

SPECIALTY GUIDELINE MANAGEMENT

BCBS RI: Rituxan® (rituximab)

PROGRAM RATIONALE

Client Requested: The intent of the criteria is to ensure that patients follow selection elements established by Blue Cross Blue Shield of Rhode Island (BCBS RI) medical policy for Rituxan.

FDA-APPROVED INDICATIONS¹

Rituxan is indicated for the treatment of:

- 1) 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
- 2) Non-Hodgkin's lymphoma (NHL)
 - a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
 - b. Previously untreated follicular, CD20-positive, B-cell NHL in combination with CVP chemotherapy
 - c. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent, after first-line CVP chemotherapy
 - d. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimens

OFF-LABEL USES²

- 1) Relapsed/refractory chronic lymphocytic leukemia (CLL)
- 2) Relapsed/refractory Waldenstrom's macroglobulinemia
- 3) Immune or idiopathic thrombocytopenic purpura

ADDITIONAL INFORMATION¹

B cells are believed to play a role in the pathogenesis of RA and associated chronic synovitis. In this setting, B cells may be acting at multiple sites in the autoimmune/inflammatory process, including through production of rheumatoid factor and other autoantibodies, antigen presentation, T cell activation, and/or proinflammatory cytokine production.

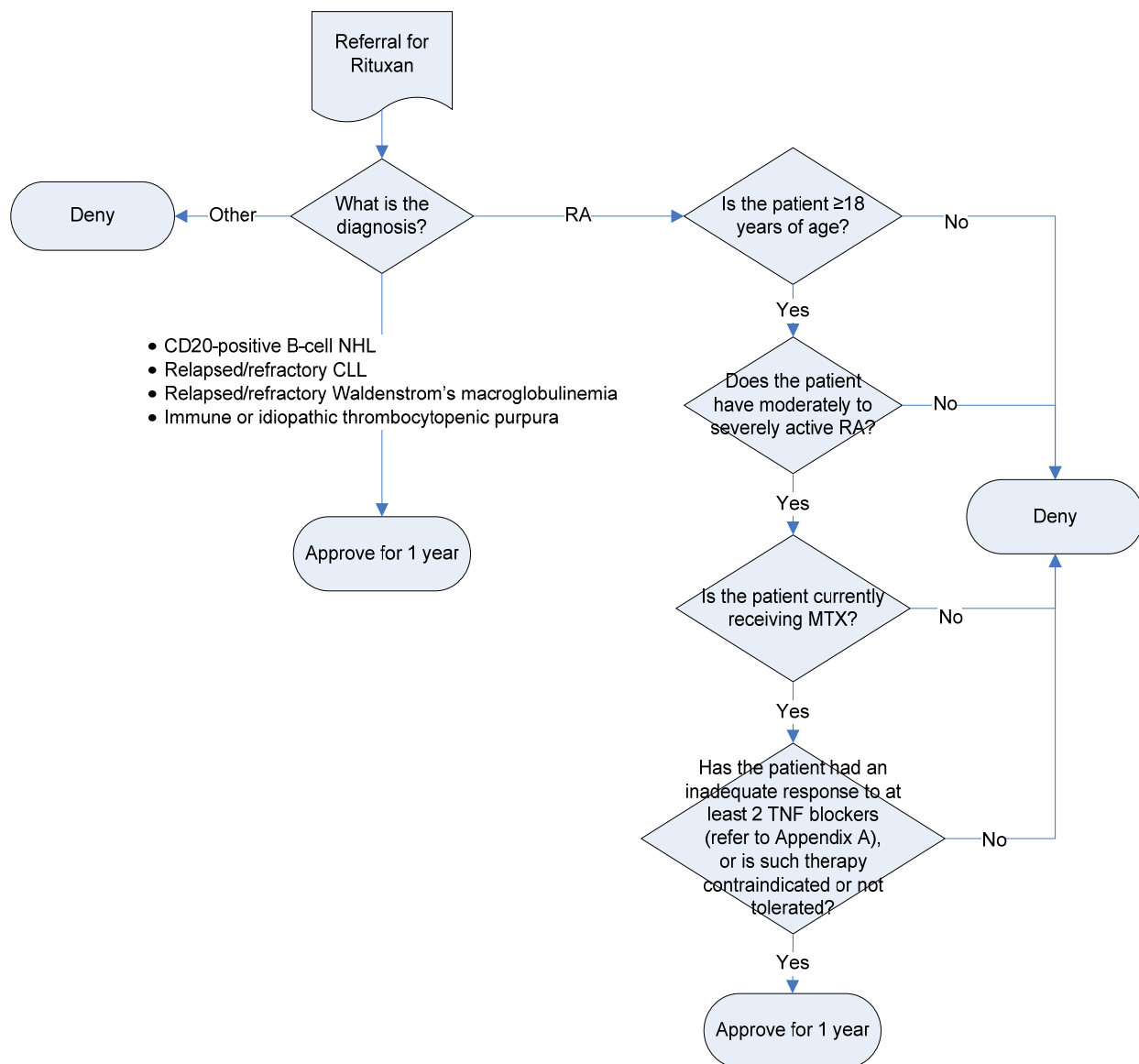
Rituximab binds specifically to the antigen CD20, a protein located on pre-B and mature B lymphocytes. CD20 regulates an early step(s) in the activation process for cell cycle initiation and differentiation, and possibly functions as a calcium ion channel. The binding of rituximab to the CD20 antigen on B lymphocytes is thought to mediate B-cell lysis as well as induce apoptosis.

Rituxan is administered as an intravenous (IV) infusion.

ALGORITHM²

(See page 2)

ALGORITHM²



ABBREVIATIONS

CLL = chronic lymphocytic leukemia
 MTX = methotrexate
 NHL = non-Hodgkin's lymphoma
 RA = rheumatoid arthritis
 TNF = tumor necrosis factor



Appendix A. Tumor Necrosis Factor (TNF) Blockers

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab)
- Remicade (infliximab)
- Simponi (golimumab)

REFERENCES

1. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; October 2009.
2. BCBS RI Prior Authorization of Benefits Policy for Rituxan.

DOCUMENT HISTORY

Written: Kathy Romaszko, Pharm.D. (11-2009)
Revised:
Reviewed: CDPR/WF 11/2009

The Participating Group signed below hereby accepts and adopts as its own the criteria for use with Specialty Guideline Management, as administered by CVS Caremark.

Signature

Date

Client Name