MetroPlus Health

Policy and Procedure

Title: UM-PT003 Benlysta (belimumab)	**Division: Medical Management** **Department: Pharmacy**
Approval Date: 4/28/2023	**LOB: Medicaid, HIV SNP, HARP, CHP, QHP, EP, Gold, Goldcare**
Effective Date: 4/28/2023	**Policy Number: UM-PT003**
Review Date: 3/4/2026	**Cross Reference Number:**
Retired Date:	**Page 1 of 5**

I. POLICY DESCRIPTION:

Monoclonal Antibody – Benlysta (belimumab)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department, Utilization Management, Integrated Care Management, Claims Department

III. DEFINITIONS:

Belimumab is an IgG1-lambda monoclonal antibody that prevents the survival of B lymphocytes by blocking the binding of soluble human B lymphocyte stimulator protein (BLyS) to receptors on B lymphocytes. This reduces the activity of B-cell mediated immunity and the autoimmune response.

IV. POLICY:

Benlysta will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes and lab work confirming member has autoantibodies relevant to Systemic Lupus Erythematosus (e.g., ANA, anti-ds DNA, anti-Sm) must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:

1. **Systemic Lupus Erythematosus (SLE)**
   - **A.** Member is ≥ 5 years and older;
   - **AND**
   - **B.** Member is receiving a stable standard treatment for SLE with ONE of the following (alone or in combination) for at least 2 months:
     - **a.** Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone);
     - **OR**
     - **b.** Antimalarials (e.g., hydroxychloroquine);
     - **OR**
     - **c.** Immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide);
   - **AND**
   - **C.** Authorization is for no more than 12 months

2. **Lupus Nephritis**
   - **A.** Member is ≥ 5 years and older;
   - **AND**

B. Member has clinically active lupus renal disease and is receiving a stable standard induction and maintenance treatment for lupus nephritis (e.g., cyclophosphamide, mycophenolate mofetil, azathioprine, glucocorticoids);

AND

C. Authorization is for no more than 12 months

RENEWAL REQUEST

1. Systemic Lupus Erythematosus (SLE)

A. Initial conditions of coverage have been met;

AND

B. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition;

AND

C. Authorization is for no more than 12 months

2. Lupus Nephritis

A. Initial conditions of coverage have been met;

AND

B. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition;

AND

C. Authorization is for no more than 12 months

V. LIMITATIONS/ EXCLUSIONS:

Benlysta is considered to be experimental and investigational if prescribed for indications that have not been approved by the FDA and will not be covered under this policy.

Benlysta will not be used concurrently with other biologics or Lupkynis.

Member does not have severe active central nervous system lupus.

Live vaccines should not be given for 30 days before or concurrently with Benlysta.

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
J0490	Injection, belimumab, 10 mg

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
M32.0	Drug-induced systemic lupus erythematosus
M32.10	Systemic lupus erythematosus, organ or system involvement unspecified
M32.11	Endocarditis in systemic lupus erythematosus
M32.12	Pericarditis in systemic lupus erythematosus
M32.13	Lung involvement in systemic lupus erythematosus
M32.14	Glomerular disease in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus
M32.19	Other organ or system involvement in systemic lupus erythematosus
M32.8	Other forms of systemic lupus erythematosus
M32.9	Systemic lupus erythematosus, unspecified

VIII. REFERENCES:

1. Benlysta [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; April 2024.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 Update of the EULAR Recommendations for the Management of Systemic Lupus Erythematosus. *Ann Rheum Dis*. 2019;78:736-745.
3. Rovin BH, Parikh SV, Hebert LA, et al. Lupus nephritis: induction therapy in severe lupus nephritis – should MMF be considered the drug of choice? *Clin J Am Soc Nephrol.* 2013;8(1):147-153.
4. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. *Arthritis Care & Research*. 2012;64(6):797-808.
5. Furie R, Rovin BH, Houssiau F, et al. Two-Year, Randomized, Controlled Trial of Belimumab in Lupus Nephritis. N Engl J Med. 2020;383(12):1117-1128.
6. Aringer M, Costenbader K, Daikh D, et al. 2019 European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus. *Ann Rheum Dis.* 2019;78:1151-1159.
7. Stohl W, Merrill JT, McKay JD, et al. Efficacy and safety of belimumab in patients with rheumatoid arthritis: a phase II, randomized, double-blind, placebo-controlled, dose-ranging Study. J Rheumatol. 2013;40(5):579-589.
8. Lupkynis™ capsules [prescribing information]. Rockville, MD: Aurinia; January 2021

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REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	SC	4/28/2023
Annual review	JL	3/4/2026

Approved:	**Date:**	**Approved:**	**Date:**
Suzana Patel	3/12/26		03.12.2026
Suzana Patel, PharmD **Senior Director of Pharmacy**		**Sanjiv Shah, MD** **Chief Medical Officer**	

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication.

MetroPlus HealthPlan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.