JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP012
		Effective Date	01/01/2019
		Review Date	10/18/2023
	Subject **Benlysta IV**	*Revision Date*	10/18/2023
		Page	1 of 3

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Benlysta IV

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**2**
IV.	**EXCLUSIONS**	**2**
V.	**RECOMMENDED DOSAGE**	**2**
VI.	**CODES**	**2**
VII.	**REFERENCES**	**2**
VIII.	**APPROVALS**	**3**

I. POLICY

Benlysta IV (belimumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. **Benlysta IV** may be approved for patients who meet the following:

1. **Systemic lupus erythematosus (SLE)**
   a. Documented diagnosis of active systemic lupus erythematosus (SLE)
   b. Patient is positive for auto-antibodies associated with SLE (defined as ANA titer = 1:80 or greater OR anti-dsDNA=30 IU/mL or higher)
      I. *Due to lab variability in standards for positive values, consideration will be given if the reported lab results do not meet the values listed above but are reported as "positive" from that lab*
   c. Patient has failed to respond adequately to at least 2 of the following standard therapies:
      I. Corticosteroids
      II. Non-steroidal anti-inflammatory drugs (NSAIDs)
      III. Anti-malarials (hydroxychloroquine, chloroquine)
      IV. Non-biologic immunosuppressants (azathioprine, methotrexate, cyclosporine, oral cyclophosphamide)
   d. Patient will be utilizing Benlysta concomitantly with standard therapies
   e. Prescriber must be a rheumatologist
2. **Lupus Nephritis**
   a. Documented diagnosis of active lupus nephritis with renal disease
   b. Patient is positive for auto-antibodies associated with SLE (defined as ANA titer = 1:80 or greater OR anti-dsDNA=30 IU/mL or higher)
      I. *Due to lab variability in standards for positive values, consideration will be given if the reported lab results do not meet the values listed above but are reported as "positive" from that lab*
   c. Patient has failed to respond adequately to at least 2 of the following standard therapies:
      I. Corticosteroids
      II. Anti-malarials (hydroxychloroquine, chloroquine)

III. Non-biologic immunosuppressants (azathioprine, methotrexate, cyclosporine, oral cyclophosphamide)

d. Patient will be utilizing Benlysta concomitantly with standard therapies

e. Prescriber must be a rheumatologist or nephrologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 3 months of therapy (5 infusions)

B. Continuation of therapy may be approved in 6-month intervals with documentation showing a beneficial response to treatment, evidence by at least one of the following:

1. Reduction of daily dosing of required oral corticosteroids
2. Documented improvement in functional impairment
3. Reduction in number of symptom exacerbations since starting Benlysta regimen

IV. EXCLUSIONS

A. Benlysta IV will **not** be covered for the following:

1. Treatment of severe active central nervous system lupus
2. Concomitant use with other biologics, calcineurin-inhibitor immunosuppressant, or IV cyclophosphamide
3. Patients with a diagnosis of HIV, hepatitis B virus, or hepatitis C virus infections
4. Patients that required acute or chronic infection treatment within the past 60 days
5. Any indications that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Benlysta 120 MG SOLR J0490 Injection, belimumab, 10 mg	J0490
Benlysta 400 MG SOLR J0490 Injection, belimumab, 10 mg	J0490

VII. REFERENCES

1. Benlysta [Prescribing Information]. GlaxoSmithKline, Research Triangle Park, NC; 2022 July
2. Kim SS, Kirou KA, Erkan D. Belimumab in systemic lupus erythematosus: an update for clinicians. Ther Adv Chronic Dis. 2012 Jan;3(1):11-23.

3. NICE. Belimumab for treating active autoantibody-positive systemic lupus erythematosus: Technology Appraisal Guidance [TAG397]. https://www.nice.org.uk/guidance/ta397/
4. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. Arthritis Care Res. 2012;64(6):797-808.
5. Rovin BH, Caster DJ, Cattran DC et al. Management and treatment of glomerular diseases (part 2): conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. Kidney Int. 2019; 95(2):281-95.
6. Institute for Clinical and Economic Review. Belimumab and Voclosporin for Lupus Nephritis: Effectiveness and Value. Final Report. April 16, 2021. Available at: www.icer.org. Accessed September 30, 2021.
7. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021 Oct;100(4S):S1-S276.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
12/19/2018	Policy Creation
05/10/2019	Updated criteria based on new age approval in FDA-approved prescribing information
01/15/2020	No policy changes- presented policy for USFHP adoption effective 3/1/2020
06/09/2021	Added criteria for Benlysta's lupus nephritis indication
09/30/2021	Clarified medication concurrent use exclusions
11/10/2021	Removed Priority Partners as an applicable LOB
08/18/2022	Updated criteria based on new age approval in FDA-approved prescribing information
10/18/2023	Updated clinical criteria

Review Date: 12/19/2018, 07/17/2019, 01/15/2020, 07/21/2021, 10/19/2022, 10/18/2023

Revision Date: 12/19/2018, 05/10/2019, 06/09/2021 , 09/30/2021, 11/10/2021, 8/18/2022, 10/18/2023