



Drug Coverage Policy

Effective Date.....9/1/2024
Coverage Policy Number IP0573
Policy Title..... Zavzpret

Migraine – Zavzpret

- Zavzpret™ (zavegepant nasal spray – Pfizer)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

Zavzpret, a calcitonin gene-related peptide receptor antagonist, is indicated for the **acute treatment of migraine headache** with or without aura in adults.¹ Limitations of Use: Zavzpret is not indicated for the preventive treatment of migraine.

Disease Overview

Migraine is a common, ongoing condition marked by paroxysmal, unilateral attacks of moderate to severe throbbing headache which are aggravated by routine physical activity (e.g., walking or climbing stairs) and associated with nausea, vomiting, and/or photophobia and phonophobia.²

Migraines have been defined as chronic or episodic. Chronic migraine is described by the International Headache Society as headache occurring on ≥ 15 days/month for more than 3 months, which has the features of migraine headache on ≥ 8 days/month. Episodic migraine is characterized by headaches that occur < 15 days/month.³

Guidelines

Zavzpret has not been included in guidelines. Triptans (e.g., almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan) are considered the gold standard for acute treatment of moderate to severe migraine headaches or mild to moderate migraine headaches that respond poorly to over-the-counter analgesics. An assessment of the preventive and acute treatment of migraine by the American Headache Society (2018; updated 2021) reaffirms previous migraine guidelines.^{4,5} The update lists the triptans, dihydroergotamine, the oral gepants (Nurtec[®] ODT [rimegepant orally disintegrating tablets,] and Ubrelvy[®] [ubrogepant tablets]), and Reyvow[®] (lasmiditan tablets) as effective treatments for moderate or severe acute migraine attacks and mild to moderate attacks that respond poorly to nonsteroidal anti-inflammatory drugs, non-opioid analgesics, acetaminophen, or caffeinated combinations (e.g., aspirin + acetaminophen + caffeine). The recommendation remains that clinicians must consider medication efficacy and potential medication-related adverse events when prescribing acute medications for migraine.

Medical Necessity Criteria

Zavzpret is considered medically necessary when the following criteria are met:

FDA-Approved Indication

- 1. Migraine, Acute Treatment.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient meets **ONE** of the following (i or ii):
 - i. ONE** of the following (a or b):
 - a) Employer Plans:** Patient has tried at least one triptan therapy
 - b) Individual and Family Plans:** Patient has tried at least two triptans
 - ii.** Patient has a contraindication to triptan(s) according to the prescriber.

Note: Examples of contraindications to triptans include a history of coronary artery disease; cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or hemiplegic or basilar migraine; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; or severe hepatic impairment.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Zavzpret™ tablets [prescribing information]. New York, NY: Pfizer; March 2023.
2. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition. *Cephalalgia*. 2018;38(1):1-211.
3. Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache*. 2015;52:103-122.
4. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
5. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;61(7):1021-1039.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	<p>Updated coverage policy title from <i>Zavegepant</i> to <i>Migraine – Zavzpret</i>.</p> <p><u>Migraine, Acute Treatment:</u> Removed reauthorization criteria. Removed concurrent use of two CGRP inhibitors as a condition not covered.</p>	9/1/2024

The policy effective date is in force until updated or retired.

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