Generic Name: Belimumab

Non-preferred: N/A

Date of Origin: 8/26/2024

Date Last Reviewed / Revised: 3/24/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Patient is positive for autoantibodies (anti-nuclear antibody (ANA) titers ≥1:80 and/or anti-double-stranded DNA (anti-dsDNA)

II. The medication is prescribed by or in consultation with a rheumatologist or nephrologist

III. Age 5 years or older

IV. Documented diagnosis of one of the following conditions A OR B and must meet criteria under each applicable diagnosis:

A. Lupus Nephritis

i. Patient has an International Society of Nephrology and Renal Pathology Society (ISN/RPS) class III or IV (with or without coexisting class V) or class V lupus nephritis confirmed with biopsy

1. Patient trialed and intolerant to or contraindicated to ONE of the following therapies including corticosteroids AND in combination of one of the following for at least six months:

a. Low dose intravenous cyclophosphamide

b. Mycophenolic acid analog (MPAA)

c. Azathioprine

d. Leflunomide

e. Calcineurin inhibitor (tacrolimus, cyclosporine, or voclosporin) with MPAA

2. Should be in combination with either MPAA or low dose intravenous cyclophosphamide AND glucocorticoids

B. Systemic Lupus Erythematosus (SLE)

i. Patient trialed and failed or intolerance to at least TWO of the following:

1. Hydroxychloroquine (alone or in combination with corticosteroids) and immunosuppressive/immunomodulating agent (methotrexate, azathioprine, or mycophenolate)

EXCLUSION CRITERIA

1. Cannot be used in combination with anifrolumab-fnia or rituximab therapy

2. Severe active central nervous system lupus
3. Pregnancy (category C)

OTHER CRITERIA

N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Lupus Nephritis
    - Adults: Eight 200 mg prefilled syringes or autoinjectors for the first 28 days, then four 200 mg prefilled syringes or autoinjectors every 28 days.
- SLE
    - Adults: Four 200 mg prefilled syringes or autoinjectors every 28 days
    - Pediatrics ≥ 40 kg: Four 200 mg prefilled syringes or autoinjectors every 28 days
    - Pediatrics 15 kg to < 40 kg: Two 200 mg prefilled syringes or autoinjectors every 28 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes confirming the current medical necessity criteria are met and showing the medication is effective

APPENDIX

N/A

REFERENCES

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2. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. *Arthritis Care Res (Hoboken)* 2012;64:797-808. And Bertsias GK, Tektonidou M, Amoura Z, et al. Joint European League Against Rheumatism and European Renal Association-European Dialysis and Transplant Association (EULAR/ERA-EDTA) recommendations for the management of adult and paediatric lupus nephritis. *Ann Rheum Dis.* 2012;71:1771-1782.
3. Furie R, Rovin BH, Houssiau F, Malvar A, Teng YKO, Contreras G, Amoura Z, Yu X, Mok CC, Santiago MB, Saxena A, Green Y, Ji B, Kleoudis C, Burriss SW, Barnett C, Roth DA: Two-year, randomized, controlled trial of belimumab in lupus nephritis. *N Engl J Med.* 2020;383: 1117–1128.
4. Fanouriakis A, Kostopoulou M, Cheema K, Anders HJ, Aringer M, Bajema I, Boletis J, Frangou E, Houssiau FA, Hollis J, Karras A, Marchiori F, Marks SD, Moroni G, Mosca M, Parodis I, Praga M, Schneider M, Smolen

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5. Kidney Disease: Improving Global Outcomes (KDIGO) Lupus Nephritis Work Group. KDIGO 2024 Clinical Practice Guideline for the management of LUPUS NEPHRITIS. Kidney Int. 2024 ;105(1S):S1-S69.
6. Fanouriakis A, Kostopoulou M, Andersen J*, et al.* EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. *Annals of the Rheumatic Diseases* 2024;83:15-29.