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 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]

INITIAL STEP THERAPY
For Lyrica, 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 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
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
The requested drug will be covered with prior authorization when the following criteria are met:
- Lyrica (pregabalin immediate-release) is being prescribed for one of the following: A) Management of fibromyalgia, B) Management of neuropathic pain associated with spinal cord injury, C) 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, D) Cancer-related neuropathic pain, E) Cancer treatment-related neuropathic pain
  AND
  - If the request is for Lyrica (pregabalin) oral solution, the patient meets one of the following: A) has difficulty swallowing oral solid dosage forms (e.g., capsules), B) requires a dose that cannot be obtained using the commercially available capsules
    AND
    - The request is NOT for continuation of therapy

    OR
    - The request is for continuation of therapy
      AND
      - The patient has achieved or maintained a positive clinical response to the requested drug

OR
- Lyrica (pregabalin immediate-release) is being prescribed for one of the following: A) Adjunctive therapy for the treatment of partial-onset seizures (i.e., focal-onset seizures) in a patient 3 years of age or older, B) Management of postherpetic neuralgia, C) Management of neuropathic pain associated with diabetic peripheral neuropathy
  AND
  - If the request is for Lyrica (pregabalin) oral solution, the patient meets one of the following: A) has difficulty swallowing oral solid dosage forms (e.g., capsules), B) requires a dose that cannot be obtained using the commercially available capsules
    AND
    - The request is NOT for continuation of therapy
      AND

- The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin immediate-release

OR

- The request is for continuation of therapy

AND

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

OR

- Lyrica CR (pregabalin extended-release), Gralise (gabapentin extended-release), or Horizant (gabapentin enacarbil extended-release) is being prescribed for the management of postherpetic neuralgia

AND

- The request is NOT for continuation of therapy

AND

- The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin immediate-release

OR

- The request is for continuation of therapy

AND

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

OR

- Lyrica CR (pregabalin extended-release) is being prescribed for the management of neuropathic pain associated with diabetic peripheral neuropathy

AND

- The request is NOT for continuation of therapy

AND

- The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to TWO of the following: A) gabapentin immediate-release, B) pregabalin immediate-release, C) duloxetine, D) venlafaxine, E) a tricyclic antidepressant

OR

- The request is for continuation of therapy

AND

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

OR

- Horizant (gabapentin enacarbil extended-release) is being prescribed for the treatment of Restless Legs Syndrome

AND

- The request is NOT for continuation of therapy

AND

- The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ANY of the following: A) pramipexole immediate-release, B) ropinirole immediate-release

OR

- The request is for continuation of therapy

AND

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

Duration of Approval (DOA):

- 656-D: DOA: 12 months

REFERENCES

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