OVERVIEW
Lyrica, Gralise, and gabapentin (Neurontin, generics) are analogs of the neurotransmitter gamma-aminobutyric acid (GABA). Horizant is a prodrug of gabapentin. These drugs exert their pharmacologic action by binding to the alpha-2-delta subunit of voltage-gated calcium channels. The binding of this subunit reduces the release of several neurotransmitters including glutamate, noradrenaline, and substance P. It has been postulated that Lyrica has a stronger receptor affinity and, therefore, may be more potent than any of the gabapentin products. The clinical relevance of this has yet to be established. Lyrica is a schedule V controlled substance; Gralise, Horizant, and gabapentin are not controlled substances. Lyrica and gabapentin are both available as capsules and oral solution; Gralise and Horizant are available as extended-release (ER) tablets.

Despite their pharmacologic similarities, Lyrica and the gabapentin products do differ in some respects. For example, Lyrica can be dosed twice daily (BID) or three times daily (TID) whereas gabapentin is dosed TID and Gralise and Horizant are dosed once daily (QD).

Lyrica is indicated for the management of postherpetic neuralgia (PHN), as adjunctive therapy in the treatment of partial onset seizures in adults, for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN), for the management of fibromyalgia, and for treatment of neuropathic pain associated with spinal cord injury. Gabapentin and Gralise are indicated for the management of PHN. Gabapentin is also approved as adjunctive therapy in the treatment of partial onset seizures in adults and children. Horizant is indicated for moderate-to-severe restless leg syndrome (RLS) in adults and PHN.

POLICY STATEMENT
A step therapy program has been developed to encourage the use of a generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy. Additionally, for Lyrica and Neurontin, a prescription for one antiepileptic drug (AED) within the 130-day look-back period is used as a surrogate marker for seizure disorders. If criteria for prior use of one AED are not met at the point-of-service, coverage will be determined by prior authorization criteria.

Step 1: gabapentin capsules, tablets, and oral solution
Step 2: Gralise, Horizant, Lyrica, Neurontin

CRITERIA
Exceptions for a Step 2 agent can be made for those who meet one of the following criteria:
1. If the patient has tried gabapentin IR (brand [Neurontin] or generic), then authorization for a Step 2 product may be given.

2. Exceptions may be made for Lyrica if the patient has tried Gralise or Horizant.

3. Exceptions may be made for Lyrica if the patient is established on therapy for a neuropathic pain condition. (e.g., Fibromyalgia, Neuropathic pain diabetes and spinal cord related, and postherpetic neuralgia.)

4. Exceptions may be made for Lyrica if the patient has a seizure disorder.

5. Exceptions may be made for Lyrica if it is being prescribed for the treatment of GAD if the patient has tried at least two of the following: a TCA (e.g., imipramine, nortriptyline), an SSRI (e.g., paroxetine, Lexapro), an SNRI (e.g., Effexor XR), or buspirone. Note: The two agents tried do not have to be from different classes. For example, an exception should be made for a patient who has tried two SSRIs.

6. No other overrides are recommended.

References