



## Prior Authorization Approval Criteria

### *Banzel (rufinamide)*

<b>Generic name:</b>	Rufinamide
<b>Brand name:</b>	Banzel
<b>Medication class:</b>	Anticonvulsants
<b>FDA-approved uses:</b>	Indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults.
<b>Available dosage forms:</b>	200 mg and 400 mg tablets
<b>Usual dose:</b>	Children 4 years of age and older: 10 mg/kg/day in two divided doses. The dose may be increased in 10 mg/kg increments every other day to a target dose of 45mg/kg or 3200 mg/day, whichever is less. Adults: 400-800 mg/day in two divided doses. The dose should be increased by 400 mg-800 mg/day every 2 days until a maximum daily dose of 3200 mg/day.
<b>Approximate monthly cost:</b> (based on AWP 2009)	\$1500.00/month based on a dose of 3200mg/day
<b>Duration of therapy:</b>	Indefinite

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- Must be clinically diagnosed with seizures associated with Lennox-Gastaut syndrome.
- Patient must be refractory to at least 2 of the following:
  - Felbamate (Felbatol)
  - Lamotrigine (Lamictal)
  - Topiramate (Topamax)
  - Valproic acid (Depakene)
  - Divalproex sodium (Depakote)
- Must be 4 years of age or older.

**Caution:**

- Use of Banzel (rufinamide) with other drugs that shorten the QT interval.
- Antiepileptic drugs increase the risk of suicidal thoughts or behavior.

**Monitoring:**

- Patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.

**Contraindication:**

- Patients with familial short QT syndrome

**Not approved if:**

- Does not meet the above stated criteria
- Patient has any contraindications to the use of rufinamide

**Special considerations:**

- The efficacy of rufinamide in treating other types of seizures remains to be established.

**Some antiepileptic drugs for LGS**

based on the Medical Letter Volume 51 March 9,2009

<b>Drug</b>	<b>Usual Adult Dose</b>	<b>Usual Pediatric Dose</b>	<b>Cost<sup>1</sup></b>
Felbamate (Felbatol)	2400-3600mg	15-45-mg/kg	\$322.80
Lamotrigine-generic Lamictal, Lamictal CD	100-500 mg	1-15 mg/kg	133.80 163.20
Rufinamide (Banzel)	3200mg	45 mg/kg	1500.00
Topiramate (Topamax)	200-400 mg	5-9 mg/kg	249.30
Valproic acid- generic Depakene	1000-3000 mg	15-60 mg/kg	35.96 324.00
Divalproex sodium (Depakote, Depakote Sprinkle) Depakote ER	1000-3000 mg 1250-3500 mg	15-60 mg/kg	214.40 238.50

1. Cost for 30 days treatment with the lowest usual dosage.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 06/10/09