

## PHARMACY COVERAGE GUIDELINE

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

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#### **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/or 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](http://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](mailto:Pharmacyprecert@azblue.com).

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## **Section A: Migraine Headaches**

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### **Medical Necessity Requirements for AIMOVIG (erenumab-aooe), AJOVY (fremanezumab-vfrm), and EMGALITY (galcanezumab-gnlm)**

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#### **Criteria for Initial Therapy:**

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#### Prescriber Qualifications

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

#### Indication

- Confirmed diagnosis of episodic or chronic migraine with moderate to severe headache pain intensity for preventive treatment

#### Age Requirement

- **ONE** of the following:
  - **For Aimovig or Emgality:** 18 years or older
  - **For Ajovy:**
    1. **Chronic migraine:** 18 years of age or older
    2. **Episodic migraine:** 6 years of age or older and weighs 45 kilograms or more

#### Baseline Clinical Evaluation

- No history of cluster headache (for Aimovig and Ajovy) or hemiplegic migraine (for any agent)
- Not for medication overuse headache, rebound headache, or medication withdrawal headache

#### Alternative Therapies

- Failure (using a stable dose for at least 2 months), contraindication, or intolerance to **TWO** of the following preventive migraine agents:
  - Beta blocker: atenolol, metoprolol, nadolol, propranolol, timolol
  - Antidepressant: amitriptyline, venlafaxine
  - Anticonvulsant: topiramate, divalproex sodium, sodium valproate
- **For Aimovig:** Failure (after a trial of at least 3 months), contraindication, or intolerance to **BOTH** of the following:
  - Ajovy
  - Emgality

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

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#### Safety

- Will not be used in combination with another CGRP antagonist or inhibitor used for preventive treatment of migraines (e.g., Aimovig, Ajoovy, Emgality, Nurtec ODT, Qulipta, Vyepti)

#### Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

#### Initial Therapy Criteria Approval Duration

- 12 months OR end of plan year
- 

#### Criteria for Continuation of Therapy (renewal therapy):

**Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy**

#### Prescriber Qualification

- Continues to be seen by **ONE** of the following:
  - Neurologist
  - A licensed professional authorized by his or her license to prescribe Aimovig, Ajoovy, or Emgality **and ONE** of the following:
    1. Is prescribing in consultation with a Neurologist or Pain Specialist
    2. Is certified as a headache specialist by the United Council for Neurologic Subspecialties (UCNS)
    3. Has earned a Certificate in Added Qualifications (CAQ) in Headache Medicine from the National Headache Foundation

#### Clinical Response

- **ALL** the following:
  - At least 50 percent reduction in the number of migraine days per month from baseline
  - Reduction in the number of days of use of acute migraine specific medications from baseline
  - Significant reduction in emergency room or urgent care visits for acute migraine treatment
  - Reduction in use of steroids for acute migraine episodes

#### Adherence

- Adherence to the prescribed therapy regimen has been documented

#### Alternative Therapies

- **For Aimovig:** Failure (after a trial of at least 3 months), contraindication, or intolerance to **BOTH** of the following:

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- Ajovy
- Emgality

#### **Brand Specific Criteria**

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### **Safety**

- Will not be used in combination with another CGRP antagonist or inhibitor used for preventive treatment of migraines (e.g., Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta, Vyepti)
- Has not developed serious hypersensitivity reaction (dyspnea, rash, delayed serious hypersensitivity, anaphylaxis)
- Has not developed new onset hypertension or worsening of preexisting hypertension or blood pressure that is inadequately controlled
- Has not developed signs and symptoms of Raynaud's phenomenon

#### **Additional Requirements**

- No history of cluster headache (for Aimovig and Ajovy) or hemiplegic migraine (for any agent)
- Not for medication overuse headache, rebound headache, or medication withdrawal headache

#### **Documentation Requirements**

- Chart notes
- Supporting clinical documentation with evidence of improvement in migraine headaches
- Lab values that confirm safe use

#### **Continuation Therapy Criteria Approval Duration**

- 12 months OR end of plan year
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## **Section B. Episodic Cluster Headaches**

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### **Medical Necessity Requirements for **EMGALITY** (galcanezumab-gnlm)**

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#### **Criteria for Initial Therapy:**

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#### Prescriber Qualifications

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

#### Indication

- Confirmed diagnosis of episodic cluster headache according to International Headache Society International Classification of Headache Disorders

#### Age Requirement

- 18 years or older

#### Baseline Clinical Evaluation

- At least five cluster headache attacks that are severe or very severe with frequency between one every other day and eight per day
- Episodic pattern with at least two cluster bout periods lasting from seven days to one year (when untreated) separated by pain free remission periods of three months or more
- Requested agent will not be used as an abortive treatment for an acute cluster headache episode
- Uses either oxygen or sumatriptan (subcutaneous or intranasal) or intranasal zolmitriptan or other abortive therapy for acute episodes of cluster headache

#### Alternative Therapies

- Failure (after use of stable dose for at least two months), contraindication, or intolerance to **TWO** of the following preventive cluster headache agents:
  - Verapamil
  - Topiramate
  - Lithium carbonate

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (FDA) (see Definitions section)

#### Safety

- Requested agent will not be used concurrently or alternating with Botox (onabotulinumtoxin A)

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- Requested agent will not be used concurrently with or alternating with CGRP related therapies or Serotonin (5 HT) 1F receptor agonist
- No history of migraine headache or hemiplegic migraine
- Not for medication overuse headache, rebound headache, or medication withdrawal headache

#### Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

#### Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year
- 

#### Criteria for Continuation of Therapy (renewal therapy):

**Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy**

#### Prescriber Qualification

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

#### Clinical Response

- **TWO** of the following:
  - A reduction in the weekly cluster headache attack frequency from baseline
  - At least a 50 percent reduction in the weekly cluster headache frequency from baseline
  - Significant reduction in emergency room or urgent care visits for acute migraine treatment

#### Adherence

- Adherence to the prescribed therapy regimen has been documented

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#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (FDA) (see Definitions section)

#### Safety

- Requested agent will not be used concurrently or alternating with Botox (onabotulinumtoxin A)
- Requested agent will not be used concurrently with or alternating with CGRP related therapies or Serotonin (5 HT) 1F receptor agonist
- Has not developed serious hypersensitivity reaction (dyspnea, rash, delayed serious hypersensitivity, anaphylaxis)
- Has not developed new onset hypertension or worsening of preexisting hypertension or blood pressure that is inadequately controlled
- Has not developed signs and symptoms of Raynaud's phenomenon

#### Additional Requirements

- Is using a preventive treatment for cluster headaches

#### Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in cluster headache
- Lab values that confirm safe use

#### Continuation Therapy Criteria Approval Duration

- **Emgality:** One carton per month with three 100 mg prefilled syringes for 12 months OR end of plan year
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### Criteria for Off-Label Use Requests:

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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#### Definitions:

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

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#### [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  $\geq 30$  minutes that meets at least one of the following:
  - $\geq 2$  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  $\geq 4$  headaches/month) or long-lasting (ex.  $\geq 12$  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

#### **Acute migraine:**

- Attacks that typically last from 4 to 72 hours and can begin suddenly, making daily activities difficult or impossible to perform

#### **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 ( $\geq 15$  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.

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- 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.

- \_\_\_\_\_ On how many days in the last 3 months did you miss work or school because of your headaches?
- \_\_\_\_\_ 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.)
- \_\_\_\_\_ 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?
- \_\_\_\_\_ How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches? (Do not include days you counted in question 3 where you did not do household work.)
- \_\_\_\_\_ On how many days in the last 3 months did you miss family, social or leisure activities because of your headaches?
- Total number of days (from questions 1 through 5): \_\_\_\_\_

#### **Answer the following for your provider:**

- \_\_\_\_\_ 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.)
- \_\_\_\_\_ 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)		
Drug	Recommendation	
	Recommendation Strength	Quality of Evidence
Almotriptan	Strong	High
Eletriptan	Strong	High
Frovatriptan	Strong	High
Naratriptan	Strong	High

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Rizatriptan	Strong	High
Sumatriptan	Strong	High
Zolmitriptan	Strong	High
Aspirin	Strong	High
Diclofenac	Strong	High
Ibuprofen	Strong	High
Naproxen	Strong	High
Acetaminophen	Strong	High
Domperidone	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
<b>Not Recommended for Use in Episodic Migraine** (Do not use***)</b>		
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:

<p><b>Cluster headache:</b>            Diagnostic criteria for cluster headache require the following:</p>
<p>A. At least <b>five attacks</b> fulfilling criteria B through D</p>
<p>B. Severe or very severe <b>unilateral</b> 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</p>

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C. <b>Either or both</b> of the following:
1. At least <b>one</b> 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
<b>Episodic cluster headache:</b> 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
<b>Chronic cluster headache:</b> 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
<i>Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018; 38:1.</i>

<b>Identification of headache type: migraine, tension, or cluster</b>			
	<b>Migraine</b>	<b>Tension</b>	<b>Cluster</b>
Location	Unilateral	Bilateral	Supraorbital/temporal
Pain intensity <sup>1</sup>	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

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Aggravated by routine activity	Yes	No	No
Aura	May be present	No	No
Associated symptoms	None	None	Miosis, ptosis, rhinorrhea
<b>1 Pain intensity</b> <ul style="list-style-type: none"> <li>• Mild—Patient is aware of a headache but is able to continue daily routine with minimum alterations.</li> <li>• Moderate—The headache inhibits daily activities; migraine pain is more noticeable but is not incapacitating.</li> <li>• Severe—The headache is incapacitating such that patient is no longer able to engage in normal activities.</li> </ul>			

**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:
  - Vyepi (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) subcutaneous injection product information, revised by manufacturer Amgen, Inc. 03-2025. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed January 29, 2026.

Ajovy (fremanezumab-vfrm) subcutaneous injection product information, revised by manufacturer Teva Pharmaceuticals USA, Inc. 08-2025. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed January 29, 2026.

Emgality (galcanezumab-gnlm) subcutaneous injection product information, revised by manufacturer Eli Lilly and Company 10-2025. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed on January 29, 2026.

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## PHARMACY COVERAGE GUIDELINE

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

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