



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GALCANEZUMAB-GNLM

Generic	Brand	HICL	GCN	Exception/Other
GALCANEZUMAB-GNLM	EMGALITY	45281		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Emgality is prescribed for the preventive treatment of migraines
 - The patient has had a previous trial of at least **ONE** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol

If yes, approve for a total of 6 months by entering **TWO** approvals as follows:

- **FIRST APPROVAL:** approve for 1 month for the requested formulation by GPID (40418 or 40419) with a quantity limit of #2mL per 30 days for one fill.
- **SECOND APPROVAL:** approve for 5 months for the requested formulation by GPID (40418 or 40419) with a quantity limit of #1mL per 30 days for 5 fills (Please enter a start date of 23 days **AFTER** the start date of the first approval).

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month **OR** the patient has experienced a reduction in migraine severity **OR** migraine duration with Emgality therapy.

If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - Emgality is prescribed for the preventive treatment of migraines
 - The patient has had a previous trial of at least **ONE** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable**]

If yes, **approve for a total of 6 months by entering TWO approvals as follows:**

- **FIRST APPROVAL:** approve for 1 month for the requested formulation by GPID (40418 or 40419) with a quantity limit of #2mL per 30 days for one fill.
- **SECOND APPROVAL:** approve for 5 months for the requested formulation by GPID (40418 or 40419) with a quantity limit of #1mL per 30 days for 5 fills (Please enter a start date of 23 days **AFTER** the start date of the first approval).

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month **OR** the patient has experienced a reduction in migraine severity **OR** migraine duration with Emgality therapy.

If no, continue to #3.

3. Is the request for the treatment of episodic cluster headache and the patient meets **ALL** of the following criterion?
- The patient is 18 years of age or older

If yes, **approve for 3 months by GPID (46397) with a quantity limit of #3mL per 30 days.**

APPROVAL TEXT: Renewal requires physician attestation of improvement in episodic cluster headache frequency as compared to baseline.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **GALCANEZUMAB-GNLM (Emgality)** requires a diagnosis of episodic or chronic migraines, or treatment of episodic cluster headache. The following criteria must also be met:

For episodic migraines, approval requires:

- The patient is 18 years of age or older
- Emgality is prescribed for the preventive treatment of migraines
- The patient has had a previous trial of at least **ONE** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol

(Initial denial text continued on the next page)

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INITIAL CRITERIA (CONTINUED)

For chronic migraines, approval requires:

- The patient is 18 years of age or older
- Emgality is prescribed for the preventive treatment of migraines
- The patient has had a previous trial of at least ONE of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note:** For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

For treatment of episodic cluster headache, approval requires:

- The patient is 18 years of age or older

RENEWAL CRITERIA

1. Is Emgality prescribed for the preventive treatment of migraines and the patient meets at least **ONE** of the following criteria?
 - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
 - The patient has experienced a reduction in migraine severity with Emgality therapy
 - The patient has experienced a reduction in migraine duration with Emgality therapy

If yes, **approve for 12 months for the requested formulation by GPID (40418 or 40419) with a quantity limit of #1mL per 30 days.**

If no, continue to #2.

2. Is Emgality prescribed for the treatment of episodic cluster headache **AND** the patient meets the following criterion?
 - Physician attestation of improvement in episodic cluster headache frequency as compared to baseline

If yes, **approve for 12 months by GPID (46397) with a quantity limit of #3mL per 30 days.**
If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **GALCANEZUMAB-GNLM (Emgality)** requires that Emgality is prescribed for preventive treatment of migraines or treatment of episodic cluster headache. In addition, the following criteria must be met:

For the preventive treatment of migraines, approval requires ONE of the following:

- The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
- The patient has experienced a reduction in migraine severity with Emgality therapy
- The patient has experienced a reduction in migraine duration with Emgality therapy

For the treatment of episodic cluster headache, approval requires:

- Physician attestation of improvement in episodic cluster headache frequency as compared to baseline

RATIONALE

For further information, please refer to the Prescribing information and/or Drug Monograph for Emgality.

REFERENCES

- Emgality [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/20

Created: 10/18

Client Approval: 11/19

P&T Approval: 10/19