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Update: FDA Approved Use of Intranasal Midazolam for Cluster Seizures

To address the needs of school nurses, the Texas Department of State Health Services (DSHS)–School Health Program has developed this repository of information. With each issue of *DSHS-School Nurse Notes* (DSHS-SNN), professionals receive the latest research, evidence-based practices, and resources in school nursing related to a topic of interest. The School Health Program wishes to thank the Texas Board of Nursing for their collaboration on this publication, in particular Linda Laws, M.S.N., R.N. for her contributions. If you have any questions or comments about this issue of DSHS-SNN, please contact School Nurse Consultant Anita Wheeler, M.S.N., R.N. at (512) 776-2909 or at anita.wheeler@DSHS.texas.gov.

Update

In May 2019, the U.S. Food and Drug Administration (FDA) approved the use of NAYZILAM ® (midazolam) nasal spray for use in children over age 12 as a rescue therapy treatment for frequent seizure activity.

NAYZILAM is a benzodiazepine 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 prescribers should consider the following prior to initiation of treatment: For patients at increased risk of respiratory depression from benzodiazepines, administration of NAYZILAM under healthcare professional supervision should be considered prior to treatment with NAYZILAM; this administration may be performed in the absence of a seizure episode.¹

School nurses may see an increase in physicians' orders to administer intranasal midazolam for the emergency treatment of seizures. With midazolam nasal spray now approved by the FDA for children 12 and older, school nurses should know the rationale and effects of medications and be able to administer them correctly, as school nurses are bound by the Nurse Practice Act to promote the safety of the student.

To assist the school nurse in promoting safety and gaining the information necessary to administer this medication in the school setting, the following information may be helpful.

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The Medication

Midazolam (MID aye zoe lam), classified as a benzodiazepine, is a nasal spray for children over 12. It is supplied as a solution for injection or as a syrup for oral use. It is used as a sedative/anesthesia in preoperative settings and known as Versed. However, midazolam is also prescribed for off-label use in the treatment of status epilepticus (SE) and may be supplied via the intranasal route patients age 12 years of age and older.

Patients and caregivers should be counseled to read carefully the "Instructions for Use" for complete directions on how to properly administer NAYZILAM per the FDA.

According to the FDA Prescribing Information NAYZILAM should be administered by the nasal route only.

Initial Dose: Administer one spray (5 mg dose) into one nostril.

Second Dose (if needed): One additional spray (5 mg dose) into the opposite nostril may be administered after 10 minutes if the patient has not responded to the initial dose.

Maximum Dosage and Treatment Frequency: Do not use more than 2 doses of NAYZILAM to treat a single episode.

It is recommended that NAYZILAM be used to treat no more than one episode every three days and no more than 5 episodes per month

For more information regarding administration and usage please refer to the [Highlights of Prescribing Information from the Federal Drug Administration.](#)

Why the Medication May be Prescribed

- A prolonged seizure is harder to stop than a brief seizure.⁴ The majority of seizures remit spontaneously. Status Epilepticus (SE) is defined as a tonic-clonic (convulsive) seizure that lasts for more than five minutes; a prolonged non-convulsive seizure; or multiple seizures that occur without recovery to baseline between events.⁵
- The longer the seizure, the longer the recovery period for patients.
- Rescue medications can prevent seizure progression to SE, transportation to an emergency department, and the associated costs of escalated treatment.⁴
- Seizure emergencies, such as SE or changes in typical seizure clusters or frequency, are rare but can be life threatening.⁷

Nursing Standards and License Considerations

The Nursing Practice Act or NPA (Texas Occupations Code, Chapter 301 et. seq.) and Board rules and regulations are written broadly so all nurses can apply them in various practice settings across the state. Because each nurse has a different background, knowledge, and level of competence, it is up to each *individual* nurse to use sound judgment when deciding whether or not to perform any particular procedure or act.

The Standards of Nursing Practice, found in [Board Rule 217.11](#), apply to all nurses and provides guidance on the use of medications. Some of the more applicable standards addressed in [Board Rule 217.11](#) section (1) include:

- (A): Requires the nurse to know and conform to not only the Texas NPA and the Board's rules and regulations but to all federal, state, or local laws, rules or regulations affecting the nurse's current area of nursing practice:
 - For a school nurse, there may be laws, rules, or regulations from the [Texas Education Agency](#), for example, that impact the use of this medication. Therefore, school nurses should be familiar with the Texas Education Code and how it affects the delivery of nursing services to students.
- (B): Requires the nurse to implement measures to promote a safe environment for clients and others;
- (C) Know the rationale for and the effects of medications and treatments and shall correctly administer the same.
- (M) Institute appropriate nursing interventions that might be required to stabilize a client's condition and/or prevent complications.

Each RN and LVN must individually determine his/her scope of practice using the Board's [Scope of Practice Decision-Making Model](#) (DMM), a step-by-step tool all nurses practicing in Texas can use to determine if any given task/procedure is within their individual scope of practice. The DMM is designed to be used in sequence, beginning at the top with question number one. In the model, nurses are asked reflective questions, and depending on how they answer, they are directed to continue through the model or stop. In your progression through the model, you can also reference professional nursing organizations or specialty associations to assist you in determining the standard of care in the setting you describe and your individual scope of practice. At any point, if you reach a **Stop Sign**, you

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should consider the activity or intervention in question beyond (or outside) your scope of practice. For example, on Question 4, if you are unable to find supporting evidence-based practice findings and/or guidelines or scope of practice/position statements from national nursing organizations, this would not be within the nursing scope of practice.

Additionally, you may wish to review Position Statement 15.14, [Duty of a Nurse in any Practice Setting](#). The referenced position statement is important for nurses to understand that they must intervene or advocate on behalf of their patients and establishes that a nurse has a responsibility and duty to a patient to provide and coordinate the delivery of safe, effective nursing care, through the NPA and Board Rules. This duty supersedes any facility policy or physician order.

Board staff cannot speak to the laws and rules of other agencies and would recommend you contact the above entities directly if you have further questions and concerns. Also, while the Board does not have purview over employment policies, Board staff recommends you review the school district's policies and procedures that address emergency situations.

Texas Board of Nursing (BON) Resources

1. [Nursing Practice Act](#), Nursing Peer Review & Nurse Licensure Compact: Occupations Code and Statutes Regulating the Practice of Nursing. As Amended September 2019.
2. [Rules & Regulations](#) relating to Nurse Education, Licensure and Practice. Published April 2019.
3. [Position Statement:](#)
 - [15.14 Duty of a Nurse in any Practice Setting](#)
4. [Scope of Practice Decision-Making Model](#)

National Association of School Nurses (NASN)

- [Code of Ethics](#)
- Position Brief (2018): [Wearable Medical Technology in Schools- The Role of the School Nurse](#)
- Position Statement (2018): [IDEIA and Section 504 Teams- The School Nurse as an Essential Team Member](#)
- Position Statement (2017): [Students with Chronic Health Conditions: The Role of the School Nurse](#)

Texas School Nurses Organization (TSNO)

- School Nursing: [Scope and Standards of Practice](#)

Research

The following articles have been compiled from a review of the scientific literature. For assistance in obtaining an article, please contact the DSHS Library at library@dshs.state.tx.us and mention inclusion of the requested article in the *School Nurse Notes*. The articles are presented on a continuum, ranging from those providing basic seizure information to those specifically addressing the use of intranasal midazolam for SE. Following each citation is a portion of the article's abstract.

1. Detynieckie K, Van Ess P, Sequeira D, Wheless J, Meng, T, Pullman. Safety and efficacy of midazolam nasal spray in outpatient treatment of patients with seizure clusters- a randomized double-blind, placebo-controlled trial. *Epilepsia*. Wiley Library. 2019; 60:1797-1808 DOI: 10.1111/epi.15159
Phase III of evaluating the safety and efficacy of midazolam administered as a single dose nasal spray in a randomized, double blind, placebo-controlled trial to patients of 12 years of age and older. Clinical Trial NCT01390220
2. Crawford D. **Implementation of Intranasal Midazolam for Prolonged Seizures in a Child Neurology Practice**. American Assoc. of Neuroscience Nurses. 2016; 48:315-321 DOI:10.1097/JNN.0000000000000234
This project focused on the development of a process to make intranasal midazolam available as a treatment option and then the creation of an educational intervention.
3. Terry D, Patel AD, Cohen DM, Scherzer D, Kline J. **Barriers to seizure management in schools: perceptions of school nurses**. *J Child Neurol*. 2016; 1-5.
Eighty-three school nurses completed an electronic survey. . . . School nurses are comfortable managing seizures in a school setting. However, a specific seizure plan for each child and education on intranasal midazolam and vagus nerve stimulator magnet use is needed.
4. Wolfe TR, Braude DA. **Intranasal medication delivery for children: A brief review and update**. *Pediatrics*. 2010; 126:532-537.
Intranasal medication delivery offers an alternative method of drug delivery that is often as fast in onset as intravenous medication, usually painless, inexpensive, easy to deliver, and effective in a variety of pediatric medical conditions. This article briefly reviews the most common uses for intranasal medication delivery in pediatrics: pain control, anxiolysis, and seizure control.
5. Grover EH, Nazzal Y, Hirsch LJ. **Treatment of convulsive status epilepticus**. *Curr Treat Options Neurol*. 2016; 18:11.
Convulsive status epilepticus (CSE) is a medical emergency with an associated high mortality and morbidity.... Current guidelines recommend the use of benzodiazepines (BNZ) as first-line treatment in CSE.... Regular use of

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home rescue medications such as nasal/buccal midazolam by patients and caregivers for prolonged seizures and seizure clusters may prevent SE, prevent emergency room visits, improve quality of life, and lower health care costs.

6. Abend NS, Loddenkemper T. **Pediatric status epilepticus management.** *Curr Opin Pediatr.* 2014; 26(6):668-674.
This review discusses management of status epilepticus (SE) in children involving both anticonvulsant medications and overall management approaches. . . An example management pathway is provided.... SE is a common neurologic emergency in children and requires rapid intervention. Having a predetermined SE management pathway can expedite management.
7. Arzimanoglou A, Lagae L, Cross JH, et al. **The administration of rescue medication to children with prolonged acute convulsive seizures in a non-hospital setting: an exploratory survey of healthcare professionals' perspectives.** *Eur J Pediatr.* 2014; 173: 773-779.
We present the findings from an exploratory telephone survey of 128 healthcare professionals (HCPs) (85 pediatric neurologists and neurologists, 28 community pediatricians, and 15 epilepsy nurses) from 6 EU countries, conducted as part of the PERFECT™ initiative.... Results of this HCP survey have identified several gaps that need to be addressed: clearer guidance that spans all settings of care, greater dissemination of such guidelines across the chain of care, more open communication and better links between HCPs and schools, and systematic training of all relevant caregivers on the appropriate management of prolonged convulsive seizures.
8. Hartman AL, Devore CDL, AAP and the SECTION ON NEUROLOGY, et al. **Rescue medicine for epilepsy in education settings.** *Pediatrics.* 2016; 137(1): e20153876.
This clinical report highlights issues that providers may consider when prescribing seizure rescue medications and creating school medical orders and/or action plans for students with epilepsy. Collaboration among prescribing providers, families, and schools may be useful in developing plans for the use of seizure rescue medications.
9. Galemore CA. **Rescue medicine for epilepsy.** *NASN School Nurse.* 2016; 339-341.
The American Academy of Pediatrics (AAP) recently published a clinical report recommending expanded options for seizure rescue medications in the school setting. School nurses can assist health care providers in determining the rescue medication most easily delivered and monitored in the variety of activities that are part of the school experience, including transportation to and from school, field trips, and before- and after-school activities, all beyond the regular classroom setting.

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10. Mula M. **The safety and tolerability of intranasal midazolam in epilepsy.** *Expert Rev Neuro Ther.* 2014;14(7):735-740.

This article aims to provide an overview of intranasal midazolam in the acute management of epileptic seizures.... Local mucosal irritation seems to occur in less than one-third of cases while serious side effects such as respiratory depression in about one percent.... Moreover, comparisons with buccal midazolam are warranted.
11. Kalviainen R. **Intranasal therapies for acute seizures.** *Epilepsy Behav.* 2015; 49: 303-306.

Intranasal midazolam (INM) is faster at aborting seizure activity than rectal diazepam and quicker to administer than intravenous diazepam.... [INM's] shorter elimination half-life may also be beneficial in that patients may more quickly return to normal function because of rapid offset of effect. On the other hand, the faster rate of elimination of midazolam may expose patients to a higher rate of seizure recurrence compared to diazepam.
12. Humphries LK, Eiland LS. **Treatment of acute seizures: Is intranasal midazolam a viable option?** *J Pediatric Pharmacol Ther.* 2013; 18(2): 79-87.

This paper will review available data pertaining to the efficacy, safety, cost, pharmacokinetics of intranasal midazolam versus rectal diazepam as treatment for acute seizures for children in the prehospital, home, and emergency department settings.
13. 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 Pediatric Adolesc Med.* 2010; 164(8): 747-753.

There was no detectable difference in efficacy between intranasal midazolam via a Mucosal Atomization Device (IN-MMAD) and rectal diazepam (RD) as a rescue medication for terminating seizures at home in pediatric patients with epilepsy. Ease of administration and overall satisfaction was higher in IN-MMAD compared with RD.
14. Kyrkou M, Harbord M, Kyrkou N, et al. **Community use of intranasal midazolam for managing prolonged seizures.** *J Intellect Dev Disabil.* 2006; 31(3): 131-138.

Following a literature review, a seizure management training package was developed to enhance the implementation of a trial treatment protocol for the administration of intranasal midazolam (INM). Parents, [caregivers], and education staff were later surveyed about their experiences and perceptions. INM was administered to 131 people (51 children and 80 adults), with 96.9 percent control of seizures, and only one minor adverse event.

Training/Continuing Education

Presentations

- American Academy of Pediatrics: [Rescue Medication and Seizure Emergency Planning in Education Settings](#)²
- Neurocritical Care Society: Guidelines for the Evaluation and Management Status Epilepticus³

Continuing Education

- Epilepsy Update Part 2: Nursing Care and Evidence-Based Treatment—Includes Resources, First Aid, and Teaching Points (2.5 hours)⁴
- Epilepsy Foundation: [Managing Students with Seizures: A Training for School Nurses](#) (3.2 hours)⁵

Tools and Resources

General Guidance

- ✓ American Academy of Pediatrics: [School Nurse Poster](#)⁶
- ✓ Seattle Children's Hospital: [How to Use Nasal Midazolam](#) (hand-out with photos)⁷
- ✓ New Hampshire Family Voices: [Seizure Description Tool](#)—Available in English and five other languages⁸
- ✓ Epilepsy Foundation: [Seizure Observation Record](#); [Questionnaire for Parent of Student with Epilepsy](#)⁹
- ✓ Children's Hospital Colorado: [Training, Delegation Authorization and Supervision Record – Intranasal Midazolam](#) (copyrighted)¹⁰
- ✓ Pediatric Neurology Nurse Video: [Administration of Intranasal Midazolam](#)¹¹
- ✓ National Association of School Nurses: [Medication Administration in the School Setting](#); [Anti-Epileptic Drugs](#) (AEDs)¹²
- ✓ Grapevine-Colleyville ISD School Health Services: [Intranasal Midazolam \(Versed\) Administration Guidelines with Consent and Release](#)¹³
- ✓ Michigan School Nurse Advisory Council: [Guidance Document for Michigan Schools—Midazolam \(Versed\) Intranasal Administration in the School Setting](#)¹⁴

Tools to Personalize

- ✓ New Hampshire Family Voices: [Seizure Action Plan](#)¹⁵
- ✓ Nevada (Clark County): [Sample Policy and Administration Procedure](#)¹⁶

References

For assistance in obtaining any resources, please contact the DSHS Library at library@dshs.state.tx.us and mention inclusion of the requested resource in the *School Nurse Notes*.

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<http://www.epilepsy.com/get-help/services-and-support/training-programs/managing-students-seizures-school-nurse-training>.
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15. New Hampshire Family Voices. Seizure Action Plan.
<http://nhfv.org/wp-content/uploads/2015/04/SeizureActionPlan.pdf>. (Accessed on 11/16/16)
16. Nevada (Clark County). Sample Policy and Administration Procedure.
<http://shoms.ccsd.net/files/ppt/versedpolicy.pdf>. (Accessed on 11/16/16)

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