Pharmacy Policy Bulletin: J-0730 CGRP Inhibitors – Commercial and Healthcare Reform	
Number: J-0730	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Aimovig, Ajovy, & Emgality:** **Prior Authorization (1.):** 1. Other Managed Prior Authorization = Yes w/ Prior Authorization **Nurtec ODT, Qulipta, Ubrelvy, & Zavzpret:** **Prior Authorization (1. or 2.):** 1. Rx Mgmt Step Therapy = Preferred 2. Rx Mgmt Performance = MRXC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** Excluding Commercial National Select Formulary (NSF)
Version: J-0730-021	**Original Date:** 05/02/2018
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Aimovig (erenumab-aooe) • Ajovy (fremanezumab-vfrm) • Emgality (galcanezumab-gnlm) • Nurtec ODT (rimegepant) • Qulipta (atogepant) • Ubrelvy (ubrogepant) • Zavzpret (zavegepant)

FDA-Approved Indication(s):	• Aimovig
	  ○ Preventive treatment of migraine in adults
	• Ajovy
	  ○ Preventive treatment of migraine in adults
	  ○ Preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more
	• Emgality
	  ○ Preventive treatment of migraine in adults
	  ○ Treatment of episodic cluster headache in adults
	• Nurtec ODT
	  ○ Acute treatment of migraine with or without aura in adults
	  ○ Preventive treatment of episodic migraine in adults
	• Qulipta
	  ○ Preventive treatment of migraine in adults
	• Ubrelvy, Zavzpret
	  ○ Acute treatment of migraine with or without aura in adults

Background:	**Migraine**
	• Migraine is a common medical condition. Approximately 10 million Americans have severe and frequent migraines, impacting their daily activities, predominantly impacting the female population.
	• There are a variety of migraine subtypes with symptoms that include weakness, numbness, visual changes or loss, vertigo, and difficulty speaking (some patients may appear as if they are having a stroke).
	• According to the International Classification of Headache Disorders (ICHD) 3rd Edition, chronic migraines are broadly defined as 15 or more headache days per month for more than 3 months, of which 8 or more are migraine days. Migraines not classified as chronic migraine have been termed episodic migraine but is not a clinical diagnosis. Episodic migraines are broadly defined as fewer than 14 headache days per 4 weeks over a 12-week period. In clinical trials, the episodic migraine group included patients with a history of 4 to 14 migraine days per month.
	• Mainstay treatment options include acute therapy options such as triptans, which when taken early, can arrest the migraine process. Preventive medications can decrease both the frequency and the severity of migraines.
	• The American Academy of Neurology (AAN) guideline supports the following medications for migraine prophylaxis:
	  ○ Level A (established as effective): divalproex/sodium valproate, metoprolol, onabotulinumtoxinA (chronic migraine only), propranolol, timolol, topiramate, and frovatriptan for menstrual migraine
	  ○ Level B (probably effective): amitriptyline, venlafaxine, atenolol, and nadolol
	  ○ Level C (possibly effective): lisinopril, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, and candesartan
	• For pediatric migraine prevention, the 2019 AAN and American Headache Society (AHS) practice guideline states the following outcomes and confidence in evidence:
	  ○ Decreased frequency of migraine or headache days: High confidence – amitriptyline with cognitive behavioral therapy (CBT). Moderate confidence – topiramate. Very low confidence – divalproex ER, amitriptyline, OnabotulinumtoxinA
	  ○ At least 50% reduction in headache frequency: high confidence – amitriptyline with CBT. Low confidence – propranolol. Very low confidence – topiramate, divalproex ER, amitriptyline, onabotulinumtoxinA
	  ○ Decreased migraine-related disability: moderate confidence – amitriptyline with CBT. Low confidence – topiramate. Very low confidence - amitriptyline
	• The 2024 AHS position statement update states that CGRP-targeting migraine therapies are a first-line option for migraine prevention. Initiation of these therapies should not require trial and failure of non-specific migraine preventive medication approaches. According to the AHS, the evidence for the efficacy, tolerability, and safety of CGRP-targeting migraine preventive therapies (erenumab, fremanezumab, galcanezumab, eptinezumab, Rimegepant, and atogepant) is substantial, and exceeds that for any other preventive treatment approach. Evidence for CGRP-targeting treatments is corroborated by extensive real-world clinical experience. The data indicates that the efficacy and tolerability of CGRP-targeting therapies are equal to or greater than those of previous first-line therapies, with fewer serious adverse events.
	• The 2021 AHS consensus statement update on integrating new migraine treatments into clinical practice state criteria for initiating acute treatment with -

gepants or -ditans include contraindication or inability to tolerate triptans or inadequate response to two or more oral triptans. This consensus statement also states that clinical benefits of injectable CGRP mAbs should be assessed after at least 3 months for monthly treatments and at least 6 months for quarterly treatments.

- Lifestyle factors can provoke migraines. This includes poor sleep patterns and trigger foods and drinks such as caffeine, alcohol, chocolate, and processed foods. Medication rebound or overutilization can also provoke migraines. This includes taking the following:
  - Butalbital more than once weekly
  - Opioids more than 8 days per month
  - Triptans, ergot alkaloids, combination analgesics for 10 days or more per month
  - Simple analgesics for 15 days or more per month

Cluster Headache

- Cluster headache (CH) is the most common type of trigeminal autonomic cephalgia but only occurs in approximately 0.1% of the population. It is one of the most severe headache disorders due to extreme pain, high frequency of attack, and associated autonomic symptoms (e.g. lacrimation, nasal congestion, eyelid edema, etc.).
- Cluster headaches can be acutely managed with subcutaneous sumatriptan, zolmitriptan nasal spray, and oxygen; however, there are limited options available to reduce overall attack frequency. The American Headache Society only gives suboccipital steroid injection a Level A (established as effective) rating for prophylaxis. Other possibly effective agents include lithium, verapamil, and melatonin.
- Episodic cluster headaches are characterized by at least two cluster periods lasting from seven days to one year (when left untreated) but separated by pain-free remission periods of three months or more. CH is considered chronic if there are no remission periods or if remission lasts less than three months.

CGRP Inhibitors

- Calcitonin Gene-Related Peptide (CGRP) is a molecule that is synthesized in neurons, which has been implicated in different pain processes, including migraine, and functions as a vasodilator. Targeted therapy with CGRP inhibitors have demonstrated efficacy in reducing monthly migraine days.
- There are limited data to support the use of CGRP inhibitors for acute migraine in combination with CGRP inhibitors for prevention of migraine. Limited data (Berman et al., Mullin et al., and Jakate et al.) include a case report, a phase 1b pharmacokinetic study and a study with small sample size (n=13). Due to this limited body of evidence, caution is warranted. All clinical trials for CGRPs inhibitors excluded patients who were concomitantly on another CGRP inhibitor.
- Prescribing Considerations:
  - Adequate therapeutic trials of preventive therapies typically require two to six months of treatment.
  - CGRPs have warnings and precautions for hypersensitivity reactions, constipations with serious complications, hypertension, and Raynaud's phenomenon.
  - Unless otherwise noted within this policy, quantity limits for CGRP inhibitors should be reviewed using policies J-0646 or J-0645.

Approval Criteria

I. Aimovig, Qulipta

A. Initial Authorization

When a benefit, coverage of Aimovig or Qulipta may be approved when all the following criteria are met **(1. through 4.)**:

1. The member is 18 years of age and older.
2. The member has a diagnosis of migraine (ICD-10: G43), classified as one (1) of the following **(a. or b.)**:
   - **a.** Episodic migraine defined as 4 to 14 headache days per month
   - **b.** Chronic migraine defined as 15 or more headache days per month of which 8 or more are migraine days
3. The prescriber attests to all of the following **(a., b., and c.)**:
   - **a.** Baseline average monthly migraine days
   - **b.** The headaches are not caused by medication rebound or overutilization or due to lifestyle factors
   - **c.** The member has experienced therapeutic failure or intolerance to one (1) agent from two (2) different plan-preferred prophylactic migraine medication classes or all are contraindicated **(i. through vii.)**:
     - **i.** Alpha-agonists
     - **ii.** Angiotensin-converting-enzyme inhibitors or angiotensin II receptor blockers
     - **iii.** Anti-epileptic drugs
     - **iv.** Beta-blockers
     - **v.** Calcium Channel Blockers
     - **vi.** Serotonin-norepinephrine reuptake inhibitors
     - **vii.** Tricyclic antidepressants
4. If the treatment plan is to use two chemically distinct CGRP inhibitors in combination for preventive and acute use, the prescriber attests that the benefits of therapy outweigh the risks of concurrent use of both medications.

B. Reauthorization

When a benefit, reauthorization of Aimovig or Qulipta may be approved when all of the following criteria are met **(1. and 2.)**:

1. The prescriber attests that the member has experienced a reduction in one (1) of the following **(a., b., or c.)**:
   - **a.** Reduction in the number of migraine days per month by at least 50% from baseline
   - **b.** Episodic migraines: a reduction in migraine days per month by at least 4 days from baseline
   - **c.** Chronic migraines: a reduction in migraine days per month by at least 5 days from baseline
2. Subsequent reauthorizations are subject to sustained improvements noted above.

II. Ajovy

A. Initial Authorization

When a benefit, coverage of Ajovy may be approved when all the following criteria are met **(1., 2., and 3.)**:

1. The member meets one (1) of the following criteria **(a. or b.):**
   - **a.** The member is 18 years of age and older and has a diagnosis of migraine (ICD-10: G43), classified as one (1) of the following **(i. or ii.)**:
     - **i.** Episodic migraine defined as 4 to 14 headache days per month
     - **ii.** Chronic migraine defined as 15 or more headache days per month of which 8 or more are migraine days
   - **b.** The member is 6 to 17 years of age and meets all of the following criteria **(i. and ii.):**
     - **i.** The member has a diagnosis of migraine (ICD-10: G43), classified as episodic migraine defined as 4 to 14 headache days per month
     - **ii.** The member weighs ≥ 45 kg.
2. The prescriber attests to all of the following **(a., b., and c.)**:
   - **a.** Baseline average monthly migraine days

b. The headaches are not caused by medication rebound or overutilization or due to lifestyle factors
c. The member has experienced therapeutic failure or intolerance to one (1) agent from two (2) different plan-preferred prophylactic migraine medication classes or all are contraindicated **(i. through vii.)**:
i. Alpha-agonists
ii. Angiotensin-converting-enzyme inhibitors or angiotensin II receptor blockers
iii. Anti-epileptic drugs
iv. Beta-blockers
v. Calcium Channel Blockers
vi. Serotonin-norepinephrine reuptake inhibitors
vii. Tricyclic antidepressants

3. If the treatment plan is to use two chemically distinct CGRP inhibitors in combination for preventive and acute use, the prescriber attests that the benefits of therapy outweigh the risks of concurrent use of both medications.

B. Reauthorization
When a benefit, reauthorization of Ajovy may be approved when all of the following criteria are met **(1. and 2.)**:
1. The prescriber attests that the member has experienced a reduction in one (1) of the following **(a., b., or c.):**
a. Reduction in the number of migraine days per month by at least 50% from baseline
b. Episodic migraines: a reduction in migraine days per month by at least 4 days from baseline
c. Chronic migraines: a reduction in migraine days per month by at least 5 days from baseline
2. Subsequent reauthorizations are subject to sustained improvements noted above.

III. Emgality

A. Initial Authorization for Migraine Prevention
When a benefit, coverage of Emgality may be approved when all the following criteria are met **(1. through 4.)**:
1. The member is 18 years of age and older.
2. The member has a diagnosis of migraine (ICD-10: G43), classified as one (1) of the following **(a. or b.):**
a. Episodic migraine defined as 4 to 14 headache days per month
b. Chronic migraine defined as 15 or more headache days per month of which 8 or more are migraine days
3. The prescriber attests to all of the following **(a., b., and c.):**
a. Baseline average monthly migraine days
b. The headaches are not caused by medication rebound or overutilization or due to lifestyle factors
c. The member has experienced therapeutic failure or intolerance to one (1) agent from two (2) different plan-preferred prophylactic migraine medication classes or all are contraindicated **(i. through vii.):**
i. Alpha-agonists
ii. Angiotensin-converting-enzyme inhibitors or angiotensin II receptor blockers
iii. Anti-epileptic drugs
iv. Beta-blockers
v. Calcium Channel Blockers
vi. Serotonin-norepinephrine reuptake inhibitors
vii. Tricyclic antidepressants

4. If the treatment plan is to use two chemically distinct CGRP inhibitors in combination for preventive and acute use, the prescriber attests that the benefits of therapy outweigh the risks of concurrent use of both medications.

B. Reauthorization for Migraine Prevention

When a benefit, reauthorization of Emgality may be approved when all of the following criteria are met **(1. and 2.):**

1. The prescriber attests that the member has experienced a reduction in one (1) of the following **(a., b., or c.):**
   - **a.** Reduction in the number of migraine days per month by at least 50% from baseline
   - **b.** Episodic migraines: a reduction in migraine days per month by at least 4 days from baseline
   - **c.** Chronic migraines: a reduction in migraine days per month by at least 5 days from baseline
2. Subsequent reauthorizations are subject to sustained improvements noted above.

C. Quantity Limit for Migraine Prevention

1. When a benefit, Emgality will require a patient level authorization (PLA) to allow for a loading dose of 240 mg prior to initiation of therapy.

D. Initial Authorization for Cluster Headache

When a benefit, coverage of Emgality may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of episodic cluster headache (ICD-10: G44.01) characterized by severe or very severe unilateral orbital, supraorbital, and/or temporal pain, lasting 15 to 180 minutes when left untreated.
3. The member is experiencing attack frequency of at least one attack every other day during a cluster period.

E. Reauthorization for Cluster Headache

When a benefit, reauthorization of Emgality may be approved when all of the following criteria are met **(1. and 2.)**:

1. The prescriber attests that the member has experienced a reduction in the number of mean weekly cluster headaches from baseline.
2. Subsequent reauthorizations are subject to sustained improvements noted above.

IV. Nurtec ODT

A. Initial Authorization for Migraine Prevention

When a benefit, coverage of Nurtec ODT may be approved when all of the following criteria are met **(1. through 4.):**

1. The member is 18 years of age or older.
2. The member has a diagnosis of migraine (ICD-10: G43), classified as episodic migraine defined as 4 to 14 headache days per month.
3. The prescriber attests to all of the following **(a., b., and c.)**:
   - **a.** Baseline average monthly migraine days
   - **b.** The headaches are not caused by medication rebound or overutilization or due to lifestyle factors
   - **c.** The member has experienced therapeutic failure or intolerance to one (1) agent from two (2) different plan-preferred prophylactic migraine medication classes or all are contraindicated **(i. through vii.)**:
     - **i.** Alpha-agonists
     - **ii.** Angiotensin-converting-enzyme inhibitors or angiotensin II receptor blockers
     - **iii.** Anti-epileptic drugs

iv. Beta-blockers
v. Calcium Channel Blockers
vi. Serotonin-norepinephrine reuptake inhibitors
vii. Tricyclic antidepressants

4. If the treatment plan is to use two chemically distinct CGRP inhibitors in combination for preventive and acute use, the prescriber attests that the benefits of therapy outweigh the risks of concurrent use of both medications.

B. Reauthorization for Migraine Prevention

When a benefit, reauthorization of Nurtec ODT may be approved when all of the following criteria are met **(1. and 2.)**:

1. The prescriber attests that the member has experienced a reduction in one (1) of the following **(a. or b.)**:
   a. Reduction in the number of migraine days per month by at least 50% from baseline
   b. A reduction in migraine days per month by at least 4 days from baseline
2. Subsequent reauthorizations are subject to sustained improvements noted above.

C. Initial Authorization for Acute Treatment of Migraine

When a benefit, coverage of Nurtec ODT may be approved when all of the following criteria are met **(1. through 4.):**

1. The member is 18 years of age or older.
2. The member has a diagnosis of migraine (ICD-10: G43), classified as acute migraine headaches with or without aura.
3. The member has experienced therapeutic failure, contraindication, or intolerance to two (2) of the following products **(a., b., or c.):**
   a. generic oral sumatriptan
   b. generic oral rizatriptan
   c. generic oral zolmitriptan
4. If the treatment plan is to use two chemically distinct CGRP inhibitors in combination for preventive and acute use, the prescriber attests that the benefits of therapy outweigh the risks of concurrent use of both medications.

D. Reauthorization For Acute Treatment of Migraine

When a benefit, reauthorization of Nurtec ODT may be approved when the following criterion is met **(1.):**

1. The prescriber attests that the member has experienced positive clinical response to therapy.

V. Ubrelvy

A. Initial Authorization

When a benefit, coverage of Ubrelvy may be approved when all of the following criteria are met **(1. through 4.):**

1. The member is 18 years of age or older.
2. The member has a diagnosis of migraine (ICD-10: G43), classified as acute migraine headaches with or without aura.
3. The member has experienced therapeutic failure, contraindication, or intolerance to two (2) of the following products **(a., b., or c.):**
   a. generic oral sumatriptan
   b. generic oral rizatriptan
   c. generic oral zolmitriptan
4. If the treatment plan is to use two chemically distinct CGRP inhibitors in combination for preventive and acute use, the prescriber attests that the benefits of therapy outweigh the risks of concurrent use of both medications.

B. Reauthorization

When a benefit, reauthorization of Ubrelvy may be approved when the following criterion is met **(1.):**

1. The prescriber attests that the member has experienced positive clinical response to therapy.

C. Quantity Limits

When a benefit**,** additional quantities of Ubrelvy 50 mg (up to a total of 32 tablets per 25 days or 96 tablets per 75 days) may be approved when one (1) of the following criteria are met **(1. or 2.):**

1. The member has experienced therapeutic failure or intolerance to lower quantities of Ubrelvy 100 mg to achieve the same dose.
2. The prescriber documents clinical rationale that dose optimization is not appropriate for the member.

VI. Zavzpret

A. Initial Authorization

When a benefit, coverage of Zavzpret may be approved when all of the following criteria are met **(1. through 4.):**

1. The member is 18 years of age or older.
2. The member has a diagnosis of migraine (ICD-10: G43), classified as acute migraine headaches with or without aura.
3. The member meets one (1) of the following criteria **(a. or b.):**
   - **a.** The member has experienced therapeutic failure, contraindication, or intolerance to two (2) of the following products **(i., ii., or iii.):**
     - **i.** generic oral sumatriptan
     - **ii.** generic oral rizatriptan
     - **iii.** generic oral zolmitriptan
   - **b.** The member meets all of the following criteria **(i. and ii.):**
     - **i.** The prescriber attests that the member experiences significant nausea and vomiting and requires a non-oral route of administration.
     - **ii.** The member has experienced therapeutic failure, contraindication, or intolerance to generic sumatriptan nasal spray.
4. If the treatment plan is to use two chemically distinct CGRP inhibitors in combination for preventive and acute use, the prescriber attests that the benefits of therapy outweigh the risks of concurrent use of both medications.

B. Reauthorization

When a benefit, reauthorization of Zavzpret may be approved when the following criterion is met **(1.):**

1. The prescriber attests that the member has experienced positive clinical response to therapy.

VII. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.
  - *For Delaware Commercial fully-insured and ACA members, a 12 month authorization must be granted pursuant to 18 Del. C. §§3376(a) and 3586(a) and market conduct examination docket #546 (Exam Authority #53287-22-701).*

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

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7. Zavzpret [package insert]. New York, NY: Pfizer; August 2025.
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16. Ailani J, Burch R, Robbins M, et al. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61:1021–1039.
17. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of

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