



Clinical Guideline

Oscar Clinical Guideline: Anti-migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists and Serotonin Receptor 5-HT_{1F} Agonists (PG008, Ver. 7)

Anti-migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists and Serotonin Receptor 5-HT_{1F} Agonists

- Calcitonin Gene-Related Peptide (CGRP) Antagonists
 - Aimovig (erenumab)
 - Ajovy (fremanezumab)
 - Emgality (galcanezumab)
 - Nurtec ODT (rimegepant)
 - Qulipta (atogepant)
 - Ubrelvy (ubrogepant)
 - Vyepti (eptinezumab)
 - Zavzpret (zavegepant)
- Selective Serotonin 1F Receptor Agonists (Ditans)
 - Reyvow (lasmiditan)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Migraines are pulsating headaches with intense, throbbing pain that can last from hours to days. It can affect one or both sides of the head, and is commonly associated with other symptoms such as sensitivity to light and/or noise, pressure behind the eye(s), nausea, and vomiting. Along with lifestyle changes, migraine headaches can be treated with medicines that relieve pain, nausea, or that prevent migraine headaches from happening. Starting in 2018, a new class of drugs called anti-calcitonin gene-related peptide (anti-CGRP) antibodies became available, allowing for new treatment options (acute treatment or prophylactic) for migraine headaches. There are some CGRP antagonists FDA indicated for use in migraine prevention, while others are FDA indicated for use in migraine treatment.

The CGRP antagonists indicated for migraine prevention include Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Nurtec ODT (rimegepant), and Vyepti (eptinezumab).

- Aimovig, Ajovy, and Emgality are available as a subcutaneous (SC) formulation.
- Nurtec ODT (rimegepant) and Qulipta (atogepant) are available in oral formulation.
- Vyepti (IV) is available as an intravenous formulation.

The CGRP antagonists indicated for migraine treatment include Nurtec ODT (rimegepant), Zavzpret (zavegepant), and Ubrelvy (ubrogepant). Reyvow, a serotonin receptor 5-HT_{1F} agonist, is also used for the acute treatment of migraines.

- Nurtec and Ubrelvy are available as an oral formulation.
- Reyvow is available in an oral tablet formulation.
- Zavzpret is available as a nasal spray.

Table 1: Calcitonin Gene-Related Peptide (CGRP) Antagonists and Serotonin Receptor 5-HT_{1F} Agonists

Drug	FDA-Approved Indications	Classification
Formulary Agents*		
Aimovig (erenumab)	is indicated for the preventive treatment of migraine in adults.	Calcitonin Gene-Related Peptide (CGRP) Antagonists
Ajovy (fremanezumab)	is indicated for the preventive treatment of migraine in adults.	
Emgality (galcanezumab)	is indicated for: <ul style="list-style-type: none">• the preventive treatment of migraine in adults.• for the treatment of episodic cluster headache in adults.	
Nurtec ODT (rimegepant)	is indicated for: <ul style="list-style-type: none">• the acute treatment of migraine with or without aura in adults .	

	<ul style="list-style-type: none"> the preventive treatment of episodic migraine in adults. 	
Non-Formulary Agents^{*†}		
Qulipta (atogepant)	is indicated for the preventive treatment of migraine in adults.	Calcitonin Gene-Related Peptide (CGRP) Antagonists
Ubrelvy (ubrogepant)	is indicated for the acute treatment of migraine with or without aura in adults.	
Vyepti (eptinezumab)	is indicated for the preventive treatment of migraine in adults.	
Zavzpret (zavegepant)	is indicated for the acute treatment of migraine with or without aura in adults.	
Reyvow (lasmiditan)	is indicated for the acute treatment of migraine with or without aura in adults.	Selective Serotonin 1F Receptor (5-HT _{1F}) Agonists (Ditans)

*The Plan may review all requests made under the Medical or Pharmacy benefit against specific prior authorization criteria, as applicable and at its discretion. Products considered Formulary or Preferred for the Plan may still require a clinical prior authorization review.

[†]Subject to Plan's Medical Necessity Criteria for Non-Formulary Products (PG069).

Definitions

"Cluster headache" is a primary headache disorder as defined by the International Classification of Headache Disorders that is associated with intense pain that often occurs in or around one eye or on one side of a person's head. Attacks often suddenly in the middle of the night in a cyclical pattern lasting for weeks or months. Common symptoms experienced during a cluster headache episode include restlessness/agitation, increased redness, swelling, or tearing of the eye, stuffy or runny nose, eyelid drooping, or facial sweating and flushing.

"Chronic cluster headache" refers to a series of cluster headache attacks occurring for one year or longer without remission or with remission periods lasting less than 3 months.

"Episodic cluster headache" refers to a series of cluster headache attacks occurring in periods lasting from 7 days to one year, separated by pain-free periods of 3 or more months.

"Migraine" is a primary headache disorder with diagnostic criteria defined by the International Classification of Headache Disorders that is associated with four distinct stages: prodrome, aura, attack and post-drome. However, everyone who has migraines does not experience all four stages. There are two major types of migraines: 1) migraine without aura and 2) migraine with aura.

"Aura" is a set of reversible symptoms that occur before or during a migraine episode. Examples of conditions associated with migraine aura include vision loss or sudden changes (such as seeing shapes, bright spots or flashes of light), hearing noises or music, tingling sensation in arms or legs, numbness of the face or side of the body, or difficulty speaking.

"Chronic migraine" is characterized by 15 or more headache days per month for 3 or more months.

"Episodic migraine" is characterized by 0 to 14 headache days per month.

Medical Necessity Criteria for Authorization

The Plan considers **Anti-migraine Agents** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

Migraine Prophylaxis (Prevention):

Medical Necessity Criteria for Initial Authorization

The Plan considers **Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab), Nurtec ODT (rimegepant), Qulipta (atogepant), and Vyepti (eptinezumab)** medically necessary for migraine prophylaxis when ALL of the following criteria are met:

1. The member is 18 years of age or older; **AND**
2. The member has a diagnosis of migraine (with or without aura) according to the International Classification of Headache Disorders (see **Appendix, Table 2**); **AND**
3. The member experiences four (4) or more migraine days per month; **AND**
4. The member is unable to use, or adequately tried and failed an 8-week trial of at least two (2) preventative therapies, from at least two (2) of the following drug classes:
 - a. Anticonvulsants (e.g., topiramate, divalproex, sodium valproate); **or**
 - b. Antidepressants (e.g., amitriptyline, nortriptyline, venlafaxine); **or**
 - c. Beta blockers (e.g., propranolol, metoprolol); **AND**
5. The requested medication will not be used concomitantly with:
 - a. Botulinum toxin (e.g. Botox, Dysport); **or**
 - b. another CGRP antagonist for migraine prophylaxis; **AND (if applicable)**

Additional Criteria for Non-Formulary Agents - Qulipta (atogepant), Vyepti (eptinezumab)

6. The member is unable to use, or has adequately tried and failed **ALL** Formulary alternatives:
 - a. Aimovig (erenumab); **and**
 - b. Ajovy (fremanezumab); **and**
 - c. Emgality (galcanezumab); **and**
 - d. Nurtec ODT (rimegepant); **AND**
7. Chart documentation substantiating the above criteria is provided for review (e.g., past medication trials, including drug names, strength/dose/frequency, duration, response, and reason for failure or discontinuation).

If the above prior authorization criteria is met, the requested medication will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if the information provided indicates **BOTH** of the following:

1. The member has experienced meaningful clinical improvement in frequency and/or severity of migraine episodes; **AND**
2. The requested medication will not be used concomitantly with:
 - a. Botulinum toxin (e.g. Botox, Dysport); **or**
 - b. another CGRP antagonist for migraine headache prophylaxis.

Acute Headache (Treatment)

Acute Migraine Treatment:

Medical Necessity Criteria for Initial Authorization

The Plan considers **Nurtec ODT (rimegepant), Reyvow (lasmiditan), Ubrovelvy (ubrogepant), and Zavzpret (zavegepant)** medically necessary for the acute treatment of migraine when **ALL** of the following criteria are met:

1. The member is 18 years of age or older; **AND**
2. The member has a diagnosis of migraine (with or without aura) according to the International Classification of Headache Disorders (see **Appendix, Table 2**); **AND**
3. The member is unable to use, or has tried and failed two (2) different triptan agents (e.g., as sumatriptan, eletriptan, naratriptan); **AND**
4. The requested medication will not be used concomitantly with another CGRP antagonist for acute/abortive migraine treatment; **AND (if applicable)**

Additional Criteria for Non-Formulary Agents - Reyvow (lasmiditan), Ubrovelvy (ubrogepant), Zavzpret (zavegepant)

5. The member is unable to use, or has adequately tried and failed Nurtec ODT (rimegepant); **AND**
6. Chart documentation substantiating the above criteria is provided for review (e.g., past medication trials, including drug names, strength/dose/frequency, duration, response, and reason for failure or discontinuation).

If the above prior authorization criteria is met, the requested medication will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if the information provided indicates **BOTH** of the following:

1. The member has experienced meaningful clinical improvement in frequency and/or severity of migraine episodes; **AND**
2. The requested medication will not be used concomitantly with another CGRP antagonist for acute/abortive treatment.

Episodic Cluster Headache Treatment:

Medical Necessity Criteria for Initial Authorization

The Plan considers Emgality (galcanezumab) medically necessary for the treatment of episodic cluster headache when **ALL** of the following criteria are met:

1. The member is 18 years of age or older; **AND**
2. The member has a diagnosis of episodic cluster headache according to the International Classification of Headache Disorders (see [Appendix, Table 2](#)); **AND**
3. The member is unable to use, or has tried and failed verapamil; **AND**
4. The requested medication will not be used concomitantly with another CGRP antagonist for acute/abortive cluster headache treatment.

If the above prior authorization criteria is met, the requested medication will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if the information provided indicates **BOTH** of the following:

1. The member has experienced meaningful clinical improvement in frequency and/or severity of cluster headache episodes; **AND**
2. The requested medication will not be used concomitantly with another CGRP antagonist for acute/abortive cluster headache treatment.

Experimental or Investigational / Not Medically Necessary

CGRP Antagonists for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

Applicable Billing Codes (HCPCS/CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
J3032	Injection, eptinezumab-jjmr, 1 mg
ICD-10 codes considered medically necessary if criteria are met:	
G43.0	Migraine without aura (common migraine)
G43.001	Migraine without aura, not intractable, with status migrainosus
G43.009	Migraine without aura, not intractable, without status migrainosus
G43.011	Migraine without aura, intractable, with status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus
G43.1	Migraine with aura (classical migraine)
G43.101	Migraine with aura, not intractable, with status migrainosus
G43.109	Migraine with aura, not intractable, without status migrainosus
G43.111	Migraine with aura, intractable, with status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.2	Status migrainosus
G43.3	Complicated migraine
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus

G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.801	Other migraine, not intractable, with status migrainosus
G43.809	Other migraine, not intractable, without status migrainosus
G43.811	Other migraine, intractable, with status migrainosus
G43.819	Other migraine, intractable, without status migrainosus
G43.901	Migraine, unspecified, not intractable, with status migrainosus
G43.909	Migraine, unspecified, not intractable, without status migrainosus
G43.911	Migraine, unspecified, intractable, with status migrainosus
G43.919	Migraine, unspecified, intractable, without status migrainosus
G44.001	Cluster headache syndrome, unspecified, intractable
G44.009	Cluster headache syndrome, unspecified, not intractable
G44.011	Episodic cluster headache, intractable
G44.019	Episodic cluster headache, not intractable
G44.021	Chronic cluster headache, intractable
G44.029	Chronic cluster headache, not intractable

CPT/HCPCS codes NOT covered under the Medical Benefit Plan: <i>(these are considered self-use and are covered under the Pharmacy Benefit Plan)</i>	
<i>Code</i>	<i>Description</i>
C9399	Aimovig (erenumab) Unclassified drugs or biologicals
C9399	Emgality (galcanezumab) Unclassified drugs or biologicals
J3031	Ajovy (fremanezumab) Injection, fremanezumab-vfrm, 1 mg
J3490	Zavzpret (zavegepant) Unclassified drugs

J3590	Aimovig (erenumab) Unclassified biologics
J3590	Emgality (galcanezumab) Unclassified biologics
J8499	Nurtec ODT (rimegepant) Unclassified biologics
J8499	Ubrovelvy (ubrogepant) Prescription drug, oral, non chemotherapeutic, nos
J8499	Qulipta (atogepant) Prescription drug, oral, non chemotherapeutic, nos
J8499	Reyvow (lasmiditan) Prescription drug, oral, non chemotherapeutic, nos

Appendix

Table 2: Diagnostic criteria according to the International Classification of Headache Disorders, 3rd edition (ICHD-3)

Diagnosis	Criteria
Migraine without aura	<p>BOTH of the following:</p> <ol style="list-style-type: none"> 1. A history of at least 5 attacks¹ meeting ALL of the following: <ol style="list-style-type: none"> a. Migraine headache lasting at least 4 hours^{2,3}; and b. Migraine headache is characterized by at least <i>TWO</i> of the following: and <ol style="list-style-type: none"> i. Aggravation by or causing avoidance of routine physical activity; or ii. Moderate to severe pain; or iii. Pulsating quality; or iv. Unilateral (one-sided) location; and c. During headache, at least <i>ONE</i> of the following: <ol style="list-style-type: none"> i. Nausea and/or vomiting; or ii. Photophobia (sensitivity to light) and/or phonophobia (sensitivity to sound); and

	<p>2. Provider attestation indicating that other potential causes of headache have been ruled out</p>
Migraine with aura	<p>BOTH of the following:</p> <ol style="list-style-type: none"> 1. A history of at least 2 attacks meeting BOTH of the following: <ol style="list-style-type: none"> a. At least ONE of the following fully reversible aura symptoms: <ol style="list-style-type: none"> i. Brainstem (e.g., dysarthria, vertigo, tinnitus, diplopia); or ii. Motor; or iii. Retinal (eg, scintillations, scotomata, blindness); or iv. Sensory, including positive features (e.g., pins and needles) and/or negative features (e.g., numbness); or v. Speech and/or language (e.g., loss of ability to express speech); or vi. Visual, including positive features (e.g., flickering lights, spots, lines) and/or negative features (e.g., loss of vision); and b. At least three of the following: <ol style="list-style-type: none"> i. At least one aura symptom is positive⁶; or ii. At least one aura symptom is unilateral⁵; or iii. At least one aura symptoms spreads gradually over 5 or more minutes; or iv. Each individual aura symptom lasts between 5 and 60 minutes⁴; or v. The aura is accompanied or followed within 60 minutes by headache; or vi. Two or more symptoms occur in succession; and 2. Provider attestation indicating that other potential causes of headache have been ruled out

Episodic Cluster Headache	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. A history of at least 5 attacks meeting ALL of the following: <ol style="list-style-type: none"> a. of severe or very severe unilateral orbital, supraorbital, and/or temporal pain lasting 15 to 180 minutes⁷; and b. occurring with a frequency between one every other day and eight per day⁸; and c. Headache is accompanied by a sense of restlessness or agitation and/or at least one of the following (on the same side of the body): <ol style="list-style-type: none"> i. Eyelid swelling or drooping; or ii. Increased redness or tearing of the eye; or iii. Forehead and facial sweating; or iv. Pupil contraction; or v. Stuffy or runny nose; and 2. The member has at least two cluster periods lasting one week to a year, separated by attack-free intervals (i.e. remission) lasting at least 3 months; and 3. Provider attestation indicating that other potential causes of headache have been ruled out
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¹ Distinguishing a single migraine attack from a symptomatic migraine-like attack can be challenging. Additionally, the nature of only one or a few attacks may be difficult to ascertain. Therefore, a diagnosis of migraine without aura requires at least five attacks to establish the disease pattern. Patients with fewer than five attacks who otherwise meet diagnostic criteria should be designated as having probable migraine without aura.

² If a migraine attack ends when the patient falls asleep, the duration of the attack should be determined based on the time up until the point of falling asleep.

³ In children and adolescents under 18 years of age, migraine attacks may last from 2 hours up to 72 hours. Evidence has not confirmed untreated attack durations of less than 2 hours in pediatric patients.

⁴ If three distinct aura symptoms occur, the maximum acceptable total duration would be 3 × 60 minutes. Motor symptoms may persist for up to 72 hours.

⁵ Aphasia should always be categorized as a unilateral symptom. Dysarthria may or may not be unilateral.

⁶ Positive aura symptoms include scintillations and pins and needles sensations.

⁷ For less than half of the duration of an active cluster headache period, some attacks may be of lesser severity and/or shorter or longer duration compared to a patient's typical attack pattern.

⁸ For less than half of the duration of an active cluster headache period, some attacks may occur at a lower frequency than is typical for a patient.

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