Clinical Policy: Amantadine ER (Gocovri)
Reference Number: ERX.NPA.58
Effective Date: 10.10.17
Last Review Date: 02.18

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Amantadine extended-release (Gocovri™) is a weak uncompetitive antagonist of the N-methyl-D-aspartate (NMDA) receptor.

FDA Approved Indication(s)
Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Gocovri is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Dyskinesia in Patients with Parkinson’s Disease (must meet all):
      1. Diagnosis of dyskinesia in patients with Parkinson’s disease;
      2. Member is receiving levodopa-based therapy;
      3. Failure of a 2-week trial of immediate-release amantadine unless contraindicated or clinically significant adverse effects are experienced;
      4. Dose does not exceed 274 mg/day.
   Approval duration: Length of Benefit

   B. Other diagnoses/indications
      1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Dyskinesia in Patients with Parkinson’s Disease (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
      2. Member is responding positively to therapy (e.g., reductions in OFF time, improvement in dyskinesia symptoms);
      3. If request is for a dose increase, new dose does not exceed 274 mg/day.
   Approval duration: Length of Benefit

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   FDA: Food and Drug Administration

   Appendix B: Therapeutic Alternatives
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>amantadine immediate-release</td>
<td>Titrated up to 100 mg PO QID</td>
<td>400 mg/day</td>
</tr>
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</table>

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.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>Dyskinesia in Parkinson’s disease due to levodopa-based therapy</td>
<td>137 mg PO QHS for 1 week. After 1 week, increase to 274 mg (two 137 mg capsules) PO QHS</td>
<td>274 mg/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

Extended-release capsules: 68.5 mg and 137 mg

VII. References


VIII. Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created</td>
<td>10.10.17</td>
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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