Gabapentin

Description

Gabapentin (Gralise*, Horizant*, Neurontin)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

Background

Gabapentin is used in the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN), neuropathic pain associated with spinal cord injury, partial onset seizures, postherpetic neuralgia, or Restless Legs Syndrome (RLS). Gabapentin is thought to reduce the release of a neurotransmitter called glutamate. Glutamate is a neurotransmitter that acts as a natural ‘nerve-exciting’ agent. It’s released when electrical signals build up in nerve cells and subsequently excites more nerve cells. As gabapentin reduces the release of this neurotransmitter it can also be used to treat nerve pain that occurs as a result of damage to or a disturbance in the function of nerves (neuropathic pain)(1-3).

Regulatory Status

FDA-approved indications: Gabapentin is indicated for postherpetic neuralgia in adults, adjunctive therapy in the treatment of partial onset seizures with and without secondary generalization in adults and pediatric patients 3 years and older and treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) (1-3).

In clinical studies, gabapentin efficacy was demonstrated over a range of doses from 1800 mg/day to 3600 mg/day (1-3).
The safety and efficacy of gabapentin in the management of postherpetic neuralgia in pediatric patients have not been established. Effectiveness as adjunctive therapy in the treatment of partial seizures in pediatric patients below the age of 3 years has not been established (1).

**Related policies**
Lyrica, Savella

**Policy**
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Gabapentin may be considered medically necessary in patients 3 years of age or older for the treatment of partial onset seizures and if the conditions indicated below are met.

Gabapentin may be considered medically necessary in patients 18 years of age or older for the treatment of neuropathic pain, postherpetic neuralgia, or restless legs syndrome (RLS) and if the conditions indicated below are met.

Gabapentin may be considered investigational in patients for all other indications and ages.

**Prior-Approval Requirements**

**Age**
3 years of age or older

**Diagnosis**

Patient must have the following:

1. Partial onset seizures
   a. Used in combination with other first line anti-epileptic medications
   b. **NO** dual therapy with pregabalin (Lyrica)

**Age**
18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:
1. Neuropathic pain
2. Postherpetic neuralgia
3. Restless legs syndrome (RLS)

AND the following:
   a. NO dual therapy with pregabalin (Lyrica)

Prior – Approval *Renewal* Requirements

Same as above

**Policy Guidelines**

**Pre - PA Allowance**

**Age**
3 years of age or older

**Quantity**

<table>
<thead>
<tr>
<th>Gabapentin</th>
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<tbody>
<tr>
<td>100mg, 300mg, 400mg, 600mg</td>
<td>540 dosage units per 90 days <strong>OR</strong></td>
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<tr>
<td>800mg</td>
<td>360 dosage units per 90 days <strong>OR</strong></td>
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<tr>
<td>50mg/mL solution</td>
<td>6480mL per 90 days</td>
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*Maximum daily limit of any combination: 3600mg*

**Prior - Approval Limits**

**Quantity**

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<tr>
<td>100mg, 300mg, 400mg, 600mg, 800mg, 50mg/mL solution</td>
<td>Pre-PA allows for the FDA recommended maximum dosage</td>
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**Medication / Strength with approved MFE only**

<table>
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<tr>
<th>Gralise 300 mg, 600 mg</th>
<th>540 dosage units per 90 days</th>
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<td>Horizant 300 mg, 600 mg</td>
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**Duration**
24 months
Prior – Approval Renewal Limits

Same as above

Rationale

Summary
Gabapentin is used in the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN), neuropathic pain associated with spinal cord injury, partial onset seizures, postherpetic neuralgia, or restless legs syndrome (RLS). Gabapentin is thought to reduce the release of a neurotransmitter called glutamate. As gabapentin reduces the release of this neurotransmitter it can also be used to treat nerve pain that occurs as a result of damage to or a disturbance in the function of nerves (neuropathic pain) (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of gabapentin while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>April 2017</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>December 2017</td>
<td>Addition of the statement “Quantity limits listed above must be used to achieve dose optimization”</td>
</tr>
<tr>
<td>March 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual review and reference update. Removal of tapers from criteria. Addition of no dual therapy with pregabalin (Lyrica)</td>
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<tr>
<td>September 2019</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review. Moved Gralise and Horizant to MFE with PA only</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on
<table>
<thead>
<tr>
<th>Section:</th>
<th>Prescription Drugs</th>
<th>Effective Date:</th>
<th>January 1, 2020</th>
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<tbody>
<tr>
<td>Subsection:</td>
<td>Neuromuscular Agents</td>
<td>Original Policy Date:</td>
<td>April 28, 2017</td>
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<td>Subject:</td>
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December 6, 2019 and is effective on January 1, 2020.