

## Anticonvulsants – Rescue Agents

Medical policy no. 72.10.00.30

Effective: February 1, 2019

**Note:**

- For non-preferred agents in this class/category, patients must have had an inadequate response or have had a documented intolerance due to severe adverse reaction or contraindication to at least TWO\* preferred agents.  
\*If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed
- If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria

**Background:**

For people with seizures who experience status epilepticus (prolonged or recurrent seizures), getting the earliest possible treatment is important. The availability of treatments at home, before emergency medical services (EMS) arrive or before being treated in an emergency room, is currently limited (Table 1), but crucial.

**Medical necessity**

Drug	Medical Necessity
Midazolam HCl solution	Midazolam may be considered medically necessary when: Administered intranasally as a rescue agent for prolonged seizures
Diazepam rectal gel (DIASSTAT®)	Diazepam rectal gel may be considered medically necessary when: Administered rectally as a rescue agent for prolonged seizures

**Clinical policy:**

Drug	Clinical Criteria (Initial Approval)
Midazolam solution	<ol style="list-style-type: none"> <li>Documentation of seizure/epilepsy</li> <li>Administered intranasally as a rescue agent for prolonged seizures lasting longer than 3 minutes</li> <li>Maximum 10mg per dose</li> </ol> <p><b>Approve for 6 months</b></p>
	<p><b>Criteria (Reauthorization)</b></p> <p>Documentation of positive clinical benefit</p> <p><b>Approve for 12 months</b></p>
Diazepam rectal gel	<ol style="list-style-type: none"> <li>Documentation of seizure/epilepsy</li> <li>Administered rectally as a rescue agent for prolonged seizures lasting longer than 3 minutes</li> </ol>

	3. Maximum 20mg per dose <b>Approve for 6 months</b>
	<b>Criteria (Reauthorization)</b>
	Documentation of positive clinical benefit <b>Approve for 12 months</b>

### Route of administration comparison for seizure rescue medications

	Advantages	Disadvantages
<b>Oral</b>	Currently available, portable.	May be difficult to administer during a seizure. Relatively slower to onset of action.
<b>Rectal</b>	FDA approved. Faster onset of action than oral administration.	Difficult to administer in many settings.
<b>Intramuscular</b>	Easy administration.	Complications at injection site. Unreliable absorption.
<b>Nasal</b>	Rapid absorption. Can be given in any position.	Administration does require minimal training. Risk of injury to nasal cavity.

### Dosage and quantity limits

Drug Name	Dose and Quantity Limits
Midazolam HCl solution	<ul style="list-style-type: none"> <li>10mg per dose; 5 doses per 30-days</li> </ul>
Diazepam rectal gel	<ul style="list-style-type: none"> <li>20mg per dose; 4 doses per 30-days</li> </ul>

### Coding:

HCPCS	Description
J2250	Injection, midazolam hydrochloride, per 1 mg
J3360	Injection, diazepam, up to 5mg

### Definitions

Term	Description
Prolonged seizures	Seizures lasting longer than 3 to 5 minutes

### References

1. Product Information: MIDAZOLAM HCl intravenous intramuscular injection, midazolam HCl intravenous intramuscular injection. Heritage Pharmaceuticals (per DailyMed), Eatontown, NJ, 2017.
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13. Crisp CB, Gannon R, & Knauft F: Continuous infusion of midazolam hydrochloride to control status epilepticus. Clin Pharm 1988; 7:322-324.
14. Mayhue FE: IM midazolam for status epilepticus in the emergency department. Ann Emerg Med 1988; 17:643-645.
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16. Chamberlain JM, Altieri MA, Futterman C, et al: A prospective, randomized study comparing intramuscular midazolam with intravenous diazepam for the treatment of seizures in children. Pediatr Emerg Care 1997; 13(2):92-94.
17. Product Information: midazolam HCl oral syrup, midazolam HCl oral syrup. West-Ward Pharmaceuticals Corp. (per DailyMed), Eatontown, NJ, 2017.
18. Zelcer M., Goldman R. D. Intranasal midazolam for seizure cessation in the community setting. Canadian Family Physician. 2016;62(7):559–561.
19. Micromedex® 2.0, (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/> (cited: 02/28/2018).

## History

Date	Action and Summary of Changes
01/25/2019	<ol style="list-style-type: none"> <li>1. Removed “Prescribed by or in consultation with a neurology/epileptology specialist”</li> <li>2. Removed required documentation regarding administration and safety.</li> </ol>
08/24/2018	Addition of diazepam
04/18/2018	New Policy