curative

Benlysta Prior Authorization

Drug(s) Applied:	**Benlysta** (belimumab)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. Active systemic lupus erythematosus (SLE) as indicated by chart notes within past 120 days

1. ONE of the following:
    a) Patient has a history of positive antinuclear antibody (ANA) results **or**
    b) Patient has positive anti-dsDNA results, **or**
    c) Patient has a history of low complement levels (C3 or C4 below the lower limit of normal) **and**
2. One or more clinical manifestations attributable to SLE within the previous 6 months (ex: inflammatory arthritis or arthralgias, fever, fatigue, mucocutaneous-related effects, cytopenias, etc) **and**
3. Patient is currently being treated with hydroxychloroquine or chart notes document contraindication to hydroxychloroquine **and**
4. Patient is currently being treated with or has had an intolerance or failure to at least ONE immunosuppressive therapy (e.g. mycophenolate, azathioprine, methotrexate, tacrolimus, cyclosporine) or has an FDA labeled contraindication to ALL guideline-recommended immunosuppressive therapies **and**
5. Patient is 5 years of age and over **and**
6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., rheumatology) **and**
7. Chart notes and/or prescriber do not provide documentation of severe active central nervous system lupus **and**
8. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another biologic agent or with Lupkynis

Approval Duration: 6 months

B. Active lupus nephritis (LN) as indicated by chart notes within past 120 days

1. Lupus nephritis is confirmed by percutaneous kidney biopsy unless contraindicated or not feasible **and**

2. ONE of the following:
    a) Patient has Class III/IV LN with or without Class V LN **or**
    b) Patient has any Class LN with refractory disease (e.g. failed 2 standard therapy courses, minimum of 6 months each) **and**
3. Patient is currently being treated with optimized standard therapy, or has a contraindication to standard therapy:
    a) Hydroxychloroquine **and**
    b) Mycophenolate or cyclophosphamide **and**
4. For patients with nephrotic range proteinuria (ex: proteinuria ≥ 3g/g) and/or relatively preserved kidney function, patient has had failure to an adequate trial of at least ONE calcineurin inhibitor (e.g. tacrolimus, cyclosporine) or prescriber has documented clinical consideration for why a calcineurin inhibitor is not appropriate **and**
5. If patient is 18 years or older, patient has tried and had an inadequate response to Gazvya or has an intolerance or FDA labeled contraindication to Gazvya **and**
6. Patient is 5 years of age and over **and**
7. If documentation shows evidence of proteinuria (above normal range), patient is starting or is currently on a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g. lisinopril, enalapril, losartan, valsartan) **and**
8. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., rheumatology, nephrology) **and**
9. Chart notes and/or prescriber do not provide documentation of severe active central nervous system lupus **and**
10. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another biologic agent or with Lupkynis

Approval Duration: 6 months

II. Continued Therapy Criteria

A. Active systemic lupus erythematosus (SLE) as indicated by chart notes within past 12 months

1. ONE of the following:
    a) Patient has a history of positive antinuclear antibody (ANA) results **or**
    b) Patient has positive anti-dsDNA results, **or**
    c) Patient has a history of low complement levels (C3 or C4 below the lower limit of normal) **and**
2. Patient is currently being treated with hydroxychloroquine or chart notes document contraindication to hydroxychloroquine **and**
3. Documented clinical benefit since starting the requested agent (e.g. remission or lower level of disease activity) **and**

4. Patient is 5 years of age and over **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., rheumatology) **and**
6. Chart notes and/or prescriber do not provide documentation of severe active central nervous system lupus **and**
7. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another biologic agent or with Lupkynis

Approval Duration: 12 months

B. Active lupus nephritis (LN) as indicated by chart notes within past 12 months

1. Lupus nephritis is confirmed by percutaneous kidney biopsy unless contraindicated or not feasible **and**
2. ONE of the following:
    a) Patient has Class III/IV LN with or without Class V LN **or**
    b) Patient has any Class LN with refractory disease (e.g. failed 2 standard therapy courses, minimum of 6 months each) **and**
3. Patient is currently being treated with optimized standard therapy, or has a contraindication to standard therapy:
    a) Hydroxychloroquine **and**
    b) Mycophenolate or cyclophosphamide **and**
4. Patient is 5 years of age and over **and**
5. ONE of the following:
    a) If member has received Benlysta for less than 12 months, there is documented clinical benefit (ie stabilization or improvement in kidney function) **or**
    b) If member has received Benlysta for 12 months or longer, there is documented clinical benefit of BOTH of the following:
        (1) Stabilization or improvement in kidney function **and**
        (2) Reduction in proteinuria by at least 50% and level is either < 3 g/g (300 mg/mmol) i.e., partial renal response or < 0.5 g/g (50 mg/mmol) i.e. complete renal response **and**
6. If documentation shows evidence of proteinuria (above normal range), patient is starting or is currently on a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g. lisinopril, enalapril, losartan, valsartan) **and**
7. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., rheumatology, nephrology) **and**
8. Chart notes and/or prescriber do not provide documentation of severe active central nervous system lupus **and**
9. Chart notes and/or prescriber do not provide documentation of using the

requested agent in combination with another biologic agent or with Lupkynis

Approval Duration: 12 months

If submitting for medical billing:

J0490, belimumab (Benlysta), 1 unit = 10 mg

References:

1. Benlysta prescribing information. GlaxoSmithKline. June 2025.
2. 2025 American College of Rheumatology (ACR) Guideline for the Treatment of Systemic Lupus Erythematosus (SLE). Guideline Summary. Link.
3. Aringer M, Costenbader K, Daikh D, et al. 2019 European League Against Rheumatism/American College of Rheumatology Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheumatol. 2019 Sep;71(9):1400-1412. PMID: 31385462. Link.
4. Fanouriakis A, Tziolos N, Bertsias G, Boupas D T. Update on the diagnosis and management of systemic lupus erythematosus. Annals of the Rheumatic Diseases 2021; 80:14-25. Link.
5. 2024 American College of Rheumatology (ACR) Guideline for the Screening, Treatment, and Management of Lupus Nephritis. Link.
6. Kidney Disease Improving Global Outcomes (KDIGO) 2024 Clinical Practice Guideline for the Management of Lupus Nephritis. Jan 2024; 105:15. Link.

Policy Owned by: Curative PBM team