Letter of Appeal Guide

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

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact the patient's health plan for specific information on their coverage policies. For more information, please call Lilly Support Services™ for EBGLYSS™ at 1-800-LillyRx (1-800-545-5979).

Guide for composing a Letter of Appeal

If coverage is denied by the patient's health plan, the plan may require an **Appeal Letter**. The sample letter attached to this document features information that many plans require to process a coverage authorization appeal. Follow the patient's plan requirements when requesting EBGLYSS™ (lebrikizumab-lbkz); otherwise, treatment initiation may be delayed.

Appeal considerations to support coverage

General Clinical Information

Below are 3 tips that may be helpful when appealing a coverage denial:

1. Provide a copy of the patient's record with details on the patient's condition (diagnosis/diagnoses), International Classification of Diseases, Tenth Revision (ICD-10) code, and assessment of severity of disease for which EBGLYSS is being/will be used, including:
   - percent of body surface area involved
   - body areas affected
   - frequency of flares
   - itch severity
2. Provide information about the current treatment(s) being used for the patient's condition and how the patient is presenting clinically while taking the current treatment(s)
3. Document the previous therapies used, dates used, and reasons for discontinuation (if applicable)

Appeal-specific rationale

The following tips may help construct an appropriate appeal:

- Provide clinically relevant and patient-specific information that supports overturning denial
- If denial was due to the plan's preferred formulary agents not being used to treat this patient, provide the clinical rationale for why these agents are not appropriate for the patient
- Provide clinically relevant and patient-specific information that makes EBGLYSS an appropriate therapy for this patient

Clinical rationale should focus only on the stated denial reason.

Lilly Support Services™ for EBGLYSS™ will work with you to help navigate patient access

For more information, please visit **www.ebglyss.lilly.com/hcp/savings-support** or call Lilly Support Services for EBGLYSS at **1-800-LillyRx (1-800-545-5979).**

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.[1]

SELECT IMPORTANT SAFETY INFORMATION

Contraindication

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

Please see page 3 for additional Important Safety Information and click to access Prescribing Information and Patient Information. Please see Instructions for Use included with the device.

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Letter of Appeal Guide

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

This template can be used by HCPs when appealing a coverage denial.

Sample Letter of Appeal for EBGLYSS with instructions

<Physician's letterhead>

<Date>
<Health plan's name>
ATTN: <Department>
<Medical director's name>
<Health plan's address>
<City, State ZIP>

<Patient's name>
<Date of birth>
<Case ID number>
<Dates of service>

Re: Appeal of Denial for EBGLYSS™ (lebrikizumab-lbkz)

To Whom It May Concern:

I am writing to appeal your denial of coverage for EBGLYSS, which I have prescribed for <patient's name>. I understand you are denying coverage for <patient's name> because:

- <reason for the denial>
- <further reason(s) for the denial, if applicable>

However, I believe the treatment with EBGLYSS is reasonable, appropriate, and medically necessary for my patient based on my clinical experience, the patient's condition, and their medical history.

Clinical Information to Support Appeal

<Patient's name> has been diagnosed with <condition> since <date of diagnosis>.

Treatment History

<Current and past treatment(s), including topicals, orals, and injectables>

<Start/stop dates>

<Reason(s) for discontinuation (if applicable)>

Clinical Rationale

<Restate the reason for denial, your clinical rationale for why the denial should be overturned, and why EBGLYSS is appropriate and medically necessary for this patient.>

If you have any additional questions, please contact me at <physician's phone number> or via email at <physician's email>. Thank you for your time and consideration.

Sincerely,

<Physician's signature and specialty, if applicable>

Enclosed: <Medical records, denial letter, copies of original request, clinical notes, medication history, and other supporting information>

Include the patient's full name, date of birth, plan ID number, and case ID number (if applicable).

Review the denial letter to identify the reason for denial. Restate the reason for denial as close to verbatim as possible.

Provide a copy of the patient's medical records, circling key clinical information, including patient history (including prior treatments), ICD-10 code, present-day condition and symptoms, as well as any allergies and existing comorbidities.

Identify drug name, dosage strength, dosage form, and therapeutic outcome.

Excess information beyond the denial reason may influence the plan to deny coverage again.

Attach any clinical documentation that supports overturning the decision to deny the request for coverage.

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View an example on pages 4 and 5 for use on your office letterhead.

Indication and Important Safety Information

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250mg/2mL injection

INDICATION

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IMPORTANT SAFETY INFORMATION

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.

Sample Letter of Appeal for EBGLYSS™ (lebrikizumab-lbkz)

<Physician's letterhead>

<Date>
<Health plan's name>
ATTN: <Department>
<Medical director's name>
<Health plan's address>
<City, State ZIP>

<Patient's name>
<Date of birth>
<Case ID number>
<Dates of service>

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Clinical Information to Support Appeal

<Patient's name> has been diagnosed with <condition> since <date of diagnosis>.

Treatment History

<Current and past treatment(s), including topicals, orals, and injectables>

<Start/stop dates>

<Reason(s) for discontinuing, if applicable>

Clinical Rationale

<Restate the reason for denial, your clinical rationale for why the denial should be overturned, and why EBGLYSS is appropriate and medically necessary for this patient.>

If you have any additional questions, please contact me at <physician's phone number> or via email at <physician's email>. Thank you for your time and consideration.

Sincerely,

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