JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS118
		Effective Date	07/17/2019
		Review Date	10/18/2023
	Subject **Benlysta Subcutaneous**	*Revision Date*	10/18/2023
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Benlysta Sub-Q

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I. POLICY

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

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Benlysta Subcutaneous** 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 auto-antibody positive (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
B. Continuation of therapy may be approved in 6-month intervals with documentation showing a beneficial response to treatment, evidenced 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 Subcutaneous 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
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

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VI. APPROVALS

Signature on file at JHHC

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DATE OF REVISION	SUMMARY OF CHANGE
07/17/2019	Benlysta Subcutaneous policy creation based on criteria established in the JHHC Benlysta IV policy
06/09/2021	Added criteria for Benlysta's lupus nephritis indication
09/30/2021	Clarified medication concurrent use exclusions
12/08/2021	Updated Exclusions section regarding physician samples
10/18/2023	Updated clinical criteria

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