Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February, 2009 December 10, 2009; April 5, 2012, April 23, 2015

BANZEL® (rufinamide)

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

- Patient must be ≥1 year old
- Must have a diagnosis of Lennox-Gastaut Syndrome verified by progress notes, discharge notes, or health conditions.
- Patients with a diagnosis of Lennox-Gastaut Syndrome must be currently on an antiepileptic regimen
    - Regimen must include one of the following: a valproate, Topamax, clonazepam, or Lamictal
- If a patient meets the age requirement, but does not have a diagnosis of Lennox Gastaut they:
    - Must have a diagnosis of seizures (verified in health conditions or progress notes) and medical documentation verifying a history of inadequately controlled seizures.
    - Must be on other anticonvulsant medication.
    - Banzel must be prescribed by a neurologist.

DOSING:

Adults: Initially, 400-800 mg/day ORALLY in 2 equally divided doses with food. The dosage should be increased every 2 days by 400—800 mg/day to a target and maximum dose of 3200 mg/day given in 2 equally divided doses. It is not known if doses less than 3200 mg/day are effective.

Children: ≥ 1 year to 17 years: Initially, 10 mg/kg/day ORALLY given in 2 equally divided doses with food. The dose should be increased every other day by 10 mg/kg to a target dose of 45 mg/kg/day or 3200 mg/day, whichever is less, given in 2 equally divided doses.

(If drug discontinuation is necessary, rufinamide should be withdrawn gradually (e.g., 25% dose reduction every 2 days) to minimize the potential for increased seizure frequency.)