

Galcanezumab-gnlm (EMGALITY) for Cluster Headache

Criteria for Use

July 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to **ANY** item below is met, then the patient should **NOT** receive galcanezumab.

- Patient has uncontrolled hypertension
- Patient has a history of Raynaud's phenomenon with ischemia (e.g., history of digital ulcers, tissue necrosis, or other critical ischemia)¹
- Concurrent preventative therapy with another CGRP targeting agent (including other CGRP-targeting monoclonal antibodies and gepants)
- Patient with diagnosis of hemiplegic migraine or tension headache

Inclusion Criteria

All of the following must be fulfilled to receive galcanezumab for cluster headache.

- Treatment initiated by a VA/VA Community Care neurologist or locally designated headache expert²
- Episodic Cluster Headache defined as attacks lasting from 7 days to one year, separated by pain-free periods lasting 3 months or more
- Contraindication, intolerance, or lack of therapeutic response to a therapeutic dose of either verapamil 240-960 mg/day or lithium 600-1500 mg/day

Footnotes

¹ Galcanezumab should be discontinued if signs or symptoms of Raynaud's phenomenon develop. All patients with a history of Raynaud's phenomenon should be monitored for and informed about the possibility of recurrence and worsening.

² Patients started on galcanezumab must have a scheduled blood pressure check 2-4 weeks after initiation of therapy

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