This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
## APPROVAL CRITERIA

Requests for Rituxan (rituximab) Truxima (rituximab-abbs), or Ruxience (rituximab-pvvr) 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. Granulomatosis with Polyangiitis and Microscopic Polyangiitis (MPA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with Granulomatosis with Polyangiitis 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 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);

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Market Applicability

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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).

Requests for Rituxan (rituximab), Truxima (rituximab-abbs), or Ruxience (rituximab-pvvr) may not be approved when the above criteria are not met and for all other non-oncologic indications.

Key References:


8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.


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