

Medical Policy

Antineoplastic – rituximab [Rituxan® (rituximab), Ruxience® (rituximab-pvvr), Truxima® (rituximab-abbs), Riabni (rituximab-arrx), Rituxan Hycela® (rituximab and hyaluronidase human)]	
MEDICAL POLICY NUMBER	MED_Clin_Ops_043b
ORIGINAL EFFECTIVE DATE	7/1/2021
CURRENT VERSION NUMBER	4
CURRENT VERSION EFFECTIVE DATE	1/01/2024
APPLICABLE PRODUCT AND MARKET*	Medicare Advantage: ALL*

*BND members subject to step therapy

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY: *These services may or may not be covered by all Brand New Day/Central Health Medicare Plan. Please refer to the member's plan document for specific coverage information.*

Brand New Day/Central Health Medicare Plan may use tools developed by third parties, such as MCG™ Care Guidelines and the ASAM Criteria™ to assist in administering health benefits. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Care Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice.

Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan.

Before using this policy, please check the member benefit plan document and any federal or state mandates, if applicable. New Day/Central Health Medicare Plan policies and practices are compliant with all federal and state requirements, including mental health parity laws.

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of rituximab therapy.

POLICY/CRITERA

Prior Authorization and Medical Review is required.

Coverage will be provided for 6 months (12 months initially for pemphigus vulgaris) and may be renewed unless otherwise specified.

- Maintenance therapy for oncology indications may be renewed for up to a maximum of 2 years.
- Relapse therapy for pemphigus vulgaris must be at least 16 weeks past a prior infusion

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Rituxan, Riabni, and Rituxan Hycela are Non-Preferred products.

The Preferred products are Truxima and Ruxience.

Rituxan, Riabni, and Rituxan Hycela may be considered medically necessary if:

- Patient has experienced a therapeutic failure or intolerance with Truxima **AND** Ruxience;
OR
- Rituxan, Riabni, and Rituxan Hycela is requested for an indication for which Truxima **AND** Ruxience have not been FDA-approved.

Initial Therapy

Coverage for **Rituxan Hycela® (rituximab and hyaluronidase human)** is provided in the following conditions:

1. Patient age is 18 years or older; **AND**

Chronic lymphocytic leukemia (CLL)

1. Patient has a diagnosis of previously untreated or previously treated CD20-positive CLL; **AND**
2. Rituxan Hycela will be used in combination with fludarabine **AND** cyclophosphamide (FC).

Diffuse Large B-Cell Lymphoma (DLBCL)

1. Patient has a diagnosis of previously untreated diffuse large B-cell lymphoma; **AND**
2. Rituxan Hycela will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens.

Follicular Lymphoma (FL)

1. Patient has a diagnosis of relapsed or refractory, follicular lymphoma; **AND**
2. Rituxan Hycela is being used as a single agent; **OR**
3. Patient has a diagnosis of previously untreated follicular lymphoma; **AND**
4. Rituxan Hycela is being used in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy; **OR**
5. Patient has a diagnosis of non-progressing (including stable disease), follicular lymphoma;
AND
6. Rituxan Hycela is being used as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.

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Coverage for **Rituxan® (rituximab), Ruxience® (rituximab-pvvr), Truxima® (rituximab-abbs), Riabni (rituximab-arrx)**, is provided in the following conditions:

1. Patient age is 18 years or older (unless otherwise specified); **AND**

Chronic lymphocytic leukemia (CLL)

1. Patient has a diagnosis of previously untreated or previously treated CD20-positive CLL; **AND**
2. Requested drug will be used in combination with fludarabine AND cyclophosphamide (FC).

Non-Hodgkin's Lymphoma (NHL)

1. Patient has a diagnosis of relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin lymphoma; **OR**
2. Patient has a diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin lymphoma; **AND**
3. Requested drug is being used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) or other anthracycline-based chemotherapy regimens; **OR**
4. Patient has a diagnosis of previously untreated follicular, CD20-positive, B-cell non-Hodgkin lymphoma; **AND**
5. Requested drug will be used in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy; **OR**
6. Patient has a diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin lymphoma; **AND**
7. Patient's disease is stable **OR** patient has achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy.

Rheumatoid Arthritis (RA)

1. Requested drug is prescribed by, or in consultation with, a rheumatologist; **AND**
2. Patient has a documented diagnosis of moderately to severely active rheumatoid arthritis; **AND**
3. Requested drug will be used in combination with methotrexate (unless the patient has a contraindication or intolerance); **AND**
4. Patient has had an inadequate response to one or more tumor-necrosis-factor antagonist therapies

Pemphigus Vulgaris - (Rituxan ONLY)

1. Patient has a diagnosis of pemphigus vulgaris **as determined by one or more of the following:**
 - a. Clinical features
 - i. Appearance of lesions, erosions and/or blisters
 - ii. Nikolsky sign (induction of blistering via mechanical pressure at the edge of a blister or on normal skin)
 - iii. Characteristic scarring and lesion distribution; **AND**
 - b. Histopathologic confirmation by skin/mucous membrane biopsy; **AND**
 - c. Presence of autoantibodies as detected by direct or indirect immunofluorescence; **AND**
2. Patient has moderate to severe disease as assessed utilizing an objective measure/tool (i.e. PDAI, PSS, ABSIS); **AND**

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3. Other causes of blistering or erosive skin and mucous membrane diseases have been ruled out

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis), Microscopic Polyangiitis (MPA)

1. Patient is 2 years of age or older; **AND**
2. Requested drug will be used in combination with glucocorticoids

Continuation Therapy

Chronic lymphocytic leukemia (CLL) & Non-Hodgkin's Lymphoma (NHL)

1. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Rheumatoid Arthritis (RA)

1. Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more or a $\geq 20\%$ improvement on the American College of Rheumatology-20 (ACR20) criteria]; **AND**
2. Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis provided that the patient has:
 - a. Shown an initial response to therapy; **AND**
 - b. Received a minimum of one maintenance dose at the dose and interval specified below; **AND**
 - c. Responded to therapy with subsequent loss of response

Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic polyangiitis (MPA)

1. Disease response as indicated by improvement in signs and symptoms of condition compared to baseline

Pemphigus Vulgaris - (Rituxan ONLY)

1. Patient is currently receiving tapering doses of corticosteroids or has discontinued use of corticosteroids; **AND**
 - a. Disease response as indicated by complete epithelialization of lesions and improvement in signs and symptoms of condition compared to baseline; **OR**
 - b. Patient has not experienced continued development of new lesions, continued extension of old lesions, or failure of established lesions to begin to heal despite therapy; **OR**
 - i. For Relapses ONLY: Patient has had active disease control; **AND**
 - ii. Patient has the appearance of 3 or more new lesions a month that do not heal spontaneously within 1 week, or by the extension of established lesions

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DOSING LIMITS

Max Units (per dose and over time) [Medical Benefit]:

Chronic Lymphocytic Leukemia (CLL)	Initial therapy: Loading dose: 375mg/m ² x 1 dose Subsequent doses: 500mg/m ² x 5 doses per 6 months Renewal therapy: 375mg/m ² dose every 8 weeks x 4 doses per 6 months
All other oncology indications	Initial therapy: 375mg/m ² dose weekly x 8 doses per 6 months Renewal therapy: 375mg/m ² dose every 8 weeks x 4 doses per 6 months
Rheumatoid Arthritis (RA)	1000mg per dose day 1 and day 15 x 2 doses in a 16-week period. May repeat after 24 weeks.
Pemphigus Vulgaris	Initiation: 1000mg per dose day 1 and day 15 x 2 doses in a 12-month period Maintenance: 500mg/dose every 16 weeks Relapse: 1000mg
All other non-oncology indications	375mg/m ² per dose weekly x 4 doses in a 6-month period

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value.

DEFINITIONS

1. RITUXAN (rituximab) injection, for intravenous use. Initial U.S. Approval: 1997
 - a. RITUXAN (rituximab) injection is a sterile, preservative-free, clear, colorless solution for intravenous infusion supplied as single dose vials.
2. RITUXAN HYCELA (rituximab and hyaluronidase human) injection, for subcutaneous use. Initial U.S. Approval: 2017
 - a. RITUXAN HYCELA (rituximab and hyaluronidase human) injection, for subcutaneous use is supplied as a sterile preservative-free liquid solution in a single-dose vial.
 - b. RITUXAN HYCELA 1,400 mg/23,400 Units providing 1,400 mg rituximab and 23,400 Units hyaluronidase human per 11.7 mL
 - c. RITUXAN HYCELA 1,600 mg/26,800 providing 1,600 mg rituximab and 26,800 Units hyaluronidase human per 13.4 mL
3. TRUXIMA (rituximab-abbs) injection, for intravenous use. Initial U.S. Approval: 2018
 - a. TRUXIMA (rituximab-abbs) is biosimilar to RITUXAN (rituximab).
 - b. TRUXIMA (rituximab-abbs) injection is a sterile, clear to opalescent, colorless to pale yellow, preservative-free solution for intravenous infusion supplied as a carton containing one 100 mg/10 mL (10 mg/mL) single-dose vial or a carton containing one 500 mg/50 mL (10 mg/mL) single-dose vial
4. RUXIENCE™ (rituximab-pvvr) injection, for intravenous use. Initial U.S. Approval: 2019
 - a. RUXIENCE (rituximab-pvvr) is biosimilar to RITUXAN (rituximab).
 - b. RUXIENCE (rituximab-pvvr) injection is a sterile, preservative-free, clear to slightly opalescent, ncolorless to pale brownish-yellow solution for intravenous infusion supplied

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as a carton containing one 100 mg/10 mL (10 mg/mL) single-dose vial or a carton containing one 500 mg/50 mL (10 mg/mL) single-dose vial

5. RIABNI™ (rituximab-arrx) injection, for intravenous use. Initial U.S. Approval: 2020
 - a. RIABNI (rituximab-arrx) is biosimilar to RITUXAN (rituximab)
 - b. RIABNI (rituximab-arrx) injection is a sterile, clear to slightly opalescent, colorless to slightly yellow preservative free solution for intravenous use supplied as a carton containing one 100 mg/10 mL (10 mg/mL) single dose vial and a carton containing one 500 mg/50 mL (10 mg/mL) single dose vial

CODING

Applicable NDC Codes	
50242-0051-xx	Rituxan 100 mg/10 mL single-use vial for injection
50242-0053-xx	Rituxan 500 mg/50 mL single-use vial for injection
63459-103-10	rituximab-abbs injection, 100 mg/10 mL (10 mg/mL) single-dose vial
63459-104-50	rituximab-abbs injection, 500 mg/50 mL (10 mg/mL) single-dose vial
50242-0108-xx	Rituxan Hycela 1,400 mg rituximab/23,400 Units hyaluronidase human single-dose vial
50242-0109-xx	Rituxan Hycela 1,600 mg rituximab/26,800 Units hyaluronidase human single-dose vial
00069-0238-xx	Ruxience 100 mg/10 mL single-use vial for injection
00069-0249-xx	Ruxience 500 mg/50 mL single-use vial for injection
55513-0224-xx	Riabni 100 mg/10 mL single-use vial for injection
55513-0326-xx	Riabni 500 mg/50 mL single-use vial for injection

Applicable Procedure Code	
J9312	Injection, rituximab, 10mg
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, 10 mg (Ruxience). Effective Date: 07/01/2020
J9311	Rituxan Hycela (hyaluronidase human, recombinant/rituximab), 10mg
Q5123	Injection, rituximab-arrx, biosimilar, (riabni). Effective Date: 07/01/2021
C9467	Injection, rituximab and hyaluronidase, 10 mg

Applicable ICD-10 Codes	
C82.00	Follicular lymphoma grade I, unspecified site
C82.01	Follicular lymphoma grade I, lymph nodes of head, face and neck
C82.02	Follicular lymphoma, grade I, intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal regional and lower limb
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I, spleen
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites

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C82.09	Follicular lymphoma grade I, extranodal and solid organ sites
C82.10	Follicular lymphoma grade II, unspecified site
C82.11	Follicular lymphoma grade II, lymph nodes of head, face and neck
C82.12	Follicular lymphoma, grade II, intrathoracic lymph nodes
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II, spleen
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites
C82.20	Follicular lymphoma grade III, unspecified, unspecified site
C82.21	Follicular lymphoma grade III, unspecified, lymph nodes of head, face and neck
C82.22	Follicular lymphoma, grade III, unspecified, intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III, unspecified, spleen
C82.28	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.30	Follicular lymphoma grade IIIa, unspecified site
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face and neck
C82.32	Follicular lymphoma, grade IIIa, intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa, spleen
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.40	Follicular lymphoma grade IIIb, unspecified site
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face and neck
C82.42	Follicular lymphoma, grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.50	Diffuse follicle center lymphoma, unspecified site
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb

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C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites
C82.60	Cutaneous follicle center lymphoma, unspecified site
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face and neck
C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma, spleen
C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites
C82.80	Other types of follicular lymphoma, unspecified site
C82.81	Other types of follicular lymphoma, lymph nodes of head, face and neck
C82.82	Other types of follicular lymphoma, intrathoracic lymph nodes
C82.83	Other types of follicular lymphoma, intra-abdominal lymph nodes
C82.84	Other types of follicular lymphoma, lymph nodes of axilla and upper limb
C82.85	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb
C82.86	Other types of follicular lymphoma, intrapelvic lymph nodes
C82.87	Other types of follicular lymphoma, spleen
C82.88	Other types of follicular lymphoma, lymph nodes of multiple sites
C82.89	Other types of follicular lymphoma, extranodal and solid organ sites
C82.90	Follicular lymphoma, unspecified, unspecified site
C82.91	Follicular lymphoma, unspecified, lymph nodes of head, face and neck
C82.92	Follicular lymphoma, unspecified, intrathoracic lymph nodes
C82.93	Follicular lymphoma, unspecified, intra-abdominal lymph nodes
C82.94	Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb
C82.95	Follicular lymphoma, unspecified lymph nodes of inguinal region and lower limb
C82.96	Follicular lymphoma, unspecified, intrapelvic lymph nodes
C82.97	Follicular lymphoma, unspecified, spleen
C82.98	Follicular lymphoma, unspecified, lymph nodes of multiple sites
C82.99	Follicular lymphoma, unspecified, extranodal and solid organ sites
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma intrathoracic lymph nodes

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C83.33	Diffuse large B-cell lymphoma intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region of lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C88.0	Waldenström macroglobulinemia
C91.1	Chronic lymphocytic leukemia of B-cell type
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
L10.0	Pemphigus vulgaris
M05.10	Rheumatoid lung disease with rheumatoid arthritis of unspecified site
M05.11	Rheumatoid lung disease with rheumatoid arthritis of right shoulder
M05.112	Rheumatoid lung disease with rheumatoid arthritis of left shoulder
M05.11	Rheumatoid lung disease with rheumatoid arthritis of unspecified shoulder
M05.12	Rheumatoid lung disease with rheumatoid arthritis of right elbow
M05.12	Rheumatoid lung disease with rheumatoid arthritis of left elbow
M05.12	Rheumatoid lung disease with rheumatoid arthritis of unspecified elbow
M05.13	Rheumatoid lung disease with rheumatoid arthritis of right wrist
M05.13	Rheumatoid lung disease with rheumatoid arthritis of left wrist
M05.13	Rheumatoid lung disease with rheumatoid arthritis of unspecified wrist
M05.14	Rheumatoid lung disease with rheumatoid arthritis of right hand
M05.14	Rheumatoid lung disease with rheumatoid arthritis of left hand
M05.14	Rheumatoid lung disease with rheumatoid arthritis of unspecified hand
M05.15	Rheumatoid lung disease with rheumatoid arthritis of right hip

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M05.15	Rheumatoid lung disease with rheumatoid arthritis of left hip
M05.15	Rheumatoid lung disease with rheumatoid arthritis of unspecified hip
M05.16	Rheumatoid lung disease with rheumatoid arthritis of right knee
M05.16	Rheumatoid lung disease with rheumatoid arthritis of left knee
M05.16	Rheumatoid lung disease with rheumatoid arthritis of unspecified knee
M05.17	Rheumatoid lung disease with rheumatoid arthritis of right ankle and foot
M05.172	Rheumatoid lung disease with rheumatoid arthritis of left ankle and foot
M05.17	Rheumatoid lung disease with rheumatoid arthritis of unspecified ankle and foot
M05.19	Rheumatoid lung disease with rheumatoid arthritis of multiple sites
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site
M05.21	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.21	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.21	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder
M05.22	Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.22	Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.22	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow
M05.23	Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.23	Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.23	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist
M05.24	Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.24	Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.24	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand
M05.25	Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.25	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip
M05.26	Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.26	Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.26	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee
M05.27	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.27	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.27	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot
M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.31	Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.31	Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.31	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder
M05.32	Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.32	Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.32	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow
M05.33	Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.33	Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist
M05.34	Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.34	Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.34	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand
M05.35	Rheumatoid heart disease with rheumatoid arthritis of right hip

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M05.35	Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.35	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip
M05.36	Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.36	Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.36	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee
M05.37	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.37	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.37	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.41	Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.41	Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder
M05.42	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.42	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.42	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand

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M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems
M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems il
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems il
M05.721	Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement

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M05.722	Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement
M05.729	Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems il
M05.731	Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement
M05.732	Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement
M05.739	Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems il
M05.741	Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement
M05.742	Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement
M05.749	Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems il
M05.751	Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement
M05.752	Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement
M05.759	Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems il
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems il
M05.771	Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems il
M05.772	Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems il
M05.779	Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems il
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.80	Other rheumatoid arthritis with rheumatoid factor of unspecified site
M05.811	Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812	Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.819	Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder
M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.87	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.87	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot

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M05.87	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot
M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site
M06.01	Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.01	Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.01	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder
M06.02	Rheumatoid arthritis without rheumatoid factor, right elbow
M06.02	Rheumatoid arthritis without rheumatoid factor, left elbow
M06.02	Rheumatoid arthritis without rheumatoid factor, unspecified elbow
M06.03	Rheumatoid arthritis without rheumatoid factor, right wrist
M06.03	Rheumatoid arthritis without rheumatoid factor, left wrist
M06.03	Rheumatoid arthritis without rheumatoid factor, unspecified wrist
M06.04	Rheumatoid arthritis without rheumatoid factor, right hand
M06.04	Rheumatoid arthritis without rheumatoid factor, left hand
M06.04	Rheumatoid arthritis without rheumatoid factor, unspecified hand
M06.05	Rheumatoid arthritis without rheumatoid factor, right hip
M06.05	Rheumatoid arthritis without rheumatoid factor, left hip
M06.05	Rheumatoid arthritis without rheumatoid factor, unspecified hip
M06.06	Rheumatoid arthritis without rheumatoid factor, right knee
M06.06	Rheumatoid arthritis without rheumatoid factor, left knee
M06.06	Rheumatoid arthritis without rheumatoid factor, unspecified knee
M06.07	Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.07	Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.07	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot
M06.08	Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.80	Other specified rheumatoid arthritis, unspecified site
M06.81	Other specified rheumatoid arthritis, right shoulder
M06.81	Other specified rheumatoid arthritis, left shoulder
M06.819	Other specified rheumatoid arthritis, unspecified shoulder
M06.82	Other specified rheumatoid arthritis, right elbow
M06.82	Other specified rheumatoid arthritis, left elbow
M06.82	Other specified rheumatoid arthritis, unspecified elbow
M06.83	Other specified rheumatoid arthritis, right wrist
M06.83	Other specified rheumatoid arthritis, left wrist
M06.83	Other specified rheumatoid arthritis, unspecified wrist
M06.84	Other specified rheumatoid arthritis, right hand
M06.84	Other specified rheumatoid arthritis, left hand
M06.84	Other specified rheumatoid arthritis, unspecified hand
M06.85	Other specified rheumatoid arthritis, right hip
M06.85	Other specified rheumatoid arthritis, left hip
M06.85	Other specified rheumatoid arthritis, unspecified hip
M06.86	Other specified rheumatoid arthritis, right knee
M06.86	Other specified rheumatoid arthritis, left knee
M06.86	Other specified rheumatoid arthritis, unspecified knee

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M06.87	Other specified rheumatoid arthritis, right ankle and foot
M06.87	Other specified rheumatoid arthritis, left ankle and foot
M06.879	Other specified rheumatoid arthritis, unspecified ankle and foot
M06.88	Other specified rheumatoid arthritis, vertebrae
M06.89	Other specified rheumatoid arthritis, multiple sites
M06.9	Rheumatoid arthritis, unspecified
M31.1	Thrombotic microangiopathy
M31.30	Wegener's granulomatosis without renal involvement
M31.31	Wegener's granulomatosis with renal involvement
M31.7	Microscopic polyangiitis
Z85.72	Personal history of non-Hodgkin lymphomas
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

EVIDENCE BASED REFERENCES

1. Rituxan [package insert]. South San Francisco, CA; Genentech, Inc; Updated September 2019. Accessed December 2022.
2. Product Information: TRUXIMA(R) intravenous injection, rituximab-abbs intravenous injection. Teva Pharmaceuticals USA Inc (per FDA), North Wales, PA, Updated September 2019. Accessed December 2022.
3. Product Information: RUXIENCE(TM) intravenous injection, rituximab-pvvr intravenous injection. Pfizer Labs (per FDA), New York, NY, 2022. Accessed December 2022.
4. Rituxan Hycela (rituximab and hyaluronidase human) prescribing information. Genentech, Inc. South San Francisco, CA 2017. Accessed December 2022.
5. Riabni [package insert]. Thousand Oaks, CA; Amgen, Inc; Updated June 2022. Accessed December 2022.

POLICY HISTORY

Revision History	Month Day, Year	Updates
Original Effective Date	JULY 1, 2021	
Revision	AUGUST 1, 2021	Added Q-Code (Q5123): Injection, rituximab-arrx, biosimilar, (riabni) Effective date: 07/01/2021
	JANUARY 1, 2022	Mandatory Step Therapy effective starting January 1, 2022 (grandfathering in place for members on therapy)
Revision	February 28, 2023	Added Rheumatoid Arthritis indication for rituximab-arrx (Riabni) & Rituximab-pvvr (Ruxience) and updated references.
	April 1, 2023	New preferred product Ruxience. Riabni is non-preferred.
	January 1, 2024	Updated to Brand New Day/Central Health Medicare Plan
P&T Committee Endorsement	MAY 24, 2021	

Medical Policy

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