

PRIOR AUTHORIZATION CRITERIA

BRAND NAME (Generic)	Benlysta (belimumab)	
Status: CVS Caremark Criteria Type: Initial Prior Authorization		MDC Ref# 862-A

FDA-APPROVED INDICATION

Benlysta is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.¹

Limitations of Use:

The efficacy of Benlysta has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus.¹ Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations.

<u>CRITERIA FOR APPROVAL</u>			
1	Has the patient been diagnosed with active, autoantibody-positive, systemic lupus erythematosus (SLE)? [If no, no further questions.]	Yes	No
2	Does the patient meet any of the following criteria: A) Patient is currently receiving standard therapy for systemic lupus erythematosus (e.g., corticosteroids, azathioprine, leflunomide, methotrexate, mycophenolate mofetil, hydroxychloroquine, non-steroidal anti-inflammatory drugs), or B) Patient has tried and had an inadequate response or intolerance to standard therapy? [If no, no further questions.]	Yes	No
3	Does the patient have either of the following exclusions to therapy: A) severe active lupus nephritis, or B) severe active central nervous system lupus?	Yes	No

Guidelines for Approval	
Duration of Approval	12 Months
Set 1: SLE	
Yes to question(s)	No to question(s)
1	3
2	

Mapping Instructions			
		Yes	No
1	Go to 2		Deny
2	Go to 3		Deny
3	Deny		Approve, 12 months

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare-approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Benlysta [package insert]. Rockville, Maryland: Human Genome Sciences, Inc.; July 2017.
2. Clinical Consult. CVS Caremark Clinical Programs Review. Focus on Rheumatology Clinical Programs. August 2012.

DOCUMENT HISTORY

Written: Specialty Clinical Development (AC) 03/2011
Revised: KP (adapted from SGM) 10/2012, KR (MDC) 11/2012, KW 04/2013, KW 09/2013 (CMS); ST 02/2014, 09/2014 (CMS), 08/2015 (CMS), 06/2016 (CMS), KF 02/2017 (annual), 07/2017 (CMS)
Reviewed: CDPR/KP 02/2012, 06/2012; DNC 04/2013, 02/2014, WLF 03/2015, LCB 03/2016, LMS 02/2017
External review: 04/2012, 08/2012, 05/2013, 04/2014, 05/2015, 04/2016