

| Pharmacy Policy Bulletin: J-1449 Gabarone (gabapentin) – Commercial and Healthcare Reform                                                                                                                                 |                                                                                                                                                                                                    |
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| <b>Number:</b> J-1449                                                                                                                                                                                                     | <b>Category:</b> Prior Authorization                                                                                                                                                               |
| <b>Line(s) of Business:</b><br><input checked="" type="checkbox"/> Commercial<br><input checked="" type="checkbox"/> Healthcare Reform<br><input type="checkbox"/> Medicare                                               | <b>Benefit(s):</b><br><b>Commercial:</b><br><b>Prior Authorization (1.):</b><br>1. Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization<br><br><b>Healthcare Reform:</b> Not Applicable |
| <b>Region(s):</b><br><input checked="" type="checkbox"/> All<br><input type="checkbox"/> Delaware<br><input type="checkbox"/> New York<br><input type="checkbox"/> Pennsylvania<br><input type="checkbox"/> West Virginia | <b>Additional Restriction(s):</b><br>None                                                                                                                                                          |
| <b>Version:</b> J-1449-001                                                                                                                                                                                                | <b>Original Date:</b> 04/09/2025                                                                                                                                                                   |
| <b>Effective Date:</b> 05/23/2025                                                                                                                                                                                         | <b>Review Date:</b> 04/09/2025                                                                                                                                                                     |

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| <b>Drugs Product(s):</b>           | <ul style="list-style-type: none"> <li>Gabarone (gabapentin)</li> </ul>                                                                                                                                                                                                |
| <b>FDA-Approved Indication(s):</b> | <ul style="list-style-type: none"> <li>Postherpetic neuralgia in adults</li> <li>Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy</li> </ul> |

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| <b>Background:</b> | <ul style="list-style-type: none"> <li>Precise mechanism for the analgesic and antiepileptic actions of gabapentin are unknown. Gabapentin is an analog of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA), and exhibits analgesic, anxiolytic and anticonvulsant activity. Gabapentin has no effect of GABA binding, uptake or degradation.</li> <li>Postherpetic neuralgia (PHN) occurs in approximately 1 out of 5 patients with herpes zoster, or shingles. It is defined as a rash sustained for at least 90 days after acute herpes zoster.</li> <li>Partial seizures, also called focal onset seizures, start in one hemisphere of the brain but can spread to the other hemisphere resulting in secondarily generalized seizures. When there is no loss of consciousness, the seizure is called a simple partial or focal onset aware seizure. When there is loss of consciousness, the seizure is called a complex partial or focal impaired awareness seizure.</li> <li>Prescribing Considerations: <ul style="list-style-type: none"> <li>If Gabarone tablets are broken in half, the unused half should be taken at next dose. Half tablets not used with 28 days should be thrown away.</li> </ul> </li> </ul> |
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| <b>Approval Criteria</b> |
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**I. Initial Authorization**

When a benefit, coverage of Gabarone may be approved when all of the following criteria are met **(A. and B.)**:

**A.** The member meets one (1) of the following criteria **(1. or 2.)**:

**1.** The member meets all of the following criteria **(a., b., and c.)**:

**a.** The member is 3 years of age or older.

- b. The member has a diagnosis of partial onset seizures (ICD-10: G40.0-G40.2).
    - c. Gabarone is being used as adjunctive treatment.
  - 2. The member meets all of the following criteria **(a. and b.)**:
    - a. The member is 18 years of age or older.
    - b. The member has a diagnosis of postherpetic neuralgia (ICD-10: B02.23).
- B. The member has experienced therapeutic failure or intolerance to plan-preferred generic gabapentin immediate release.

## II. Reauthorization

When a benefit, coverage of Gabarone may be approved when all of the following criteria are met **(A. and B.)**:

- A. The prescriber attests that the member has experienced positive clinical response to therapy.
- B. The member has experienced therapeutic failure or intolerance to plan-preferred generic gabapentin immediate release.

- III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

## Limitations of Coverage

- I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

## Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

## Automatic Approval Criteria

None

## References:

1. Gabarone [package insert]. Fairmont, WV: INA Pharmaceuticals Inc.; December 2024.
2. Neurontin [package insert]. Coral Springs, FL: ACI Healthcare USA, Inc.; December 2023.
3. AmericanFamilyPhysician. Herpes Zoster and Postherpetic Neuralgia: Prevention and Management. Available at: <https://www.aafp.org/pubs/afp/issues/2017/1115/p656.html>. Accessed January 29, 2025.
4. Epilepsy Foundation. Focal Onset Aware Seizures (simple partial seizures). Available at: <https://www.epilepsy.com/learn/types-seizures/focal-onset-aware-seizures-aka-simple-partialseizures>. Accessed January 29, 2025.

*Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect Highmark's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.*

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