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MIGRAINE CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS NASAL ZAVZPRET (zavegepant)

RATIONALE FOR INCLUSION IN PA PROGRAM

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.

Limitations of Use: 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).

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



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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.