**Original Effective Date: 01/01/2019**
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**Policy Number: C15443-C**

# Calcitonin Gene-Related Peptide (CGRP) Antagonist

## PRODUCTS AFFECTED

Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Emgality (galcanezumab-gnlm), Vyepti (eptinezumab), Ubrelvy (ubrogepant), Nurtec ODT (rimegepant), Qulipta (atogepant)

## COVERAGE POLICY

*Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.*
*This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.*

***Documentation Requirements:***
*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

**DIAGNOSIS:**
Episodic or chronic migraine, Cluster headaches

**REQUIRED MEDICAL INFORMATION:**
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. EPISODIC MIGRAINE PREVENTION (AIMOVIG, AJOVY, EMGALITY, NURTEC, QULIPTA AND VYEPTI ONLY):
1. Documented diagnosis of episodic migraine disorder
AND

2. Documentation of baseline number of monthly migraine days (MMD)
   AND
3. Documentation of trial and ineffectiveness/failure after 2 months or serious side effects or contraindication to THREE of the following therapeutic classes: beta blockers (propranolol, timolol, atenolol, metoprolol, nadolol), antiepileptics (divalproex sodium, topiramate), antidepressants (amitriptyline, nortriptyline, venlafaxine, duloxetine), antihypertensive (verapamil, lisinopril, candesartan)
   AND
4. Prescriber attests that requested product is not prescribed concurrently with other CGRP inhibitors (e.g., Aimovig, Ajovy, Vyepti) or botulinum toxin products. Reviewer Note: Dual therapy may be considered if the member is refractory to at least two preventative treatments and has experience a partial response to Botox.
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review
   a. [Contraindications to AIMOVIG® (erenumab-aooe) include: patients with serious hypersensitivity to erenumab-aooe or to any of the excipients,
   b. Contraindications to EMGALITY (galcanezumab-gnlm) include: patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients,
   c. Contraindications to AJOVY TM (fremanezumab-vfrm) include: patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients,
   d. Contraindications to Vyepti (eptinezumab-jjmr) include patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients,
   e. Contraindications to Nurtec (Rimegepant) include: Patients with a history of hypersensitivity reaction to rimegepant, NURTEC ODT, or to any of its components]
   AND
6. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of a trial (3 months) and failure of the preferred formulary/PDL CGRP inhibitors with this labeled indication. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

B. CHRONIC MIGRAINE PREVENTION (AIMOVIG, AJOVY, EMGALITY AND VYEPTI ONLY):
1. Documentation of diagnosis of chronic tension-type and/or migraine headaches
   AND
2. Documentation of baseline number of monthly migraine days (MMD)
   AND
3. Documentation of trial and ineffectiveness/failure after 2 months or serious side effects or contraindication to THREE of the following therapeutic classes: beta blockers (propranolol, timolol, atenolol, metoprolol, nadolol), antiepileptics (divalproex sodium, topiramate), antidepressants (amitriptyline, nortriptyline, venlafaxine, duloxetine), antihypertensive (verapamil, lisinopril, candesartan)
   AND
4. Prescriber attests that requested product is not prescribed concurrently with other injectable CGRP inhibitors (e.g., Aimovig, Ajovy, Vyepti) or botulinum toxin products. Reviewer Note: Dual therapy may be considered if the member is refractory to at least two preventative treatments and has experienced a partial response to Botox.
   AND
5. FOR AIMOVIG AND VYEPTI ONLY: Documentation of a trial (3 months) and failure of preferred CGRP inhibitors Ajovy (fremanezumab-vfrm) AND Emgality (galcanezumab-gnlm)
   AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the

documentation submitted for review

- [Contraindications to AIMOVIG® (erenumab-aooe) include: patients with serious hypersensitivity to erenumab-aooe or to any of the excipients,
- Contraindications to EMGALITY (galcanezumab-gnlm) include: patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients,
- Contraindications to AJOVYTM (fremanezumab-vfrm) include: patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients,
- Contraindications to Vyepti (eptinezumab-jjmr) include patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients]

C. ACUTE TREATMENT OF MIGRAINE (UBRELVY AND NURTEC ODT ONLY):
1. Documentation member has a diagnosis of migraine, with or without aura
AND
2. Prescriber attests that medication overuse as a possible cause of migraine has been ruled out
AND
3. Prescriber attests that member's migraine severity is classified as moderate to severe
AND
4. (a) Documentation of trial (30 days) and inadequate response or intolerance to TWO formulary triptan agents up to maximally tolerated doses
OR
(b) Individual has one of the following cardiovascular or non-coronary vascular contraindications to use of triptans: Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina); OR history of stroke or transient ischemic attack (TIA); OR Peripheral vascular disease; OR Ischemic bowel disease; OR Uncontrolled hypertension.
AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Nurtec (Rimegepant) include: Patients with a history of hypersensitivity reaction to rimegepant, NURTEC ODT, or to any of its components, Contraindications to Ubrelvy (ubrogepant) include: Concomitant use with strong CYP3A4 inhibitors (i.e., ketoconazole, itraconazole, clarithromycin), patients with a history of serious hypersensitivity to ubrogepant or any component of Ubrelvy]
AND
6. FOR NURTEC ODT ONLY: Documentation of a trial (3 months) and failure of Ubrelvy

D. TREATMENT OF EPISODIC CLUSTER HEADACHE (EMGALITY ONLY):
1. Documented diagnosis of episodic cluster headache
*NOTE: Cluster periods usually last between 2 weeks and 3 months*
AND
2. Documentation of trial (3 weeks) and failure of the following: verapamil at a dose of 240-480 mg per day, unless contraindicated or clinically significant adverse effects were experienced[34]
AND
3. Prescriber attests that requested product is not prescribed concurrently with other injectable CGRP inhibitors (e.g., Aimovig, Ajovy, Vyepti) or botulinum toxin
AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to EMGALITY (galcanezumab-gnlm) include: patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients]

**CONTINUATION OF THERAPY:**

A. FOR EPISODIC OR CHRONIC MIGRAINE PREVENTION:

1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Response to therapy as defined by 50% reduction in monthly migraine days (MMD) [Molina Reviewer: Compare baseline to follow-up MMD to determine if at least a 50% reduction attained]

B. ACUTE TREATMENT OF MIGRAINE:

1. Documentation that member has experienced clinical improvement as defined by ONE of the following: Ability to function normally within 2 hours of dose OR Headache pain disappears within 2 hours of dose OR Therapy works consistently in majority of migraine attacks
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

C. CLUSTER HEADACHE (EMGALITY ONLY):

1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)
   AND
2. Documentation that member has experienced clinical improvement as defined by reduction in cluster headache attack frequency
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
4. Prescriber attests that member's cluster period is lasting longer that 3 months and has reviewed for continued medical necessity OR documentation member has had pain-free remission periods of three months since member last received Emgality therapy

**DURATION OF APPROVAL:**

CLUSTER HEADACHE: Initial authorization: up to 3 months or until the length of typical cluster period for member, Continuation of therapy: 3 months
ALL OTHER INDICATIONS: Initial authorization: 3 months, Continuation of therapy: 12 months

**PRESCRIBER REQUIREMENTS:**

Prescribed by or in consultation with a board-certified neurologist or migraine headache specialist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

**AGE RESTRICTIONS:**

18 years of age and older

**QUANTITY:**

Aimovig: 70 mg or 140 mg injected SC once monthly. Maximum one autoinjector/prefilled syringe per 30 days.

Ajovy: 225mg (1) per 28 days OR 675mg (3) per 90 days

Emgality:
FOR MIGRAINE: Loading dose: 240mg (two-120mg injections), Maintenance dose: 120mg (one-120mg injection) once monthly
FOR CLUSTER HEADACHE: 300mg (three- 100mg injections) once monthly at onset of cluster period then monthly until the end of the cluster period

Vyepti: 100mg IV every 3 months; some patients may benefit from a dosage of 300mg [NOTE: Criteria for higher dosing must be met]
****FOR VYEPTI ONLY: FOR REQUEST FOR INCREASED DOSING****

1. Documentation that lower dosing has been tried for at least one treatment (30 days) and clinical response has not been optimal as defined by 50% reduction in monthly migraine days (MMD). DOCUMENTATION REQUIRED of follow-up MMD. [Molina Reviewer: Compare baseline MMD versus follow-up MMD]
   AND
2. Clinical rationale and documentation supporting therapy with a higher dose, including ALL the following: Response to therapy as defined by 50% reduction in monthly migraine days has not been attained, however positive response has been documented by at least TWO (2) of the following: Severity of headaches and migraines, Reduction in acute pharmacological medication, or reduction in monthly acute migraine-specific medication treatment days,
   AND
3. Member has not experienced ANY of the following: Intolerable adverse effects or unacceptable toxicity from the drug, poor response to treatment as evidenced by physical findings and/or clinical symptoms

Nurtec ODT for acute treatment: 8 tablets per 30 days

Nurtec ODT for prophylaxis: 16 tablets for 30 days

Ubrelvy: up to 200mg within 24 hours, limit of 10 tablets of either strength per 30 days
***For approval of up to a maximum of 16 tabs per 30 days of any one strength of Ubrelvy [the safety of treating more than 15 migraines in a 30-day period has not been established] the member must meet the following criteria:

1. Member has had a previous trial (minimum of 60 days) and an inadequate response (i.e. no change in headache days, no change in severity or duration of migraines) to one of the following formulary daily preventive therapies (AAN/AHA 2012/2015, ICSI 2013): (i) A tricyclic antidepressant [such as but not limited to amitriptyline, doxepin]; OR (ii) A beta blocker [such as but not limited to metoprolol tartrate, propranolol, timolol, atenolol, nadolol, nebivolol]; OR (ii) A calcium channel blocker [such as but not limited to nicardipine, verapamil]; OR (iv) an ACE inhibitor [such as but not limited to lisinopril];OR (v) an angiotensin receptor blocker (ARBs) [such as but not limited to candesartan]; OR (vi) an alpha-2 agonist [such as but not limited to guanfacine]; OR (vii) an antiepileptic [such as but not limited to divalproex sodium, sodium valproate, topiramate, carbamazepine, gabapentin]; OR (viii) Other select antidepressants [such as but not limited to venlafaxine]; OR (ix) Cyproheptadine (Periactin)
   AND
2. Documentation of adherence to prophylactic therapies tried

Qulipta: 10mg OR 30mg OR 60mg tablets once daily – maximum of 30 tablets of any one strength per 30 days

**PLACE OF ADMINISTRATION:**
Ubrelvy (ubrogepant), Nurtec ODT (rimegepant), Qulipta (atogepant)

Drug and Biologic Coverage Criteria

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Emgality (galcanezumab-gnlm)
The recommendation is that subcutaneous injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

Vyepti (eptinezumab)
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

**Note:** Site of Care Utilization Management Policy applies for Vyepti (eptinezumab-jjmr). For information on site of care, see

Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

## DRUG INFORMATION

**ROUTE OF ADMINISTRATION:**
Oral, Subcutaneous, Intravenous

**DRUG CLASS:**
Calcitonin Gene-Related Peptide (CGRP) antagonist, CGRP Receptor Antagonists – Monoclonal Antibodies

**FDA-APPROVED USES:**
Aimovig (erenumab-aooe) Ajovy (fremanezumab-vfrm), and Vyepti (eptinezumab): Indicated for the preventive treatment of migraine in adults

Emgality (galcanezumab-gnlm): indicated in adults for the preventive treatment of migraine and treatment of episodic cluster headache

Ubrelvy (ubrogepant): Indicated for the acute treatment of migraine with or without aura in adults.
*Limitations of use: Not indicated for preventive treatment of migraine*

Nurtec ODT (rimegepant): indicated for the: acute treatment of migraine with or without aura in adults and preventive treatment of episodic migraine in adults

Qulipta (atogepant): indicated for the preventive treatment of episodic migraine in adults

**COMPENDIAL APPROVED OFF-LABELED USES:**
None

## APPENDIX

**APPENDIX:**

## 1.2 Migraine with aura

**Previously used terms:**

Classic or classical migraine: ophthalmic, hemiparaesthetic. hemiplegic or aphasic migraine: migraine accompagnee: complicated migraine.

**Description:**

Recurrent attacks, lasting minutes, of unilateral fully-reversible visual, sensory or other central nervous system symptoms that usually develop gradually and are usually followed by headache and associated migraine symptoms.

**Diagnostic criteria:**

A. At least two attacks fulfilling criteria B and C
B. One or more of the following fully reversible aura symptoms:

1. visual
2. sensory
3. speech and/or language
4. motor
5. brainstem
6. retinal

C. At least three of the following six characteristics:

1. at least one aura symptom spreads gradually over ≥ 5 minutes
2. two or more aura symptoms occur in succession
3. each individual aura symptom lasts 5-60 minutes[1]
4. at least one aura symptom is unilateral[2]
5. at least one aura symptom is positive[3]
6. the aura is accompanied, or followed within 60 minutes, by headache

D. Not better accounted for by another ICHD-3 diagnosis.

**Appendix 1: International Headache Society Criteria for Migraine Diagnosis (It HD-3)**

| Migraine without aura | Migraine without aura |
|---|---|
| A. At least five attacks fulfilling criteria B-D<br>B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)<br><br>C. Headache has at least two of the following four characteristics:<br>1. unilateral location<br>2. pulsating quality<br>3. moderate or severe pain intensity<br>4. aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)<br>D. During headache at least one of the following:<br>1. nausea and/or vomiting<br>2. photophobia and phonophobia<br><br>Not better accounted for by another 1CHD-3 diagnosis. | A. At least two attacks fulfilling criteria B and C<br>B. One or more of the following fully reversible aura symptoms:<br>1. visual<br>2. sensory<br>3. speech and/or language<br>4. motor<br>5. brainstem<br>6. retinal<br>C. At least three of the following six characteristics:<br>1. at least one aura symptom spreads gradually over ≥5 minutes<br>2. two or more aura symptoms occur in succession<br>3. each individual aura symptom lasts 5-60 minutes<br>4. at least one aura symptom is unilateral<br>5. at least one aura symptom is positive<br>6. the aura is accompanied, or followed within 60 minutes, by headache<br><br>D. Not better accounted for by another ICHD-3 diagnosis |

## BACKGROUND AND OTHER CONSIDERATIONS

Types of Migraine
• Episodic migraine (EM) is characterized by 0 to 14 headache-days per month; represents 90% of migraineurs.
• Chronic migraine (CM) is characterized by 15 or more headache-days per month; represents 10% of migraineurs.
• Cluster headaches (CH) are recurrent, severe headaches on one side of the head, typically around the eye. The duration of a typical CH attack ranges from about 15 to 180 minutes. Most untreated attacks (about 75%) last less than 60 minutes. Attacks occur every day for weeks, or even months, then disappear for up to a year. Approximately 80% of cluster patients are male, most between the ages of 20 and 50 years. A rare form of migraine, CH affects 0.1% of adults, with 80% of CH patients in the episodic category, and only 20% in the chronic category. Nurtec is not approved for cluster headaches.

Ubrelvy is the first approved oral calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine with or without aura in adults. Unlike the large molecule injectable CGRPs approved for the prevention of migraines, Ubrelvy is a small molecule CGRP antagonist that passes through the blood brain barrier to stop a migraine in progress.
Ubrelvy also does not have the cardiovascular concerns associated with other usual acute migraine treatments such as triptans.

The efficacy of Ubrelvy for the acute treatment of migraine was demonstrated in two Phase 3 randomized, double-blind, placebo-controlled trials, Study 1 (ACHIEVE I/NCT02828020) and Study 2 (ACHIEVE II/NCT02867709). Study 1 randomized patients to placebo (n=559) or Ubrelvy 50 mg (n=556) or 100 mg (n=557), and Study 2 randomized patients to placebo (n=563) or Ubrelvy 50 mg

(n=562). In all studies, patients were instructed to treat a migraine with moderate to severe headache pain intensity. A second dose of study medication (Ubrelvy or placebo), or the patient's usual acute treatment for migraine, was allowed between 2 and 48 hours after the initial treatment for a non- responding or recurrent migraine headache. Up to 23% of patients were taking preventive medications for migraine at baseline. None of these patients was on concomitant preventive medication that acts on the CGRP pathway. The primary efficacy analyses were conducted in patients who treated a migraine with moderate to severe pain. The efficacy of Ubrelvy in Studies 1 and 2 was established by measurement compared to placebo:

• Effect on pain freedom at 2 hours post-dose

• Freedom from most bothersome symptom (MBS) at 2 hours post-dose

Pain freedom was defined as a reduction of moderate or severe headache pain to no pain, and MBS freedom was defined as the absence of the self-identified MBS (i.e. photophobia, phonophobia, or nausea). In both studies, the percentage of patients achieving headache pain freedom and MBS freedom 2 hours post- dose was significantly greater among patients receiving Ubrelvy compared to those receiving placebo. In Study 1, the results found nearly twice as many patients were pain-free in the high-dosage treatment group after 2 hours as in the placebo group: 21.2% compared with 11.8%. The low-dose 50 mg group results in both studies were lower, but not far behind the high-dose 100mg results

**Efficacy Endpoints for Ubrelvy in Studies 1 and 2**

| | Study 1 | | | Study 2 | |
|---|---|---|---|---|---|
| | UBRELVY 50 mg | UBRELVY 100 mg | Placebo | UBRELVY 50 mg | Placebo |
| **Pain Free at 2 hours** | | | | | |
| N | 422 | 448 | 456 | 464 | 456 |
| % Responders | 19.2 | 21.2 | 11.8 | 21.8 | 14.3 |
| Difference ficim placebo (%) | 7.4 | 9.4 | | 7.5 | |
| p value | 0.002 | <0.001 | | 0.007 | |
| **Most Bothersome Symptom Free at *2* hours** | | | | | |
| N | 420 | 448 | 454 | 463 | 456 |
| % Responders | 38.6 | 37.7 | 27.8 | 38.9 | 27.4 |
| Difference from placebo (%) | 10.8 | 9.9 | | 11.5 | |
| p value | <0.001 | <0.001 | | <0.001 | |
| **Pain Relief at 2 hours** | | | | | |
| N | 422 | 448 | 456 | 464 | 456 |
| % Responders | 60.7 | 61.4 | 49.1 | 62.7 | 48.2 |
| p value | <0.001 | <0.001 | | <0.001 | |
| **Sustained Pain Freedom 2-24 hours** | | | | | |
| N | 418 | 441 | 452 | 457 | 451 |
| % Responders | 12.7 | 15.4 | 8.6 | 14.4 | 8.2 |
| p value | *NS | 0.002 | | 0.005 | |

*Not statistically significant (NS)

## CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of (CGRP) Antagonists are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Aimovig (erenumab-aooe) include: patients with serious hypersensitivity to erenumab-aooe or to any of the excipients. Contraindications to Emgality (galcanezumab-gnlm) include: patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients. Contraindications to Ajovy (fremanezumab-vfrm) include: patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients. Contraindications to Vyepti (eptinezumab-jjmr) include patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients. Contraindications to Nurtec (Rimegepant) include: Patients with a history of hypersensitivity reaction to rimegepant, Nurtec ODT, or to any of its components. Contraindications to Ubrelvy (ubrogepant) include: Concomitant use with strong CYP3A4 inhibitors (i.e., ketoconazole, itraconazole, clarithromycin), patients with a history of serious hypersensitivity to ubrogepant or any component of Ubrelvy. Contraindications to Qulipta (atogepant) include: No labeled contraindications.

## OTHER SPECIAL CONSIDERATIONS:

Amgen has updated manufacturing changes related to needle shields and caps. The needle shield within the white or orange cap of the AIMOVIG® prefilled SureClick autoinjector and gray needle cap of the AIMOVIG prefilled syringe contain dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex. The most recent labeling state that the AIMOVIG prefilled autoinjectors and prefilled syringes are not made with natural rubber latex.

## CODING/BILLING INFORMATION

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

| HCPCS CODE | DESCRIPTION |
|---|---|
| J3032 | Injection, eptinezumab-jjmr, 1 mg |

**AVAILABLE DOSAGE FORMS**:
Aimovig SureClick 70mg/mL Autoinjector Solution for Injection ,1 pre-filled syringe autoinjector, (box)
Aimovig 140mg/mL Autoinjector 1 pre-filled syringe autoinjector, (box)
Ajovy syringe 225mg/1.5ml Autoinjector and prefilled syringe
Emgality 120mg/ml PFS and PEN
Emgality 100mg/ml (300mg dose) 3 injectors/box
Vyepti 100mg/ml per vial
Ubrelvy 50mg (box of 10)
Ubrelvy 100mg (box of 10)
Nurtec 75mg tabs (box of 8 tabs)
Qulipta 10mg, 30mg, 60mg (30 count bottles)

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4. Emgality (galcanezumab-gnlm) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; March 2021
5. Vyepti (eptinezumab) [prescribing information]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals Inc; October 2022.
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| SUMMARY OF REVIEW/REVISIONS | DATE |
|---|---|
| REVISION- Notable revisions:<br>Required Medical Information<br>Continuation of Therapy<br>Duration of Approval<br>Quantity<br>Contraindications/Exclusions/Discontinuation<br>Other Special Considerations<br>References | Q2 2023 |
| REVISION- Notable revisions:<br>Required Medical Information<br>Continuation of Therapy<br>Quantity | Q2 2022 |
| Q2 2022 Established tracking in new format | Historical changes on file |