



Guidelines for Medication Coverage:

Rituximab[®] (Rituxan)

Background:

Rituximab is a monoclonal anti-CD20 antibody. The CD20 antigen is highly expressed on B-cells with the exception of stem cells, pro-B lymphocytes, and plasma cells. Administration of rituximab results in a selective depletion of the B-cell population.

The role of B-cells in the pathogenesis of rheumatoid arthritis includes: production of rheumatoid factor in the synovium; secretion of pro-inflammatory cytokines and chemokines in the synovium; and stimulation of T-cell activation. Depletion of B-cells in the peripheral bloodstream has been associated with a decrease in rheumatoid arthritis disease activity.

Administration:

Rituxan is administered by intravenous infusion. The majority of recipients experience some degree of infusion reaction with the first dose. Most reactions are mild, usually consisting of fever, chills, and rigors, and require only supportive care and slowing of the infusion rate. On less frequent occasions, angioedema, hypotension, bronchospasm, and urticaria have been observed.

Criteria for Authorization:

A. Non-Hodgkin's Lymphoma:

Rituxan does not require prior authorization for coverage when prescribed for an oncology indication and administered under the direction of a hematologist/ oncologist in an outpatient infusion or physician office setting.

B. Rheumatoid Arthritis:

Prior authorization is required for the use of Rituxan for treatment of all non-cancer diagnoses.

The use of Rituxan for the management of moderately-to-severely active **rheumatoid arthritis** will be covered if the following criteria are met:

- 1) The patient is under the care of a rheumatologist and Rituxan therapy directed by a rheumatologist.
- 2) That patient has a documented failure to an adequate (six month) trial of therapy with at least one injectable TNF antagonist therapy one of which must be either Enbrel (etanercept) or Humira (adalimumab) or has a documented clinical contraindication to TNF antagonist therapy.
- 3) Rituxan should be used in combination with methotrexate therapy

Rituximab dosing in rheumatoid arthritis:

Initial Therapy: Rituximab should be administered as two 1000mg I.V. infusions administered two weeks apart.

Subsequent Treatment (Retreatment): Safety and efficacy of rituximab retreatment in rheumatoid arthritis has not been documented in clinical trials. Subsequent courses of rituximab will only be authorized for patients in whom an ACR 20 response was documented 24 weeks after the initial course of rituximab. Retreatment should not be initiated sooner than 6 months (24 weeks) after completion of the initial course of therapy.

Special Instructions:

- Rituxan must be administered by intravenous infusion. Providers must have the capability to monitor patients for potential infusion-related adverse reactions.
- Rituxan is covered under the SummaCare medical benefit for commercial enrollees. Coverage for SummaCare Medicare enrollees is subject to Medicare Part B vs. Part D. determination. Providers should contact the SummaCare Authorization Unit at 1(888) 996-8710 for further information or authorization.

Approved: November 2, 2006

Revised and Reviewed: September 6, 2007

Medical Director

Pharmacy Director

References:

Genentech, Inc. *Prescribing Information for Rituxan®*. San Francisco: August 2007.

Rituximab (Rituxan) for Rheumatoid Arthritis. *Med Lett Drugs Ther* 2006; 48: 34-35.

Ghazvini P, Singh A, Treadwell P, Honeywell M, Canty N. Rituximab for Patients with Refractory Rheumatoid Arthritis. *P&T* 2006; 31(4): 201-207.

Singh A, Ghazvini P, Honeywell M, Treadwell P. Rituximab for the Treatment of Refractory Rheumatoid Arthritis: New Information from Clinical Trials. *P&T* 2006; 31(6): 321-22.