Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Rituxan (rituximab)

CG-DRUG-94

Override(s)	Approval Duration
Prior Authorization	1 year; unless state regulations require otherwise

Medications
Rituxan (rituximab)

APPROVAL CRITERIA

I. **Rheumatoid Arthritis**
Rituximab **may be approved** when all of the following are met:
- A. Individual is 18 years of age or older with moderately to severely active rheumatoid arthritis; **AND**
- B. Rituximab is given in combination with methotrexate unless intolerant of or has a medical contraindication; **AND**
- C. Individual had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies, or has a medical contraindication to TNF antagonist therapy.

II. **Wegener's Granulomatosis and Microscopic Polyangiitis**
Rituximab in combination with glucocorticoids, **may be approved** for the treatment of individuals with Wegener's granulomatosis and microscopic polyangiitis.

III. **Other Indications**
Rituximab **may be approved** for the treatment of **any** of the following conditions:
- A. Acquired inhibitors in individuals with hemophilia who fail cyclophosphamide and prednisone therapy; **OR**
- B. Autoimmune hemolytic anemia, refractory; **OR**
- C. Cryoglobulinemia, primary Sjogren Syndrome , or systemic lupus erythematosus refractory to standard therapy (that is, lack of response to corticosteroids **and** at least two (2) immunosuppressive agents); **OR**
- D. Graft-Versus-Host Disease as third line of therapy or greater; **OR**
- E. Hepatitis C virus infection-related cryoglobulinemic vasculitis in conjunction with intravenous methylprednisolone, and concomitant antiviral therapy for individuals with any of the following:
    1. Nephrotic proteinuria; **OR**
    2. Evidence of rapidly progressive kidney disease; **OR**
    3. Uncontrolled nephrotic syndrome; **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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4. Acute flare of cryoglobulinemia; **OR**

F. Immunoglobulin G4-related disease when **any** of the following are met:
   1. Failure to respond to prednisone or other corticosteroid agents; **OR**
   2. Unable to tolerate tapering of prednisone or other corticosteroid agents; **OR**
   3. Has a medical contraindication to prednisone or other corticosteroid agents; **OR**

G. Multiple sclerosis when **both** of the following are met:
   1. Individual has a relapsing-remitting form of multiple sclerosis; **AND**
   2. Has had an inadequate response to, **or** is unable to tolerate, **or** has a medical contraindication to at least two alternative drug therapies indicated for the treatment of multiple sclerosis; **OR**

H. Neuromyelitis optica ; **OR**

I. Pediatric nephrotic syndrome when **all** of the following are met:
   1. Individual 18 years of age or younger; **AND**
   2. Has steroid-dependent, relapsing disease; **AND**
   3. Has an inadequate response to, is intolerant of, or has a medical contraindication to corticosteroid or immunosuppressive drug therapy (such as, cyclosporine, cyclophosphamide, or mycophenolate mofetil); **OR**

J. Pemphigus vulgaris and other autoimmune blistering skin diseases (for example, Pemphigus foliaceus, bullous pemphiboid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus) when refractory; **OR**

K. Renal transplant setting for either of the following indications:
   1. Pre-transplant to suppress panel reactive anti-human leukocyte antigens (HLA) antibodies in individuals with high panel reactive antibody (PRA) levels to HLAs; **OR**
   2. Post-transplant in individuals with acute rejection who had received rituximab treatment pre-transplant; **OR**

L. Thrombocytopenic purpura, immune or idiopathic; **OR**

M. Thrombotic thrombocytopenic purpura (TTP), refractory or relapsing disease (that is, lack of response to plasma exchange therapy and glucocorticoids) in an individual who meets the diagnostic criteria for TTP [that is, TTP is confirmed by severely reduced baseline activity of ADAMTS 13 (less than 5%), with or without the presence of an ADAMTS 13 inhibitor in the appropriate clinical setting].

Rituximab may <u>NOT</u> be approved for the following:

A. Criteria above are not met: **OR**

B. All other non-oncologic indications, including but ***<u>not</u>*** limited to:
   1. Chronic inflammatory demyelinating polyradiculoneuropathy; **OR**
   2. Graft-Versus-Host Disease as first or second-line therapy; **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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3. Membranous glomerulonephropathy; **OR**
4. Multiple sclerosis, other than relapsing forms (such as, primary progressive or secondary progressive); **OR**
5. Renal transplant rejection, except as specified above (Section III. K.); **OR**
6. Stiff person syndrome.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

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Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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