BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.99.01

Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Miscellaneous Products	**Original Policy Date:**	December 7, 2011
Subject:	Benlysta	**Page:**	1 of 7

Last Review Date: March 12, 2021

Benlysta

Description

Benlysta (belimumab)

Background
Benlysta is used to treat patients 5 years of age and older with active, systemic lupus erythematosus (SLE or lupus); and adult patients with active lupus nephritis who are receiving standard therapy. Benlysta is in a group of medicines called monoclonal antibodies. Lupus is a disease of the immune system (the body system that fights infection). People with active lupus often have high levels of a certain protein in their blood. Benlysta binds to and limits the activity of the protein, called the B-lymphocyte stimulator (BLyS) protein, which may reduce the number of abnormal B cells thought to be a problem in lupus (1).

Regulatory Status
FDA-approved indication: Benlysta is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of: (1)

1. patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.
2. 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 (1).

Serious and sometimes fatal infections can occur in patients receiving Benlysta. It is recommended that practitioners exercise caution when using Benlysta in patients with chronic infections. Patients receiving any treatment for a chronic infection should not begin therapy with Benlysta. Consider interrupting Benlysta therapy in patients who develop a new infection while undergoing treatment with Benlysta and monitor these patients closely (1).

Acute hypersensitivity reactions, including anaphylaxis and death, have been reported in association with Benlysta. These events may occur within hours of the infusion; however they may occur later. Benlysta infusions should be administered by healthcare providers prepared to manage infusion reactions. Patients should be monitored during and for an appropriate period of time after administration of Benlysta (1).

A patient may self-inject or the patient caregiver may administer Benlysta subcutaneously after the healthcare provider determines it is appropriate (1).

Live vaccines should not be given for 30 days before or concurrently with Benlysta as clinical safety has not been established. Based upon the mechanism of action, Benlysta may interfere with the response to immunizations (1).

The safety and effectiveness of Benlysta in pediatric patients less than 5 years of age for uses other than active, autoantibody-positive, systemic lupus erythematosus (SLE) have not been established (1).

The safety and effectiveness of Benlysta in patients less than 18 years of age for the treatment of active lupus nephritis have not been established (1).

Subcutaneous dosing of Benlysta has not been evaluated and is not approved for patients younger than 18 years of age (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Benlysta may be considered **medically necessary** in patients 5 years of age or older for the treatment of active, autoantibody-positive, systemic lupus erythematosus (SLE); and in adult patients with active lupus nephritis if the conditions indicated below are met.

Benlysta may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 5 years of age or older

Diagnosis

Patient must have the following:

Systemic lupus erythematosus (SLE)

AND ALL of the following:

1. Must have active SLE
2. Must be autoantibody-positive
3. Must be receiving standard therapy [e.g. corticosteroids, NSAID, azathioprine, leflunomide, methotrexate, mycophenolate, tacrolimus, and antimalarials (e.g. hydroxychloroquine, chloroquine, quinine, quinidine, mefloquine)]
4. Patients age **5-17 only**: Patient will be receiving Benlysta as an intravenous infusion

AND NONE of the following:

1. Chronic infection, including, but not limited to Hepatitis B, Hepatitis C, HIV, TB
2. Severe active central nervous system lupus
3. Concurrent therapy with a biologic medication
4. Given concurrently with live vaccines

Age 18 years of age or older

Diagnosis

Patient must have the following:

Lupus nephritis

AND ALL of the following:

1. Must have active lupus nephritis
2. Must be receiving standard therapy (e.g. corticosteroids, cyclosporine, tacrolimus, cyclophosphamide, azathioprine, mycophenolate and rituximab)

AND NONE of the following:

1. Chronic infection, including, but not limited to Hepatitis B, Hepatitis C, HIV, TB
2. Severe active central nervous system lupus
3. Concurrent therapy with a biologic medication
4. Given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Age 5 years of age or older

Patient must have the following:

Systemic lupus erythematosus (SLE)

AND ALL of the following:

1. Must be receiving standard therapy
2. Documented clinical benefit from therapy (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to the start of Benlysta)
3. Patients age **5-17 only**: Patient will be receiving Benlysta as an intravenous infusion

AND NONE of the following:

1. Chronic infection, including, but not limited to Hepatitis B, Hepatitis C, HIV, TB
2. Severe active central nervous system lupus
3. Concurrent therapy with a biologic medication
4. Given concurrently with live vaccines

Age 18 years of age or older

Diagnosis

Patient must have the following:

Lupus nephritis

AND ALL of the following:

1. Must be receiving standard therapy (i.e. corticosteroids, cyclosporine, tacrolimus, cyclophosphamide, azathioprine, mycophenolate and rituximab)
2. Documented clinical benefit from therapy (i.e. decrease or stabilization of symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to the start of Benlysta)

AND NONE of the following:

1. Chronic infection, including, but not limited to Hepatitis B, Hepatitis C, HIV, TB
2. Severe active central nervous system lupus
3. Concurrent therapy with a biologic medication
4. Given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary

Benlysta is indicated for the treatment of patients 5 years of age and older with active, autoantibody-positive, systemic lupus erythematosus (SLE); and in adult patients with active lupus nephritis who are receiving standard therapy. 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. Serious and sometimes fatal infections can occur in patients receiving Benlysta. Serious and fatal hypersensitivity reactions have been reported. Benlysta infusions should be administered by healthcare providers prepared to manage infusion reactions. Subcutaneous administration can be self-injected after the healthcare provider determines it is appropriate. The safety and effectiveness of Benlysta in pediatric patients less than 5 years of age for uses other than active, autoantibody-positive, systemic lupus erythematosus (SLE); and in patients less than 18 years of age for the treatment of active lupus nephritis have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Benlysta while maintaining optimal therapeutic outcomes.

References

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

Policy History

Date	Action
December 2011	New Policy
December 2012	Annual editorial review
June 2014	Annual editorial review and reference update Addition to criteria requirements that the patient must not have severe active lupus nephritis, not have active central nervous system lupus,

	patient must not use Benlysta in combination with biologic medication nor intravenous cyclophosphamide
September 2015	Annual editorial review and reference update
December 2015	Annual review and reference update
December 2016	Annual editorial review and reference update Addition of age to the renewal section Policy number change from 5.11.01 to 5.99.01
June 2017	Annual editorial review and reference update
June 2018	Annual review and reference update
May 2019	Reduced age limit from 18 and older to 5 and older. Added requirement that patients age 5-17 must use Benlysta as an intravenous infusion
June 2019	Annual review
June 2020	Annual review and reference update
January 2021	Addition of indication: active lupus nephritis in adult patients. Updated Limitations of Use to remove severe active lupus nephritis and no dual therapy with IV cyclophosphamide
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.