GABAPENTIN
(Gralise, Horizant, Neurontin)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Gabapentin is used in the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN), neuropathic pain associated with spinal cord injury, partial onset seizures, postherpetic neuralgia, or Restless Legs Syndrome (RLS). Gabapentin is thought to reduce the release of a neurotransmitter called glutamate. Glutamate is a neurotransmitter that acts as a natural 'nerve-exciting' agent. It's released when electrical signals build up in nerve cells and subsequently excites more nerve cells. As gabapentin reduces the release of this neurotransmitter it can also be used to treat nerve pain that occurs as a result of damage to or a disturbance in the function of nerves (neuropathic pain)(1-3).

Regulatory Status
FDA-approved indications: Gabapentin is indicated for postherpetic neuralgia in adults, adjunctive therapy in the treatment of partial onset seizures with and without secondary generalization in adults and pediatric patients 3 years and older and treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) (1-3).

In clinical studies, gabapentin efficacy was demonstrated over a range of doses from 1800 mg/day to 3600 mg/day (1-3).

The safety and efficacy of gabapentin in the management of postherpetic neuralgia in pediatric patients have not been established. Effectiveness as adjunctive therapy in the treatment of partial seizures in pediatric patients below the age of 3 years has not been established (1).

Summary
Gabapentin is used in the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN), neuropathic pain associated with spinal cord injury, partial onset seizures, postherpetic neuralgia, or restless legs syndrome (RLS). Gabapentin is thought to reduce the release of a neurotransmitter called glutamate. As gabapentin reduces the release of this neurotransmitter it can also be used to treat nerve pain that occurs as a result of damage to or a disturbance in the function of nerves (neuropathic pain) (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Gabapentin FEP Clinical Rationale
gabapentin while maintaining optimal therapeutic outcomes.

References