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

EBGLYSS Electronic Health Record (EHR) Order Set Instructions in the EMA® EHR System

These instructions are created specifically to update order sets in the EMA® 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.

EMA typically comes with a wide range of dermatology-specific protocols. New protocols may be created by the user and shared with other clinicians within the practice. 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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EMA instructions

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Consider creating 2 separate plans (1 for the initial dosage and 1 for the maintenance dosage) for EBGLYSS if this approach is aligned with your governing EHR plans, conventions, and builds. Capabilities, functionality, and setup (customization) for each EHR system may vary. While these instructions are specific to creating new protocols in EMA, existing EBGLYSS protocols may be available and modified, if appropriate, based on the practice preferences. No administrative privileges are required to create new protocols.

1. Open the web version of EMA.
2. Click **Preferences** (in the top-right corner of the window) and then click **Manage Protocols**.
3. In the Protocol Library, search for existing Protocols in the system. On **Manage Protocols**, toggle between **My Protocols** and **Practice Protocols**.
4. Click **Add Protocol** (select My Protocols to update a personal Protocol, select Practice Protocols to update Practice Protocols).
5. Complete the Protocol information by entering a unique title, eg, "EBGLYSS Initiation for Atopic Dermatitis" and "EBGLYSS Maintenance for Atopic Dermatitis." Consider adding keywords such as "moderate-to-severe atopic dermatitis" or "atopic dermatitis" to help users with searching for Protocols. Set the "Gender" field to be non-gender specific (EBGLYSS is indicated as gender-neutral).
6. Under Shared with Everyone in Firm, select the **Yes** radio button to make the Protocol available to other users in the practice. This will provide options on whom you would like to receive the Protocol. If the Protocol is for personal use only, select the "No" radio button.
7. Click **Save**. The **Virtual Exam Room** will open to complete the Protocol.

THE VIRTUAL EXAM ROOM

8. In the **Findings/Impression** field, select the appropriate impression or diagnosis of Atopic Dermatitis.
9. In the Plans section, add EBGLYSS and complete the medication details:

a. For the initial dosage of EBGLYSS for Atopic Dermatitis Treatment Plan, 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

b. For the maintenance dosage of EBGLYSS for Atopic Dermatitis Treatment Plan, complete the medication details below*:

- The recommended maintenance dosage of EBGLYSS is 250 mg every 4 weeks (see How supplied on page 2)
- In the free text-sig, enter: "Maintenance dosing for 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

***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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EMA instructions (cont'd)

10. In the **Counseling** section, consider adding:
    - A link to the current EBGLYSS **Prescribing Information** (which includes the EBGLYSS recommended vaccinations, 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 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
11. In the Follow-Up section, set any follow-up appointments as desired.
12. Click **Save Visit Protocol.**

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.