BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 5/17/18**
SECTION: DRUGS	**LAST REVIEW DATE: 5/16/19**
	LAST CRITERIA REVISION DATE: 5/16/19
	ARCHIVE DATE:

AIMOVIG™ (erenumab) subcutaneous injection
AJOVY™ (fremanezumab-vfrm) subcutaneous injection
EMGALITY™ (galcanezumab-gnlm) subcutaneous injection

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

AIMOVIG™ (erenumab) subcutaneous injection
AJOVY™ (fremanezumab-vfrm) subcutaneous injection
EMGALITY™ (galcanezumab-gnlm) subcutaneous injection (cont.)

Criteria:

- **Criteria for initial therapy:** Aimovig (erenumab) and Emgality (galcanezumab-gnlm) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is **ONE** of the following:
   - A Neurologist
   - A licensed professional authorized by his or her license to prescribe Aimovig or Emgality **and** **ONE** of the following:
     - Is prescribing in consultation with a Neurologist or Pain Specialist
     - Is certified as a headache specialist by the United Council for Neurologic Subspecialties (UCNS)
     - 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. A confirmed diagnosis of **ONE** of the following types of migraine:
   - Episodic migraine, defined as an individual with migraine who has between 4-14 migraine headache days per month but not more than 14 headache days per month
   - Chronic migraine, defined as an individual with migraine who has 15 or more headache days per month for more than 3 months, of which 8 days per month meet the features of migraine with or without aura
4. Botox (onabotulinumtoxin A) will not be used concurrently or alternating with Aimovig, Ajovy, or Emgality or other similar acting medication
5. There is no history of cluster headache or hemiplegic migraine
6. Use is not for medication overuse headache or rebound headache or medication withdrawal headache
7. The patient has had a previous trial of any **TWO** of the following preventative migraine agents where the dose has been stable for at least 2 months (60 days)
   - Beta-blocker: atenolol, metoprolol, nadolol, propranolol, or timolol
   - Antidepressant: amitriptyline or venlafaxine
   - Anticonvulsant: topiramate, divalproex sodium, or sodium valproate
8. **ONE** migraine prevention agent will be continued

AIMOVIG™ (erenumab) subcutaneous injection
AJOVY™ (fremanezumab-vfrm) subcutaneous injection
EMGALITY™ (galcanezumab-gnlm) subcutaneous injection (cont.)

Initial approval duration:

Aimovig: One pack auto-injector or prefilled syringe per month for 3 months
Emgality: First dose: One time approval of a carton with two 120 mg prefilled pens or syringes
Maintenance: One carton per month with one 120 mg prefilled pen or syringe for 2 months

- **Criteria for continuation of coverage (renewal request):** Aimovig (erenumab) and Emgality (galcanezumab-gnlm) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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

2. Individual's condition responded while on therapy
   - Response is defined as **ALL** of the following:
     - At least a 50% reduction in the number of migraine days per month from baseline
     - A reduction in the number of days of use of acute migraine-specific medications from baseline
     - No emergency room or urgent care visits for acute migraine treatment

3. Individual has been adherent with the medication

4. Botox (onabotulinumtoxin A) will not be used concurrently or alternating with Aimovig, Ajovy, or Emgality or other similar acting medication

5. Uses one migraine prevention agent

6. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use

Renewal duration:

Aimovig: One pack auto-injector or prefilled syringe per month for 6 months
Emgality: One carton per month with one 120 mg prefilled pen or syringe for 6 months

AIMOVIG™ (erenumab) subcutaneous injection
AJOVY™ (fremanezumab-vfrm) subcutaneous injection
EMGALITY™ (galcanezumab-gnlm) subcutaneous injection (cont.)

Criteria:

- **Criteria for initial therapy:** Ajovy (fremanezumab-vfrm) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is **ONE** of the following:
   - A Neurologist
   - A licensed professional authorized by his or her license to prescribe Ajovy **and ONE** of the following:
     - Is prescribing in consultation with a Neurologist or Pain Specialist
     - Is certified as a headache specialist by the United Council for Neurologic Subspecialties (UCNS)
     - 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. A confirmed diagnosis of **ONE** of the following types of migraine:

   - Episodic migraine, defined as an individual with migraine who has between 4-14 migraine headache days per month but not more than 14 headache days per month

   - Chronic migraine, defined as an individual with migraine who has 15 or more headache days per month for more than 3 months, of which 8 days per month meet the features of migraine with or without aura

4. Botox (onabotulinumtoxin A) will not be used concurrently or alternating with Aimovig, Ajovy, or Emgality or other similar acting medication

5. There is no history of cluster headache or hemiplegic migraine

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

7. The patient has had a contraindication or intolerance or trial of at least 3 months to **BOTH** Aimovig (erenumab) and Emgality (galcanezumab-gnlm)

8. The patient has had a previous trial of any **TWO** of the following preventative migraine agents where the dose has been stable for at least 2 months (60 days)

   - Beta-blocker: atenolol, metoprolol, nadolol, propranolol, or timolol

   - Antidepressant: amitriptyline or venlafaxine

   - Anticonvulsant: topiramate, divalproex sodium, or sodium valproate

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9. **ONE** migraine prevention agent will be continued

Initial approval duration:
Ajovy: 3 months, as **one** of the following:
One single dose prefilled syringe per month for 3 months
Three single dose prefilled syringes in a 3-month period

- **Criteria for continuation of coverage (renewal request):** Ajovy (fremanezumab-vfrm) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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

2. Individual's condition responded while on therapy
   - Response is defined as **ALL** of the following:
     - At least a 50% reduction in the number of migraine days per month from baseline
     - A reduction in the number of days of use of acute migraine-specific medications from baseline
     - No emergency room or urgent care visits for acute migraine treatment

3. Individual has been adherent with the medication

4. Botox (onabotulinumtoxin A) will not be used concurrently or alternating with Aimovig, Ajovy, or Emgality or other similar acting medication

5. Uses one migraine prevention agent

6. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use

Renewal duration:
Ajovy: 6 months, as **one** of the following:
One single dose prefilled syringe per month for 6 months
Three single dose prefilled syringes every 3 months for 6 months

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Definitions:

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

Episodic migraine:
Individual with migraine who has between 4 to 14 migraine headache days per month

Chronic migraine:
Individual with migraine who has 15 or more headache days per month for more than 3 months, of which 8 days per month meet the features of migraine with or without aura

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.

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

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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***)**		
Butalbutal 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

Resources:

Aimovig (erenumab) product information accessed 09-25-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b998ed05-94b0-47fd-b28f-cddd1e128fd8

Ajovy (fremanezumab-vfrm) product information accessed 09-25-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=98e344ea-5916-4947-b6f2-4a76ccc04b6b

Emgality (galcanezumab-gnlm) product information accessed 10-05-2018 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=33a147be-233a-40e8-a55e-e40936e28db0

UpToDate: Acute treatment of migraines in adults. Current through Apr 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/acute-treatment-of-migraine-in-adults?search=migraine&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

UpToDate: Pathophysiology, clinical manifestations, and diagnosis of migraine in adults. Current through Apr 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/pathophysiology-clinical-manifestations-and-diagnosis-of-migraine-in-adults?search=migraine&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

UpToDate: Preventive treatment of migraine in adults. Current through Apr 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/preventive-treatment-of-migraine-in-adults?topicRef=3347&source=see_link

Worthington I, Pringsheim T, Gawel MJ, et al.: Targeted Review: Medications for Acute Migraine Treatment. Can J Neurol Sci 2013; 40: Suppl 3: S10-S32

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.