Letter of Medical Necessity 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).

Composing a Letter of Medical Necessity

The purpose of a **Letter of Medical Necessity (LMN)** is to explain the prescribing healthcare provider's (HCP's) rationale and clinical decision-making for choosing a treatment.* Many health plans require that a LMN accompany submissions of Appeal, Formulary Exception Request, and Tiering Exception Request Letters.

This resource, **Letter of Medical Necessity Guide**, provides information on the process of drafting a LMN. The sample letter attached to this document features information that plans often require. Note that some plans have specific forms that must be utilized to document a LMN. Follow the patient's plan requirements when requesting EBGLYSS™ (lebrikizumab-lbkz); otherwise, treatment initiation may be delayed.

Common clinical evidence required for Letters of Medical Necessity:

- 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
- 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)
- Previous therapies used, dates used, and reasons for discontinuation (if applicable)
- Clinical rationale for why other treatments are not appropriate, if applicable
- Clinically relevant and patient-specific information that makes EBGLYSS an appropriate therapy for the patient

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.

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

*For Medicare beneficiaries, specific requirements need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please **click here**.

Lilly

Letter of Medical Necessity Guide

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

This template can be used by HCPs for explaining medical necessity.

Sample Letter of Medical Necessity 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>

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

Re: Letter of Medical Necessity for EBGLYSS™ (lebrikizumab-lbkz)

To Whom it May Concern:

I am writing to request coverage for EBGLYSS, a medically necessary treatment that I have prescribed for <patient's name>. This letter includes information about my patient's medical history along with my rationale for prescribing EBGLYSS.

Medical History

Provide information that is applicable to the primary diagnosis/diagnoses.

<Please include an overview of the patient's disease history, including date of diagnosis and assessment of disease severity. If there have been any changes in this disease activity or patient assessment of condition, include that information as well.>

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

Treatment History

<Current therapies (including topicals, orals, biologics) and start dates>

<History of previous therapies (including topicals, orals, biologics) and start/stop dates>

<Documentation of inadequate response and/or intolerable adverse events or reason for discontinuation (if applicable)>

Document current and prior treatments, treatment response, dates of therapy, and rationale for discontinuing (if applicable).

Clinical Rationale

<Clinical rationale for why your patient's recent severity of symptoms and impact of the disease warrant treatment with EBGLYSS>

<For plans that have formulary exclusions or step therapy, include information on why other agents are not an appropriate option, including comorbidities and contraindications.>

<Renewal Requests-Response>
I am requesting renewal of coverage for my patient, who has been taking EBGLYSS since <date> and has shown clinical improvement. <Provide information on clinical response.> I have included documentation of positive clinical response.

[next page]

View an example on pages 5 and 6 for use on your office letterhead.

Letter of Medical Necessity Guide

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

This template can be used by HCPs for explaining medical necessity.

Sample Letter of Medical Necessity for EBGLYSS with instructions

<Physician's letterhead>

<Placeholder for tiering exception (Medicare)>
<Explain why lower-tiered formulary drugs would not be as medically appropriate as EBGLYSS. If the patient is currently being treated with EBGLYSS, explain the benefits that the patient has experienced since starting EBGLYSS and the expected outcomes if EBGLYSS was to be discontinued.>

Please note, the patient will not be taking EBGLYSS in combination with another biologic therapy or JAK (Janus kinase) inhibitor.

Based on my professional experience, treatment with EBGLYSS is appropriate, medically necessary, and supported by their individual medical history. Attached are medical records to support my rationale.

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, clinical notes, medication history, severity assessments, documentation of positive clinical response, and other supporting information>

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

View an example on pages 5 and 6 for use on your office letterhead.

Indication and Important Safety Information

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

INDICATION

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IMPORTANT SAFETY INFORMATION FOR EBGLYSS

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 Medical Necessity for EBGLYSS™ (lebrikizumab-lbkz)

<Physician's letterhead>

<Date>
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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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