Benlysta

**Description**

Benlysta (belimumab)

**Background**
Benlysta is used to treat patients with active, systemic lupus erythematosus (SLE or lupus) who are receiving standard therapy, including corticosteroids, antimalarials, immunosuppressives, and nonsteroidal anti-inflammatory drugs. 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 patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy (1).

**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 (1).

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

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 have not been established (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 and if the conditions indicated below are met.

Benlysta may be considered **investigational** in patients less than 5 years of age and 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 [corticosteroids, NSAID, azathioprine, leflunomide, methotrexate, mycophenolate, tacrolimus, and antimalarials (e.g. hydroxychloroquine, chloroquine, quinine, quinidine, melfloquine)]
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 lupus nephritis
3. Severe active central nervous system lupus
4. Concurrent therapy with a biologic medication or intravenous cyclophosphamide

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 lupus nephritis
3. Severe active central nervous system lupus
4. Concurrent therapy with a biologic medication or intravenous cyclophosphamide

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 with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy, including corticosteroids, antimalarials, immunosuppressives, and nonsteroidal anti-inflammatory drugs. 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. Serious and sometimes fatal infections can occur in patients receiving Benlysta. Serious and fatal hypersensitivity reactions have been reported. Benlysta should be administered by healthcare providers prepared to manage infusion reactions. The safety and effectiveness of Benlysta in pediatric patients less than 5 years of age 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

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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.