

**Nayzilam nasal spray (midazolam)**  
**Effective 06/01/2020**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	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
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

### Overview

Nayzilam 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 new to the plan 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  $\geq 12$  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

1. Bhattacharyya M, Kalra V, and Gulati S, "Intranasal Midazolam vs Rectal Diazepam in Acute Childhood Seizures," *Pediatr Neurol*, 2006, 34(5):355-9. [\[PubMed 16647994\]](#)
2. Burtin P, Jacqz-Aigrain E, Girard P, et al, "Population Pharmacokinetics of Midazolam in Neonates," *Clin Pharmacol Ther*, 1994, 56(6 Pt 1):615-25. [\[PubMed 7995003\]](#)
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. [\[PubMed 15753426\]](#)
4. de Haan GJ, van der Geest P, Doelman G, et al. A comparison of midazolam nasal spray and diazepam rectal solution for the residential treatment of seizure exacerbations. *Epilepsia*. 2010;51(3):478-482. [\[PubMed 19817813\]](#)
5. Fişgin T, Güner 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. [\[PubMed 17413428\]](#)
10. Holsti M, Dudley N, Schunk J, et al, "Intranasal Midazolam vs Rectal Diazepam for the Home Treatment of Acute Seizures in Pediatric Patients With Epilepsy," *Arch Pediatr Adolesc Med*, 2010, 164(8):747-53. [\[PubMed 20679166\]](#)
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

03/18/2020 – Reviewed at P&T (effective 6/1/20)

09/21/2022 – Reviewed at Sept P&T; Separated Comm/Exch vs MH policy; no clinical updates.

