Emgality® (galcanezumab-gnlm) injection

Composing a Letter of Medical Necessity

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 third-party payers for specific information on their coverage policies. For more information, please call The Emgality Answers Center at 1-833-EMGALITY (1-833-364-2548).

Many health plans require that a Letter of Medical Necessity (LMN) accompany an Appeal Letter. The purpose of an LMN is to explain the prescribing healthcare provider's (HCP) rationale and clinical decision-making when choosing a treatment.* LMNs are often required by plans when submitting an Appeal Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter.

This resource, **Composing a Letter of Medical Necessity**, provides information on the process of drafting an LMN. A checklist is included below that can be followed when creating an LMN. In addition, a sample letter is attached to this document and includes information that plans often require. Note that some plans have specific Coverage Authorization Forms that must be utilized to document an LMN.

Follow the patient's plan requirements when requesting **Emgality® (galcanezumab-gnlm) injection 300 mg (three 100 mg/mL prefilled syringes)**; otherwise, treatment may be delayed.

LMN CONSIDERATIONS

- Include the patient's full name, plan identification number, date of birth, and the case identification number. If a decision has already been rendered, the doctor would provide the case ID number
- Provide a copy of the patient's records with the following details:
  - The patient's history, diagnosis with specific International Classification of Diseases (ICD) code, and present-day condition and symptoms
  - The patient's allergies and existing comorbidities
- Indicate the severity of the patient's condition, if applicable
- Document prior treatments and the duration of each treatment. It may be beneficial to include Current Procedural Terminology, 4th Edition (CPT-4) and/or J-codes to define prior services/treatments so that the health plan can conduct research and make a timely determination request
  - Describe the rationale for why each treatment was discontinued
- Attach clinical documentation that supports your recommendation; this information may be found in the Emgality Prescribing Information and/or clinical peer-reviewed literature

*For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal.

Please see Important Safety Information on page 4 and Full Prescribing Information, including Patient Information, for Emgality. See Instructions for Use included with the device.

Lilly

Sample Letter of Medical Necessity

Emgality® (galcanezumab-gnlm) injection

The purpose of an LMN is to explain the prescribing HCP's rationale and clinical decision-making when choosing Emgality® (galcanezumab-gnlm) injection 300 mg (three 100 mg/mL prefilled syringes) for a patient. LMNs are often required by plans when submitting an Appeal Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter.

[Date]

Re: [Patient's name]

[Prior authorization department]

[Plan identification number]

[Name of health plan]

[Date of birth]

[Mailing address]

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of Emgality (galcanezumab-gnlm) coverage. We understand that the reason for your denial is **[copy reason verbatim from the plan's denial letter]**. However, we believe that Emgality **[dose, frequency]** is the appropriate treatment for the patient. In support of our recommendation for Emgality treatment, we have provided an overview of the patient's relevant clinical history below.

Sample wording from page 3 of this document can be placed after this sentence if this appeal has been previously denied by the plan.

For Patients Diagnosed With Episodic Cluster Headache

The International Classification of Headache Disorders Diagnosis

Episodic cluster headache – Diagnosed (Date): _____

Number of cluster headache periods per year: _____

Duration of cluster headache periods: _____

Impairment due to episodic cluster headache:

- ○ No impairment
- ○ Moderate impairment
- ○ Severe impairment

Please detail all past treatments used to reduce the frequency of episodic cluster headache attacks, including any calcium channel blocker, antipsychotic (lithium), antiepileptic/anticonvulsant, steroids, nerve block, neurostimulation, or neutraceutical/supplement.

Past treatment(s) – including name, strength, and dosage form	Start/stop dates	Reason(s) for discontinuing

Provide the information that is applicable to the primary diagnosis.

Sample Letter of Medical Necessity

Emgality® (galcanezumab-gnlm) injection

[Provide patient-specific clinical rationale for this treatment; this information may be found in the Emgality Prescribing Information.]

[INSERT PEER-REVIEWED DATA HERE]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Emgality.]

Please feel free to contact me, **[HCP name]**, at **[office phone number]** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

_____

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

Encl: **[Medical records, clinical trial information]**

INFORMATION FOR PATIENTS WHO HAVE BEEN TREATED WITH EMGALITY:

HCPs can utilize the following language for patients who **HAVE** been treated with Emgality and have had treatment interruptions.

To whom it may concern:

I am writing to provide additional information to support my claim for **[patient's name]**'s treatment of episodic cluster headache **[ICD code]** with Emgality® (galcanezumab-gnlm). In brief, continued treatment with Emgality 300 mg, at the onset of, and then monthly until the end of the cluster period, is medically appropriate and necessary for this patient. This letter includes the patient's medical history, previous treatments, and disease severity **[if applicable]** that support my recommendation for treatment with Emgality.

[In this section, describe the frequency and duration of your patient's episodic cluster headache experience and what kind of impact it is having on work, family, and ability to function. Describe the patient's clinical response to Emgality in previous treatment and the reason why reinitiation is necessary.]

INDICATION

Emgality is a calcitonin-gene related peptide (CGRP) antagonist indicated in adults for the:

- preventive treatment of migraine
- treatment of episodic cluster headache

IMPORTANT SAFETY INFORMATION FOR EMGALITY

Contraindications

Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

Warnings and Precautions

Hypersensitivity Reactions

Hypersensitivity reactions, including dyspnea, urticaria, and rash, have occurred with Emgality in clinical studies and the postmarketing setting. Cases of anaphylaxis and angioedema have also been reported in the postmarketing setting. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

Adverse Reactions

The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in Emgality clinical studies were injection site reactions.

Please see Full Prescribing Information, including Patient Information, for Emgality. See Instructions for Use included with the device.

GZ HCP ISI 10DEC2019

Reference

Emgality [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC.