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.

Lvrica

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

Compendial Uses

- Cancer-Related Neuropathic Pain^{6,12}
- Cancer Treatment Related Neuropathic Pain^{6,12}

Lyrica CR

Lyrica CR is indicated for the management of:

- Neuropathic pain associated with diabetic peripheral neuropathy
- Postherpetic neuralgia

Lyrica, Gralise, Horizant Step Therapy Policy 656-D 05-2019

©2019 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

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

If the patient has filled a prescription for at least a 30 day supply of immediate-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 immediaterelease generic gabapentin

OR

- Lyrica (pregabalin) is being prescribed for the management of fibromyalgia or the management of neuropathic pain associated with spinal cord injury
- Horizant (gabapentin enacarbil) is being prescribed for the treatment of Restless Legs Syndrome

REFERENCES

- 1. Gralise [package insert]. Newark, CA: Depomed, Inc.; September 2015.
- Horizant [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2016.
- 3. Lyrica [package insert]. New York, NY: Parke-Davis; May 2019.
- 4. Lyrica CR [package insert]. New York, NY: Parke-Davis; October 2017.
- 5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed May 2019.
- Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed May 2019.
- 7. Neurontin [package insert]. New York, NY: Parke-Davis Division of Pfizer Inc; February 2018.
- 8. French J, Kanner A, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs II: Treatment of refractory epilepsy Report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology* 2004;62:1252-1260.
- 9. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology* 2018:91:82-90.
- 10. Dworkin RH, O'Connor AB, Audette J, et al. Recommendations for the Pharmacological Management of Neuropathic Pain: An Overview and Literature Update. *Mayo Clin Proc.* 2010;85(3)(suppl):S3-S14.
- 11. Wiffen PJ, Derry S, Moore RA, et al. Antiepileptic drugs for neuropathic pain and fibromyalgia an overview of Cochrane reviews (Review). *Cochrane Database of Systematic Reviews*. 2013; 1: Art. No.: CD010567.
- 12. NCCN Guidelines. Version 2.2019 Adult Cancer Pain. http://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed May 2019.
- 13. American Diabetes Association. Microvascular Complications and Foot Care: Standards of Medical Care in Diabetes—2019. *Diabetes Care* 2019; 42(Supp 1):S124-S138.
- 14. Winkelman, J, Armstrong M, et al. Practice guideline summary: Treatment of restless leg syndrome in adults. *Neurology* 2016;87:2585–2593.
- 15. Mann D, Liu J, Chew ML, et al. Safety, tolerability, and pharmacokinetics of pregabalin in children with refractory partial seizures: A phase I, randomized controlled study. *Epilepsia*; 2014:55(12):1934-43.
- 16. Haig GH, Bockbrader HN, Wesche DL, et al. Single-Dose Gabapentin Pharmacokinetics and Safety in Healthy Infants and Children. *Journal of Clinical Pharmacology*; 2001:41:504-14

Lyrica, Gralise, Horizant Step Therapy Policy 656-D 05-2019

©2019 CVS Caremark. All rights reserved.

17.	Burnsed JC, Heinan K, Letzkus L, et al. Gabapenting for pain, movement disording infants. <i>Developmental Medicine and Child Neurology</i> . Available at: https://onlinelibrary.wiley.com/doi/10.1111/dmcn.14324.	ders, and irritability in neonates and
vri	ca Gralise Horizant Step Therapy Policy 656-D 05-2019	@2019 CVS Caremark All rights reserved