UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1227-6
Program	Prior Authorization/Notification
Medication	Benlysta® (belimumab)* *This program applies to the subcutaneous formulation of belimumab
P&T Approval Date	9/2017, 9/2018, 9/2019, 9/2020, 2/2021, 7/2021
Effective Date	10/1/2021; Oxford only: 10/1/2021

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 **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

(b) Lupkynis (voclosporin)

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 **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
(b) Lupkynis (voclosporin)

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 **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
(b) Lupkynis (voclosporin)

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 **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
(b) Lupkynis (voclosporin)

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.
- The intravenous infusion is typically covered under the medical benefit. Please refer to the UnitedHealthcare Drug Policy for Benlysta.

4. References:

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

Program	Prior Authorization/Notification - Benlysta (belimumab)
Change Control	
9/2017	New program.
9/2018	Annual review with no changes to coverage criteria. Updated reference.
9/2019	Annual review with no changes to coverage criteria. Updated background to align with updated FDA label. Updated reference. Added general NCCN recommended review criteria.
9/2020	Annual review. Updated reauthorization duration. Removed NCCN recommended review criteria. Updated reference.
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.
7/2021	Added not to be used in combination with Lupkynis to criteria.