

Date Effective: 9/2017
Reviewed: 9/2017, 12/2018, 11/2019, 9/2020, 01/2021, 4/2021, 01/2022, 9/2022, 01/2023, 12/2023, 02/2024
Pharmacy Scope (SQ): Medicaid
Medical Scope (IV): Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

BENLYSTA (belimumab)

POLICY

Initial Criteria:

Systemic Lupus Erythematosus (SLE)

- Patient is 5 years of age or older*; **AND**
- Patient has documented diagnosis of active SLE **AND**
- Patient has one of the following:
 - Safety of Estrogen in Lupus National Assessment -Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12; **OR**
 - British Isles Lupus Assessment Group (BILAG) B organ domain score ≥ 2 ; **AND**
- Patient has failed to respond adequately to at least two (2) standard therapies such as anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, or immunosuppressives (excluding intravenous cyclophosphamide); **AND**
- Used in combination with standard therapy (e.g. anti-malarials, corticosteroids, nonsteroidal anti-inflammatory drugs, immunosuppressives); **AND**
- Patient must not have an active infection; **AND**
- Patient has not received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**
- Will not be used in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab); **AND**
- Patient does not have any of the following exclusion criteria:
 - Severe active central nervous system lupus
 - Individuals who are on other biologics

Lupus Nephritis

- Patient is 5 years of age or older* ; **AND**
- Patient has active lupus nephritis Class III, IV, or V as confirmed by renal biopsy; **AND**
- Patient has failed to respond adequately to standard therapies including corticosteroids; **AND** either cyclophosphamide or mycophenolate mofetil; **AND**
- Baseline measurement of one or more of the following is provided: urine protein:creatinine ratio (uPCR), estimated glomerular filtration rate (eGFR), or urine protein; **AND**
- Used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); **AND**
- Patient must not have an active infection; **AND**
- Patient has not received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**

Date Effective: 9/2017
Reviewed: 9/2017, 12/2018, 11/2019, 9/2020, 01/2021, 4/2021, 01/2022, 9/2022, 01/2023, 12/2023, 02/2024 Pharmacy Scope (SQ): Medicaid Medical Scope (IV): Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

- Will not be used in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab); **AND**
- Patient does not have any of the following exclusion criteria:
 - Severe active central nervous system lupus
 - Individuals who are on other biologics; **AND**

*Benlysta 200mg/ml subcutaneous injection is only indicated for patients that are 18 years of age and older.

Continuation of Therapy Criteria:

- Meets all initial criteria and is tolerating treatment; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: depression, suicidal thoughts, serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reactions/anaphylaxis, serious infusion reactions, etc.; **AND**

SLE:

- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
 - Improvement in the SELENA-SLEDAI score of ≥ 4 points; **OR**
 - No new BILAG-A organ domain score or 2 new BILAG-B organ domain scores; **OR**
 - No worsening (<30 -point point increase) in Physician’s Global Assessment (PGA) score; **OR**
 - Seroconverted (negative) or had a 20% reduction in autoantibody level; **OR**

Lupus Nephritis:

- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
- Urine protein:creatinine ratio (uPCR); **OR**
- Estimated glomerular filtration rate (eGFR); **OR**
- Urine protein

Coverage Durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

Date Effective: 9/2017
Reviewed: 9/2017, 12/2018, 11/2019, 9/2020, 01/2021, 4/2021, 01/2022, 9/2022, 01/2023, 12/2023, 02/2024
Pharmacy Scope (SQ): Medicaid
Medical Scope (IV): Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Pharmacy Quantity Limit and Dosing:

Benlysta 200mg/ml subcutaneous injection has a quantity limit of 4 injections per 28 days (daily dose of 0.143), with a post-limit loading dose for of 8 injections per 28 days (daily dose of 0.286) for a diagnosis of Lupus Nephritis only.

Benlysta 200mg/ml subcutaneous injection is only indicated for patients that are 18 years of age and older.

Indication	Dose (subcutaneous- Adults ONLY)
SLE	200mg once weekly
Lupus Nephritis	Loading dose: 400mg once weekly for 4 doses Maintenance dose: 200mg once weekly

Medical Quantity Limit and Dosing:

Indication	Dose	Maximum dose (1 billable unit = 10 mg)
SLE or Lupus Nephritis	<u>Loading Dose:</u> 10 mg/kg intravenously (by a healthcare provider) every 2 weeks x 3 doses (days 1, 15 and 29)	<u>Loading Dose (on days 1, 15 and 29):</u> 360 billable units per 29 days
	<u>Maintenance Dose:</u> 10 mg/kg intravenously (by a healthcare provider) every 4 weeks	<u>Maintenance Dose:</u> 120 billable units per 28 days

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0490	Injection, belimumab, 10mg

References:

1. Benlysta [package insert]. Rockville, MD; Human Genome Sciences/GlaxoSmithKline; July 2022. Accessed August 2022.
2. Boyce EG, Fusco BE. Belimumab: review of use in systemic lupus erythematosus. Clin Ther. 2012 May;34(5):1006-22. doi: 10.1016/j.clinthera.2012.02.028. Epub 2012 Mar 30.
3. Navarra SV, Guzmán RM, Gallacher AE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomised, placebo-controlled, phase 3 trial.

Date Effective: 9/2017
Reviewed: 9/2017, 12/2018, 11/2019, 9/2020, 01/2021, 4/2021, 01/2022, 9/2022, 01/2023, 12/2023, 02/2024
Pharmacy Scope (SQ): Medicaid
Medical Scope (IV): Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

- Lancet. 2011 Feb;377(9767):721-31. doi: 10.1016/S0140-6736(10)61354-2. Epub 2011 Feb 4.
4. Furie R, Petri M, Zamani O, et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. *Arthritis Rheum.* 2011 Dec;63(12):3918-30. doi: 10.1002/art.30613.
 5. Petri M, Orbai AM, Alarcón GS, et al. Derivation and validation of the Systemic Lupus International Collaborating Clinics classification criteria for systemic lupus erythematosus. *Arthritis Rheum.* 2012 Aug;64(8):2677-86. doi: 10.1002/art.34473
 6. Furie R, Stohl W, Ginzler EM, et al. Biologic activity and safety of belimumab, a neutralizing anti-B-lymphocyte stimulator (BLyS) monoclonal antibody: a phase I trial in patients with systemic lupus erythematosus. *Arthritis Res Ther.* 2008;10(5):R109. doi: 10.1186/ar2506. Epub 2008 Sep 11.
 7. Kim SS, Kirou KA, Erkan D. Belimumab in systemic lupus erythematosus: an update for clinicians. *Ther Adv Chronic Dis.* 2012 Jan;3(1):11-23. doi: 10.1177/2040622311424806.
 8. Calvo-Alén J1, Silva-Fernández L, Úcar-Angulo E, et al. SER consensus statement on the use of biologic therapy for systemic lupus erythematosus. *Reumatol Clin.* 2013 SepOct;9(5):281-96.
 9. Gordon C, Amissah-Arthur MB, Gayed M, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults. *Rheumatol* 2017 Oct 6. doi: 10.1093/rheumatology/kex286.
 10. NICE. Belimumab for treating active autoantibody-positive systemic lupus erythematosus: Technology Appraisal Guidance [TAG397]. <https://www.nice.org.uk/guidance/ta397/> Accessed March 2019.
 11. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus in adults. *Arthritis Rheum.* 1999;42(9):1785–1796.
 12. Lam NC, Ghetu MV, Bieniek ML. Systemic Lupus Erythematosus: Primary Care Approach to Diagnosis and Management. *Am Fam Physician.* 2016 Aug 15;94(4):284-94.
 13. Wisconsin Physician Service Insurance Corp. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L34741). Centers for Medicare & Medicare Services. Updated on 05/24/2018 with effective dates 06/01/2018. Accessed March 2019.