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Policy Number: C10423-A

Rituxan (rituximab) and Biosimilars

PRODUCTS AFFECTED

Riabni (rituximab-arrx), Rituxan (rituximab), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Rheumatoid arthritis, Pemphigus vulgaris, Chronic graft versus host disease, Wegner's granulomatosis, Primary Sjogren syndrome, Neuromyelitis optica spectrum disorder, Relapsing-remitting multiple sclerosis, Refractory thrombocytopenia, Systemic lupus erythematous, Lupus nephritis (refractory), Recurrent and resistant dermatomyositis and polymyositis, Autoimmune Hemolytic anemia, Cold Agglutinin Disease, Autoimmune encephalitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment

AND

2. (a) IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.
   AND
   (b) If request is for reference product with a biosimilar available for initial or continuation of therapy requests: Documentation of a trial and failure, serious side effects, or contraindication to a majority (not more than 3) biosimilar product(s) is required (unless otherwise specified per applicable state regulations and/or there is data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs).
   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non- descriptive symptoms are not adequate rationale (e.g., stomachache).]
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.
   OR
3. FOR INITIAL OR CONTINUATION OF THERAPY REQUESTS OF A PHYSICIAN ADMINISTERED MEDICATION: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug per applicable state regulations and/or there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:
   (a) Treatment with at least two associated biosimilar drug(s) has been ineffective, resulted in serious side effects, or is contraindicated (i.e. an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient diary or medical charted notes)

   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non- descriptive symptoms are not adequate rationale (e.g., stomachache).]

A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:
   1. Documentation of moderate to severe rheumatoid arthritis diagnosis
      AND
   2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
      AND
   3. (a) Member is currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity
      OR
      (b) Member has an FDA labeled contraindication or serious side effects to methotrexate, as determined by the prescribing physician AND Member has tried one additional disease- modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months
      NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the member has already had a 3-month trial of at least one biologic. These members who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD.
      AND
   4. Age Restriction: 18 years of age and older
      AND

5. Quantity: Two 1,000 mg IV infusions separated by 2 weeks (in combination with methotrexate); subsequent courses maybe administered every 24 weeks (based on clinical evaluation), if necessary, may be repeated no sooner than every 16 weeks.
   AND
6. Duration of Approval: Initial authorization: 6 months, Continuation of therapy 12 months

B. ONCOLOGY INDICATIONS and POST-TRANSPLANT LYMPHOPROLIFERATIVE DISEASE: (SEE STANDARD ONCOLOGY CRITERIA)

C. PEMPHIGUS VULGARIS:
1. Documentation of a diagnosis of pemphigus vulgaris confirmed by the presence of any of the following on biopsy: Intraepithelial cleavage with acantholysis (detached keratinocytes) primarily localized to the suprabasal region, Retention of basal keratinocytes along the basement membrane zone, resulting in an appearance that resembles a "row of tombstones" or Sparse inflammatory infiltrate in the dermis with eosinophils [DOCUMENTATION REQUIRED]
   AND
2. (a) Documentation of a trial (2 weeks) and inadequate response, serious side effects, or contraindication to systemic glucocorticoids
   OR
   (b) Rituximab is initiated in combination with a glucocorticoid (e.g., prednisone)
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
4. Age Restriction: 18 years of age and older
   AND
5. Quantity: Two 1,000 mg IV infusions separated by 2 weeks followed by 500 mg infusion at month 12 and every 6 months thereafter. Use 1000 mg if relapse. Subsequent infusions may be administered no sooner than 16 weeks following the previous infusion.
   AND
6. Duration of Approval: Initial authorization: 1 month, Continuation of therapy: 6 months

D. CHRONIC, REFRACTORY, GRAFT-VS-HOST DISEASE:
1. Documented diagnosis of chronic graft versus host disease (GVHD)
   AND
2. (a) Documentation member has tried one immunosuppressant (e.g., one corticosteroid such as methylprednisolone, cyclosporine, thalidomide, tacrolimus, mycophenolate mofetil, sirolimus, Nipent®, imatinib)
   OR
   (b) Documentation member is concurrently receiving at least one of these medications (e.g., one corticosteroid such as methylprednisolone, cyclosporine, Thalomid, tacrolimus, mycophenolate mofetil, sirolimus, Nipent, imatinib) with Rituxan.
   OR
   (c) Documentation member was already given inpatient induction doses and request is for completion of regimen outpatient.
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
4. Age Restriction: 18 years of age and older
   AND
5. Quantity: 375 mg/m2 IV once weekly for up to four doses; a second course of 4 weekly doses may be administered 8 weeks after initial therapy OR 375 mg/m2 once weekly for 4-8 doses
   AND
6. Duration of Approval: Initial authorization: 1 month, Continuation of therapy: 6 months

E. WEGENER'S GRANULOMATOSIS (Granulomatosis with polyangiitis and microscopic polyangiitis):
1. Documented diagnosis of Wegener's granulomatosis or microscopic polyangiitis
   AND
2. Documentation that member is receiving concurrent therapy with glucocorticoids or has a history of a contraindication or intolerance to glucocorticoids
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
4. Age Restriction: 2 years of age and older
   AND
5. Quantity Limitation for Adults (18 years of age and older): Induction dosing (for active granulomatosis with polyangiitis): 375 mg/m2 once weekly for 4 doses. Follow up dosing (after achieving disease control with induction): two 500 mg infusions separated by 2 weeks, followed by 500 mg once every 4-6 months thereafter
   OR
   Quantity Limitation for Pediatrics (2-17 years of age): Induction dosing: 375 mg/m2 once weekly for 4 doses. Follow up dosing (after achieving disease control with induction): two 250 mg/m2 infusions separated by 2 weeks, followed by 250 mg/m2 once every 6 months thereafter
   AND
6. Duration of Approval: Initial authorization: 6 months, Continuation of therapy 12 months

F. PRIMARY SJOGREN'S SYNDROME:
1. Documented diagnosis of moderate to severe Sjogren's syndrome [DOCUMENTATION REQUIRED]
   AND
2. Documentation member has tried and failed or has a contraindication to TWO of the following: hydroxychloroquine, methotrexate, azathioprine, leflunomide, mycophenolate or cyclosporine
   AND
3. Age Restriction: 18 years of age and older
   AND
4. Quantity: 1000 mg IV infusion on days 1 and 15
   AND
5. Duration of Approval: 1-month, single course of two doses

G. NEUROMYELITIS OPTICA SPECTRUM DISORDER:
1. Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
   AND
2. Documentation of serologic testing for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies [DOCUMENTATION REQUIRED]
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
4. Age Restriction: 18 years of age and older
   AND
5. Quantity: 1000 mg once every 2 weeks for 2 doses OR 375 mg/m2 IV once weekly for four doses, then 1000 mg once every 6 months or when monthly CD19 cells counts are >0.1% of total lymphocytes
   AND
6. Duration of Approval: Initial authorization: 6 months, Continuation of therapy 12 months

H. RELAPSING-REMITTING MULTIPLE SCLEROSIS:
1. Documentation of a definitive diagnosis of a relapsing form of multiple sclerosis
   AND
2. Documentation that member has had an inadequate response or was unable to tolerate at least ONE other high efficacy disease-modifying agent for MS (e.g., Ocrevus™ [ocrelizumab IV infusion],

Gilenya [fingolimod capsules], [dimethyl fumarate delayed- release capsules, or Lemtrada [alemtuzumab IV injection])
AND

3. Prescribed by or in consultation with a physician who specializes in the treatment of MS and/or a neurologist.
AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
5. Are Restriction: 18 years of age and older
AND
6. Quantity: 1000 mg once every 2 weeks for 2 doses then 1000 mg once every 6 to 12 months OR 500 mg or 1000 mg IV single infusion every 6 to 12 months
AND
7. Duration of Approval: Initial authorization: 6 months, Continuation of therapy: 12 months

I. REFRACTORY IMMUNE THROMBOCYTOPENIA:

1. Documented diagnosis of chronic ITP (disease course greater than 6 months)
AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to one other therapy (e.g., intravenous immunoglobulin [IVIG], anti-D [RHO]immunoglobulin, corticosteroids, or splenectomy).
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
4. Age Restriction: 18 years of age and older
AND
5. Quantity: 375 mg/m2 IV once weekly for 4 doses
AND
6. Duration of Approval: Initial authorization: 1 month, Continuation of therapy: additional 1 month if 6 months or greater have passed since the first dose of previous Rituxan regimen
NOTE: Any requests outside of this duration please refer to off-label policy

J. SYSTEMIC LUPUS ERYTHEMATOUS (SLE) AND LUPUS NEPHRITIS:

1. Documented diagnosis of systemic lupus erythematosus (SLE)
AND
2. (a) Documentation member has neuropsychiatric manifestations of SLE AND has tried at least ONE other therapy (e.g., at least one antidepressant, antipsychotic, corticosteroid, immunosuppressant, or plasma exchange)
OR
(b) Documentation member has lupus nephritis AND has tried and failed or a labeled contraindication to BOTH mycophenolate mofetil AND cyclophosphamide with or without glucocorticoids
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
4. Age Restriction: 18 years of age and older
AND
5. Quantity: 375 mg/m2 once weekly for 4 doses, or 1000 mg (flat dose) on days 0 and 15
AND
6. Duration of Approval: Initial authorization: 6 months, Continuation of therapy: 12 months

K. DERMATOMYOSITIS AND POLYMYOSITIS:

1. Documented diagnosis of dermatomyositis or polymyositis confirmed by positive biopsy [DOCUMENTATION REQUIRED]
   AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (measurable, objective measures of CPK levels, muscle strength, or EMG abnormalities) [DOCUMENTATION REQUIRED]
   AND
3. Documentation of ANY of the following: (i) Severe active disease state, (ii) Muscle weakness in all upper and/or lower limbs, (iii) Cutaneous manifestations
   AND
4. Documented refractory disease (as evidenced by persistently elevated serum creatine kinase and/or lack of improvement on muscle strength improvement scales) that has failed to respond to at least an adequate three month trial of the following first and second-line conventional therapies (unless contraindicated): Corticosteroids AND Immunosuppressants (e.g., azathioprine, methotrexate, cyclophosphamide, and cyclosporine)
   AND
5. Age Restriction: 18 years of age and older
   AND
6. Quantity: 1000 mg once every 1-2 weeks for 2 doses
   AND
7. Duration of Approval: Initial authorization: 3 months, Continuation of therapy: 6 months

L. AUTOIMMUNE HEMOLYTIC ANEMIA:

1. Documented diagnosis of warm-type autoimmune hemolytic anemia confirmed by detection of antibody and/or complement components on the surface of the RBC [usually by the direct antiglobulin (Coombs) test] [DOCUMENTATION REQUIRED]
   AND
2. Documented treatment failure, serious side effects or clinical contraindication to corticosteroid therapy
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
4. Age Restriction: 18 years of age and older
   AND
5. Quantity: 375 mg/m2 once weekly for 4 doses
   AND
6. Duration of Approval: Initial authorization: 6 months, Continuation of therapy: 6 months

M. COLD AGGLUTININ DISEASE (CAD):

1. Documented diagnosis of primary cold agglutinin disease (CAD)
   AND
2. Documentation member has the presence of one or more symptoms associated with CAD such as symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event
   AND
3. Age Restriction: 18 years of age and older
   AND
4. Quantity: Monotherapy: 375 mg/m2 once weekly for 4 weeks; Combination: 4 cycles
   AND
5. Duration of Approval: Initial authorization: 6 months, Continuation of therapy: N/A

N. AUTOIMMUNE ENCEPHALITIS:

1. Documented diagnosis of autoimmune encephalitis

AND

2. Documentation diagnosis was confirmed by imaging (MRI), electroencephalogram (EEG), cerebrospinal fluid (CSF) analysis, and autoantibody testing
   AND
3. Documentation of baseline neurologic symptoms (e.g., seizures, psychiatric symptoms, memory deficits, etc.)
   AND
4. Documentation of trial and failure, serious side effects, or clinical contraindication to glucocorticoids, IVIG, or plasma exchange therapy
   AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal
   AND
6. Age Restriction: No restriction
   AND
7. Quantity: 500mg – 1000mg every 2 weeks x 2 doses OR 375-750 mg/m2 (max 1g) every 2 weeks x 2 doses OR 375 mg/m2 (max 1g) weekly x 4 doses
   AND
8. Duration of Approval: Initial authorization: 6 months, Continuation of therapy: 6 months

CONTINUATION OF THERAPY:

A. ALL INDICATIONS (EXCEPT SJOGREN'S SYNDROME AND CAD):

1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
2. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]
   AND
3. IF THIS IS A PHYSICIAN ADMINISTERED MEDICATION REQUEST: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug per applicable state regulations and/or there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:
   (a) Treatment with at least two associated biosimilar drug(s) has been ineffective, resulted in serious side effects, or is contraindicated (i.e. an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient diary or medical charted notes)

   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]

DURATION OF APPROVAL:

SEE REQUIRED MEDICAL INFORMATION
MOLINA REVIEWER NOTE: For Illinois Marketplace, Kentucky Marketplace, Mississippi Marketplace, Ohio Marketplace, Kentucky Medicaid, and Mississippi Medicaid, please see Appendix.

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a specialist in the area of disease being treated. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
SEE REQUIRED MEDICAL INFORMATION

QUANTITY:

SEE REQUIRED MEDICAL INFORMATION

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Riabni (rituximab-arrx), Rituxan (rituximab), Ruxience (rituximab-pvvr), and Truxima (rituximab-abbs). For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Antineoplastic – Anti-CD20 Antibodies

FDA-APPROVED USES:
Rituxan (rituximab) is indicated for:

- Adult patients with Non-Hodgkin's Lymphoma (NHL).
- Pediatric patients aged 6 months and older with mature B-cell NHL and mature B-cell acute leukemia (B-AL)
- Adult patients with Chronic Lymphocytic Leukemia (CLL).
- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies.
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids.
- Moderate to severe Pemphigus Vulgaris (PV) in adult patients.

RIABNI (rituximab-arrx), RUXIENCE (rituximab-pvvr), TRUXIMA (rituximab-abbs) are indicated for:

- Adult patients with Non-Hodgkin's Lymphoma (NHL)
- Adult patients with Chronic Lymphocytic Leukemia (CLL)
- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids
- Moderate to severe Pemphigus Vulgaris (PV) in adult patients

COMPENDIAL APPROVED OFF-LABELED USES:
Chronic graft versus host disease, Lupus nephritis (refractory), Recurrent and resistant dermatomyositis and polymyositis, Autoimmune Hemolytic anemia, Refractory immune thrombocytopenia, Relapsing- remitting MS, Systemic lupus erythematous, Primary Sjogren syndrome, Neuromyelitis Optica Spectrum disorder, Cold Agglutinin Disease, Autoimmune encephalitis

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 200/60) Sec. 60. Length of prior authorization approval. *A prior authorization approval shall be valid for the lesser of 6 months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined* by the patient's health care professional or the renewal of the plan, and the *approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug* prescribed by the health care professional. All dosage increases must be based on established evidentiary standards and nothing in this Section shall prohibit a health insurance issuer from having safety edits in place. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids. Except to the extent required by medical exceptions processes for prescription drugs set forth in Section 45.1 of the Managed Care Reform and Patient Rights Act, nothing in this Section shall require a policy to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's covered benefits without regard for whether the care, treatment, or services are medically necessary. (Source: P.A. 102-409, eff. 1-1-22.)"
"(215 ILCS 200/65) Sec. 65. Length of prior authorization approval for *treatment for chronic or long-term conditions*. If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, *the approval shall remain valid for the lesser of 12 months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional*. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids. Except to the extent required by medical exceptions processes for prescription drugs set forth in Section 45.1 of the Managed Care Reform and Patient Rights Act, nothing in this Section shall require a policy to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's covered benefits without regard for whether the care, treatment, or services are medically necessary. (Source: P.A. 102-409, eff. 1-1-22.)"
Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

Kentucky (Source: Kentucky Revised Statutes)
KY304.17A-167 Time span of authorizations
(Subsection 2) "Unless otherwise provided in subsection (3) of this section or prohibited by state or federal law, if a provider receives a prior authorization for a drug prescribed to a covered person with a condition that requires ongoing medication therapy, and the provider continues to prescribe the drug, and the drug is used for a condition that is within the scope of use approved by the United States Food and Drug Administration or has been proven to be a safe and effective form of treatment for the patient's specific underlying condition based on clinical practice guidelines that are developed from peer-reviewed publications, the prior authorization received shall: (a) Be valid for the lesser of: 1. One (1) year from the date the provider receives the prior authorization; or

2. Until the last day of coverage under the covered person's health benefit plan during a single plan year; and
(b) Cover any change in dosage prescribed by the provider during the period of authorization." (Subsection 3) "Except as provided in paragraph (b) of this subsection, the provisions of subsection (2) of this section shall not apply to: 1. Medications that are prescribed for a non-maintenance condition; 2. Medications that have a typical treatment period of less than twelve (12) months; 3. Medications where there is medical or scientific evidence that does not support a twelve (12) month approval; or 4. Medications that are opioid analgesics or benzodiazepines. (b) Paragraph (a) of this subsection shall not apply to any medication that is prescribed to a patient in a community-based palliative care program."
Re-authorization (approved authorization previously issued by Molina Healthcare) for maintenance medications within this policy shall be approved for a 12 month duration when request meets policy requirements, unless exceptions noted above have been met.

Mississippi (Source: Mississippi Legislature)
"SECTION 13. Length of approvals. (1) A prior authorization approval shall be valid for the lesser of six (6) months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined by the patient's health care professional or the renewal of the policy or plan, and the approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug prescribed by the health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his/her health care professional may extend a prior authorization approval for a longer period, by agreement. All dosage increases must be based on established evidentiary standards, and nothing in this section shall prohibit a health insurance issuer from having safety edits in place. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment or services are medically necessary.
SECTION 14. Approvals for chronic conditions. (1) If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, including, but not limited to, chemotherapy for the treatment of cancer, the approval shall remain valid for the lesser of twelve (12) months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his or her health care professional may extend a prior authorization approval for a longer period, by agreement. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment, or services are medically necessary."

Ohio (Source: Ohio Revised Code)
Chapter 3923 Sickness And Accident Insurance Section 3923.041 Policies with prior authorization requirement provisions "(B)(6)(a) For policies issued on or after January 1, 2017, *for a prior approval related to a chronic condition*, the insurer or plan shall honor a prior authorization *approval for an approved drug for the lesser of the following from the date of the approval: (i) Twelve months*; (ii) The last day of the covered person's eligibility under the policy or plan.
(b) The duration of all other prior authorization approvals shall be dictated by the policy or plan."

State Medicaid
Kentucky (Source: Kentucky Revised Statutes)
KY304.17A-167 Time span of authorizations
(Subsection 2) "Unless otherwise provided in subsection (3) of this section or prohibited by state or federal law, if a provider receives a prior authorization for a drug prescribed to a covered person with a condition that requires ongoing medication therapy, and the provider continues to prescribe the drug, and the drug is used for a condition that is within the scope of use approved by the United States Food and Drug Administration or has been proven to be a safe and effective form of treatment for the patient's specific underlying condition based on

clinical practice guidelines that are developed from peer-reviewed publications, the prior authorization received shall: (a) Be valid for the lesser of: 1. One (1) year from the date the provider receives the prior authorization; or 2. Until the last day of coverage under the covered person's health benefit plan during a single plan year; and (b) Cover any change in dosage prescribed by the provider during the period of authorization." (Subsection 3) "Except as provided in paragraph (b) of this subsection, the provisions of subsection (2) of this section shall not apply to: 1. Medications that are prescribed for a non-maintenance condition; 2. Medications that have a typical treatment period of less than twelve (12) months; 3. Medications where there is medical or scientific evidence that does not support a twelve (12) month approval; or 4. Medications that are opioid analgesics or benzodiazepines. (b) Paragraph (a) of this subsection shall not apply to any medication that is prescribed to a patient in a community-based palliative care program."

Re-authorization (approved authorization previously issued by Molina Healthcare) for maintenance medications within this policy shall be approved for a 12 month duration when request meets policy requirements, unless exceptions noted above have been met.

Mississippi (Source: Mississippi Legislature)

"SECTION 13. Length of approvals. (1) A prior authorization approval shall be valid for the lesser of six (6) months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined by the patient's health care professional or the renewal of the policy or plan, and the approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug prescribed by the health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his/her health care professional may extend a prior authorization approval for a longer period, by agreement. All dosage increases must be based on established evidentiary standards, and nothing in this section shall prohibit a health insurance issuer from having safety edits in place. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.

(2) Nothing in this section shall require a policy or plan to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment or services are medically necessary.

SECTION 14. Approvals for chronic conditions. (1) If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, including, but not limited to, chemotherapy for the treatment of cancer, the approval shall remain valid for the lesser of twelve (12) months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his or her health care professional may extend a prior authorization approval for a longer period, by agreement. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.

(2) Nothing in this section shall require a policy or plan to cover any care, treatment or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment, or services are medically necessary."

APPENDIX 1:

A biosimilar is highly similar version of a brand name biological drug that meets strict controls for structural, pharmaceutical, and clinical consistency. A biosimilar manufacturer must demonstrate that there are no meaningful clinical differences (i.e., safety and efficacy) between the biosimilar and the reference product. Clinical performance is demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.1 As costs for biological specialty drugs continue to rise, the growing biosimilar market will benefit providers and patients by broadening biological treatment options and expanding access to these medications at lower costs. Molina Healthcare, Inc. continues to be committed to continually reevaluating Preferred strategies and applying innovative cost-controls to ensure patients receive safe, effective, and quality healthcare. This commitment includes potentially creating a preference for biosimilars when value can be added without compromising Member satisfaction and safety.

1. Food and Drug Administration. Biosimilar and Interchangeable Products. Retrieved from

https://www.fda.gov/drugs/biosimilars/biosimilar- and-interchangeable-products.AccessedOctober8, 2019.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

The use of Rituxan is also supported in clinical guidelines in numerous other situations, both as first-line therapy and in patients who are refractory or have relapsed following treatment with other therapies.2-8Rituxan features prominently in the National Comprehensive Cancer Network (NCCN) guidelines for treatment of B-cell lymphomas and CLL/small lymphocytic lymphoma and is included in multiple treatment regimens across the spectrum of disease.

Guidelines from the American College of Rheumatology (ACR) [2015] have tumor inhibitors and non-TNF biologics (including Rituxan IV), equally positioned following a trial of a conventional synthetic DMARD. EULAR/ERA-EDTA recommendations for ANCA-associated vasculitis mention Rituxan in combination with low-dose corticosteroids as a potential treatment option for remission-maintenance therapy. Remission- maintenance therapy is recommended for at least 24 months following induction of sustained remission.

The British Committee for Standards in Hematology (BCSH) and the British Society for Bone Marrow Transplant recommendations for the management of chronic GVHD (2012) list Rituxan as a potential second-line treatment for patients with refractory cutaneous or musculoskeletal chronic GVHD or third- line for treatment of GVHD involving other organs.

Guidelines from the American Society of Hematology (ASH) for ITP (2011) mention Rituxan as an appropriate agent for children and adolescents with ITP who have significant on-going bleeding despite treatment with intravenous immunoglobulin G (IVIG), anti-D, or corticosteroids.3 Rituxan is also appropriate as an alternative to splenectomy in children/adolescents with chronic ITP or in Member who do not respond to splenectomy. In adults, Rituxan in recommended for patients with ITP who are at risk for bleeding and who have failed one other line of therapy (e.g., corticosteroids, IVIg, splenectomy).

EULAR recommendations for the management of systemic lupus erythematosus with neuropsychiatric manifestations (2010) mention Rituxan as a therapeutic option for patients with neuropsychiatric SLE refractory to standard immunosuppressive therapies.4 Rituxan is used in patients with a refractory acute confusional state or other psychiatric disorders (e.g., lupus psychosis), and in severe peripheral nervous system disorders (e.g., polyneuropathy, mononeuropathy, acute inflammatory demyelinating polyradiculoneuropathy, myasthenia gravis, plexopathy). EULAR in combination with the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) has recommendations for the management of adult and pediatric lupus nephritis (2012).19 Rituxan is an alternative for patients who do not respond to first-line therapies. ACR recommendations for management of lupus nephritis (2012)5 note that Rituxan may be appropriate in certain patients with lupus nephritis who have tried mycophenolate mofetil and cyclophosphamide and in patients whose nephritis fails to improve or worsens following 6 months of one induction therapy.

Rituxan Hycela is a combination of rituximab and hyaluronidase human. It contains the identical molecular antibody of rituximab available in Rituxan IV, but hyaluronidase has been added to facilitate systemic delivery. Rituxan Hycela should be administered under the care of a healthcare professional with appropriate medical support to manage severe and potentially fatal reactions. The dose of Rituxan Hycela is fixed regardless of the patient's body surface area (BSA); dose reductions are not recommended. When given in combination with chemotherapy, reduce the dose of chemotherapeutic drugs to manage adverse events (AEs). Rituxan Hycela is not indicated for treatment of non-malignant conditions.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Riabni (rituximab-arrx), Rituxan (rituximab), Ruxience (rituximab-pvvr), and Truxima (rituximab-abbs) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to rituximab include: No labeled contraindications to Rituxan or any biosimilar product.

OTHER SPECIAL CONSIDERATIONS:

Rituximab has a black box warning for: fatal infusion-related reactions, severe mucocutaneous reactions, hepatitis b virus reactivation and progressive multifocal leukoencephalopathy.

Waste Management for All Indications: Dosing is either a standard dose (e.g., 1,000 mg/dose) or the dose is based on body surface area (kg/m2). If a standard dose is used, use the lowest amount of Rituxan possible to achieve the dose required. If the dose is based on body surface area, the dose should be calculated, and the number of vials needed assessed.

Rituxan Hycela has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions: Granulomatosis with Polyangiitis (GPA) [Wegener's granulomatosis] or Microscopic Polyangiitis (MPA): Rituxan IV is indicated for treatment of GPA or MPA. Rituxan Hycela has not been evaluated and does not have established dosing for GPA or MPA. Rheumatoid Arthritis (RA): Rituxan IV is indicated for treatment of RA.5 Rituxan Hycela has not been evaluated and does not have established dosing for RA.

Rituxan Hycela (rituximab and hyaluronidase human) is indicated for:

- Follicular Lymphoma (FL)
- Diffuse Large B-cell Lymphoma (DLBCL)
- Chronic Lymphocytic Leukemia (CLL)

Limitations of Use: Initiate treatment with RITUXAN HYCELA only after patients have received at least one full dose of a rituximab product by intravenous infusion. ***RITUXAN HYCELA is not indicated for the*** **treatment of non-malignant conditions.**

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J9312	Rituxan-Injection, rituximab, 10mg
Q5115	Injection, rituximab-abbs, biosimilar, (truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg

AVAILABLE DOSAGE FORMS:
Riabni SOLN 100MG/10ML
Riabni SOLN 500MG/50ML

REFERENCES

1. Rituxan (rituximab) injection, for intravenous use [prescribing information]. South San Francisco, CA: Genentech, Inc.; December 2021.
2. Rituxan Hycela (rituximab and hyaluronidase human) injection, for subcutaneous use [prescribing information]. South San Francisco, CA: Biogen and Genentech/Roche; June 2021.
3. Truxima (rituximab-abbs) injection, for intravenous use [prescribing information]. North Wales, PA: Teva Pharmaceuticals; June 2025.
4. Ruxience (rituximab-pvvr) injection, for intravenous use [prescribing information]. Cork, Ireland: Pfizer; June 2025.
5. Riabni (rituximab-arrx) injection, for intravenous use [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; July 2025.
6. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol.2016;68(1):1-26.
7. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence- based practice guideline for immune thrombocytopenia. Blood. 2011;117(16):4190-4207.
8. Bertsias GK, Ioannidis JP, Aringer M, et al. EULAR recommendations for the management of systemic lupus erythematosus with neuropsychiatric manifestations: report of a task force of the EULAR standing committee for clinical affairs. Ann Rheum Dis. 2010;69(12):2074-2082.
9. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. Arthritis Care Res (Hoboken). 2012;64(6):797-808
10. The NCCN Drugs and Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on October 16, 2018. Search term: rituximab.
11. Yates M, Watts RA, Bajema IM, et al. EULAR/ERA-EDTA recommendations for the management of ANCA-associated vasculitis. Ann Rheum Dis.2016;75(9):1583-1594.
12. Guerry MJ, Brogan P, Bruce IN, et al. Recommendations for the use of rituximab in anti- neutrophil cytoplasm antibody-associated vasculitis. Rheumatology (Oxford).2012;51(4):634- 643.
13. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. Ann Rheum Dis. 2013;72 Suppl2:ii2-34.
14. Jones RB, Ferraro AJ, Chaudhry AN, et al. A multicenter survey of rituximab therapy for refractory antineutrophil cytoplasmic antibody associated vasculitis. Arthritis Rheum.2009;60(7):2156-2168.
15. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (Version 5.2018 – October 2, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on October 16, 2018.
16. Bosch F, Abrisqueta P, Villamor N, et al. Rituximab, fludarabine, cyclophosphamide, and mitoxantrone: a new, highly active chemoimmunotherapy regimen for chronic lymphocytic leukemia. J Clin Oncol.2009;27(27):4578-4584.
17. van Oers MH, Van Glabbeke M, Giurgea L, et al. Rituximab maintenance treatment of relapsed/resistant follicular non-Hodgkin's lymphoma: long-term outcome of theEORTC20981 phase III randomized intergroup study. J Clin Oncol. 2010;28(17):2853- 2858.
18. van Oers MH, Klasa R, Marcus RE, et al. Rituximab maintenance improves clinical outcome of relapsed/resistant follicular non-Hodgkin lymphoma in patients both with and without rituximab during induction: results of a prospective randomized phase 3 intergroup trial. Blood.2006;108(10):3295-3301
19. Efficacy and safety of rituximab in patients with active proliferative lupus nephritis: the Lupus Nephritis Assessment with Rituximab study. Rovin BH, Furie R, Latinis K, Looney RJ, Fervenza FC, Sanchez-Guerrero J, Maciuca R, Zhang D, Garg JP, Brunetta P, Appel G, LUNAR Investigator Group. Arthritis Rheum. 2012 Apr;64(4):1215-26. Epub 2012 Jan9.

20. Brodsky, R., 2019. Warm Autoimmune Hemolytic Anemia. New England Journal of Medicine, 381(7), pp.647-654.
21. Cutler, C., Miklos, D., Kim, H., Treister, N., Woo, S., & Bienfang, D. et al. (2006). Rituximab for steroid-refractory chronic graft-versus-host disease. Blood, 108(2), 756-762. doi: 10.1182/blood-2006-01-0233
22. Malard, F., Labopin, M., Yakoub-Agha, I., Chantepie, S., Guillaume, T., & Blaise, D. et al. (2017). Rituximab-based first-line treatment of cGVHD after allogeneic SCT: results of a phase 2 study. Blood, 130(20), 2186-2195. doi: 10.1182/blood-2017-05-786137
23. Meijer, J., Meiners, P., Vissink, A., Spijkervet, F., Abdulahad, W., & Kamminga, N. et al. (2010). Effectiveness of rituximab treatment in primary Sjögren's syndrome: A randomized, double-blind, placebo- controlled trial. Arthritis & Rheumatism, 62(4), 960-968. doi: 10.1002/art.27314
24. Ciron, J., Audoin, B., Bourre, B., Brassat, D., Durand-Dubief, F., & Laplaud, D. et al. (2018). Recommendations for the use of Rituximab in neuromyelitis optica spectrum disorders. Revue Neurologique, 174(4), 255-264. doi: 10.1016/j.neurol.2017.11.005
25. Salzer, J., Svenningsson, R., Alping, P., Novakova, L., Björck, A., & Fink, K. et al. (2016). Rituximab in multiple sclerosis. Neurology, 87(20), 2074-2081. doi: 10.1212/wnl.0000000000003331
26. Clark, W., Rock, G., Barth, D., Arnold, D., Webert, K., & Yenson, P. et al. (2015). A phase-II sequential case-series study of all patients presenting to four plasma exchange centres with presumed relapsed/refractory thrombotic thrombocytopenic purpura treated with rituximab. British Journal Of Haematology, 170(2), 208-217. doi: 10.1111/bjh.13408
27. Miyakawa, Y., Imada, K., Ichinohe, T., Nishio, K., Abe, T., & Murata, M. et al. (2016). Efficacy and safety of rituximab in Japanese patients with acquired thrombotic thrombocytopenic purpura refractory to conventional therapy. International Journal Of Hematology, 104(2), 228-235. doi: 10.1007/s12185- 016-2019-x
28. Melander, C., Sallée, M., Trolliet, P., Candon, S., Belenfant, X., & Daugas, E. et al. (2009). Rituximab in Severe Lupus Nephritis: Early B-Cell Depletion Affects Long-Term Renal Outcome. Clinical Journal Of The American Society Of Nephrology, 4(3), 579-587. doi: 10.2215/cjn.04030808
29. Weidenbusch, M., Römmele, C., Schröttle, A., & Anders, H. (2012). Beyond the LUNAR trial. Efficacy of rituximab in refractory lupus nephritis. Nephrology Dialysis Transplantation, 28(1), 106-111. doi: 10.1093/ndt/gfs285
30. Mahler, E., Blom, M., Voermans, N., van Engelen, B., van Riel, P., & Vonk, M. (2011). Rituximab treatment in patients with refractory inflammatory myopathies. Rheumatology, 50(12), 2206-2213. doi: 10.1093/rheumatology/ker088
31. Oddis, C. V., Reed, A. M., Aggarwal, R., Rider, L. G., Ascherman, D. P., Levesque, M. C., Barohn, R. J., Feldman, B. M., Harris-Love, M. O., Koontz, D. C., Fertig, N., Kelley, S. S., Pryber, S. L., Miller, E.W., Rockette, H. E., & RIM Study Group (2013). Rituximab in the treatment of refractory adult and juvenile dermatomyositis and adult polymyositis: a randomized, placebo-phase trial. Arthritis and rheumatism, 65(2), 314–324. https://doi.org/10.1002/art.37754
32. Jäger, U., Barcellini, W., Broome, C. M., Gertz, M. A., Hill, A., Hill, Q. A., Jilma, B., Kuter, D. J., Michel, M., Montillo, M., Röth, A., Zeerleder, S. S., & Berentsen, S. (2020). Diagnosis and treatment of autoimmune hemolytic anemia in adults: Recommendations from the First International Consensus Meeting. Blood reviews, 41, 100648. https://doi.org/10.1016/j.blre.2019.100648
33. Wolff, D., Schleuning, M., von Harsdorf, S., Bacher, U., Gerbitz, A., Stadler, M., … Holler, E. (2011). Consensus Conference on Clinical Practice in Chronic GVHD: Second-Line Treatment of Chronic Graft-versus-Host Disease. Biology of Blood and Marrow Transplantation, 17(1), 1–17. https://doi.org/10.1016/j.bbmt.2010.05.011
34. Pendergraft, W. F., Cortazar, F. B., Wenger, J., Murphy, A. P., Rhee, E. P., Laliberte, K. A., & Niles, J. L. (2014). Long-Term Maintenance Therapy Using Rituximab-Induced Continuous B-Cell Depletion in Patients with ANCA Vasculitis. Clinical Journal of the American Society of Nephrology, 9(4), 736–744. https://doi.org/10.2215/cjn.07340713
35. Devauchelle-Pensec, V., Mariette, X., Jousse-Joulin, S., Berthelot, J.-M., Perdriger, A., Puéchal, X., … Saraux, A. (2014). Treatment of Primary Sjögren Syndrome With Rituximab. Annals of Internal Medicine, 160(4), 233–242. https://doi.org/10.7326/m13-1085
36. Bellinvia, A., Prestipino, E., Portaccio, E., Razzolini, L., Mattia Fonderico, Fratangelo, R., … Maria Pia Amato. (2020). Experience with rituximab therapy in a real-life sample of multiple sclerosis patients. Neurological Sciences, 41(10), 2939–2945. https://doi.org/10.1007/s10072-020-04434-1
37. Rovin, B. H., Adler, S. G., Barratt, J., Bridoux, F., Burdge, K. A., Chan, T. M., … Ronco, P. (2021).

KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney International, 100(4), S1–S276. https://doi.org/10.1016/j.kint.2021.05.021
38. Jürgen Floege, David R.W. Jayne, Sanders, J.-S. F., Tesar, V., & Rovin, B. H. (2024). KDIGO 2024 Clinical Practice Guideline for the Management of Antineutrophil Cytoplasmic Antibody (ANCA)–Associated Vasculitis. Kidney International, 105(3), S71–S116. https://doi.org/10.1016/j.kint.2023.10.008
39. Berentsen S, Tjønnfjord GE. Diagnosis and treatment of cold agglutinin mediated autoimmune hemolytic anemia. Blood Rev 2012; 26:107
40. Schöllkopf C, Kjeldsen L, Bjerrum OW, et al. Rituximab in chronic cold agglutinin disease: a prospective study of 20 patients. Leuk Lymphoma 2006; 47:253.
41. Berentsen S, Ulvestad E, Gjertsen BT, et al. Rituximab for primary chronic cold agglutinin disease: a prospective study of 37 courses of therapy in 27 patients. Blood 2004; 103:2925.
42. Gueli A, Gottardi D, Hu H, et al. Efficacy of rituximab-bendamustine in cold agglutinin haemolytic anaemia refractory to previous chemo-immunotherapy: a case report. Blood Transfus 2013; 11:311.
43. Fattizzo B, Zaninoni A, Pettine L, et al. Low-dose rituximab in autoimmune hemolytic anemia: 10 years after. Blood 2019; 133:996.
44. Berentsen S, Randen U, Oksman M, et al. Bendamustine plus rituximab for chronic cold agglutinin disease: results of a Nordic prospective multicenter trial. Blood 2017; 130:537.
45. Jäger, U., Barcellini, W., Broome, C. M., Gertz, M. A., Hill, A., Hill, Q. A., … Berentsen, S. (2020). Diagnosis and treatment of autoimmune hemolytic anemia in adults: Recommendations from the First International Consensus Meeting. Blood Reviews, 41(1), 100648. https://doi.org/10.1016/j.blre.2019.100648
46. Nosadini, M., Thomas, T., Eyre, M., Anlar, B., Armangue, T., Benseler, S. M., … Sharma, S. (2021). International Consensus Recommendations for the Treatment of Pediatric NMDAR Antibody Encephalitis. Neurology - Neuroimmunology Neuroinflammation, 8(5). https://doi.org/10.1212/NXI.0000000000001052
47. Abboud, H., Probasco, J. C., Irani, S., Ances, B., Benavides, D. R., Bradshaw, M., … Rojas, G. (2021). Autoimmune encephalitis: proposed best practice recommendations for diagnosis and acute management. Journal of Neurology, Neurosurgery & Psychiatry, 92(7), 757–768. https://doi.org/10.1136/jnnp-2020-325300

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Place of Administration FDA-Approved Uses Appendix References	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Products Affected Diagnosis Required Medical Information Appendix Background Other Special Considerations References	Q4 2024

REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Continuation of Therapy Duration of Approval Quantity Drug Class FDA-Approved Uses Compendial Approved Off-Labeled Contraindications/Exclusions/Discontinuation Coding/Billing Information Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Age Restrictions Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file