Pharmacy Policy Bulletin

Title: Rufinamide (Banzel™)

Policy #: Rx.01.81

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

Rufinamide (Banzel™) is indicated foradjunctive treatment of seizures associated with Lennox-Gastaut syndrome in adults and children 4 years of age and older.

The use of rufinamide (Banzel™) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

Description:

Rufinamide (Banzel™) is an anticonvulsant. While the precise mechanism(s) by which rufinamide exerts its antiepileptic effect is unknown, it is thought that as per invitro studies that it modulates the activity of sodium channels and then prolongs the inactive state of the channel.

Policy:

Rufinamide (Banzel™)is approved when the following inclusion criterion is met:

- Documentation of a diagnosis of seizures associated with Lennox-Gastaut syndrome

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Banzel™ (rufinamide). In: Facts and Comparisons [online through Facts and Comparisons Online]. Available at www.Factsandcomparisons.com Accessed April 8, 2011.

Banzel™ (rufinamide). In: Drugdex [online through Micromedex Healthcare Series]. Available at www.micromedex.com

. Accessed April 8, 2011.

Banzel™ (rufinamide).Woodcliff Lake, NJ; Novartis Pharma AG: November 2008.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Banzel	rufinamide

Cross References:

Policy Version Number: 1.00

P&T Approval Date: March 08, 2012

Policy Effective Date: June 01, 2012

Next Required Review Date: March 08, 2013