UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Benlysta

Program	Prior Authorization
Medication	Benlysta® (belimumab)* *This program applies to the subcutaneous formulation of belimumab
Issue Date	9/2017
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

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

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. Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. 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,

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methotrexate]

-AND-

(4) Patient does **not** have **either** of the following:

(a) Severe active lupus nephritis
(b) 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) Intravenous cyclophosphamide

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) Intravenous cyclophosphamide

Authorization will be issued for 12 months.

3. References:

1. Benlysta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; July 2017.

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

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