Clinical Policy: Rufinamide (Banzel)
Reference Number: CP.PMN.157
Effective Date: 12.01.14
Last Review Date: 08.20
Line of Business: HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Rufinamide (Banzel®) is a triazole derivative.

FDA Approved Indication(s)
Banzel is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in pediatric patients 1 year of age and older and in adults.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Banzel is medically necessary when the following criteria are met:

I. Initial Approval Criteria
A. Lennox-Gastaut Syndrome (must meet all):
   1. Diagnosis of LGS;
   2. Prescribed by or in consultation with a neurologist;
   3. Age ≥ 1 year;
   4. Failure of two preferred alternatives for LGS (see Appendix B for examples) unless all are contraindicated or clinically significant adverse effects are experienced;
   5. Dose does not exceed 3,200 mg (8 tablets or 80 mLs) per day.
   
   Approval duration: 12 months

B. Other diagnoses/indications
   1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy
A. Lennox-Gastaut Syndrome (must meet all):
   1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Banzel for Lennox-Gastaut syndrome and has received this medication for at least 30 days;
   2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 3,200 mg (8 tablets or 80 mLs) per day.

**Approval duration: 12 months**

B. **Other diagnoses/indications** (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      
      **Approval duration: Duration of request or 12 months (whichever is less); or**
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

- **Appendix A: Abbreviation/Acronym Key**
  
  FDA: Food and Drug Administration
  
  LGS: Lennox-Gastaut syndrome

- **Appendix B: Therapeutic Alternatives**
  
  This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Examples</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticonvulsants for LGS</td>
<td>clonazepam (Klonopin®), felbamate (Felbatol®), lamotrigine (Lamictal®), topiramate (Topamax®), valproic acid (Depakene®), divalproex sodium (Depakote®), clobazam (Onfi®)</td>
<td>Varies according to the agent used</td>
</tr>
</tbody>
</table>

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

- **Appendix C: Contraindications / Boxed Warnings**
  
  - Contraindication(s): familial short QT syndrome
  
  - Boxed warning(s): none reported

**V. Dosage and Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>LGS</td>
<td><em>Pediatric patients 1 year to less than 17 years:</em> 3,200 mg/day</td>
<td></td>
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</tbody>
</table>

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### Indication | Dosing Regimen | Maximum Dose
--- | --- | ---
Starting daily dose: 10 mg/kg per day in two equally divided doses; increase by 10 mg/kg increments every other day to maximum dose of 45 mg/kg per day, not to exceed 3,200 mg per day, in two divided doses
*Adults (17 years and older):* Starting daily dose: 400-800 mg per day in two equally divided doses; increase by 400-800 mg every other day until a maximum dose of 3,200 mg per day, in two divided doses, is reached

### VI. Product Availability
- Film-coated tablets: 200 mg, 400 mg
- Oral suspension: 40 mg/mL

### VII. References

### Reviews, Revisions, and Approvals
<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reformatted guideline to new format. Added Workflow reference document.</td>
<td>12.15</td>
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</table>
Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified requirement related to formulary trial to include trial and failure of two formulary alternatives. Removed workflow document. Updated references to reflect current literature search.</td>
<td>08.16</td>
<td>08.16</td>
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<tr>
<td>Converted to new template. Added prescriber specialty; removed continuity of care from initial approval section and incorporated it in the continuation criteria; added max dose. Updated references.</td>
<td>04.17</td>
<td>08.17</td>
</tr>
<tr>
<td>3Q 2018 annual review: new policy for Medicaid line of business; added age requirement; references reviewed and updated.</td>
<td>04.06.18</td>
<td>08.18</td>
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<tr>
<td>3Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>05.19.19</td>
<td>08.19</td>
</tr>
<tr>
<td>3Q 2020 annual review: no significant changes; references reviewed and updated.</td>
<td>05.04.20</td>
<td>08.20</td>
</tr>
</tbody>
</table>

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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