STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GALCANEZUMAB-GNLM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GALCANEZUMAB-GNLM	EMGALITY	45281		GPI-10 (6770203530)	

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
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy, Aimovig, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
   - The patient had a trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, 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 by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #2mL per 30 days.**
   - **SECOND APPROVAL: approve for 5 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days. (Please enter a start date of 23 days AFTER the start date of the first approval).**

   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
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy, Aimovig, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
   - The patient had a trial of ONE of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, 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 by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #2mL per 30 days.**
   - **SECOND APPROVAL: approve for 5 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days. (Please enter a start date of 23 days AFTER the start date of the first approval).**

   If no, continue to #3.

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

   If yes, **approve for 3 months by GPID or GPI-14 for Emgality 100mg/mL with a quantity limit of #3mL per 30 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:
   A. You have migraines or episodic cluster headaches (very painful headaches that occur in patterns)
   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy, Aimovig, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy, Aimovig, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
   4. You have tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

D. **If you have episodic cluster headaches, approval also requires:**
   5. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is Emgality prescribed for the preventive treatment of migraines **AND** does the patient meet the following criterion?
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy, Aimovig, Vyepti, Nurtec ODT, Qulipta) for migraine prevention

   If yes, continue to #2.
   If no, continue to #3.

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RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **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 by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Is Emgality prescribed for the treatment of episodic cluster headache **AND** does the patient meet the following criterion?
   - The patient had improvement in episodic cluster headache frequency as compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 for Emgality 100mg/mL with a quantity limit of #3mL per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:
   A. Emgality is being prescribed for preventive treatment of migraines OR for the treatment of episodic cluster headache (very painful headaches that occur in patterns)
   B. **If you have migraines, renewal also requires:**
      1. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy, Aimovig, Vyepti, Nurtec ODT, Qulipta) for migraine prevention
      2. You meet ONE of the following:
         a. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
         b. You have experienced a reduction in migraine severity with Emgality therapy
         c. You have experienced a reduction in migraine duration with Emgality therapy
   C. **If you have episodic cluster headaches, renewal also requires:**
      1. You had improvement in episodic cluster headache frequency as compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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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; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 10/18
Client Approval: 02/22
P&T Approval: 01/22