Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Benlysta (belimumab)

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

Medications	Comments	Dosing/Quantity Limit
Benlysta (belimumab) 120 mg, 400 mg vial for intravenous (IV) infusion	For Medicaid, applicable to AGP, VA MCD ONLY	10 mg/kg every 4 weeks*
Benlysta (belimumab) 200 mg/ml prefilled autoinjector/syringe for subcutaneous use	For Medicaid, applicable to all MCD	4 injections per 28 days

*For initiation of therapy, may approve 10 mg/kg dosing at 2 week intervals for the first 3 doses.

APPROVAL CRITERIA

Requests for Benlysta (belimumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of Systemic Lupus Erythematosus (SLE) per the American College of Rheumatology (ACR); **AND**
II. Disease is active as documented by a SELENA-SLEDAI score greater than or equal to 6 while on current treatment regimen; **AND**
III. Individual has a 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**
IV. Individual has no evidence of severe renal disease (defined as proteinuria greater than 6 gm/day, serum creatinine greater than 2.5 mg/dl, or requiring dialysis); **AND**
V. Individual has no evidence of active central nervous system lupus (including psychosis or seizures); **AND**
VI. Individual's SLE remains active while on corticosteroids, antimalarials, or immunosuppressants (alone or as combination therapy) for at least the last 30 days.

Continuation of therapy with Benlysta (belimumab) may be approved if all of the following criteria are met:

I. Confirmation of previous improvement in disease activity following treatment with belimumab indicating a therapeutic response; **AND**

Market Applicability							
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Applicable	X	X	X	X	X	X	X

II. Individual has no evidence of severe renal disease (defined as proteinuria greater than 6 gm/day, serum creatinine greater than 2.5 mg/dl, or requiring dialysis); **AND**
III. Individual has no evidence of active central nervous system lupus including psychosis or seizures).

Benlysta (belimumab) may not be approved for the following:

I. Individual is 18 years of age or older ad has a history of the following:
   A. Individual has been treated with IV cyclophosphamide within the past 180 days; **OR**
   B. Individual has required prednisone doses greater than 100 mg/day (or equivalent dose of another steroid) within the past 90 days; **OR**
II. Individual is 17 years of age or younger and has any of the following:
   A. Individual has been treated with IV cyclophosphamide within the past 60 days (NCT01649765); **OR**
   B. Individual has required prednisone doses greater than 1.5mg/kg/day within the past 60 days (NCT01649765); **OR**
   C. Individual is requesting Benlysta (belimumab) prefilled autoinjector or syringe for subcutaneous use; **OR**
III. Individuals treated with intravenous immunoglobulin (Ig) within the past 90 days; **OR**
IV. Individual is treated with rituximab or any other B cell targeted therapy within the past year; **OR**
V. Individual has required treatment for an acute or chronic infection within the past 60 days (NCT00424476, NCT00410384);**OR**
VI. Individual has human immunodeficiency virus (HIV) infection, hepatitis B virus infection, or hepatitis C virus infection (NCT00424476, NCT00410384).

Key References:

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2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Furie R, Petri M, Zamani O, et al. BLISS-76 Study Group. 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.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

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.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

7. Navarra SV, Guzman RM, Gallacher AE, et al. BLISS-52 Study Group. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomized, placebo-controlled, phase 3 trial. Lancet. 2011; 377(9767):721-731.
8. NCT00410384. U.S. National Library of Medicine, ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT00410384?term=nct+00410384&rank=1. Accessed June 26, 2019.
9. NCT00424476. U.S. National Library of Medicine, ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT00424476?term=nct+00424476&rank=1. Accessed June 26, 2019.
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