UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Benlysta

Program	Prior Authorization
Medication	Benlysta® (belimumab)* *This program applies to the subcutaneous formulation of belimumab
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2018
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

1. Background:

Benlysta® is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy and adult patients with active lupus nephritis who are receiving standard therapy.

Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics. Use of Benlysta is not recommended in these situations.

2. Coverage Criteria:

A. Systemic Lupus Erythematosus

1. Initial Authorization

a. **Benlysta** will be approved based on **all** of the following criteria:

(1) Diagnosis of systemic lupus erythematosus

-AND-

(2) Laboratory testing has documented the presence of autoantibodies [e.g. ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]

-AND-

(3) Patient is currently receiving standard immunosuppressive therapy [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

-AND-

(4) Patient does **not** have severe active central nervous system lupus

-AND-

(5) Patient is not receiving Benlysta in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Benlysta** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Benlysta therapy

-AND-

(2) Patient is not receiving Benlysta in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Authorization will be issued for 12 months.

B. Active Lupus Nephritis

1. Initial Authorization

a. **Benlysta** will be approved based on **all** of the following criteria:

(1) Diagnosis of active lupus nephritis

-AND-

(2) Patient is currently receiving standard immunosuppressive therapy for systemic lupus erythematosus [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

-AND-

(3) Patient does **not** have severe active central nervous system lupus

-AND-

(4) Patient is not receiving Benlysta in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Benlysta** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Benlysta therapy

-AND-

(2) Patient is not receiving Benlysta in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Benlysta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2020.

Program	Prior Authorization –Benlysta (belimumab)
Change Control	
Date	Change
9/2017	New program.

9/2018	Annual review. Updated reference.
9/2019	Updated background to reflect expanded age indication. Updated reference.
9/2020	Annual review. Updated reference. Added Additional Clinical Rules section.
2/2021	Off cycle review. Background and clinical criteria updated to align with updated FDA label for new indication for adult patients with active lupus nephritis who are receiving standard therapy. References updated.