

## STEP THERAPY CRITERIA

**BRAND NAME  
(generic)**

**GRALISE  
(gabapentin extended release tablet)**

**HORIZANT  
(gabapentin enacarbil extended release tablet)**

**LYRICA  
(pregabalin)**

**LYRICA CR  
(pregabalin extended-release)**

**Status: CVS Caremark Criteria**

**Type: Initial Step Therapy; Post Step Therapy Prior Authorization**

### POLICY

#### FDA-APPROVED INDICATIONS

##### **Gralise**

Gralise is indicated for the management of postherpetic neuralgia.

Gralise is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.

##### **Horizant**

###### Treatment of Restless Legs Syndrome

Horizant (gabapentin enacarbil) Extended-Release Tablets are indicated for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) in adults.

Horizant is not recommended for patients who are required to sleep during the daytime and remain awake at night.

###### Management of Postherpetic Neuralgia

Horizant (gabapentin enacarbil) Extended-Release Tablets are indicated for the management of postherpetic neuralgia (PHN) in adults.

##### **Lyrice**

Lyrice is indicated for:

- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunctive therapy for adult patients with partial onset seizures
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

#### Compendial Uses

- **Cancer-Related Neuropathic Pain<sup>6</sup>**

Lyrice, Gralise, Horizant Step Therapy Policy 05-2017

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- Cancer Treatment Related Neuropathic Pain<sup>6,13</sup>

### **Lyrica CR**

Lyrica CR is indicated for the management of:

- Neuropathic pain associated with diabetic peripheral neuropathy
- Postherpetic neuralgia

Efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures.

### **INITIAL STEP THERAPY CRITERIA**

If the patient has filled a prescription for at least a 30 day supply of regular-release generic gabapentin within the past 120 days under a prescription benefit administered by CVS/caremark, then the requested Gralise, Horizant, Lyrica, or Lyrica CR will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the system will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

### **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has experienced an inadequate treatment response, intolerance, or contraindication to regular-release generic gabapentin  
**OR**
- Lyrica (pregabalin) or Lyrica CR (pregabalin extended-release) is being prescribed for the management of neuropathic pain associated with diabetic peripheral neuropathy  
**OR**
- Lyrica (pregabalin) is being prescribed for the management of fibromyalgia, the management of neuropathic pain associated with diabetic peripheral neuropathy, or the management of neuropathic pain associated with spinal cord injury  
**OR**
- Horizant (gabapentin enacarbil) being prescribed for the treatment of Restless Legs Syndrome

### **REFERENCES**

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