BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 4/1/19
LAST REVIEW DATE: 2/21/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

BENLYSTA® (belimumab) auto-injector and prefilled syringe

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

BENLYSTA® (belimumab) auto-injector and prefilled syringe (cont.)

Criteria:

- **Criteria for initial therapy:** Benlysta (belimumab) auto-injector and prefilled syringe is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in or is in consultation with a Rheumatologist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of active autoantibody-positive, systemic lupus erythematosus (SLE)
  4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     - Positive for anti-nuclear antibody (ANA) and/or anti-double stranded DNA (anti-dsDNA)
  5. No evidence of severe active lupus nephritis or severe active central nervous system lupus
  6. Will continue standard therapy for SLE which can include any of the following (alone or in combination): corticosteroids, immunosuppressives (azathioprine, methotrexate, and mycophenolate), and antimalarials (hydroxychloroquine, chloroquine, quinacrine), or NSAIDS
  7. Benlysta is not being used concurrently with rituximab or intravenous cyclophosphamide
  8. No evidence of chronic infections when initiating or continuing Benlysta
  9. No evidence of administration of a live vaccine within 30 days prior to initiation of Benlysta or concurrently

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Benlysta (belimumab) auto-injector and prefilled syringe is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by Prescriber is a physician specializing in or is in consultation with a Rheumatologist
  2. Individual's condition responded while on
     - Response is defined as **TWO** of the following:
       - Improvement in involved organ systems (mucocutaneous, musculoskeletal, and immune)
       - Able to reduce corticosteroid dose by at least 25% over baseline
       - No new organ involvement or evidence of disease progression
       - Reduced SLE flares or a prolonged time to SLE flare
  3. Individual has been adherent with the medication
  4. No evidence of severe active lupus nephritis or severe active central nervous system lupus

BENLYSTA® (belimumab) auto-injector and prefilled syringe (cont.)

5. Will continue standard therapy for SLE which can include any of the following (alone or in combination): corticosteroids, immunosuppressives (azathioprine, methotrexate, and mycophenolate), and antimalarials (hydroxychloroquine, chloroquine, quinacrine), or NSAIDS

6. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
    - Significant adverse effect such as:
        - Anaphylaxis or severe hypersensitivity reaction to Benlysta
        - Serious infections
        - Progressive multifocal leukoencephalopathy (PML)
        - Severe depression and/or suicidal behaviors

Renewal duration: 12 months

- Benlysta (belimumab) auto-injector and prefilled syringe for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
3. Insufficient evidence to support improvement of the net health outcome, and
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to:*
- Treatment with dosing or frequency outside the FDA-approved dosing and frequency

Description:

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

Belimumab is a human IgG1λ monoclonal antibody specific for soluble human B lymphocyte stimulator protein (BLyS, also referred to as BAFF and TNFSF13B) that blocks the binding of soluble BLyS, a B-cell survival factor, to its receptors on B cells. Benlysta (belimumab) does not bind B cells directly, but by binding with BLyS, Benlysta (belimumab) inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

Systemic lupus erythematosus (SLE) is a chronic inflammatory disease of unknown cause that can affect virtually every organ, the most common pattern is a mixture of constitutional complaints with skin, musculoskeletal, mild hematologic, and serologic involvement. Some patients will have predominately hematologic, renal, or central nervous system manifestations. The disease may be characterized by periods of remissions and of chronic or acute relapses and the symptoms may vary from mild to severe depending upon the type of organs involved. Renal involvement is clinically apparent in approximately 50 percent of SLE patients. Neuropsychiatric

BENLYSTA® (belimumab) auto-injector and prefilled syringe (cont.)

involvement of SLE consists of a broad range of neurologic and psychiatric manifestations including cognitive dysfunction, organic brain syndromes, delirium, psychosis, seizures, headache, and/or peripheral neuropathies. Other less common problems are movement disorders, cranial neuropathies, myelitis, and meningitis.

SLE treatment regimen medications included any of the following (alone or in combination): corticosteroids, immunosuppressives (including azathioprine, methotrexate, and mycophenolate), antimalarials (hydroxychloroquine, chloroquine, quinacrine), and NSAIDs. Most patients (>70%) were receiving 2 or more classes of SLE medications.

Resources:

Benlysta (belimumab) product information accessed 12-18-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2fa3c528-1777-4628-8a55-a69dae2381a3

UpToDate: Overview of the clinical manifestations of systemic lupus erythematosus in adults. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-clinical-manifestations-of-systemic-lupus-erythematosus-in-adults?search=sle&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

UpToDate: Overview of the management and prognosis of systemic lupus erythematosus in adults. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-management-and-prognosis-of-systemic-lupus-erythematosus-in-adults?search=sle&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

UpToDate: Diagnosis and differential diagnosis of systemic lupus erythematosus in adults. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/diagnosis-and-differential-diagnosis-of-systemic-lupus-erythematosus-in-adults?search=sle&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.