

## Medical Policy: BENLYSTA® (belimumab)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.71	July 26, 2023	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth 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). EmblemHealth 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 and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. 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 web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Benlysta is a human IgG1 lambda monoclonal antibody that inhibits the binding of soluble B lymphocyte stimulator protein (BLyS) to its B cell receptors.

## Length of Authorization

Coverage will be provided for 12 months and may be renewed.

## Dosing Limits [Medical Benefit]

### Max Units (per dose and over time) [Medical Benefit]:

- Loading Dose (doses administered on days 1, 15 and 29):
  - 360 billable units per 29 days
- Maintenance Dose:
  - 120 billable units per 28 days

## Guideline

### I. INITIAL APPROVAL CRITERIA

#### 1. Systemic Lupus Erythematosus (SLE)

- A. Patient is 5 years of age or older; **AND**
- B. Patient has autoantibody-positive SLE test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] antibody; **AND**
- C. Patient meets **ONE** of the following:
  - i. The medication is being used concurrently with at least one other standard therapy; **OR**  
*Note: Examples of standard therapies include an antimalarial (e.g., hydroxychloroquine), systemic corticosteroid (e.g., prednisone), and other immunosuppressants (e.g., azathioprine, mycophenolate mofetil, methotrexate).*
  - ii. Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; **AND**
- D. Patient must NOT have an active infection; **AND**
- E. Patient has NOT received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**
- F. Patient does NOT have any of the following exclusion criteria:
  - i. Severe active central nervous system lupus
  - ii. Individuals who are on other biologics

#### 2. Lupus Nephritis

- A. Patient is  $\geq 5$  years of age; **AND**
- B. Patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody; **AND**
- C. Patient meets **ONE** of the following:
  - i. The medication is being used concurrently with at least one other standard therapy; **OR**  
*Note: Examples of standard therapies include corticosteroids AND mycophenolate mofetil OR corticosteroids with cyclophosphamide for induction followed by azathioprine for maintenance.*
  - ii. Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber; **AND**
- D. Patient must NOT have an active infection; **AND**
- E. Patient has NOT received a live vaccine within 30 days before starting or concurrently with Benlysta; **AND**
- F. Patient does NOT have any of the following exclusion criteria:
  - i. Severe active central nervous system lupus
  - ii. Individuals who are on other biologics

### II. RENEWAL CRITERIA

Authorizations can be renewed based on the following criteria:

1. Patient continues to meet the criteria identified in section I; **AND**
2. Adequate documentation of disease stability and/or improvement as determined by the prescriber; **AND**  
Note: FOR SLE- Examples of a response include reduction in flares, reduction in corticosteroid dose, decrease of anti-dsDNA titer, improvement in complement levels (i.e., C3, C4), or improvement in specific organ dysfunction (e.g., musculoskeletal, blood, hematologic, vascular, others).  
Note: For Lupus Nephritis - Examples of a response include improvement in organ dysfunction, reduction in flares, reduction in corticosteroid dose, decrease of anti-dsDNA titer, and improvement in complement levels (i.e., C3, C4).
3. Absence of unacceptable toxicity from the drug.  
Note: Examples of unacceptable toxicity include the following: depression, suicidal thoughts, serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reaction, etc.

## Dosing/Administration

Indication	Dose
Systemic lupus erythematosus (SLE)	<ul style="list-style-type: none"> <li>• ≥5 years for IV and ≥18 years for SC</li> <li>• IV: Loading Dose: 10 mg/kg intravenously (by a healthcare provider) every 2 weeks x 3 doses (days 1, 15 and 29) Maintenance Dose: 10 mg/kg intravenously (by a healthcare provider) every 4 weeks</li> <li>• SC: 200 mg once weekly</li> </ul>
Lupus Nephritis	<ul style="list-style-type: none"> <li>• ≥5 years for IV and ≥18 years for SC</li> <li>• IV: 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter</li> <li>• SC: 400-mg dose (two 200-mg injections) once weekly for the first 4 doses, then 200 mg once weekly thereafter</li> </ul>

## Applicable Procedure Codes

Code	Description
J0490	Injection, belimumab, 10 mg; 1 billable unit = 10 mg

## Applicable NDCs

Code	Description
49401-0101-xx	Benlysta 120 mg/5 mL SDV for injection
49401-0102-xx	Benlysta 400 mg/20 mL SDV for injection

## ICD-10 Diagnoses

Code	Description
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

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & Connecticare	7/26/2023	Annual Review: No criteria changes
EmblemHealth & Connecticare	4/25/2023	SLE: Removed from initial Criteria: SELENA-SLEDAI score $\geq 6$ for IV and $\geq 8$ for SC
EmblemHealth & Connecticare	9/12/2022	<p>-Addition of Lupus Nephritis to criteria to align with FDA label.</p> <p>SLE Criteria:</p> <p>-Revision of wording for age limits under SLE criteria (change from “Adult greater than 5” to “Patient is 5 years of age or greater”</p> <p>-Addition of “The medication is being used concurrently with at least one other standard therapy; OR Patient is determined to be intolerant to standard therapy due to a significant toxicity, as determined by the prescriber” to SLE criteria</p> <p>-Removal of 1.Patient has one of the following: a.Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12 b British Isles Lupus Assessment Group (BILAG) A organ domain score <math>\geq 1</math> c.BILAG B organ domain score <math>\geq 2</math> ADDED SELENA-SLEDAI score <math>\geq 6</math> for IV and <math>\geq 8</math> for SC</p> <p>- Removal of Patient has failed to respond adequately to at least two (2) standard therapies (anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives (excluding intravenous cyclophosphamide)</p>
EmblemHealth & ConnectiCare	4/01/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	8/12/2019	Updated age-range from 18 to 5 years of age and older for IV

## References

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