BlueCross BlueShield Federal Employee Program

BENLYSTA
(belimumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Benlysta (belimumab) is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of systemic lupus erythematosus (SLE) and lupus nephritis. In many patients with SLE, higher concentrations of BLyS promote increased B-cell survival, including the survival of autoreactive B cells. Benlysta binds to soluble BLyS, inhibiting its binding to B-cell receptors. By binding to BLyS, Benlysta inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells. By reducing the autoreactive B-cell population, Benlysta decreases the production of autoantibodies and lupus disease activity (1).

Regulatory Status

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

1. Patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy.
2. Patients aged 5 years and older 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. Use of Benlysta is not recommended in this situation (1).

Limitations of Use in Underrepresented Populations: Benlysta did not demonstrate significant clinical benefit in Black/African American subjects in the original two pivotal trials based on subgroup analysis. A subsequent large randomized, multicenter prospective trial over 52 weeks in 448 African American subjects with SLE did not achieve statistical significance for efficacy benefit compared with standard drug therapy. In the treatment of SLE and acute lupus nephritis, Benlysta has limited data in the Black/African American population and its improvement in response rates versus standard treatment has not been established (2).

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 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 in patients with lupus nephritis (1).

Summary Benlysta (belimumab) is indicated for the treatment of systemic lupus erythematosus (SLE) and lupus nephritis. Benlysta has limited data in the Black/African American population and its improvement in response rates versus standard treatment has not been established. The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Serious and sometimes fatal infections and hypersensititivy reactions can occur in patients receiving Benlysta. Benlysta infusions 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 (1-2).

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; May 2024.
2. Ginzler E, Guedes Barbosa LS, D'Cruz D, et al. Phase III/IV, Randomized, Fifty-Two-Week Study of the Efficacy and Safety of Belimumab in Patients of Black African Ancestry With Systemic Lupus Erythematosus. Arthritis Rheumatol. 2021 Jun 23. doi: 10.1002/art.41900. Epub ahead of print. PMID: 34164944