



MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
09/25/2013	08/11/2017	10/04/2016
Policy Name		Policy Number
Rituxan (rituximab)		SRx-0030
Policy Type		
<input checked="" type="checkbox"/> Pharmacy	<input type="checkbox"/> Administrative	<input type="checkbox"/> Payment

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Rituxan (rituximab)

B. BACKGROUND

The intent of the Rituxan (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A

D. POLICY

- I. CareSource will approve the use of Rituxan and consider its use as medically necessary when the following criteria have been met for:
 - A. **ANCA-associated vasculitis** (e.g. Wegener Granulomatosis (WGA). Microscopic Polyangiitis (MPA), Granulomatosis with Polyangiitis (GPA)) and **ALL** of the following:
 1. Prescribed by or under the recommendation of a nephrologist or rheumatologist
 2. Patient is age 18 years or older
 3. Administered in combination with glucocorticoids
 4. Plus, **ONE** of the following:
 - a. Patient has failed treatment with cyclophosphamide
 - b. Further cyclophosphamide treatment would exceed the maximum cumulative cyclophosphamide dose
 - c. Cyclophosphamide is contraindicated or not tolerated



- d. The person has not completed their family and treatment with cyclophosphamide may materially affect their fertility
 - e. The disease has remained active or progressed despite a course of cyclophosphamide lasting 3-6 months
 - f. The person has had uroepithelial malignancy
 - g. Patients who are at high risk of infection
- B. Chronic lymphocytic leukemia and ALL of the following:**
- 1. Patient is age 18 years or older
 - 2. Prescribed by an oncologist or under the recommendation of an oncologist
 - 3. CD20-positive
 - 4. Administered in combination with fludarabine and cyclophosphamide
 - 5. Symptomatic disease, as indicated by **1 or more** of the following:
 - a. Autoimmune anemia or thrombocytopenia that is poorly responsive to corticosteroids
 - b. Bulky adenopathy
 - c. Fatigue
 - d. Fever for 2 or more weeks without evidence of infection
 - e. Hyperviscosity
 - f. Night sweats without evidence of infection
 - g. Organomegaly (e.g. hepatomegaly, splenomegaly)
 - h. Progressive anemia or thrombocytopenia
 - i. Progressive lymphocytosis (i.e. increase of more than 50% over 2-month period or lymphocyte doubling times of less than 6 months)
 - j. Unintentional weight loss
- C. Non-Hodgkin lymphoma, as indicated by 1 or more of the following:**
- 1. **Initial** course of rituximab and **ALL of the following:**
 - a. Patient is age 18 years or older
 - b. Prescribed by an oncologist or under the recommendation of an oncologist
 - c. CD20-positive B-cell non-Hodgkin lymphoma and **1 or more** of the following:
 - (1) Diffuse large-cell disease, in combination with first-line chemotherapy with **1 or more** of the following:
 - i. CHOP chemotherapy regimen (cyclophosphamide, doxorubicin, vincristine, and prednisone)
 - ii. EPOCH chemotherapy regimen (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)
 - iii. Other chemotherapy regimens for patients with poor left ventricular function who cannot tolerate high-dose anthracycline-based therapy
 - (2) Follicular disease, in combination with first-line chemotherapy
 - (3) Non-progressing low-grade disease with **1 or more** of the following:
 - i. Complete response after first-line treatment with 6 to 8 cycles of cyclophosphamide, vincristine, and prednisone
 - ii. Partial response after first-line treatment with 6 to 8 cycles of cyclophosphamide, vincristine, and prednisone
 - iii. Stable disease after first-line treatment with 6 to 8 cycles of cyclophosphamide, vincristine, and prednisone
 - (4) Relapsed or refractory low-grade or follicular disease
 - 2. **Subsequent** course of rituximab and **ALL** of the following:
 - a. Patient is age 18 years or older
 - b. CD20-positive B-cell non-Hodgkin lymphoma and **1 or more** of the following:
 - (1) Diffuse large-cell disease with favorable response to prior first-line therapy with rituximab and chemotherapy



- (2) Follicular disease with favorable response to prior first-line therapy with rituximab
 - (3) Relapsed or refractory low-grade or follicular disease with favorable response to induction with rituximab
 - (4) Non-progressing low-grade disease at time of initial administration of rituximab, with **1 or more** of the following:
 - i. Complete or partial response after first-line treatment with 6 to 8 cycles of cyclophosphamide, vincristine, and prednisone
 - ii. Stable disease after first-line treatment with 6 to 8 cycles of cyclophosphamide, vincristine, and prednisone
- D. **Rheumatoid arthritis** and **ALL** of the following:
- 1. Age 18 years or older
 - 2. Moderate to severe active rheumatoid arthritis
 - 3. Prescribed by a rheumatologist or under recommendation of a rheumatologist
 - 4. Administered in combination with methotrexate, unless unable to tolerate methotrexate
 - 5. Inadequate response to two or more tumor necrosis factor antagonist drugs (e.g. adalimumab, etanercept, infliximab)

All other uses of Rituxan are considered experimental/investigational and therefore, will follow CareSource's Off-Label policy.

Note: Documented diagnosis must be confirmed by portions of the individual's medical record which need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office, or hospital admission notes.

Note: Patient is required to have completed the trial(s) listed in the above criteria unless the patient is unable to tolerate or has a contraindication to trial medications. Documentation such as chart notes or pharmacy claims may be requested to verify trial(s), intolerance, or contraindication(s).

Refer to the product package insert for dosing, administration and safety guidelines.

For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

Place of Service

Office, Outpatient

Note: CareSource supports administering injectable medications in various setting provided those services are furnished in the most appropriate and cost effective setting for the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

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AUTHORIZATION PERIOD

For ANCA-Vasculitis, authorizations are valid for 4 weeks. Safety and efficacy of treatment with subsequent courses of rituximab have not been established.

For CLL, NHL, and Rheumatoid Arthritis, approved initial authorizations are valid for 6 months. Continued treatment may be considered when the member has shown biological response to treatment. A reauthorization after successful initiation period will be placed for 1 year. **ALL** authorizations are subject to continued eligibility.

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued: 08/20/2013
Date Reviewed: 08/20/2013, 09/25/2013, 07/15/2014, 07/15/2015, 08/11/2016
Date Revised: 08/20/2013 – Change in diagnosis
07/15/2014 – Added diagnosis TTP and additional criteria to CD20+ CLL
07/15/2015 – Added MCG 19th edition criteria
10/04/2016 – Change in diagnoses to FDA approved uses, updated references with supporting guidelines and literature

G. REFERENCES

1. Rituxan (rituximab). Prescribing Information [Internet] Genentech, Inc. 04/2016 August Accessed at: <http://www.rituxan.com>
2. Ntatsaki E, Carruthers D, Chakravarty K, et al. BSR and BHRP guideline for the management of adults with ANCA-associated vasculitis. *Rheumatology* April 2014; ket445
3. Stone JH, Merkel PA, Spiera R, et al. Rituximab versus cyclophosphamide for ANCA-associated vasculitis. *N Engl J Med* 2010; 363:221.
4. Jones RB, Tervaert JW, Hauser T, et al. Rituximab versus cyclophosphamide in ANCA-associated renal vasculitis. *N Engl J Med* 2010; 363:211.
5. Jones RB, Tervaert JW, Hauser T, et al. Rituximab versus cyclophosphamide in ANCA-associated renal vasculitis: 2-year results of a randomized trial. *Ann Rheum Dis* 2015; 74(6): 1178-1182.
6. Latimer NR, Carroll C, Wong R, et al. Rituximab in combination with corticosteroids for the treatment of anti-neutrophil cytoplasmic antibody-associated vasculitis: a NICE single technology appraisal. *Pharmacoeconomics* 2014; 32(12): 1171-1183.
7. Pagnoux C. Updates in ANCA-associated vasculitis. *Eur J Rheumatol* 2015
8. Singh JA, Saag KG, Bridges Jr. SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research* 2015: 1-25.
9. NCCN Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas Version 4.2014.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.