Nayzilam

Description

Nayzilam (midazolam nasal spray)

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).

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

Related policies
Diacomit, Epidiolex

Policy

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

Nayzilam may be considered medically necessary for patients 12 years and older for the acute treatment of seizures and if the conditions indicated below are met.

Nayzilam may be considered investigational in patients less than 12 years of age and for all other indications.

Prior-Approval Requirements

Patients with a paid claim for a seizure medication such as: divalproex sodium (Depakote, Depakote ER), topiramate (Topamax), levetiracetam (Lamictal) in the past 180 days are exempt from these initial PA requirements

Age 12 years of age or older
Diagnosis

Patient must have the following:

Intermittent seizure episodes (i.e. seizure clusters, acute repetitive seizures)

AND ALL of the following:

a. Episodes are distinct from the patient’s usual epilepsy seizure pattern
b. Patient is on a stable regimen of antiepileptic therapy
c. Prescriber agrees to assess the patient before prescribing concomitant opioid therapy to limit opioid dosages and durations to the minimum required
d. Inadequate treatment response, intolerance, or contraindication to at least TWO benzodiazepines
e. NOT being used for the treatment of anxiety

Prior–Approval Renewal Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

Intermittent seizure episodes (i.e. seizure clusters, acute repetitive seizures)

AND ALL of the following:

a. Episodes are distinct from the patient’s usual epilepsy seizure pattern
b. Patient is on a stable regimen of antiepileptic therapy
c. Prescriber agrees to assess the patient before prescribing concomitant opioid therapy to limit opioid dosages and durations to the minimum required
d. NOT being used for the treatment of anxiety
Pre–PA Allowance

None

Prior–Approval Limits

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Strength</th>
<th>Quantity Limit per 90 days</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>5 mg single-dose nasal spray</td>
<td>30 units per 90 days</td>
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</tbody>
</table>

Duration 3 months

Prior–Approval Renewal Limits

<table>
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</table>

Duration 6 months

Rationale

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_α 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

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.