MDWISE PRIOR AUTHORIZATION CRITERIA

DIASTAT® (diazepam rectal gel) Gel: 2.5mg FORMULARY STATUS: Formulary
DIASTAT® AcuDial™ (diazepam rectal gel) Gel: 10mg & 20mg FORMULARY STATUS: Formulary

PA CRITERIA FOR APPROVAL:
• Diagnosis of refractory epilepsy.
  AND
• Patient is currently on a stable regimen of anti-epileptic agents who requires intermittent use of diazepam to control bouts of increased seizure activity.

If the above conditions are met, the request will be approved with a 3 month duration; if the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.

If the request is for > 5 doses per month, the request will be referred to a Medical Director for medical necessity review.

FDA INDICATION:
For the management of selected, refractory patients with epilepsy on stable regimens of anti-epileptic agents who require intermittent use of diazepam to control bouts of increased seizure activity.

DOSAGE AND ADMINISTRATION:
Diastat is administered rectally at doses between 0.2 to 0.5 mg/kg depending on age.

- **Age 2 to 5 years of age:** 0.5 mg/kg.
- **Age 6 to 11 years of age:** 0.3 mg/kg.
- **Greater than or equal to 12 years of age:** 0.2 mg/kg.

The following table provides acceptable weight ranges for each dose, and age category:

<table>
<thead>
<tr>
<th>Dexamphetamine Rectal Dosing Based on Age and Weight</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2-5 yrs of age Weight (kg)</td>
<td>6-11 yrs of age Weight (kg)</td>
</tr>
<tr>
<td>6-10</td>
<td>10-16</td>
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<tr>
<td>11-15</td>
<td>17-25</td>
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<tr>
<td>16-20</td>
<td>2633</td>
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<td>21-25</td>
<td>34-41</td>
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<tr>
<td>26-30</td>
<td>42-50</td>
</tr>
<tr>
<td>31-35</td>
<td>51-58</td>
</tr>
<tr>
<td>36-44</td>
<td>59-74</td>
</tr>
</tbody>
</table>

(The recommended dose is calculated by rounding upward to the next available unit dose.)

In elderly and debilitated patients, it is recommended that the dosage be adjusted downward to reduce the likelihood of ataxia or oversedation. A second dose, when required, may be given 4 to 12 hours after the first dose. Do not treat > 5 episodes per month or > 1 episode every 5 days. The 20 mg syringe cannot be used for a 10 mg dose. The minimum dose in the 20 mg syringe is 12.5 mg.

REFERENCES:

Revision/Review Date: MAC 10/12/2011
Associated Policy: Prior Authorization of Medications 236.200

**NOTE:** Physician review must override criteria when, in his/her professional judgement, the requested item is medically necessary.