



Rituxumab (Rituxan®)

Revision: 3

Policy Number: M-0018

Last Update: 6/4/2014

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

When appropriate compendia references the use of one of the chemotherapeutic agents listed in this Article as part of a 'combination therapy', the drug is only approved for use in such 'combinations', and the documentation should reflect, and be specific about, the use of the additional 'combination therapy' drugs.

Coverage Guidelines:

FDA Indications

- Chronic lymphoid leukemia, In combination with fludarabine and cyclophosphamide
- Microscopic polyarteritis nodosa, In combination with glucocorticoids
- Non-Hodgkin's lymphoma, Diffuse, large B-cell, CD20-positive, in combination for first-line treatment
- Non-Hodgkin's lymphoma, Follicular, CD20-positive, B-cell, in combination with first-line chemotherapy & as single-agent maintenance
- Non-Hodgkin's lymphoma, Low-grade, CD20-positive, B-cell, stable or responsive to prior CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
- Non-Hodgkin's lymphoma, Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell
- Rheumatoid arthritis (Moderate to Severe), In combination with methotrexate, in patients who had an inadequate response to one or more tumor-necrosis-factor antagonist therapies
- Wegener's granulomatosis, In combination with glucocorticoids

Off Labeled Indications

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- Autoimmune hemolytic anemia
- B-cell lymphoma
- Chronic lymphoid leukemia, In combination for first-line treatment
- Chronic lymphoid leukemia, Relapsed or refractory
- Evans syndrome, Refractory to immunosuppressive therapy
- Graft-versus-host disease, chronic, Steroid-refractory
- Hodgkin's disease, CD20-positive, as monotherapy
- Idiopathic thrombocytopenic purpura
- Mantle cell lymphoma, Untreated, induction therapy, in combination with anthracycline-based regimens
- Minimal change disease, Refractory, steroid-dependent or steroid-resistant
- Pemphigus vulgaris, Severe
- Post-transplant lymphoproliferative disorder
- Primary Sjögren's syndrome
- Rheumatoid arthritis, In combination with methotrexate, in patients with an inadequate response to methotrexate
- Systemic lupus erythematosus, Refractory to immunosuppressive therapy; Adjunct
- Waldenström macroglobulinemia

Coding Information:

HCPCS Code(s)

J9310	INJECTION, RITUXIMAB, 100 MG
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ICD-9 Code(s)

200.00 - 200.88	RETICULOSARCOMA UNSPECIFIED SITE - OTHER NAMED VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
202.00 - 202.98	NODULAR LYMPHOMA UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE INVOLVING LYMPH NODES OF MULTIPLE SITES
204.00	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION
204.01	LYMPHOID LEUKEMIA ACUTE IN REMISSION
204.10 - 204.12	CHRONIC LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC LYMPHOID LEUKEMIA, IN RELAPSE
273.3	MACROGLOBULINEMIA
273.4	ALPHA-1-ANTITRYPSIN DEFICIENCY

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283.0	AUTOIMMUNE HEMOLYTIC ANEMIAS
287.30 - 287.33	PRIMARY THROMBOCYTOPENIA, UNSPECIFIED - CONGENITAL AND HEREDITARY THROMBOCYTOPENIC PURPURA
446.0	POLYARTERITIS NODOSA
446.4	WEGENER'S GRANULOMATOSIS
446.6	THROMBOTIC MICROANGIOPATHY
694.4 - 694.61	PEMPHIGUS - BENIGN MUCOUS MEMBRANE PEMPFIGOID WITH OCULAR INVOLVEMENT
714.0 - 714.33	RHEUMATOID ARTHRITIS - MONOARTICULAR JUVENILE RHEUMATOID ARTHRITIS
795.79	OTHER AND UNSPECIFIED NONSPECIFIC IMMUNOLOGICAL FINDINGS

Background:

Rituximab, a murine/human monoclonal antibody, binds specifically to the antigen CD20 that is located on pre-B and mature B lymphocytes. The antigen is expressed on more than 90% of B-cell non-Hodgkin's lymphomas, but not expressed on hematopoietic stem cells, pro-B cells, normal plasma cells, or other normal tissues. CD20 regulates an early step or steps in the activation process for cell cycle initiation and differentiation and may also function as a calcium ion channel. The mechanism of antineoplastic action may involve mediation of B cell lysis (seen in vitro) by means of binding of the Fab domain of rituximab to the CD20 antigen on B lymphocytes and by recruitment of immune effector functions by the Fc domain. Cell lysis may be the result of complement-dependent cytotoxicity (CDC) and antibody-dependent cellular cytotoxicity (ADCC). In addition, the antibody has been shown to induce apoptosis in the DHL-4 human B-cell lymphoma line. In rheumatoid arthritis, B cells are believed to be involved at multiple sites in the autoimmune/inflammatory process, including production of rheumatoid factor and other autoantibodies, antigen presentation, T-cell activation, and/or proinflammatory cytokine production



Black Box Warning:

WARNING: FATAL INFUSION REACTIONS, TUMOR LYSIS SYNDROME (TLS), SEVERE MUCOCUTANEOUS REACTIONS, and PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML)

Infusion Reactions

Rituxan administration can result in serious, including fatal infusion reactions. Deaths within 24 hours of Rituxan infusion have occurred. Approximately 80% of fatal infusion reactions occurred in association with the first infusion. Carefully monitor patients during infusions. Discontinue Rituxan infusion and provide medical treatment for Grade 3 or 4 infusion reactions.

Tumor Lysis Syndrome (TLS)

Acute renal failure requiring dialysis with instances of fatal outcome can occur in the setting of TLS following treatment of non-Hodgkin's lymphoma (NHL) with Rituxan monotherapy.

Severe Mucocutaneous Reactions

Severe, including fatal, mucocutaneous reactions can occur in patients receiving Rituxan.

Progressive Multifocal Leukoencephalopathy (PML)

JC virus infection resulting in PML and death can occur in patients receiving Rituxan.

Definitions:

HCCPS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.



ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

Monoclonal antibodies (mAb or moAb)—monospecific antibodies that are the same because they are made by identical immune cells that are all clones of a unique parent cell. Monoclonal antibodies have monovalent affinity, in that they bind to the same epitope.

References:

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2. The NCCN Drugs & Biologics Compendium™ © 2010 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 25, 2012.
3. Local Coverage Article for Drugs and Biologics – Chemotherapeutic Agents (A48896) (R4). Available at: http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=48896&ver=89&ContrId=213&ContrVer=1&CtrctrSelected=213*1&Date=01%2f01%2f2013&DocID=A48896&bc=hAAAAAgAEAAAA%3d%3d&. Accessed June 4, 2014.
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For the Archived Policy, please go

to <http://www.vivaprovider.com/Resources/CoveragePolicies.aspx> and click on the Archived Policies Link.

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