| Reference number(s) |
| --- |
| 656-D |

# Initial Step Therapy; Post Step Therapy Prior Authorization Lyrica, Lyrica Controlled-Release (CR), Gralise, Horizant

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Gralise | gabapentin |
| Horizant | gabapentin enacarbil |
| Lyrica | pregabalin |
| Lyrica CR | pregabalin |

## Indications

### FDA-approved Indications

#### Gralise

Gralise is indicated for the management of postherpetic neuralgia.

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


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### Horizant

**Treatment of Restless Legs Syndrome**

Horizant is 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 is indicated for the management of postherpetic neuralgia (PHN) in adults.

### Lyrica

Lyrica is indicated for:

- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

### 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.

## Compendial Uses

Lyrica

- Cancer-Related Neuropathic Pain[10,14]
- Cancer Treatment-Related Neuropathic Pain[10,14]
- Restless Legs Syndrome (RLS)[9,14]

# Initial Step Therapy

## For Lyrica CR, or Gralise

If the patient has filled a prescription for at least a 30 day supply of gabapentin immediate-release within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug


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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.

### For Horizant or Lyrica

If the patient has filled a prescription for at least a 30 day supply of any of the following: pramipexole immediate-release, ropinirole immediate-release, or gabapentin immediate-release within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug 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

## Adjunctive Therapy for the Treatment of Partial-Onset Seizures (i.e., Focal-Onset Seizures) in a patient 1 Month to Up to 3 Years of Age, Cancer-Related Neuropathic Pain, Cancer Treatment-Related Neuropathic Pain, Fibromyalgia, Neuropathic Pain associated with Spinal Cord Injury

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The request is for Lyrica (pregabalin immediate-release).
- The requested drug is being prescribed for ONE of the following:
    - Adjunctive therapy for the treatment of partial-onset seizures (i.e., focal-onset seizures) in a patient 1 month to up to 3 years of age.
    - Cancer-related neuropathic pain.
    - Cancer treatment-related neuropathic pain.
    - Management of fibromyalgia.
    - Management of neuropathic pain associated with spinal cord injury.
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules).
    - Requires a dose that cannot be obtained using the commercially available capsules.


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## Adjunctive therapy for the treatment of Partial-Onset Seizures (i.e., Focal-Onset Seizures) in a patient 3 years of age or older

Authorization may be granted when the requested drug is being prescribed for adjunctive therapy for the treatment of partial-onset seizures (i.e., focal-onset seizures) in a patient 3 years of age or older when ALL of the following criteria are met:

- The request is for Lyrica (pregabalin immediate-release).
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules).
    - Requires a dose that cannot be obtained using the commercially available capsules.
- The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin immediate-release.

## Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

Authorization may be granted when the requested drug is being prescribed for the management of neuropathic pain associated with diabetic peripheral neuropathy when ONE of the following criteria is met:

- The request is for Lyrica (pregabalin immediate-release) and ALL of the following criteria are met:
    - If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
        - Has difficulty swallowing oral solid dosage forms (e.g., capsules).
        - Requires a dose that cannot be obtained using the commercially available capsules.
    - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin immediate-release.
- The request is for Lyrica CR (pregabalin extended-release) and ALL of the following criteria are met:
    - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following:
        - Gabapentin immediate-release.
        - Pregabalin immediate-release.
        - Duloxetine.
        - Venlafaxine.
        - A tricyclic antidepressant.

## Postherpetic Neuralgia

Authorization may be granted when the requested drug is being prescribed for the management of postherpetic neuralgia when ALL of the following criteria are met:


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- The request is for Lyrica (pregabalin immediate-release), Lyrica CR (pregabalin extended-release) Gralise (gabapentin extended-release), or Horizant (gabapentin enacarbil extended-release).
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
  - Has difficulty swallowing oral solid dosage forms (e.g., capsules).
  - Requires a dose that cannot be obtained using the commercially available capsules.
- The patient experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin immediate-release.

### Restless Legs Syndrome

Authorization may be granted when the requested drug is being prescribed for the management of Restless Legs Syndrome in adults when ALL of the following criteria are met:

- The request is for Horizant (gabapentin enacarbil extended-release) or Lyrica (pregabalin immediate-release).
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
  - Has difficulty swallowing oral solid dosage forms (e.g., capsules).
  - Requires a dose that cannot be obtained using the commercially available capsules.
- The patient experienced an inadequate treatment response, intolerance, or has a contraindication to ANY of the following: pramipexole immediate-release, ropinirole immediate-release, or gabapentin immediate-release

# Continuation of Therapy

### Adjunctive Therapy for the Treatment of Partial-Onset Seizures (i.e., Focal-Onset Seizures) in a Patient 1 Month to Up to 3 Years of Age, Adjunctive Therapy for the Treatment of Partial-Onset Seizures (i.e., Focal-Onset Seizures) in a Patient 3 Years of Age or Older, Cancer-Related Neuropathic Pain, Cancer Treatment-Related Neuropathic Pain, Fibromyalgia, Neuropathic Pain Associated with Spinal Cord Injury

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The request is for Lyrica (pregabalin immediate-release).
- The requested drug is being prescribed for ONE of the following:
  - Adjunctive therapy for the treatment of partial-onset seizures (i.e., focal-onset seizures) in a patient 1 month to up to 3 years of age.
  - Adjunctive therapy for the treatment of partial-onset seizures (i.e., focal-onset seizures) in a patient 3 years of age or older.


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    - Cancer-related neuropathic pain.
    - Cancer treatment-related neuropathic pain.
    - Management of fibromyalgia.
    - Management of neuropathic pain associated with spinal cord injury.
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules).
    - Requires a dose that cannot be obtained using the commercially available capsules.
- The patient has achieved or maintained a positive clinical response to the requested drug.

## Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

Authorization may be granted when the requested drug is being prescribed for the management of neuropathic pain associated with diabetic peripheral neuropathy when ALL of the following criteria are met:

- The request is for Lyrica (pregabalin immediate-release) OR Lyrica CR (pregabalin extended-release).
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules).
    - Requires a dose that cannot be obtained using the commercially available capsules.
- The patient has achieved or maintained a positive clinical response to the requested drug.

## Postherpetic Neuralgia

Authorization may be granted when the requested drug is being prescribed for the management of postherpetic neuralgia when ALL of the following criteria are met:

- The request is for Lyrica (pregabalin immediate-release), Lyrica CR (pregabalin extended-release), Gralise (gabapentin extended-release), or Horizant (gabapentin enacarbil extended-release).
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules).
    - Requires a dose that cannot be obtained using the commercially available capsules.
- The patient has achieved or maintained a positive clinical response to the requested drug.

## Restless Legs Syndrome

Authorization may be granted when the requested drug is being prescribed for the management of Restless Legs Syndrome in adults when ALL of the following criteria are met:

- The request is for Horizant (gabapentin enacarbil extended-release) or Lyrica (pregabalin immediate-release).
- If the request is for Lyrica (pregabalin) oral solution, the patient meets ONE of the following:
    - Has difficulty swallowing oral solid dosage forms (e.g., capsules).
    - Requires a dose that cannot be obtained using the commercially available capsules.


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- The patient has achieved or maintained a positive clinical response to the requested drug.

# Duration of Approval (DOA)

- 656-D: DOA: 12 months

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