

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, 3/2025
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**

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- 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;
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*Benlysta 200mg/ml auto-injector for subcutaneous injection (not prefilled syringe) is indicated for the treatment of SLE in patients that are 5 years of age and older that weigh at least 15kg.

**Benlysta 200mg/mL subcutaneous injection (auto-injector and prefilled syringe) is indicated for the treatment of SLE and lupus nephritis in patients 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

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Coverage Durations:

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

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 auto-injector for subcutaneous injection (not prefilled syringe) is indicated for the treatment of SLE in patients that are 5 years of age and older and weigh at least 15kg. Benlysta 200mg/mL subcutaneous injection (auto-injector and prefilled syringe) is indicated for the treatment of SLE and lupus nephritis in patients 18 years of age and older.

Indication	Dose (subcutaneous)
SLE	<p>Patients 5 years of age and older (Auto-injector only):</p> <p>15 kg to <40 kg: 200 mg once every 2 weeks.</p> <p>≥ 40 kg: 200 mg once weekly</p> <p>Adults (Auto-injector or prefilled syringe):</p> <p>200 mg once weekly</p>
Lupus Nephritis	<p>Adults (Auto-injector or prefilled syringe):</p> <p>Loading dose: 400mg once weekly for 4 doses</p> <p>Maintenance dose: 200mg once weekly</p>

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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>Maintenance Dose:</u> 10 mg/kg intravenously (by a healthcare provider) every 4 weeks	<u>Loading Dose (on days 1, 15 and 29):</u> 360 billable units per 29 days <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:

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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.