

Federal Employee Program® 1310 G Street, N.W. Washington, D.C. 20005 202.942.1000 Fax 202.942.1125

5.70.085

Section: Prescription Drugs Effective Date: January 1, 2024

Subsection: Analgesics and Anesthetics Original Policy Date: August 4, 2023

Subject: Migraine CGRP Antagonists **Page:** 1 of 6

Nasal

Last Review Date: December 8, 2023

Migraine Calcitonin Gene-Related Peptide (CGRP) Antagonists Nasal

Description

Zavzpret (zavegepant)

Background

Zavzpret (zavegepant) is a calcitonin gene-related peptide receptor (CGRP) antagonist. CGRP is a neuropeptide widely distributed in the nervous system, particularly at anatomical areas thought to be involved with migraine, including the trigeminovascular nociceptive system. In studies, CGRP has been shown to be released during severe migraine attacks. CGRP mechanism blockade either by small molecule receptor antagonists or by monoclonal antibodies can have an abortive or preventive effect in migraine (1-2).

Regulatory Status

FDA-approved indication: (1)

Zavzpret is indicated for the acute treatment of migraine with or without aura in adults.

<u>Limitations of Use</u>: Zavzpret is not indicated for the preventative treatment of migraine (1).

The recommended dose of Zavzpret is 10 mg given as a single spray in one nostril, as needed. The maximum dose in a 24-hour period is 10mg (one spray). The safety of treating more than 8 migraines in a 30-day period has not been established (1).

The safety and effectiveness of Zavzpret in pediatric patients less than 18 years of age have not been established (1).

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Related policies

5-HT1 Agonists, Butalbital analgesics, Dihydroergotamine Nasal Sprays, Elyxyb, Maxalt, Migraine CGRP Antagonists IV, Migraine CGRP Antagonists Oral, Migraine CGRP Antagonists SC, Migraine Powders

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zavzpret may be considered **medically necessary** if the conditions indicated below are met.

Zavzpret may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Acute treatment of migraine with or without aura

AND ALL of the following:

- a. **NOT** used for the prevention of migraines
- Patient has completed an adequate 3-month trial OR patient has an intolerance or contraindication to at least TWO Triptan Agents
- c. **NO** dual therapy with Triptan Agents at Prior Authorization quantities
- d. Patient has **ONE** of the following:
 - 1. **NO** dual therapy with another CGRP antagonist (see Appendix 1)
 - 2. Dual therapy with a preventative CGRP antagonist if **ONE** of the following applies:

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 Patient has completed an adequate 3-month trial of at least 2 preventative CGRP antagonists (i.e., Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta, and Vyepti)

ii. Patient has completed an adequate 3-month trial of a preventative CGRP antagonist in combination with a triptan agent

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Prior-Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Acute treatment of migraine with or without aura

AND ALL of the following:

- a. **NOT** used for the prevention of migraines
- b. NO dual therapy with Triptan Agents at Prior Authorization quantities
- c. Patient has **ONE** of the following:
 - 1. **NO** dual therapy with another CGRP antagonist (see Appendix 1)
 - Dual therapy with a preventative CGRP antagonist if **ONE** of the following applies:
 - i. Patient has completed an adequate 3-month trial of at least 2 preventative CGRP antagonists (i.e., Aimovig, Ajovy, Emgality, Nurtec ODT, Qulipta, and Vyepti)
 - ii. Patient has completed an adequate 3-month trial of a preventative CGRP antagonist in combination with a triptan agent

Policy Guidelines

Pre-PA Allowance

None

Prior-Approval Limits

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Quantity

Medication/Strength	Diagnosis	Quantity
Zavzpret 10 mg	Acute treatment	24 nasal spray devices per 90 days

Duration 6 months

Prior-Approval Renewal Limits

Quantity

Medication/Strength	Diagnosis	Quantity
Zavzpret 10 mg	Acute treatment	24 nasal spray devices per 90 days

Duration 12 months

Rationale

Summary

Zavzpret (zavegepant) is a CGRP antagonist. In studies, CGRP has been shown to be released during severe migraine attacks. CGRP mechanism blockade either by small molecule receptor antagonists or by monoclonal antibodies can have an abortive or preventive effect in migraine. Zavzpret is indicated for the acute treatment of migraine with or without aura in adults. The safety and effectiveness of Zavzpret in pediatric patients less than 18 years of age have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of CGRP antagonists nasal while maintaining optimal therapeutic outcomes.

References

- 1. Zavzpret [package insert]. New York, NY: Pfizer Inc.; March 2023.
- 2. Karsan N, Goadsby PJ. "Calcitonin gene-related peptide and migraine." Curr Opin Neurol. 2015 Jun;28(3):250-4.

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Policy History	
Date	Action
August 2023	Addition to PA
September 2023	Annual review
October 2023	Per FEP, revised criteria to allow dual therapy between CGRP antagonists if patient is using one preventative and one acute treatment together after an adequate trial and failure of other CGRPs and triptans either alone or in combination
December 2023	Annual review
Keywords	

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.

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Appendix 1 - List of CGRP Antagonists

Generic Name	Brand Name
atogepant	Qulipta
eptinezumab-jjmr	Vyepti
erenumab-aooe	Aimovig
fremanezumab-vfrm	Ajovy
galcanezumab-gnim	Emgality
rimegepant	Nurtec ODT
ubrogepant	Ubrelvy
zavegepant	Zavzpret