Ebglyss™
(lebrikizumab-lbkz)
250mg/2mL injection

EBGLYSS Electronic Health Record (EHR) order set instructions in the Epic® EHR System

These instructions are created specifically to update order sets in the Epic® EHR system and will not work in other EHR systems. These instructions are designed to be used with EBGLYSS for the indication mentioned below and should not be used for other conditions, treatments, or therapeutic areas.

The processes outlined in this resource are variable and not all steps will apply to every customer. Any steps or settings that are not part of a customer's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The customer is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR resources.

A customer may choose to modify existing EHR order sets with EBGLYSS. Order sets can consolidate notes, referrals, imaging studies, laboratory orders and bundles, medications, patient education, coding and billing information, and other orderable items used to manage a condition or problem. Order sets can improve the user experience and help reduce customer variation. These instructions detail specifically how to add the initial and maintenance dosing of EBGLYSS to existing order sets.

Treatment selection is always a decision made by the healthcare provider, and order sets may be overridden to reflect this. An EHR newsletter or other communication medium may be considered to notify end users of the availability and contents of any updated order sets.

INDICATION

EBGLYSS is indicated for the treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. EBGLYSS can be used with or without topical corticosteroids.

SELECT IMPORTANT SAFETY INFORMATION

Contraindication: EBGLYSS is contraindicated in patients with prior serious hypersensitivity to lebrikizumab-lbkz or any excipients of EBGLYSS.

Please see additional Important Safety Information on page 6, and click to access Prescribing Information and Patient Information. Please see Instructions for Use included with the device.

Starting EBGLYSS

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250mg/2mL injection

How supplied

EBGLYSS is supplied as a single-dose prefilled pen, with a strength of 250 mg/2 mL, packed in a carton of 1. EBGLYSS is also available as a single-dose prefilled syringe with needle shield, with a strength of 250 mg/2 mL, packed in a carton of 1. Each prefilled pen and prefilled syringe with needle shield is designed to deliver 250 mg of EBGLYSS in 2 mL.

EBGLYSS provides the opportunity for monthly maintenance dosing

The recommended dosage of EBGLYSS is an initial dose of 500 mg (two 250-mg injections) at week 0 and week 2, followed by 250 mg every 2 weeks until week 16 or later, when adequate clinical response is achieved. The maintenance dose is 250 mg every 4 weeks.

Injections are subcutaneous.

[a]Loading dose of 500 mg (two 250-mg injections) at weeks 0 and 2.
[b]Patients who do not achieve an adequate clinical response at week 16 can continue Q2W dosing until an adequate response is achieved.
Q2W=every 2 weeks.

SELECT IMPORTANT SAFETY INFORMATION

Vaccinations: EBGLYSS may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to therapy with EBGLYSS, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines immediately prior to or during treatment with EBGLYSS. No data are available on the response to live vaccines.

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Epic instructions

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Updating existing SmartSets requires minimal time but must be implemented at the system level. First, identify the SmartGroups with the moderate-to-severe atopic dermatitis medications listed. Once a SmartGroup has been modified, it may be used in SmartSets.

Step 1 Update the SmartGroup

1. Open the Management Console: **Tools > Management Console** (use of the Management Console typically requires appropriate user rights and privileges).
2. Select **SmartGroups** from the **Decision Support** menu to launch a new window.
3. **Select** the desired SmartGroup Order Set Group (OSG) record to be modified (one or more moderate-to-severe atopic dermatitis medication SmartGroups may be available). If there are no existing SmartGroup records, consider creating a new SmartGroup.* If desired, other SmartGroups may be updated (labs, patient education, imaging, etc, that might benefit from updates). For example:
   - For the Patient Education Resources SmartGroup, you may add desired links to the EBGLYSS patient education resources
   - For the General Provider and Nursing Notes SmartGroup (naming conventions and selections of the appropriate SmartGroup may vary; review which SmartGroup may be most relevant based on system naming conventions and guidelines), you may add desired links to the EBGLYSS age-appropriate immunizations according to current immunization guidelines, concomitant topical therapies, and missed dose information. Alternatively, this information can be added to the EBGLYSS Order Composer settings (see Step 8 below)
4. Click the **Create** tab.
5. Update the **Name**, **ID**, **Contact Date**, and **Record Type** of the SmartGroup if needed. Click **Accept** once done.
6. Click **Configuration** from the menu.
7. Click **Add Item** and select the **Item Type** (eg, Medications).
8. Select the EBGLYSS 250-mg injection dosing option and complete the dosing details (500 mg [two 250-mg injections] at week 0 and week 2, followed by 250 mg every 2 weeks until week 16 or later, when adequate clinical response is achieved). In the Admin Instruction section, add that the 500-mg dose is the initial dose at week 0 and week 2. Continue to add the EBGLYSS maintenance dosing option (250 mg every 4 weeks) to the Medications section.

   a. For the initial dosage of EBGLYSS for Atopic Dermatitis plan of treatment, complete the medication details below†:
   - The recommended dosage of EBGLYSS is an initial dose of 500 mg (two 250-mg injections) at week 0 and week 2, followed by 250 mg every 2 weeks until week 16 or later, when adequate clinical response is achieved (see How supplied on page 2)
   - In the free text-sig, enter: "Initial dosing 500 mg (two 250-mg injections) at week 0 and week 2, followed by 250 mg every 2 weeks until week 16 or later, when adequate clinical response is achieved"
   - This dosing is for adults and pediatric patients age 12 years and older who weigh at least 40 kg

*If creating a new SmartGroup, the system should consider what other medications may also warrant inclusion.
†**Note:** These are example medication details. Individual practice selections may vary. Complete the **Notes to Pharmacist** field with any additional details your practice may desire.

SELECT IMPORTANT SAFETY INFORMATION

Hypersensitivity: Hypersensitivity reactions, including angioedema and urticaria, have been reported with use of EBGLYSS. If a serious hypersensitivity reaction occurs, discontinue EBGLYSS and institute appropriate therapy.

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Epic instructions (cont'd)

8a. (cont'd)

- Additional Order Composer settings can be adjusted per health system preference (eg, consider the EBGLYSS recommended vaccinations prior to treatment initiation, concomitant topical therapies, important administration instructions, and missed dose information [see sections 2.1, 2.3, 2.4, and 2.5 in the Prescribing Information, respectively])
  - EBGLYSS may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to therapy with EBGLYSS, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines immediately prior to or during treatment with EBGLYSS. No data are available on the response to live vaccines. Limited data are available regarding coadministration of EBGLYSS with non-live vaccines
  - EBGLYSS can be used with or without topical corticosteroids (TCS). Topical calcineurin inhibitors (TCI) may be used, but reserved for sensitive areas only, such as the face, neck, intertriginous, and genital areas. If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time

b. For the EBGLYSS for Atopic Dermatitis plan of treatment, complete the medication details below*:

- The recommended maintenance dosage of EBGLYSS is 250 mg every 4 weeks
- In the free text-sig, enter: "Maintenance dosing for adult patients for EBGLYSS is 250 mg every 4 weeks"
- This dosing is for adults and pediatric patients age 12 years and older who weigh at least 40 kg
- Additional Order Composer settings can be adjusted per health system preference (ie, consider the EBGLYSS recommended vaccinations prior to treatment initiation, concomitant topical therapies, important administration instructions, and missed dose information) [see sections 2.1, 2.3, 2.4, and 2.5 in the Prescribing Information, respectively]
  - EBGLYSS may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to therapy with EBGLYSS, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines immediately prior to or during treatment with EBGLYSS. No data are available on the response to live vaccines.
  - EBGLYSS can be used with or without TCS. TCI may be used, but reserved for sensitive areas only, such as the face, neck, intertriginous, and genital areas. If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time

9. Select **General Info** and set the record name, display name, and other information as desired.
10. Release after satisfactory testing has been completed.

Step 2 Update all applicable SmartSets

1. Identify all SmartSets that could benefit from the modified SmartGroup using search terms such as "moderate-to-severe atopic dermatitis" or "atopic dermatitis."
2. Update the desired SmartSets with the modified SmartGroup record created in Step 1.
3. Release after satisfactory testing has been completed.

***Note:** These are example medication details. Individual practice selections may vary. Complete the **Notes to Pharmacist** field with any additional details your practice may desire.

SELECT IMPORTANT SAFETY INFORMATION

Conjunctivitis and Keratitis: Conjunctivitis and keratitis adverse reactions have been reported in clinical trials. Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received EBGLYSS compared to those who received placebo. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered during the treatment period. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Please see additional Important Safety Information on page 6, and click to access Prescribing Information and Patient Information. Please see Instructions for Use included with the device.

Notes

- The Customers (ie, physician, healthcare organization, and organized medical group) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each Customer's EHR system
- Capabilities, functionality, and setup (customization) for each EHR system may vary. Lilly shall not be responsible for revising the implementation instructions it provides to any Customer if the Customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Lilly
- While Lilly tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and Lilly shall have no liability thereto
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment, treatment, and referral, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and Lilly shall have no liability related to a provider's decision and action (or inaction) regarding any patient identified or treated using this resource
- The instructions have not been designed to meet and are not resources and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirements
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Important Safety Information

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Contraindication: EBGLYSS is contraindicated in patients with prior serious hypersensitivity to lebrikizumab-lbkz or any excipients of EBGLYSS.

Warnings and Precautions

Hypersensitivity

Hypersensitivity reactions, including angioedema and urticaria, have been reported with use of EBGLYSS. If a serious hypersensitivity reaction occurs, discontinue EBGLYSS and institute appropriate therapy.

Conjunctivitis and Keratitis

Conjunctivitis and keratitis adverse reactions have been reported in clinical trials. Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received EBGLYSS compared to those who received placebo. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered during the treatment period. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Parasitic (Helminth) Infections

Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if EBGLYSS will influence the immune response against helminth infections by inhibiting IL-13 signaling. Treat patients with pre-existing helminth infections before initiating treatment with EBGLYSS. If patients become infected while receiving EBGLYSS and do not respond to antihelminth treatment, discontinue treatment with EBGLYSS until the infection resolves.

Vaccinations

EBGLYSS may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to therapy with EBGLYSS, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines immediately prior to or during treatment with EBGLYSS. No data are available on the response to live vaccines.

Adverse Reactions

The most common (≥1%) adverse reactions are conjunctivitis, injection site reactions, and herpes zoster.

EBGLYSS is available as a 250mg/2mL subcutaneous injection prefilled pen or prefilled syringe.

Please click to access Prescribing Information and Patient Information.
Please see Instructions for Use included with the device.

LK HCP ISI AD APP

Reference: EBGLYSS (lebrikizumab-lbkz). Prescribing Information. Lilly USA, LLC.