

NAYZILAM **(midazolam nasal spray)**

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Nayzilam (midazolam) is a benzodiazepine. Nayzilam's mechanism of action is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA_A receptor (1).

Regulatory Status

FDA-approved indication: Nayzilam is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older (1).

Nayzilam has a boxed warning regarding the concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of benzodiazepines and opioids for use in patients for whom alternative treatment options are inadequate and dosages and durations should be limited to the minimum required (1).

Nayzilam should be limited to 2 doses to treat a seizure cluster. Nayzilam should be used to treat no more than one episode every three days and treat no more than five episodes per month (1). Benzodiazepines, including Nayzilam, can increase intraocular pressure in patients with glaucoma. Measurements of intraocular pressure in patients without eye disease show a moderate lowering following induction with midazolam. Nayzilam may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. Patients with open-angle glaucoma may need to have their ophthalmologic status evaluated following treatment with Nayzilam. Nayzilam is contraindicated in patients with narrow-angle glaucoma. (1)

Antiepileptic drugs (AEDs), including Nayzilam, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior (1).



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The safety and effectiveness of Nayzilam in pediatric patients less than 12 years of age have not been established (1).

Summary

Nayzilam (clobazam) is a benzodiazepine. Nayzilam's mechanism of action is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA_A receptor. The safety and effectiveness of Nayzilam in pediatric patients less than 12 years of age have not been established (1).

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

References

1. Nayzilam [package insert]. Smyrna, GA: UCB, Inc.; January 2023.