RATIONALE FOR INCLUSION IN PA PROGRAM

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 and is delivered directly into a vein (intravenous infusion). 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 adult patients 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).

Benlysta is for intravenous infusion only and must be reconstituted and diluted prior to administration. Do not administer as an intravenous push or bolus (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).

Safety and effectiveness of Benlysta have not been established in children (1).

**Summary**

Benlysta is indicated for the treatment of adult 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. Benlysta is for intravenous infusion only. 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. Safety and effectiveness of Benlysta have not been established in children (1).

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

**References**