Galcanezumab

Adjudication Guideline

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Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmaceutical Standards & Governance	NA

Table of Contents

1. Abstract

1.1 For Members

Galcanezumab can only be obtained with a prescription and should be used under the supervision of a doctor experienced in diagnosing and treating Migraine or Cluster Headache.

1.2 For Medical Professionals

Galcanezumab is a calcitonin-gene related peptide antagonist.

2. Scope

The scope of this adjudication rule is to highlight the medical indications, and coverage details for Galcanezumab as per the policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Galcanezumab is a calcitonin-gene related peptide antagonist indicated for the treatment of:

1. Cluster Headache.
2. Migraine

Dosage and Administration:

- The recommended dosage of Galcanezumab for treatment of Migraine is 240 mg (two consecutive subcutaneous injections of 120 mg each) once as a loading dose, followed by monthly doses of 120 mg injected subcutaneously.
- The recommended dosage of Galcanezumab for treatment of Cluster Headache is 300 mg (three consecutive subcutaneous injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period.

Missed dose:

If a dose is missed, the dose should be administered as soon as possible. Thereafter, dosing should be resumed at the regular scheduled time

Dosage forms and strengths available:

- Injection: 120 mg/mL solution in a single-dose prefilled pen.
- Injection: 120 mg/mL solution in a single-dose prefilled syringe
- Injection: 100 mg/mL solution in a single-dose prefilled syringe

Diagnostic Criteria for Cluster Headache:

A. At least five attacks fulfilling criteria B or D
B. Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated)
C. Either or both of the following:
    1. at least one of the following symptoms or signs, ipsilateral to the headache:
        - conjunctival infection and/or lacrimation
        - nasal congestion and/or rhinorrhoea
        - eyelid oedema
        - forehead and facial sweating
        - miosis and/or ptosis
    2. a sense of restlessness or agitation
D. Occurring with a frequency between one every other day and 8 per day
E. Not better accounted for by another ICHD-3 diagnosis.

Cluster Headache treatment criteria with Galcanezumab:

Documentation of ONE of the following (i or ii):
i. Inadequate response to ONE of the following (a or b)
    a) Sumatriptan injectable
    b) Zolmitriptan
ii. Contraindication or intolerance to sumatriptan injectable and zolmitriptan.

Episodic Migraine Treatment Criteria:

i. Galcanezumab is recommended as an option for preventing migraine in adults, only if they have 4 or more migraine days a month.

ii. Stop Galcanezumab after 12 weeks of treatment if in episodic migraine (less than 15 headache days a month) the frequency does not reduce by at least 50%.

Chronic Migraine Treatment Criteria:

A. Headache (migraine-like or tension-type-like) on ≥15 days/month for >3 months, and fulfilling criteria B and C
B. Occurring in a patient who has had at least five attacks fulfilling criteria B-D for 1.1 Migraine without aura and/or criteria B and C for Migraine with aura
C. On ≥8 days/month for >3 months, fulfilling any of the following2:
    1. criteria C and D for Migraine without aura
    2. criteria B and C for Migraine with aura
    3. believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative
D. Not better accounted for by another ICHD-3 diagnosis

Migraine treatment Criteria with Galcanezumab:

Documentation of ONE of the following (i, ii, or iii):

i. Inadequate response following a minimum 8-week trial of TWO migraine prevention therapies from different classes of medications including the following:
a) Angiotensin receptor blockers or angiotensin converting enzyme inhibitors
b) Antidepressants
c) Antiepileptic drugs
d) Beta-blockers

ii. Contraindication or intolerance to ALL the following: angiotensin receptor blockers/angiotensin converting enzyme inhibitors, antidepressants, antiepileptic drugs, and beta-blockers

Dose Continuation:

The treatment benefit should be assessed within 3 months after initiation of treatment. Any further decision to continue treatment should be taken on an individual patient basis. Evaluation of the need to continue treatment is recommended regularly thereafter.

Special warnings and precautions for use:

- Traceability
- Cardiovascular risk
- Serous hypersensitivity
- No drug interaction studies were conducted. No pharmacokinetic drug interactions are expected based on the characteristics of Galcanezumab.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: If a serious hypersensitivity reaction occurs, discontinue administration of Galcanezumab and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

Paediatric Use:

The safety and efficacy of Galcanezumab in patients younger than 18 years of age have not yet been established.

3.2 Requirements for Coverage

- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.
- Kindly code the ICD-10 and the CPT codes to the highest level of specificity
- Eligible clinician specialities

Eligible clinician categories
Neurology/Neurosurgery
Internal Medicine

Questionnaire link:

https://www.damanhealth.ae/main/pdf/support/Questionnaire/Preapproval%20Form%20%20for%20Galcanezumab.pdf
attached below

3.3 Non-Coverage

- Not covered for visitor plan
- Age less than 18 years

3.4 Payment and Coding Rules

Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC-004	Service is not clinically indicated based on good clinical practice
MNEC-003	Diagnoses are not covered
AUTH-001	Prior approval is required and was not obtained

5. Appendices

5.1 References

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf2
http://www.medicines.org.uk/emc/product/10478/smpc3.
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https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761063s010lbl.pdf
Emgality 120 mg solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc) | 10478
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5.2 Revision History

Date	Version No.	Change(s)
25/07/2023	V1.0	Release of V1.0
08/09/2023	V2.0	Migraine criteria and literature Update
1/11/2024	V3.0	No changes / updated in the new format
25/11/2025	V4.0	Guideline Review/ New reference added-No changes

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Medical Standards & Research Pre-approval Form

This is a pre-requisite form provided upon request for the drug **Galcanezumab**.

Kindly fill in all the requested information given below. This is a mandatory step to proceed further. Failure to provide information relevant to approval will delay the processing of the applicant's request. The provider will be contacted in case further clarifications are required.

GENERAL INFORMATION

- Member's Name:
- Member Card #:
- Policy:
- Age:
- Gender: ☐ Female ☐ Male
- Date: / /202_

PROVIDER INFORMATION

- Provider's Name:
- Ordering Clinician (ID # & Name):
- Performing Provider Name:
- Performing Clinician Specialty (ID # & Name):
- Referring Physician (ID # & Name):

SERVICE REQUESTED

- Principal/ Primary Diagnosis:
- ICD-10:
- Requested Drug and Dose:
- Number of episodes per month:
- Initial Dose: ☐ Refill ☐
- Quantity requested:

ADDITIONAL REQUIRED INFORMATION

- Documentation of beneficial response (for example, reduction in monthly migraine days o hours or reduction in days (please attach):
- ICHD-3 Classification criteria fulfilled? ☐ Yes ☐ No

All pre-approval forms need Line managers approval prior to publishing.
Add more rows if needed.