PHARMACY COVERAGE GUIDELINE

AIMOVIG™ (erenumab-aooe) subcutaneous injection
AJOVY™ (fremanezumab-vfrm) subcutaneous injection
EMGALITY™ (galcanezumab-gnlm) subcutaneous injection
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

Section A. Migraine Headaches:
AIMOVIG (erenumab-aooe)
AJOVY (fremanezumab-yfrm)
EMGALITY (galcanezumba-gnlm)

- **Criteria for initial therapy:** Aimovig (erenumab), Ajovy (fremanezumab-vfrm), Emgality (galcanezumab-gnlm), and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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1. Prescriber is **ONE** of the following:
    a. A Neurologist
    b. A licensed professional authorized by his or her license to prescribe Aimovig, Ajovy, or Emgality **and ONE** of the following:
        i. Is prescribing in consultation with a Neurologist or Pain Specialist
        ii. Is certified as a headache specialist by the United Council for Neurologic Subspecialties (UCNS)
        iii. Has earned a Certificate in Added Qualifications (CAQ) in Headache Medicine from the National Headache Foundation

2. Individual is 18 years of age or older

3. Individual has a confirmed diagnosis of episodic or chronic migraine of moderate to severe headache pain intensity and is used for preventive treatment of migraine (see Definitions section)

4. There is no history of cluster headache (for request for Aimovig and Ajovy) or hemiplegic migraine (for requests for any agent) (**Note**: see Cluster Headache criteria below)

5. Use is **not** for medication overuse headache or rebound headache or medication withdrawal headache

6. If available: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Individual has failure (using a stable dose for at least 2-months), contraindication per FDA label, intolerance, or is not a candidate for previous trial of any **TWO** of the following preventative migraine agents where the dose has been stable for at least 2 months (60 days):
    a. Beta-blocker: atenolol, metoprolol, nadolol, propranolol, or timolol
    b. Antidepressant: amitriptyline or venlafaxine
    c. Anticonvulsant: topiramate, divalproex sodium, or sodium valproate

8. Agent will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta, Vyepti)

9. **Additional criteria for Emgality (galcanezumab-gnlm) only:** Individual has failure (after a trial of at least 3 months), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** Aimovig (erenumab) **AND** Ajovy (fremanezumab-vfm)

Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Aimovig (erenumab), Ajovy (fremanezumab-vfrm), Emgality (galcanezumab-gnlm) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by **ONE** of the following:
    a. Neurologist
    b. A licensed professional authorized by his or her license to prescribe Aimovig or Emgality **and ONE** of the following:
        i. Is prescribing in consultation with a Neurologist or Pain Specialist
        ii. Is certified as a headache specialist by the UCNS
        iii. Has earned a CAQ in Headache Medicine from the National Headache Foundation

2. Individual's condition has responded while on therapy with response defined as **ALL** of the following:
    a. At least a 50% reduction in the number of migraine days per month from baseline
    b. A reduction in the number of days of use of acute migraine-specific medications from baseline
    c. Significant reduction in emergency room or urgent care visits for acute migraine treatment
    d. Reduction in use of steroids for acute migraine episodes

3. Individual has been adherent with the medication

4. There is no history of cluster headache (for request for Aimovig and Ajovy) or hemiplegic migraine (for requests for any agent) (**Note**: see Cluster Headache criteria below)

5. Use is **not** for medication overuse headache or rebound headache or medication withdrawal headache

6. If available: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Agent will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta, Vyepti)

8. **Additional criteria for Emgality (galcanezumab-gnlm) only:** Individual has failure (after a trial of at least 3 months), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** Aimovig (erenumab) **AND** Ajovy (fremanezumab-vfm)

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of Non-Cancer Medications**

    2. **Off-Label Use of Cancer Medications**

Section B. Episodic Cluster Headaches: EMGALITY (galcanezumab-gnlm)

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Generic Equivalent (if available)

- **Criteria for initial therapy:** Emgality (galcanezumab-gnlm) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is **ONE** of the following:
    a. A Neurologist
    b. A licensed professional authorized by his or her license to prescribe Emgality **and ONE** of the following:
        i. Is prescribing in consultation with a Neurologist or Pain Specialist
        ii. Is certified as a headache specialist by the United Council for Neurologic Subspecialties (UCNS)
        iii. Has earned a Certificate in Added Qualifications (CAQ) in Headache Medicine from the National Headache Foundation

2. Individual is 18 years of age or older

3. Individual has a confirmed diagnosis of **episodic cluster headache** according to International Headache Society (IHS) International Classification of Headache Disorders (ICHD) (see Definitions section)

4. Individual has at least **five cluster headache attacks** that are severe or very severe that have a frequency between one every other day and eight per day that are episodic with at least **two cluster bout periods** lasting from seven days to one year (when untreated) which are separated by pain-free remission periods of three months or more

5. Requested agent will **not** be used as an abortive treatment for an acute cluster headache episode

6. If available: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Individual uses **either** oxygen or sumatriptan (subcutaneous or intranasal) or intranasal zolmitriptan or other abortive therapy for acute episodes of cluster headache

8. Individual has failure (after use of stable dose for at least 2 months), contraindication per FDA label, intolerance, or not a candidate for trial of any **TWO** of the following preventative cluster headache agents
    a. Verapamil
    b. Topiramate
    c. Lithium carbonate

9. Requested agent will **not** be used concurrently or alternating with Botox (onabotulinumtoxin A)

10. Requested agent will **not** be used concurrently with or alternating with CGRP related therapies or Serotonin (5-HT) 1F receptor agonist (see Definitions section)

11. There is no history of migraine headache or hemiplegic migraine

12. Use is not for medication overuse headache or rebound headache or medication withdrawal headache

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Emgality (galcanezumab-gnlm) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by **ONE** of the following:
    a. Neurologist
    b. A licensed professional authorized by his or her license to prescribe Emgality **and ONE** of the following:
        i. Is prescribing in consultation with a Neurologist or Pain Specialist
        ii. Is certified as a headache specialist by the UCNS
        iii. Has earned a CAQ in Headache Medicine from the National Headache Foundation

2. Individual's condition responded while on therapy with response defined as **TWO** of the following:
    a. A reduction in the weekly cluster headache attack frequency from baseline
    b. At least a 50% reduction in the weekly cluster headache frequency from baseline
    c. Significant reduction in emergency room or urgent care visits for acute migraine treatment

3. If available: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

4. Individual is using a preventive treatment for cluster headaches

5. Requested agent will **not** be used concurrently or alternating with Botox (onabotulinumtoxin A)

6. Requested agent will **not** be used concurrently with or alternating with CGRP related therapies or Serotonin (5-HT) 1F receptor agonist (see Definitions section)

Renewal duration:
Emgality: One carton per month with three 100 mg prefilled syringes for 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

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Generic Equivalent (if available)

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Migraine day:
- Any calendar day in which the patient experiences a qualified migraine headache (onset, continuation, or recurrence of the migraine headache)
- A qualified migraine is defined a migraine with or without aura, lasting ≥ 30 minutes that meets at least one of the following:
  - ≥ 2 of the following pain features: unilateral, throbbing, moderate to severe, or exacerbated with exercise/physical activity
  - > 1 of the following associated non-pain features: nausea and or vomiting, or both photophobia, and phonophobia
- Any calendar day on which acute migraine-specific medication was used is counted as a migraine day

Treatment considerations:
- There are no strict definitions for the precise frequency or duration of migraine headaches that would prompt preventive therapy
- Migraine prevention therapy may be indicated for those with migraine headaches that are frequent (ex. as ≥ 4 headaches/month) or long-lasting (ex. ≥12 hours) and those that cause significant disability or diminished quality of life
- The goals of preventive therapy are to reduce the frequency, severity, and duration of headaches, to improve treatment responsiveness of therapies for acute attacks, prevent progression or transformation of episodic migraine to chronic migraine and to improve overall function or reduce the risk of neurologic impairment

Episodic migraine:
- Individual with migraine who has between 4 to 14 headache days per month, of which at least 4 were migraine days

Chronic migraine:
- Chronic migraine is defined as headache occurring 15 or more headache days a month for more than 3 months, of which 8 days per month meet the features of migraine with or without aura.
- Some patients with an episodic migraine pattern (<15 headache days a month) transition to a chronic migraine pattern (≥15 headache days a month), a transition that has been called "transformation" and "chronification"
- Features of migraine headache include:
  - Lasts 4-72 hours **AND** has at least 2 of the following 4 characteristics:
    - Unilateral, pulsating, moderate or severe pain intensity, aggravates or causes avoidance of routine physical activity
  - **AND** associated with at least one of the following during the headache:
    - Nausea and/or vomiting or photophobia and phonophobia.

- The management of chronic migraine should focus on prophylactic therapy and avoidance of acute headache medication overuse

Migraine Disability Assessment (MIDAS):

Please answer the following questions about **ALL** of the headaches you have had over the last 3 months. Select zero if you did not have the activity in the last 3 months.

1. _____ On how many days in the last 3 months did you miss work or school because of your headaches?

2. _____ How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches? (Do not include days you counted in question 1 where you missed work or school.)

3. _____ On how many days in the last 3 months did you not do household work (such as housework, home repairs and maintenance, shopping, caring for children and relatives) because of your headaches?

4. _____ How many days in the last 3 months was your productivity in household work reduced by half of more because of your headaches? (Do not include days you counted in question 3 where you did not do household work.)

5. _____ On how many days in the last 3 months did you miss family, social or leisure activities because of your headaches?

6. Total number of days (from questions 1 through 5): _____

Answer the following for your provider:

1. _____ On how many days in the last 3 months did you have a headache? (If a headache lasted more than 1 day, count each day.)

2. _____ On a scale of 0 - 10, on average how painful were these headaches? (where 0 = no pain at all, and 10 = pain as bad as it can be.)

MIDAS Grade	Definition	MIDAS Score
I	Little or No disability	0-5
II	Mild disability	6-10
III	Moderate disability	11-20
IV	Severe disability	21+

2013 Canadian Headache Society (CHS) – medications for acute migraine:

2013 Canadian Headache Society (CHS) Summary of Recommendations*		
Recommended For Use in Episodic Migraine (Use)**		
	Recommendation	
Drug	**Recommendation Strength**	**Quality of Evidence**
Almotriptan	Strong	High
Eletriptan	Strong	High
Frovatriptan	Strong	High

Naratriptan	Strong	High
Rizatriptan	Strong	High
Sumatriptan	Strong	High
Zolmitriptan	Strong	High
Aspirin	Strong	High
Diclofenac	Strong	High
Ibuprofen	Strong	High
Naproxen	Strong	High
Acetaminophen	Strong	High
Domeridone	Strong	Low
Metoclopramide	Strong	Moderate
Dihydroergotamine	Weak	Moderate
Ergotamine	Weak, not recommended for routine use	Moderate
Opioid containing compounds	Weak, not recommended for routine use	Low
Tramadol containing compounds	Weak, not recommended for routine use	Moderate
Not Recommended for Use in Episodic Migraine (Do not use***)**		
Butalbital containing compounds	Strong	Low
Butorphanol	Strong	Low
*Utilizing Grading of Recommendations Assessment, Development and Evaluation (GRADE) Criteria **Migraine with headache on less than 15 days a month *** Except under exceptional circumstances		

Metoclopramide strongly recommended for use when necessary

Cluster headache:

- The most common type of Trigeminal Autonomic Cephalalgias (TAC)
- Attacks of severe orbital, supraorbital, or temporal pain, accompanied by autonomic phenomena and/or restless or agitation
- Unilateral autonomic symptoms associated with cluster headache include ptosis, miosis, lacrimation, conjunctival injection, rhinorrhea, and nasal congestion, occur only during the pain attack and are ipsilateral to the pain
- The attacks may strike up to eight times a day and are relatively short-lived (usually 15-180 minutes)
- The headache is strictly unilateral; the symptoms remain on the same side of the head during a single cluster attack
- The symptoms can switch to the other side during a different cluster attack (so-called side shift) in approximately 15% of cases
- In contrast to migraine, patients with cluster are restless and prefer to pace about or sit and rock back and forth

Diagnostic criteria for cluster headache:

Cluster headache: Diagnostic criteria for cluster headache require the following:
A. At least **five attacks** fulfilling criteria B through D

B. Severe or very severe **unilateral** orbital, supraorbital, and/or temporal pain lasting 15-180 minutes when untreated; during part (but less than half) of the active time course of cluster headache, attacks may be less severe and/or of shorter or longer duration
C. **Either or both** of the following:
1. At least **one** of the following symptoms or signs ipsilateral to the headache:
a) Conjunctival injection and/or lacrimation
b) Nasal congestion and/or rhinorrhea
c) Eyelid edema
d) Forehead and facial sweating
e) Miosis and/or ptosis
2. A sense of restlessness or agitation
D. Attacks have a frequency between one every other day and eight per day; during part (but less than half) of the active time-course of cluster headache, attacks may be less frequent
E. Not better accounted for by another ICHD-3 diagnosis
Episodic cluster headache: Diagnostic criteria for episodic cluster headache require the following:
A. Attacks fulfilling criteria for cluster headache and occurring in bouts (cluster periods)
B. At least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of three months or more
Chronic cluster headache: Diagnostic criteria for chronic cluster headache require the following:
A. Attacks fulfilling criteria for cluster headache
B. Attacks occurring without a remission period, or with remissions lasting less than three months, for at least one year
Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018; 38:1.

Identification of headache type: migraine, tension, or cluster			
	Migraine	**Tension**	**Cluster**
Location	Unilateral	Bilateral	Supraorbital/temporal
Pain intensity[1]	Moderate to severe	Mild to moderate	Severe
Duration	4–72 hours	30 minutes to 7 days	15–180 minutes
Characterization of pain	Pulsing	Pressure/squeezing	Boring/stabbing
Sensitivity to light/sound	One or both may be present	Both are absent or only one is present	No

Nausea/vomiting	One or both may be present	No	One or both may be present
Aggravated by routine activity	Yes	No	No
Aura	May be present	No	No
Associated symptoms	None	None	Miosis, ptosis, rhinorrhea
1 Pain intensity • Mild—Patient is aware of a headache but is able to continue daily routine with minimum alterations. • Moderate—The headache inhibits daily activities; migraine pain is more noticeable but is not incapacitating. • Severe—The headache is incapacitating such that patient is no longer able to engage in normal activities.			

Abortive (symptomatic) treatment of acute migraine:

- Simple analgesics such as non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen, triptans, antiemetics, calcitonin gene-related peptide (CGRP) antagonists (remigepant, ubrogepant, zavegepant), lasmiditan, and dihydroergotamine

Non-Calcitonin gene-related peptide (Non-CGRP) preventative (episodic or chronic) migraine agent(s):

- Beta-blocker: atenolol, metoprolol, nadolol, propranolol, or timolol
- Antidepressant: amitriptyline or venlafaxine
- Anticonvulsant: topiramate, divalproex sodium, or sodium valproate

Botulinum toxin injection:

- Treatment of chronic migraine:
    - Botox (onabotulinumtoxinA)

CGRP related agents:

- Preventive treatment of episodic or chronic migraine:
    - Vyepti (eptinezumab-jjmr)
    - Aimovig (erenumab-aooe)
    - Ajovy (fremanezumab-vfrm)
    - Emgality (galcanezumab-gnlm) – also used in cluster headache
- Preventive treatment of episodic migraine:
    - Qulipta (atogepant)
    - Nurtec ODT (rimegepant)
- Acute (abortive) treatment of migraine:
    - Oral:
        - Nurtec ODT (rimegepant)
        - Ubrelvy (ubrogepant)
    - Nasal:
        - Zavzpret (zavegepant)

Serotonin (5-HT) 1F receptor agonist:

- Acute (abortive) treatment of migraine
    - Reyvow (lasmiditan)

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Resources:

Aimovig (erenumab-aooe) product information, revised by manufacturer Amgen, Inc. 08-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Ajovy (fremanezumab-vfrm) product information, revised by manufacturer Teva Pharmaceuticals USA, Inc. 10-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Emgality (galcanezumab-gnlm) product information, revised by manufacturer Eli Lilly and Company 03-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on February 17, 2025.

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May A. Cluster headache: Epidemiology, clinical features, and diagnosis. In: UpToDate, Swanson JW, Goddeau RP (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2025. Topic last updated August 16, 2024. Accessed March 28, 2025.

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Ailani J, Burch RC, Robbins MS, et al.: The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache 2021;16:1021-1039. Accessed October14, 2022. Re-evaluated March 28, 2025.

Charles AC, Digre KB, Goadsby PJ, et al.: Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024;00:1-9. Accessed April 13, 2024. Re-evaluate March 28, 2025.

Institute for Clinical and Economic Review (ICER): Calcitonin Gene-Related Peptide (CGRP) Inhibitors as Preventive Treatments for Patients with Episodic or Chronic Migraine: Effectiveness and Value. Final Evidence Report; July 03, 2018; 1-275. Available at https://icer.org/. Accessed April 27, 2023. Re-evaluated March 28, 2025.

Puledda F, Sacco S, Hans-Christop D, et al.: International Headache Society global practice recommendations for the acute pharmacological treatment of migraine. Cephalalgia 2024; 44(8): 1–45. Accessed March 27, 2025.

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Qassem A, Cooney T, Exteandia-Ikobaltzeta I, et al.: Prevention of Episodic Migraine Headache using Pharmacologic Treatments in Outpatient Settings: A Clinical Guideline from the American College of Physicians. 2025; 178:426-433. doi:10.7326/ANNALS-24-01052. Assessed March 27, 2025.

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