

**Nayzilam nasal spray (midazolam)
Effective February 1, 2020**

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Binds to stereospecific benzodiazepine receptors on the postsynaptic GABA neuron at several sites within the central nervous system, including the limbic system, reticular formation. Enhancement of the inhibitory effect of GABA on neuronal excitability results by increased neuronal membrane permeability to chloride ions. This shift in chloride ions results in hyperpolarization (a less excitable state) and stabilization. Benzodiazepine receptors and effects appear to be linked to the GABA-A receptors

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Nayzilam excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member is ≥ 12 years of age
2. The member is using medication for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from a patient’s usual seizure pattern
3. The provider specialty is neurology or provider is working in consultation with a neurologist.

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member’s condition.

Limitations

1. Authorizations will be approved for a duration of 12 months



2. The following quantity limits apply:

Nayzilam 5mg/0.1mL (2 per box)	5 boxes (10 units total) per 30 days
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References

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3. Castro Conde JR, Hernández Borges AA, Doménech Martínez E, et al, "Midazolam in Neonatal Seizures With No Response to Phenobarbital," *Neurology*, 2005, 64(5):876-9. [PubMed 15753426]
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5. Fişgin T, Gürer Y, Senbil N, et al, "Nasal Midazolam Effects on Childhood Acute Seizures," *J Child Neurol*, 2000, 15(12):833-5. [PubMed 11198507]
6. Fraser G, "Intranasal Midazolam," *Hosp Pharm*, 1992, 27:73-4.
7. Hayashi K, Osawa M, Aihara M, et al, "Efficacy of Intravenous Midazolam for Status Epilepticus in Childhood," *Pediatr Neurol*, 2007, 36(6):366-72. [PubMed 17560497]
8. Holmes GL and Riviello JJ Jr, "Midazolam and Pentobarbital for Refractory Status Epilepticus," *Pediatr Neurol*, 1999, 20(4):259-64. [PubMed 10328273]
9. Holsti M, Sill BL, Firth SD, et al, "Prehospital Intranasal Midazolam for the Treatment of Pediatric Seizures," *Pediatr Emerg Care*, 2007, 23(3):148-53. [PubMed 17413428]
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11. Kutlu NO, Yakinci C, Dogrul M, et al, "Intranasal Midazolam for Prolonged Convulsive Seizures," *Brain Dev*, 2000, 22(6):359-61. [PubMed 11042416]
12. Nayzilam (midazolam) [prescribing information]. Plymouth, MN: Proximagen, LLC; May 2019.
13. Rivera R, Segnini M, Baltodano A, et al, "Midazolam in the Treatment of Status Epilepticus in Children," *Crit Care Med*, 1993, 21(7):991-4.
14. Yoshikawa H, Yamazaki S, Abe T, Oda Y. Midazolam as a first-line agent for status epilepticus in children. *Brain Dev*. 2000;22(4):239-242. [PubMed 10838111]

Review History

12/16/2019 – reviewed and approved by DCC

03/18/2020 – criteria reviewed at P&T

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