

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

\*FHK- Florida Healthy Kids

## Rituxan (rituximab)

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

Medications
Rituxan (rituximab)

### APPROVAL CRITERIA

Requests for Rituxan (rituximab) may be approved for the following:

- I. Rheumatoid arthritis (RA) when each of the following criteria are met:
  - A. Individual is 18 years of age or older with moderate to severe (RA); **AND**
  - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] (ACR 2015); **AND**
  - C. Individual had an inadequate response, is intolerant of, or has a contraindication to one or more tumor necrosis factor (TNF) antagonist therapies;
- OR**
- II. Wegener's Granulomatosis and Microscopic Polyangiitis (MPA) when each of the following criteria are met:
  - A. Individual is 18 years of age or older with Wegener's Granulomatosis and MPA; **AND**
  - B. Individual is using concomitantly with glucocorticoids;
- OR**
- III. Autoimmune blistering skin diseases (such as but not limited to pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus) (Ahmed 2016, Maley 2016) when either of the following criteria are met:
  - A. As first-line treatment in adults with moderate to severe pemphigus vulgaris; **OR**
  - B. Disease is treatment-refractory;
- OR**
- IV. Acquired inhibitors in individuals with hemophilia who fail cyclophosphamide and prednisone therapy (Collins 2009, Rossi 2016); **OR**
- V. Autoimmune hemolytic anemia, refractory (Birgens 2013, Michel 2017, DP B IIb); **OR**
- VI. Cryoglobulinemia, primary Sjogren Syndrome, or systemic lupus erythematosus

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refractory to standard therapy (Ramos 2009, DP B IIb) including:

- A. Corticosteroids; **AND**
- B. Two (2) or more immunosuppressive agents (such as but not limited to azathioprine, cyclosporine, methotrexate, or hydroxychloroquine);

**OR**

- VII. Graft-Versus-Host Disease as third-line of therapy or greater (Cutler 2006, DP B IIb); **OR**
- VIII. Hepatitis C virus infection-related cryoglobulinemic vasculitis in conjunction with intravenous methylprednisolone, and concomitant antiviral therapy for individuals with any of the following (KDIGO 2012):
  - A. Nephrotic proteinuria; **OR**
  - B. Evidence of rapidly progressive kidney disease; **OR**
  - C. Uncontrolled nephrotic syndrome; **OR**
  - D. Acute flare of cryoglobulinemia;

**OR**

- IX. Immunoglobulin G4-related disease when any of the following are met (Khosroshahi 2015):
  - A. Failure to respond to prednisone or other corticosteroid agents; **OR**
  - B. Unable to tolerate tapering of prednisone or other corticosteroid agents; **OR**
  - C. Has a medical contraindication to prednisone or other corticosteroid agents;

**OR**

- X. Multiple sclerosis when each of the following are met (AAN 2018, DP B IIb):
  - A. Individual has a relapsing-remitting form of multiple sclerosis; **AND**
  - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to at least two (2) alternative treatments for multiple sclerosis;

**OR**

- XI. Neuromyelitis optica (Scott 2011);

**OR**

- XII. Pediatric nephrotic syndrome when each of the following criteria are met (KDIGO 2012, DP B IIb):
  - A. Individual 18 years of age or younger; **AND**
  - B. Individual has steroid-dependent, relapsing disease; **AND**
  - C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to corticosteroids or immunosuppressive agents (such as but not limited to cyclosporine, cyclophosphamide, or mycophenolate);

**OR**

- XIII. Renal transplant setting for either of the following indications (Vo 2010, KDIGO 2017):
  - A. Pre-transplant to suppress panel reactive anti-human leukocyte antigens (HLA) antibodies in individuals with high panel reactive antibody (PRA) levels to HLAs; **OR**
  - B. Post-transplant in individuals with acute rejection who had received rituximab treatment pre-transplant;

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**OR**

XIV. Antibody-mediated solid organ transplant rejection (KDIGO 2009, ISHLT 2010);

**OR**

XV. Thrombocytopenic purpura, immune or idiopathic (ASH 2011);

**OR**

XVI. Immune mediated thrombotic thrombocytopenic purpura (TTP) when each of the following criteria are met (Scully 2012, DP B IIb):

- A. TTP is confirmed by severely reduced baseline activity of ADAMTS 13 (less than 5%), with the presence of an ADAMTS 13 inhibitor; **AND**
- B. Individual has refractory or relapsing disease as defined by lack of response to plasma exchange therapy and glucocorticoids;

**OR**

XVII. Myasthenia gravis when the following criteria are met (MGFA 2016, DP B I):

- A. Individual is 18 years of age or older with myasthenia gravis; **AND**
- B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to two or more immunosuppressive drug agents (such as azathioprine, cyclosporine, or methotrexate).

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

**Key References:**

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CRX-ALL-0353-19

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