Rituxan Step Therapy

Rituxan (rituximab) J9312 IV and Rituxan Hycela (rituximab/hyaluronidase human) J9311, Truxima (rituximab-abbs) IV Q5115 is non-preferred. The preferred products are: Ruxience (rituximab-pvvr) Q5119, Riabni (rituximab-arrx) Q5123

Prior Authorization Step Therapy Medicare Part B Request Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	Date Requested _____
	Requestor _____ Clinic name: _____ Phone / Fax

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug ☐ Self-administered	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).

Prior Authorization Group – Rituximab PA

Drug Name(s):

RITUXAN (rituximab) IV
RIABNI
TRUXIMA
RITUXAN HYCELA (rituximab/hyaluronidase human)
RUXIENCE

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE of the formulary alternatives: **Ruxience, Riabni** OR
   - There is clinical documentation stating formulary alternatives are contraindicated.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Rituxan/Hycela: Approval will be for 6 months
Preferred Brands: Approval will be for 12 months

FDA Indications:

Rituxan, Ruxience, Riabni, Truxima

- Acute leukemia, Mature B-cell, previously untreated, in combination with chemotherapy (Rituxan only)
- Burkitt's lymphoma, In combination with chemotherapy (Rituxan only)
- Chronic lymphoid leukemia, In combination with fludarabine and cyclophosphamide
- Granulomatosis with polyangiitis, In combination with glucocorticoids
- Microscopic polyangiitis, In combination with glucocorticoids
- Non-Hodgkin's lymphoma, Diffuse, large B-cell, CD20-positive, in combination for first-line treatment
- Non-Hodgkin's lymphoma, Follicular, CD20-positive, B-cell, in combination with first-line chemotherapy & as single-agent maintenance
- Non-Hodgkin's lymphoma, Low-grade, CD20-positive, B-cell, stable or responsive to prior CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
- Non-Hodgkin's lymphoma, Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell
- Pemphigus vulgaris (Moderate to Severe) (Rituxan only)
- Rheumatoid arthritis (Moderate to Severe), In combination with methotrexate, in patients who had an inadequate response to one or more tumor-necrosis-factor antagonist therapies

Rituxan Hycela

- Chronic lymphoid leukemia, In combination with fludarabine and cyclophosphamide
- Diffuse large B-cell lymphoma, In combination with first-line treatment

- Follicular lymphoma, In combination with first-line chemotherapy & as single-agent maintenance
- Follicular lymphoma, Relapsed or refractory
- Follicular lymphoma, Stable or responsive to prior CVP (cyclophosphamide, vinCRIStine, and predniSONE) chemotherapy

Off-Label Uses:

Rituxan

- Autoimmune hemolytic anemia
- B-cell lymphoma
- Cardiac transplant rejection, Antibody-mediated, adjunctive treatment
- Chronic lymphoid leukemia, In combination for first-line treatment
- Chronic lymphoid leukemia, Maintenance, following rituximab-containing chemotherapy
- Chronic lymphoid leukemia, Relapsed or refractory
- Desensitization therapy - Transplantation of heart
- Evans syndrome, Refractory to immunosuppressive therapy
- Graft-versus-host disease, chronic, Steroid-refractory
- Hodgkin's disease, CD20-positive, as monotherapy
- Immune thrombocytopenia
- Immune thrombocytopenia, Previously treated
- Liver transplant rejection, Antibody-mediated, adjunctive treatment
- Lung disease with systemic sclerosis
- Lupus nephritis, Refractory
- Mantle cell lymphoma, Maintenance, following first-line induction therapy
- Mantle cell lymphoma, Untreated, induction therapy, in combination with anthracycline-based regimens
- Minimal change disease, Refractory, steroid-dependent or steroid-resistant
- Myasthenia gravis, Refractory
- Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia, CD20-positive, in combination with chemotherapy
- Post-transplant lymphoproliferative disorder
- Primary Sjögren's syndrome
- Rheumatoid arthritis, In combination with methotrexate, in patients with an inadequate response to methotrexate
- Systemic lupus erythematosus, Refractory to immunosuppressive therapy; Adjunct
- Thrombotic thrombocytopenic purpura, In combination with steroids and plasma exchange
- Thyroid eye disease (Moderate to Severe), Second line therapy, excluding patients with risk for dysthyroid optic neuropathy
- Waldenstrom macroglobulinemia

Step Therapy Drug(s) and FDA Indications:

Ruxience, Riabni

- Chronic lymphoid leukemia, In combination with fludarabine and cyclophosphamide
- Granulomatosis with polyangiitis, In combination with glucocorticoids
- Microscopic polyangiitis, In combination with glucocorticoids
- Non-Hodgkin's lymphoma, Diffuse, large B-cell, CD20-positive, in combination with anthracycline-based chemotherapy for first-line treatment
- Non-Hodgkin's lymphoma, Follicular, CD20-positive, B-cell, in combination with first-line chemotherapy and as single-agent maintenance
- Non-Hodgkin's lymphoma, Low-grade, CD20-positive, B-cell, non-progressing (including stable) after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
- Non-Hodgkin's lymphoma, Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell
- Rheumatoid arthritis (Moderate to Severe), In combination with methotrexate, in patients who had an inadequate response to one or more tumor-necrosis-factor antagonist therapies

Age Restrictions:

2 years and older

Other Clinical Consideration:

Patients should be screened for hepatitis B virus (HBV)

Resouces:

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https://careweb.careguidelines.com/ed24/ac/ac04_069.htm