

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Benlysta (belimumab)

DRUG.00044

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Comments	Quantity Limit
Benlysta (belimumab) 120mg Intravenous Solution	For Medicaid, applicable to AGP, VA MCD ONLY	N/A
Benlysta (belimumab) 400mg Intravenous Solution		
Benlysta (belimumab) 200mg/ml Prefilled autoinjector/syringe	For Medicaid, applicable to all MCD	4 injections per 28 days

### **APPROVAL CRITERIA**

Requests for Benlysta (belimumab) may be approved for individuals age 18 or older when **ALL** the following criteria are met prior to initiating therapy:

- I. Clinical diagnosis of SLE per the American College of Rheumatology (ACR) criteria; **AND**
- II. Unequivocally positive ANA (anti-nuclear antibody) titer greater than or equal to 1:80 or anti-dsDNA (double stranded DNA antibody) greater than or equal to 30 IU/mL; **AND**
- III. SLE is active as documented by a SELENA-SLEDAI score greater than or equal to 6 while on current treatment regimen; **AND**
- IV. There is no evidence of severe renal disease (proteinuria greater than 6 gm/day, serum creatinine greater than 2.5 mg/dl, or requiring renal dialysis); **AND**
- V. There is no evidence of active central nervous system lupus (for example, psychosis or seizures); **AND**
- VI. SLE remains active while on corticosteroids, antimalarials, or immunosuppressants (alone or as combination therapy) for at least the last 30 days.

Continuing therapy with Benlysta (belimumab) for treatment of SLE may be approved for individuals age 18 or older when **ALL** the following criteria are met:

- I. Clinical diagnosis of SLE per the ACR criteria; **AND**

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- II. There is documentation of previous improvement in disease activity following treatment with belimumab indicating a therapeutic response; **AND**
- III. There is no evidence of severe renal disease (proteinuria greater than 6 gm/day, serum creatinine greater than 2.5 mg/dl, or requiring renal dialysis); **AND**
- IV. There is no evidence of active central nervous system lupus (for example, psychosis or seizures).

**May NOT be approved:**

Benlysta (belimumab) **may not** be approved for active SLE when all of the criteria specified above are not met, or when any of the following contraindications are present:

- Individuals treated with rituximab or any other B cell targeted therapy within the past year.
- Individuals treated with IV cyclophosphamide within the past 180 days.
- Individuals treated with intravenous immunoglobulin (Ig) within the past 90 days.
- Individuals that have required prednisone at doses greater than 100 mg/day (or equivalent dose of another steroid) within the past 90 days.
- Individuals that have required treatment for an acute or chronic infection within the past 60 days.
- Individuals with human immunodeficiency virus (HIV) infection, hepatitis B virus infection, or hepatitis C virus infection.

Benlysta (belimumab) **may not** be approved for all other indications.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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