Pharmacy Management Drug Policy

SUBJECT: Headache Disorders
POLICY NUMBER: PHARMACY-74
EFFECTIVE DATE: 06/19/2018
LAST REVIEW DATE: 08/14/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

This policy contains the coverage requirements for the treatment of chronic, episodic, and acute headache disorders for the following drug classes: calcitonin gene-related peptide (CGRP) antagonists, gepants (small molecule CGRP antagonists), triptans, ditans, and non-steroidal anti-inflammatory drugs (NSAIDs).

The calcitonin gene-related peptide (CGRP) antagonists are a novel class of medications used for the prevention of migraine headaches. Migraine headaches are thought to be caused by the activation of the trigeminal system. CGRP is a vasodilating neuropeptide that is released upon activation of the trigeminal system and plays a key role in the pathophysiology of migraine headaches. The level of CGRP is increased during the activation of the trigeminal system causing vasodilation, pro-inflammatory effects, and pain signaling which ultimately results in a migraine attack. The circulating level of CGRP results in increased pain, phonophobia, photophobia, and nausea. CGRP inhibitors bind to either the CGRP receptor or ligand thereby preventing receptor stimulation and, ultimately, a migraine attack.

The American Academy of Neurology (AAN) and the American Headache society (AHS) have clinical practice guidelines published regarding the management of patients with migraine headache. The following medications are recommended for the treatment of migraine prevention by both guidelines as these medications have been established as effective treatments: antiepileptic drugs (AEDs): divalproex sodium, sodium valproate, topiramate and beta-blockers: metoprolol, propranolol, timolol. In addition, the AAN guideline recommends botulinum neurotoxin for the treatment of migraine prevention for patients with chronic migraine.

One CGRP antagonist, Emgality 300 mg, has been approved for the treatment of episodic cluster headaches in adult patients. Cluster headaches are considered to be one of the most severe headache disorders due to extreme pain coupled with a high rate of frequency of attacks. The AHS have clinical practice guidelines published regarding the management of patients with cluster headaches. The following medications are recommended for the treatment of cluster headache by the AHS as these medications have been established as effective treatments: suboccipital steroid injections, lithium, and verapamil. The level of evidence for the use of oral steroids (prednisone) is lacking; however, it is still widely used due to the lack of other treatment options.

The acute treatment of migraine with or without aura in adults has added additional treatment options with the approval of Reyvow, a (5-HT) 1F receptor agonist (also known as a ditan), Ubrelvy and Nurtec ODT, small molecule CGRP antagonists (also known as gepants). Reyvow's mechanism of action is similar to triptans; however, because (5-HT) 1F receptors are not found in the smooth muscle cells of the vasculature, it does not have the cardiovascular risks that are associated with triptans. Ubrelvy and Nurtec ODT have the same mechanism of action as the large molecule CGRPs; however, they are faster acting and taken by mouth. The AHS guidelines for the acute treatment of migraine headaches says that treatment with: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan (oral, nasal spray, patch and subcutaneous), zolmitriptan (oral and nasal spray), acetaminophen, ergots, NSAIDS, butorphanol nasal spray and acetaminophen/aspirin/caffeine and sumatriptan/naproxen combination therapies have a Level A recommendation. The AHS emphasize that prescribers should take patient specific factors into consideration, as well as potential side effects of the prescribed drug.

In addition, the guidelines recommend limiting the use of acute therapies to less than 2-3 days per week **OR** 8 days per month. Re-evaluation of the patient's clinical picture (including diagnosis and use of preventative treatments) is recommended if patients are using acute therapies more frequently.

Please note: For migraine treatment medications not contained in this pharmacy management drug policy, please refer to our Clinical Review Prior Authorizations (CRPA) Rx Drug Policy, our Non-Steroidal Anti-Inflammatory Drug Policy, our Low Clinical Impact Drugs Policy, or our Step Therapy Policy.

POLICY:

Aimovig (erenumab-aooe) - Rx benefit; Ajovy (fremanezumab-vfrm) - Rx or Medical benefit; Emgality 120 mg (galcanezumab-gnlm) - Rx benefit
1. The following requirement must be met based on the drug being requested (a or b): a. For Aimovig or Emgality, must be 18 years or older **OR** b. For Ajovy, one of the following must be met (i or ii) i. Must be 18 years or older **OR** ii. Must be 6-17 years of age and weigh 45 kg or more **AND** 2. The prescriber must attest that one of the following are met (a or b): a. For adult patients (18 years or older), the medication is being used for migraine headache prevention for a diagnosis of either episodic or chronic migraine headache **OR** b. For pediatric patients 6-17 years requesting Ajovy, the medication is being used for migraine headache prevention for episodic migraine headache **AND** 3. The prescriber must attest that the patient experiences 4 or more migraine headache days per month **AND** 4. <u>The following only applies to adult patients (18 years or older):</u> a. The prescriber must attest that the patient has had serious side effects or drug failure to at least 3 months of **TWO** different medications from **TWO** different medication classes that are used for the prevention of migraine headaches (including, but not limited to tricyclic antidepressants, beta blockers, anticonvulsants, or Botox). If the patient is unable to tolerate a medication, a 3-month trial of that medication is not required 5. Initial approval will be for 1 year a. Recertification after the initial 1-year approval will require prescriber attestation of a clinical response to treatment. A clinical response to treatment is defined as a decrease in the number of migraine headache days experienced each month. If the recertification requirements are met, the request will be approved for 1 year. b. Yearly recertification thereafter will require prescriber attestation that the patient has maintained a clinical response to treatment.

6. Approved dosing:
   Aimovig (erenumab-aooe): 70 mg or 140 mg subcutaneously once monthly.
   Ajovy (fremanezumab-vfrm): 225 mg subcutaneously once monthly or 675 mg every three months (quarterly). The 675 mg quarterly dosage is only approved for use in adults and is administered as three consecutive injections of 225 mg each.
   Emgality (galcanezumab-gnlm): A loading dose of 240 mg subcutaneously followed by a 120 mg subcutaneously once monthly. The 240 mg loading dose is administered as two consecutive injections of 120 mg each.
   Maintenance dosing above 120 mg once monthly will be considered not medically necessary as clinical studies do not show any additional clinical benefit when given at doses exceeding this.
7. Administration:
   Aimovig (erenumab-aooe): Self-administered.
   Ajovy (fremanezumab-vfrm): Self-administered or administered by a health care professional.
   a. For administration by a health care professional (coverage under the medical benefit), the patient must have a documented inability to self-inject.
   Emgality (galcanezumab-gnlm): Self-administered.
8. Quantity limit:
   Aimovig (erenumab-aooe):
   a. 70 mg single-dose package is 1 mL per 30 days (1-70 mg prefilled SureClick autoinjector)
   b. 140 mg single-dose package is 1 mL per 30 days (1-140 mg prefilled SureClick autoinjector)
   Ajovy (fremanezumab-vfrm): 1.5 mL per 30 days (1-225 mg prefilled syringe/autoinjector) **OR** 4.5 mL per 90 days (3-225 mg prefilled syringe/autoinjector)
   Emgality (galcanezumab-gnlm): 2 mL (2-120 mg single-dose prefilled pens/syringes) for 30 days for a **1 time loading dose** followed by 1 mL per 30 days (1-120 mg single-dose prefilled pen/syringe) thereafter.

Elyxyb (celecoxib oral solution)

1. Must be 18 years of age or older **AND**
2. Must be prescribed by headache specialist or neurologist **AND**
3. Must be used for acute treatment of migraine **AND**
4. Must have had serious side effects or drug failure of BOTH of the following:
   a. One oral triptan (as acute monotherapy)
   b. One oral triptan in combination with a generic NSAID
5. Failure of treatment with triptans will require documentation that the patient has been evaluated for the possible of triptan-overuse headaches (rebound headache)
6. Quantity limit: 6 bottles (28.8 mL) per 30 days
   a. Requests exceeding this quantity limit will be reviewed using the Quantity Limits (Pharmacy-43) policy.

Ergomar (ergotamine tartrate)

1. Must be 18 years of age or older **AND**
2. Must be prescribed by a headache specialist or neurologist **AND**
3. Must be used to abort or prevent migraine headaches **AND**
4. Must have had serious side effects or drug failure of **ALL** the following:
   a. One oral triptan (as acute monotherapy)
   b. One oral triptan in combination with an NSAID
   c. Ergotamine-caffeine
5. Failure of treatment with triptans will require documentation that the patient has been evaluated for the possibility of triptan-overuse headaches (rebound headache)

Emgality 300 mg (galcanezumab-gnlm) - Rx benefit

1. The patient must be 18 years of age or older **AND**
2. The prescriber must attest that the patient has a documented diagnosis of episodic cluster headache per the International Classification of Headache Disorders (ICHD) diagnostic criteria with cluster periods (at least 2) lasting from seven days to one year (when untreated) and separated by pain-free remission periods of ≥ 3 months **AND**
3. Step Therapy Applies:
    a. The prescriber must attest that the patient has had serious side effects or drug failure of **TWO** *preferred* preventative medications used for episodic cluster headaches (including, but not limited to verapamil, oral steroids, and lithium)
4. Initial approval will be for 1-year
    a. Recertification after the initial 1-year approval will require prescriber attestation of a clinical response to treatment and that the patient is in an active episodic cluster period. A clinical response to treatment is defined as a decrease in the frequency of cluster headache attacks during the most recent episodic cluster period. If the recertification requirements are met, the request will be approved for 1-year
    b. Subsequent 1-year approvals will require prescriber attestation that the patient has maintained a clinical response to treatment (defined above) and that the patient is in an active episodic cluster period.
5. Emgality 300 mg is approved by the Food and Drug Administration (FDA) to be used, once per month, at the onset of an episodic cluster period until the end of the episodic cluster period. Emgality 300 mg is not intended to be used when the patient is **NOT** in an episodic cluster period. According to the clinical definition, episodic cluster periods do not last longer than 1 year and are separated by pain-free remission periods of ≥ 3 months. A cluster period lasting 1 year or longer, without a remission period or with a remission period lasting < 3 months, meets the clinical definition of a chronic cluster headache diagnosis.
    a. Clinical trials of Emgality 300 mg failed to show efficacy in patients with chronic cluster headache and, as a result, Emgality 300 mg did not receive FDA approval for chronic cluster headache; therefore, treatment with Emgality 300 mg for a diagnosis of chronic cluster headache is considered experimental/investigational.
6. Emgality 300 mg will not be approved for patients with a diagnosis of migraine headache.
    a. Please see the Emgality 120 mg policy above for use in migraine headache prevention
        i. Note, per the migraine headache policy for Emgality 120 mg, maintenance dosing of Emgality, for a diagnosis of migraine headache, above 120 mg once monthly will be considered not medically necessary as clinical studies do not show any additional clinical benefit when given at doses exceeding this.
7. Approved dosing:
   Emgality 300 mg (galcanezumab-gnlm): 300 mg subcutaneously at onset for cluster period followed by once monthly injections until the end of the cluster period. Given as three consecutive subcutaneous injections of 100 mg each.
8. Administration:
   Emgality 300 mg (galcanezumab-gnlm): Self-administered.
9. Quantity limit:
   Emgality 300 mg (galcanezumab-gnlm): 3 mL (3-100 mg single-dose prefilled syringes) for 30 days

dihydroergotamine 1 mg/mL ampule, Migranal, dihydroergotamine 4 mg/mL nasal spray– Rx benefit

1. Must be 18 years of age or older **AND**
2. Must be prescribed by a headache specialist or neurologist **AND**
3. Must be used for the acute treatment of migraine headaches **OR** the acute treatment of cluster headache episodes **AND**
4. Must have had serious side effects or drug failure of **ALL** the following:
    a. One oral triptan (as acute monotherapy)
    b. One oral triptan in combination with an NSAID
    c. One parenteral generic sumatriptan product (injectable or nasal spray)
5. Failure of treatment with triptans will require documentation that the patient has been evaluated for the possibility of triptan-overuse headaches (rebound headache)

Nurtec ODT (rimegepant) – Rx benefit

1. The patient must be 18 years of age or older **AND**
2. Must be used for ONE of the following:
    a. The prescriber must attest that the medication is being used for the acute treatment of migraine with or without aura in adults **AND**
        i. The prescriber must attest that the patient has had serious side effect or drug failure of **TWO** different triptans with different active ingredients
            a) Failure of treatment with triptans will require prescriber attestation that the patient has been evaluated for the possibility of triptan-overuse headache (rebound headache).
            b) A trial of treatment with triptans will not be required if contraindicated (i.e., CV risk)
    b. The prescriber must attest that the medication is being used for the preventative treatment of episodic migraine headache **AND**
        i. The prescriber must attest that the patient is experiencing 4 or more migraine headache days per month **AND**
        ii. The prescriber must attest that the patient has had serious side effects or drug failure to at least 3 months of **TWO** different medications from **TWO** different medication classes that are used for the prevention of migraine headaches (including, but not limited to tricyclic antidepressants, beta blockers, anticonvulsants, or Botox). If the patient is unable to tolerate a medication, a 3-month trial of that medication is not required.
3. Approved dosing:
    a. Acute migraine headache treatment: 75 mg by mouth. Max of 75 mg within 24 hours.
    b. Episodic migraine headache prevention: 75 mg by mouth once every other day. Max of 75 mg within 24 hours.
4. Quantity Limit of 8 tablets per 30 days:
    a. For preventive treatment of episodic migraine headache:
        i. A quantity of 15 tablets/30 days (1 tablet once every other day) will be granted.
    b. For the acute treatment of migraine with or without aura in adults:
        i. For coverage of more than 8 tablets per month, see the **Quantity Limit Criteria for Ubrelvy, Nurtec ODT, Reyvow, and Zavzpret** section of this policy

Qulipta (atogepant) – Rx benefit

1. The patient must be 18 years of age or older **AND**
2. The prescriber must attest all the following:
    a. The medication is being used for preventative treatment of either episodic or chronic migraine headache **AND**

b. The patient experiences 4 or more migraine headache days per month **AND**
c. The patient has had serious side effects or drug failure to at least 3 months of **TWO** different medications from **TWO** different medication classes that are used for the prevention of migraine headaches (including, but not limited to tricyclic antidepressants, beta blockers, anticonvulsants, or Botox). If the patient is unable to tolerate a medication, a 3-month trial of that medication is not required **AND**

3. Approved dosing:
   a. Episodic Migraine: 10 mg, 30 mg, or 60 mg by mouth once daily
   b. Chronic Migraine: 60 mg by mouth once daily
   c. Coverage will not be granted for dose requests above the Food and Drug Administration (FDA) approved dosing
4. Quantity Limit of 30 tablets per 30 days

Reyvow (lasmiditan) – Rx benefit

1. The patient must be 18 years of age or older **AND**
2. Must be prescribed by a headache specialist or neurologist **AND**
3. Must be used for the acute treatment of migraine with or without aura in adults **AND**
4. Must have had serious side effect or drug failure of **TWO** different triptans with different active ingredients
   a. Failure of treatment with triptans will require documentation that the patient has been evaluated for the possibility of triptan-overuse headache (rebound headache)
   b. A trial of treatment with triptans will not be required if contraindicated (i.e., CV risk) **AND**
5. Must have had serious side effects or drug failure of an oral Calcitonin Gene-Related Peptide antagonist used for the acute treatment of migraine headaches
6. Approved dosing: 50 mg, 100 mg, or 200 mg once, by mouth, as needed.
7. Quantity Limit of 4 tablets per 30 days. For coverage of more than 4 tablets per month, see the **Quantity Limit Criteria for Ubrelvy, Nurtec ODT, Reyvow, and Zavzpret** section of this policy

Ubrelvy (ubrogepant) – Rx benefit

1. The patient must be 18 years of age or older **AND**
2. The prescriber must attest that the medication is being used for the acute treatment of migraine with or without aura in adults **AND**
3. The prescriber must attest that the patient has had serious side effect or drug failure of **TWO** different triptans with different active ingredients
   a. Failure of treatment with triptans will require prescriber attestation that the patient has been evaluated for the possibility of triptan-overuse headache (rebound headache)
   b. A trial of treatment with triptans will not be required if contraindicated (i.e., CV risk)
4. Approved dosing: 50 mg or 100 mg by mouth. If needed, a second dose may be taken at least 2 hours after the initial dose. Max of 200 mg within 24 hours.
5. Quantity Limit of 8 tablets per 30 days. For coverage of more than 8 tablets per month, see the **Quantity Limit Criteria for Ubrelvy, Nurtec ODT, Reyvow, and Zavzpret** section of this policy

Vyepti (eptinezumab-jjmr) – Medical benefit

1. Must be prescribed by a headache specialist or neurologist **AND**
2. The patient must be 18 years of age or older **AND**
3. Must be used for the preventative treatment of either episodic or chronic migraine headache **AND**
4. The prescriber must submit documentation that confirms the patient experiences 4 or more migraine headache days per month
   a. Documentation of the average number of migraine headache days experienced per month will be required **AND**
5. The patient must have had serious side effects or drug failure to at least 3 months of **TWO** different medications from **TWO** different medication classes that are used for the prevention of migraine

headaches (including, but not limited to tricyclic antidepressants, beta blockers, anticonvulsants, or Botox). If the patient is unable to tolerate a medication, a 3-month trial of that medication is not required **AND**

6. The patient must have an inability to self-inject
   a. The prescriber must submit documentation that confirms the patient's inability to self-inject
7. Initial approval will be for 6 months.
   a. New starts will be required to initiate treatment with the 100 mg dose. If no response/poor response after 3 months, then the patient will be granted coverage of the 300 mg dose for 6-months.
   b. Recertification after the initial 6-month approval will require documentation of a clinical response to treatment. A clinical response to treatment is defined as a decrease in the number of migraine headache days experienced each month. If the recertification requirements are met, the request will be approved for 1 year
   c. Yearly recertification thereafter will require documentation that the patient has maintained a clinical response to treatment
7. Approved Dosing:
   Vyepti (eptinezumab-jjmr): 100 mg intravenous (IV) over 30 minutes every 3 months. Some patients may benefit from 300 mg IV every 3 months
8. Administration:
   Vyepti (eptinezumab-jjmr): Healthcare administered

Zavzpret (zavegepant) – Rx benefit

1. The patient must be 18 years of age or older **AND**
2. Must be prescribed by a headache specialist or neurologist **AND**
3. Must be used for the acute treatment of migraine with or without aura in adults **AND**
4. Must have had serious side effect or drug failure of TWO different triptans with different active ingredients
   a. At least one trial must have been a triptan nasal spray (sumatriptan, zolmitriptan)
   b. Failure of treatment with triptans will require documentation that the patient has been evaluated for the possibility of triptan-overuse headache (rebound headache)
   c. A trial of treatment with triptans will not be required if contraindicated (i.e., CV risk) **AND**
5. Step Therapy Applies:
   a. Must have had serious side effects or drug failure with an oral Calcitonin Gene-Related Peptide (CGRP) antagonist used for the acute treatment of migraine headache (i.e., Nurtec ODT, Ubrelvy)
6. Approved Dosing: one spray (10 mg/1 unit) in one nostril as needed
   a. Max of 1 spray (10 mg) in a 24-hour period. Requests for the use of more than 10 mg (2 or more sprays) in a 24-hour period will be considered not medically necessary as there is no evidence confirming additional clinical benefit.
7. Quantity Limit: 6 units (sprays)/30 days
   a. For coverage of more than 6 units per month, see the **Quantity Limit Criteria for Ubrelvy, Nurtec ODT, Reyvow, and Zavzpret** section of this policy

Quantity Limit Criteria for Ubrelvy, Nurtec ODT, Reyvow, and Zavzpret

Quantity Limit for Ubrelvy, Nurtec ODT, and Zavzpret

Quantity Limit:

A. Ubrelvy**:**
   a. 50 mg tablets: 8 tablets per 30 days
   b. 100 mg tablets: 8 tablets per 30 days

B. Nurtec ODT**:** 8 tablets per 30 days
   a. Applicable to acute use only (see Nurtec ODT criteria for more information)

C. Zavzpret: 6 units (sprays)/30 days

For consideration of approval for a quantity above our health plans quantity limit (stated above), the following criteria applies:

1. Must be prescribed by a headache specialist or neurologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of moderate-to-severe migraine headache **AND**
4. Documentation must be submitted which says how many migraine-attacks the patient has had per month on average (over the last 3 months) **AND**
5. Must have been evaluated for the possibility of rebound headache (or medication overuse headache) **AND**
6. Must have had a reasonable trial resulting in serious side effects or drug failure from **TWO** different classes of the following preventative treatments:
   - Beta Blockers
   - Calcium Channel Blockers
   - Tricyclic Antidepressants
   - Anticonvulsants
   - Toxins (i.e., Botox) **AND**
7. Must have had a reasonable trial resulting in serious side effects or drug failure with an injectable Calcitonin Gene-Related Peptide antagonist **AND**
8. If being used for the acute treatment of migraine headache, the patient must currently be using a migraine preventative treatment(s).
9. Maximum quantity allowed:
   a. For the acute treatment of migraine headache (Ubrelvy and Nurtec ODT): any additional quantity approved for will be limited to the number of migraines attacks the prescriber says patient has each month in accordance with approved dosing (e.g., if a patient has 5 migraine attacks per month, the quantity limit will be set to 10 tablets for Ubrelvy or 5 tablets for Nurtec ODT) with a MAX of the following:
      i. 16 tablets per 30 days for Ubrelvy as the prescribing information states that the safety of treating more than 8 migraines in a 30-day period has not been established
      ii. 18 tablets per 30 days for Nurtec ODT (includes when used as both preventative and acute therapy) as the prescribing information states that the safety of using more than 18 doses in a 30-day period has not been established
   b. For the acute treatment of migraine headache (Zavzpret only): 8 units (sprays) per 30 days for Zavzpret as the prescribing information stated that the safety of treating more than 8 migraines in a 30-day period has not been established
10. Approval will be for 1 year **OR** through the end of the approval period of the respective drugs prior authorization if applicable

Quantity Limit for Reyvow

Quantity Limit:
Reyvow:

a. 50 mg: 4-50 mg tablets per 30 days
b. 100 mg: 4-100 mg tablets per 30 days
c. 200 mg: 8-100 mg tablets per 30 days
   i. For a quantity of 8-100 mg tablets per 30 days (a dose of 200 mg per migraine attack), the patient must have had a reasonable trial of the 100 mg tablet which was not effective at treating the patient's migraine **AND** the patient must be ≥ 18 years of age.
   ii. Approval will be for 1 year **OR** through the end of the approval period of Reyvow's prior authorization if applicable

According to the Reyvow package insert, a second dose of Reyvow has not been shown to be effective for the same migraine attack. In addition, the safety of treating an average of more than 4 migraine attacks in a 30-day period has not been established. Therefore, there will be a quantity limit of 4 doses per 30 days.

POLICY GUIDELINES:

1. Unless otherwise stated above within the approval time-period section, approval time periods will be for 1 year.
   - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
2. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., prescriber attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting prescriber, then trial of the preferred drug(s) will not be required.
   - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
   - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
     The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
   - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
   - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
   - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
4. Non-FDA approved indications for CGRP inhibitors will not be approved. Emgality 120 mg once monthly is only FDA approved for the prevention of Chronic or Episodic Migraine Headache. Emgality 100 mg (300 mg once monthly) is only FDA approved for the treatment for Episodic Cluster Headache.

5. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
6. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to approved language being added to the policy.
7. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
8. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
9. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
10. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
11. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

Codes may not be covered under all circumstances. Please read the policy and guideline statements carefully. Codes may not all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I). Not medically necessary/appropriate = (NMN).

HCPCS:

Description (Number): **Ajovy (J3031), Vyepti (J3032)**

UPDATES:

Date	Revision
08/14/2025	Revised & Reviewed / P&T Committee Approval
03/06/2025	Revised
01/02/2025	Revised
01/01/2025	Revised
09/13/2024	Revised
08/15/2024	Reviewed / P&T Committee Approval
06/24/2024	Revised
04/18/2024	Revised

12/06/2023	Revised
08/24/2023	Reviewed & P&T Committee Approval
06/12/2023	Revised
04/28/2023	Revised
07/2022	P&T Committee Approval
03/2022	Revised
10/2021	Revised
07/2021	Reviewed & P&T Committee Approval
06/2021	Revised
12/2020	Revised
10/2020	Revised
09/2020	Revised and P&T Committee Approval
08/2020	Reviewed
05/2020	Revised
03/2020	Revised
02/2020	Revised
07/2019	Revised
11/2018	Revised
10/2018	Revised
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