Getting patients started with at-home administration

Benlysta (belimumab) Subcutaneous Use 200 mg/mL

GSK is committed to ensuring support for the continued care of patients during these challenging times. If you decide at-home administration with the **BENLYSTA Autoinjector** is right for your patient, BENLYSTA Gateway is one of many resources that can help your patients get started.

Initiate a benefit investigation and submit a new prescription for the BENLYSTA Autoinjector

You can verify benefits by working with BENLYSTA Gateway or by contacting the payer directly.

If your patient is enrolled in BENLYSTA Gateway, call to request a new benefit investigation for the Autoinjector at **844-4-BENLYSTA** (1-877-423-6597).

If your patient is NOT enrolled in BENLYSTA Gateway, please complete an **enrollment form** on the Access and Reimbursement page of BENLYSTAHCP.com. This will initiate a benefit investigation.

- BENLYSTA Gateway cannot provide program services without a completed and signed enrollment form. To avoid delays in receiving Gateway program offerings, please ensure both provider and patient signatures are on the enrollment form
- Patients can sign the form in-office or electronically. If electronic signature is preferred, please include a valid patient email address and alert the patient that two emails from "GSK Sign" will be coming

Submit a Prior Authorization to the patient's insurance, as required

BENLYSTA Gateway will check the payer's prior authorization requirements and obtain plan-specific forms as needed and if available.

The specialty pharmacy will contact the patient to complete the process

- Upon receiving insurance approval and a new prescription, the designated specialty pharmacy will contact the patient directly to confirm, collect the co-pay, and ship BENLYSTA Autoinjector directly to the patient's home
- **Instruct the patient to accept and return calls to prevent delays in starting treatment.** Specialty pharmacies may not mention BENLYSTA in messages, as brand names are omitted to protect privacy. Even if the patient is not sure the call is about BENLYSTA, encourage them to call the specialty pharmacy back

Overall response times with payers and specialty pharmacies may be longer due to the ongoing impact of COVID-19; please check with them for updates.

INDICATION

BENLYSTA is indicated for patients aged ≥5 years with active, autoantibody-positive systemic lupus erythematosus (SLE) who receive standard therapy. The subcutaneous (SC) formulation is approved for patients aged ≥18 years. BENLYSTA is not indicated or recommended in patients with severe active lupus nephritis, or severe active central nervous system lupus, or in combination with other biologics or intravenous cyclophosphamide.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

Previous anaphylaxis with BENLYSTA.

WARNINGS AND PRECAUTIONS

Mortality: In adult intravenous (IV) clinical trials, death occurred in 0.8% of patients treated with BENLYSTA and in 0.4% of patients receiving placebo; etiologies included infection, cardiovascular disease, and suicide. In the adult SC clinical trial, death occurred in 0.5% of patients receiving BENLYSTA and in 0.7% of patients receiving placebo; infection was the most common cause of death.

Serious Infections: Serious and sometimes fatal infections have been reported in patients receiving immunosuppressive agents, including BENLYSTA. The most frequent serious infections in adults treated with BENLYSTA IV included pneumonia, urinary tract infection, cellulitis, and bronchitis. Use caution in patients with severe or chronic infections, and consider interrupting therapy in patients with a new infection.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Medication Guide, for BENLYSTA.

Questions on submitting a new BENLYSTA prescription?

Call **877-4-BENLYSTA** (1-877-423-6597)

Monday – Friday 8am to 8pm ET or visit **benlystagatewayonline.com**

BENLYSTA Gateway services*

- Patient-specific benefits investigations
- Re-verification of benefits for annual health plan changes
- Coding and billing details
- Prescription referral triage to an in-network specialty pharmacy
- Prior authorization tracking assistance
- Claims appeals tracking assistance
- Estimate of insurance coverage and cost-share information
- Eligibility determinations for the BENLYSTA Co-pay Program and the Patient Assistance Program for Uninsured Patients
- Alternative coverage research

Have questions about BENLYSTA Gateway?

Call **877-4-BENLYSTA** (1-877-423-6597) Monday to Friday, 8 AM to 8 PM ET or visit **benlystagatewayonline.com**

* Gateway services are not a guarantee of coverage or reimbursement. The payer will make individual coverage determinations based upon the specific circumstances of the patient. Providers should contact third-party payers for specific information on coding, coverage, or reimbursement.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Progressive Multifocal Leukoencephalopathy (PML): Cases of JC virus-associated PML resulting in neurological deficits, including fatal cases, have been reported in patients with SLE receiving immunosuppressants, including BENLYSTA. If PML is confirmed, consider stopping immunosuppressant therapy, including BENLYSTA.

Hypersensitivity Reactions (Including Anaphylaxis): Acute hypersensitivity reactions, including anaphylaxis (eg, hypotension, angioedema, urticaria or other rash, pruritus, and dyspnea) and death, have been reported, including in patients who have previously tolerated BENLYSTA. Generally, reactions occurred within hours of the infusion but may occur later. Non-acute hypersensitivity reactions (eg, rash, nausea, fatigue, myalgia, headache, and facial edema) typically occurred up to a week after infusion. Patients with a history of multiple drug allergies or significant hypersensitivity may be at increased risk. With BENLYSTA SC, systemic hypersensitivity reactions were similar to those in IV trials.

Healthcare providers (HCPs) should monitor patients during and after IV administration and be prepared to manage anaphylaxis; discontinue immediately in the event of a serious reaction. Premedication may mitigate or mask a hypersensitivity response. Advise patients about hypersensitivity symptoms and instruct them to seek immediate medical care if a reaction occurs.

Infusion Reactions: Serious infusion reactions (eg, bradycardia, myalgia, headache, rash, urticaria, and hypotension) were reported in adults. HCPs should monitor patients and manage reactions if they occur. Premedication may mitigate or mask a reaction. If an infusion reaction develops, slow or interrupt the infusion.

Depression and Suicidality: In clinical trials, psychiatric disorders (depression, suicidal ideation and behavior) were reported more frequently in patients receiving BENLYSTA than placebo. In adult trials, psychiatric events reported more frequently with BENLYSTA IV related primarily to depression-related events, insomnia, and anxiety; serious psychiatric events included serious depression and suicidality, including 2 completed suicides. No serious depression-related events or suicides were reported in the BENLYSTA SC trial. Before adding BENLYSTA, physicians should assess patients' risk of depression and suicide and monitor them during treatment. Instruct patients to contact their HCP if they experience new/worsening depression, suicidal thoughts, or other mood changes.

Malignancy: The impact of BENLYSTA on the development of malignancies is unknown; its mechanism of action could increase the risk for malignancies.

Immunization: Live vaccines should not be given for 30 days before or concurrently with BENLYSTA as clinical safety has not been established.

Use With Biologic Therapies or IV Cyclophosphamide: BENLYSTA has not been studied and is not recommended in combination with other biologic therapies, including B-cell targeted therapies, or IV cyclophosphamide.

ADVERSE REACTIONS

The most common serious adverse reactions in adults were serious infections: BENLYSTA IV 6.0% (placebo 5.2%), some of which were fatal. Adverse reactions occurring in ≥3% of adults and ≥1% more than placebo: nausea 15% (12%); diarrhea 12% (9%); pyrexia 10% (8%); nasopharyngitis 9% (7%); bronchitis 9% (5%); insomnia 7% (5%); pain in extremity 6% (4%); depression 5% (4%); migraine 5% (4%); pharyngitis 5% (3%); cystitis 4% (3%); leukopenia 4% (2%); viral gastroenteritis 3% (1%).

Adverse reactions in pediatric patients aged ≥5 years receiving BENLYSTA IV were consistent with those observed in adults.

The safety profile observed for BENLYSTA SC in adults was consistent with the known safety profile of BENLYSTA IV with the exception of local injection site reactions.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are insufficient data in pregnant women to establish whether there is drug-associated risk for major birth defects or miscarriage. After a risk/benefit assessment, if prevention is warranted, women of childbearing potential should use contraception during treatment and for ≥4 months after the final treatment.

Pregnancy Registry: HCPs are encouraged to register patients and pregnant women are encouraged to enroll themselves by calling 1-877-681-6296.

Lactation: No information is available on the presence of belimumab in human milk, the effects on the breastfed infant, or the effects on milk production. Consider developmental and health benefits of breastfeeding with the mother's clinical need for BENLYSTA and any potential adverse effects on the breastfed child or from the underlying maternal condition.

Pediatric Use: The safety and effectiveness have not been established for BENLYSTA IV in patients <5 years of age and for BENLYSTA SC in patients <18 years of age.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Medication Guide, for BENLYSTA.

To report SUSPECTED ADVERSE REACTIONS, contact GSK at 1-888-825-5249 or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch.**

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