Emgality® (galcanezumab-gnlm) injection

Preparing an Appeal Letter

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).

If coverage determination or prior authorization is denied by the patient's health plan, the payer may require an Appeal Letter. Depending on the plan, there may be varying levels of appeal. If you are uncertain about a plan's appeal levels or specific procedures, always refer to the plan's appeal guidelines.

This resource, **Preparing an Appeal Letter**, provides information to healthcare professionals (HCPs) when appealing a coverage determination or prior authorization for a patient's plan. A checklist is included below that can be followed when creating an Appeal Letter. In addition, a sample letter is attached to this document and features information that many plans require to process a coverage authorization appeal. 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.

An Appeal Letter originates from the patient and the prescribing HCP.* It should be submitted with the following 2 additional items: the patient's medical records and a Letter of Medical Necessity (LMN).

COVERAGE AUTHORIZATION: APPEAL CONSIDERATIONS

- Include the patient's full name, plan identification number, and date of birth
- Add the prescribing HCP's National Provider Identifier (NPI) number and specialty
- Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with the case identification number from the initial denial letter
- Provide a copy of the patient's records with the following details:
  - The patient's history, diagnosis and International Classification of Diseases (ICD) code(s), and present-day condition and symptoms
- Indicate the severity of the patient's condition, if applicable
- Document prior treatments and the duration of each
  - Describe the rationale for why each treatment was discontinued
- Explain why the plan's preferred formulary agents are not appropriate for the patient
  - List the dates of treatment of the preferred agents
- Provide the clinical rationale for treatment; this information may be found in the Emgality Prescribing Information and/or clinical peer-reviewed literature
- Summarize your recommendation at the end of the letter
- Include an LMN

*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.

Sample Appeal Letter

Emgality® (galcanezumab-gnlm) injection

If the Coverage Authorization Request Letter is denied by the patient's health plan, it is necessary to proceed to Preparing an Appeal Letter. Some plans may require an LMN to accompany the appeal letter.

HCPs CAN FOLLOW THIS FORMAT FOR PATIENTS WHO ARE NOT CURRENTLY RECEIVING TREATMENT WITH EMGALITY® (GALCANEZUMAB-GNLM) INJECTION 300 MG (THREE 100 MG/ML PREFILLED SYRINGES):

[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 4 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

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 Appeal Letter

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]**

Sample Appeal Letter

Emgality® (galcanezumab-gnlm) injection

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:

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]**. **[Sample wording from the following section can be placed after this sentence if this appeal has been previously denied by the plan.]** 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.

[In this section, highlight the clinical benefit the patient has received since the patient was first prescribed Emgality. In addition, include a summary of the patient's clinical response to Emgality and list improvements in symptoms and disease impact since treatment began. It may be necessary to review past medical records to gather this information.]

STEP THERAPY INFORMATION

If this Appeal Letter is intended to appeal a plan's step therapy requirement, sample copy should include the following: This is our **[add level of request]** coverage authorization appeal. A copy of the most recent denial letter is attached for reference. The patient's medical records are also included in response to the denial.

[Please provide statement(s) indicating why these step therapy requirements are inappropriate for this patient. Include examples of previous treatments and failures with other therapies due to lack of response or intolerance to the drug.]

[Provide clinical rationale for this treatment; this information may be found in the Emgality Prescribing Information and/or clinical peer-reviewed literature.]

[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]** or **[patient's name]** at **[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 #]

[Patient's name and signature]

Encl: **[Medical records and clinical notes, clinical trial information, photo(s), Letter of Medical Necessity, original denial letter]**

Emgality® (galcanezumab-gnlm) injection

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.

Lilly