Gabapentin Compounding Powder

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Gabapentin capsules, tablets, and oral solution are used to help control certain types of seizures in people who have epilepsy. Gabapentin capsules, tablets, and oral solution are also used to relieve the pain of postherpetic neuralgia (PHN; the burning, stabbing pain or aches that may last for months or years after an attack of shingles). Gabapentin extended-release tablets (Horizant) are used to treat restless legs syndrome (RLS; a condition that causes discomfort in the legs and a strong urge to move the legs, especially at night and when sitting or lying down). Gabapentin is in a class of medications called anticonvulsants. Gabapentin treats seizures by decreasing abnormal excitement in the brain. Gabapentin relieves the pain of PHN by changing the way the body senses pain (1).

Gabapentin is commercially available as 100mg, 300mg, and 400mg capsules and tablets, 600mg and 800mg tablets, and a 250mg/5 ml solution (2).

Regulatory Status
Gabapentin is FDA-approved in an oral formulation for the management of postherpetic neuralgia in adults and also as an adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients 12 years of age with epilepsy, and as adjunctive therapy in the treatment of partial seizures in pediatric patients age 3 to 12 years. Gabapentin is also indicated for treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) in adults (2-3).

Gabapentin is recommended for add-on therapy in patients 3 years of age and older. Effectiveness in pediatric patients below the age of 3 years has not been established (2).

Off-Label Uses:
Off-label (non-FDA approved) compounded topical preparations of gabapentin have not been shown to be superior to commercially available topical diclofenac preparations.

Summary
Gabapentin is FDA-approved in an oral formulation for the management of postherpetic neuralgia
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in adults, as an adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients 12 years of age with epilepsy and as adjunctive therapy in the treatment of partial seizures in pediatric patients age 3 to 12 years (2). Gabapentin is also indicated for the treatment of Restless Legs Syndrome (RLS). There are no clinical studies to support the safety and effectiveness of gabapentin in a topical delivery system (1-3).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of gabapentin while maintaining optimal therapeutic outcomes.

References