RX.PA.030.CCH RITUXIMAB PRODUCTS

The purpose of this policy is to define the prior authorization process for non-oncologic indications for the rituximab products – Riabni (rituximab-arrx), Rituxan (rituximab), Rituxan Hycela (rituximab and hyaluronidase human), Ruxience (rituximab-PVVR), and Truxima (rituximab-abbs).

NCH reviews prior authorization requests for all oncology related indications for rituximab products.

Rituximab is indicated for the following:

- Treatment of patients with:
  - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell Non-Hodgkin's Lymphoma (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 Rituxan® (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 CVP chemotherapy
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimens
- In combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive Chronic Lymphocytic Leukemia (CLL)
- In combination with methotrexate, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies
- In combination with glucocorticoids, for the treatment of adult and pediatric patients 2 years of age and older with Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)
- Moderate to severe pemphigus vulgaris in adults

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity and approval by the Medical Policy Committee.

The rituximab products are subject to the prior authorization process.

PROCEDURE

I. Plan Design Summary

Requests for Rituxan are subject to the preferred medical drug list program. This program applies to the rituximab products specified in this policy. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

	Products
Preferred	• Ruxience (rituximab-pvvr) • Riabni (rituximab-arrx) • Truxima (rituximab-abbs)
Non-preferred	• Rituxan (rituximab) • Rituxan Hycela (rituximab and hyaluronidase human)

Requests for a non-preferred drug must meet one of the following exception criteria in addition to clinical criteria:

II. Exception Criteria (Use for Rituxan Requests Only)

This program only applies to members requesting treatment for an indication that is FDA-approved for the preferred product(s). If the non-preferred product is requested for an indication that the preferred products are NOT FDA-approved for, the program does not apply.

Coverage for the non-preferred product, Rituxan, is provided when the member has had a documented intolerable adverse event to the preferred products. The adverse event must not be an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication).

III. Clinical Criteria (Use for *ALL* Drug Requests)

Initial Authorization Criteria:

Must meet all the criteria listed under the respective diagnosis:

1. Rheumatoid Arthritis

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderately to severely active rheumatoid arthritis
- Must have an adequate trial (of at least 3 months) of methotrexate to a therapeutic dose of 15mg per week with an inadequate response
    - Members with significant side effects/toxicity or who have a contraindication to methotrexate, must have an adequate trial of at least 3 months of a different conventional DMARD (such as leflunomide, hydroxychloroquine, or sulfasalazine) with an inadequate response, or significant side effect/toxicity, or have a contraindication to these therapies
- Must have an adequate trial (of at least 3 months each) of at least 2 preferred biologic or targeted synthetic DMARDs (such as TNF-alpha inhibitors or JAK inhibitors) with inadequate responses, significant side effects/toxicities, or a have a contraindication to these therapies
    - Preferred alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/
- Must be on concurrent methotrexate therapy
- Must currently not be using a TNF-blocking agent or other biologic agents in combination with rituximab
- Must currently not have progressive multifocal leukoencephalopathy (PML) or have a history of PML
- Must have no evidence of severe, active infection

2. Granulomatosis with Polyangiitis (GPA)/Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)

- Must be prescribed by a rheumatologist
- Must be age 2 years or older
- Must have a diagnosis of Granulomatosis with Polyangiitis/Wegener's Granulomatosis or Microscopic Polyangiitis
- For induction therapy, must be on concomitant therapy with glucocorticoids
- For maintenance therapy, must have an adequate trial (of at least 3 months) of azathioprine or methotrexate with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have no evidence of severe, active infection

3. Renal and/or Pancreatic Transplant Desensitization in Combination with IVIG

- Must be prescribed by a transplant specialist
- Must be age 18 years or older
- Must currently not have PML or have a history of PML
- Must be awaiting kidney and/or pancreas transplant requiring desensitization as defined by:
    - For deceased donor transplants, must have one of the following:
        - Panel reactive antibody (PRA) level >30%
        - PRA <30% with a previous kidney and/or pancreas transplant
    - For living donor transplants, must have the following:
        - Positive crossmatch
        - Positive donor-specific antibody using Luminex® assay

4. Oncology

******All prior authorization requests for an oncology indication needs to be forwarded to NCH for review******

5. Pemphigus Vulgaris (PV)

- Must have a diagnosis of biopsy-proven moderate to severe pemphigus vulgaris
- Must be prescribed by a dermatologist
- Must be age 18 years or older
- Must currently not have PML or have a history of PML
- Must have an adequate trial of at least one of the following with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
    - Immunosuppressants (such as azathioprine or methotrexate)
    - Corticosteroids
- In rapidly progressive, extensive, or debilitating cases (i.e., Stevens JohnsonSyndrome), rituximab may be approved along with corticosteroids or immunosuppressive agents

Reauthorization Criteria:

All prior authorization renewals are reviewed to determine the Medical Necessity for the continuation of treatment. Authorization is extended as specified below:

1. Rheumatoid Arthritis:

- For an additional course of treatment, based upon review of documentation from the prescriber indicating that the member's condition has improved as a result of therapy. Authorization is not granted until 16 weeks has passed since the previous treatment.

2. Granulomatosis with Polyangiitis/Wegener's Granulomatosis and Microscopic Polyangiitis:

- For an additional 6 months, based upon review of documentation from the prescriber indicating that the member is continuing to benefit from treatment.

3. Renal and/or Pancreatic Desensitization Candidates:

- For an additional course of treatment (with the above regimen) if the member has not yet received a renal and/or pancreatic transplant. Authorization is not granted until 6 months have passed since the initial treatment.

4. Pemphigus Vulgaris (PV)

- For an additional course of treatment, based upon review of documentation from the prescriber indicating that the member's condition has improved as a result of therapy. Authorization is not granted until 12 months has passed since the initial treatment and 6 months for every subsequent treatment after the second treatment course.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Transplant Desensitization: 1 course of treatment (one 1000mg dose given on day 15) • All other diagnoses: 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, ifrequired for the plan and level of request.

CPT Codes:

JCode	Description
J9311	INJECTION, RITUXIMAB 10 MG AND HYALURONIDASE
J9312	INJECTION, RITUXIMAB, 10 MG
Q5115	INJECTION, RITUXIMAB-ABBS, BIOSIMILAR, (TRUXIMA), 10 MG
Q5119	INJECTION, RITUXIMAB-PVVR, BIOSIMILAR (RUXIENCE), 10 MG
Q5123	INJECTION, RITUXIMAB-ARRX, BIOSIMLAR, (RIABNI), 10 MG

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial Review	3/22
Updated authorization durations to 1 year for applicable diagnoses, added Riabni, updated preferred and non-preferred products	2/23

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of

Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

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