient is not able to use these therapies to manage their medical condition.
- **For severe disease, a trial of glucocorticoid and methotrexate is not required**
- Documentation indicating that rituximab is being used concurrently with glucocorticoids.
- Documentation the patient will be receiving PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) during treatment or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the patient is 18 years of age or older, and the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration;
if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis

- Ritux~~im~~aban is being prescribed at an FDA approved dose.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)

Initial Authorization:

- **Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.**
- **Patient meets one of the following:**
 - **Bohan and Peter score indicating definite DM or PM**
 - **Bohan and Peter score indicating probable DM or PM AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)**
- **Patient does NOT have cancer associated myositis defined as myositis within 2 years of cancer diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cured)**
- **One of the following:**
 - **Patient has a documented trial and failure of, or has a documented medical reason for not using methotrexate (MTX) OR azathioprine**
 - **Patient has severe, life-threatening weakness or dysphagia**
- **Rituximab is prescribed at a dose per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I or IIa recommendation).**
- **If the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.**

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- Rituximab is prescribed at a medically accepted dose per the medical compendia.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

OTHER MEDICALLY ACCEPTED INDICATIONS

Initial Authorization:

- The medication is prescribed for a non-FDA approved indication but is considered to be a medically accepted use of the medication per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I or IIa recommendation.
- ~~Exclusion Criteria: Diagnosis of Dermatomyositis, polymyositis, dermatopolymyositis~~
- The medication is prescribed at a medically accepted dose per the medical compendia as defined above.
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Documentation was submitted indicating that the member has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses of medications) of ALL first line medical therapies as recommended by the medical compendia and standard care guidelines and/or has another documented medical reason (e.g. intolerance, contraindications, etc.) for not receiving or trying all first line medical treatment(s).
- If the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 3 month duration.

If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- The medication is prescribed at a medically accepted dose per the medical compendia
- The medication is recommended and prescribed a specialist in the field to treat the member's respective medical condition.
- Documentation from medical chart was submitted indicating that the member has significantly clinically benefited from the medication.

If all of the above conditions are met, the request will be approved for up to a 3 month duration.

If all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

NOTE: Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.

Revision/Review Date: ~~6/2021~~7/2022