Clinical Policy Title:	gabapentin
Policy Number:	RxA.147
Drug(s) Applied:	Gralise®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of Business

Background

Gralise® is an analog of gamma-aminobutyric acid (GABA) that has GABA agonist activity. It is indicated for the management of postherpetic neuralgia (PHN).

Limitation(s) of use: Gralise® is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
gabapentin (Gralise®)	postherpetic neuralgia (PHN)	Gralise® should be initiated and titrated as follows: Day 1: 300 mg PO Day 2: 600 mg PO Days 3 to 6: 900 mg PO once daily Days 7 to 10: 1,200 mg PO once daily Days 11 to 14: 1,500 mg PO once daily Days ≥ 15: 1,800 mg PO once daily Take with evening meal. If dose is reduced, discontinued, or substituted with an alternative medication, this should be done gradually over a minimum of 1 week or longer (at the discretion of the prescriber). Renal impairment: Dose should be adjusted in patients with reduced renal function. Gralise® should not be used in patients with CrCl less than 30 or in patients on hemodialysis.	1,800 mg/day

Dosage Forms

- Tablets: 300 mg, 600 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the provisions of the pharmacy benefit administer by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Postherpetic Neuralgia (must meet all)**:**

1. Diagnosis of PHN;
2. Age ≥ 18 years;
3. Failure of a ≥ 30 day trial of immediate-release gabapentin at ≥ 1,800 mg per day, unless contraindicated to its excipients or clinically significant adverse effects are experienced;
4. Dose does not exceed 1,800 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Postherpetic Neuralgia (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1,800 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GABA: Gamma-aminobutyric acid
PHN: Post herpetic neuralgia

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
gabapentin (Neurontin®)	PHN: 300 mg PO as a single dose on day 1, then 600 mg/day (300 mg PO BID) on day 2, and 900 mg/day (300 mg PO TID) on day 3. The dose can then be titrated up as needed for pain relief to a dose of 1800 mg/day	3,600 mg/day

	(600 mg PO TID).	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Gralise® is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Not Applicable

References

1. Gralise® Prescribing Information. Morristown, NJ: Almatica Pharma LLC.; April 2020. Available at: https://www.gralise.com/. Accessed February 18, 2021.
2. Rowbotham M, Harden N, Stacey B, Bernstein P, Magnus-Miller L. Gabapentin for the treatment of postherpetic neuralgia: a randomized controlled trial. JAMA 1998; 280:1837-42. Accessed February 18, 2021.
3. Rice ACS, Maton S. Gabapentin in postherpetic neuralgia: a randomised, double blind, placebo controlled study. Pain 2001; 94:215–224. Accessed February 18, 2021.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 18, 2021.
5. Gabapentin. Lexicomp. Wolters Kluwer. Hudson, OH. Available at https://online.lexi.com/lco/action/doc/retrieve/docid/gdh_f/132773?cesid=9IlGZVgnZKO&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dgabapentin%26t%3Dname%26va%3Dgabapentin. Accessed February 18, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	1/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Initial and Continued Therapy Approval criteria: Commercial approval duration was updated from length of benefit to 12 months; Medicaid approval	6/22/2020	09/14/2020

duration was included. 6. References were updated.		
Policy was reviewed: 1. Last review date was updated. 2. Clinical policy verbiage added " The provision of provider samples does not guarantee…" 3. Continued Therapy criteria II.A.1 was rephrased from 4. "Currently receiving medication that has been authorized by RxAdvance..." 5. Appendix B: "Therapeutic alternatives verbiage was updated to below are suggested therapeutic alternatives based on clinical guidance...." 6. Appendix C: Contraindication updated to "Gralise® is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients." 7. References were reviewed and updated. 8. Dosing regimen updated to include: If dose is reduced, discontinued, or substituted with an alternative medication, this should be done gradually over a minimum of 1 week or longer (at the discretion of the prescriber). Renal impairment: Dose should be adjusted in patients with reduced renal function. Gralise® should not be used in patients with CrCl less than 30 or in patients on hemodialysis. Take with evening meal.	02/18/2021	06/10/2021