Amantadine Extended-Release

Description

Gocovri, Osmolex ER

Background
Gocovri, an extended release amantadine, is indicated for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy with or without concomitant dopaminergic medications. Osmolex ER is another formulation of extended release amantadine, and similarly can be used to treat drug induced extrapyramidal reactions in adult patients (including those with Parkinson’s disease). Motor problems and dyskinesia are significant complications of levodopa therapy used to treat patients with Parkinson’s disease (PD) and increases in frequency the longer patients are treated with levodopa for Parkinson’s disease. Currently, treatment of dyskinesia related to Parkinson’s disease includes adjusting levodopa doses and dosing schedule, adding additional medications to treat Parkinson’s disease (thereby allowing for a decrease in the dose needed of levodopa), and lastly adding a medication to specifically treat dyskinesia (amantadine) (1-3).

Regulatory Status
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 (1).

Osmolex ER is indicated for the treatment of Parkinson’s disease and drug-induced extrapyramidal reactions in adult patients (2).
Adverse reactions reported include: falling asleep during activities of daily living and somnolence, suicidality and depression, hallucinations/psychotic behavior, dizziness and orthostatic hypotension, and impulse control/compulsive behaviors. Additionally, the use of these medication are contraindicated in patient with end-stage renal disease (below 15 mL/min/1.73 m²) as this medication is primarily excreted renally (1-2).

Safety and effectiveness in pediatric patients have not been established (1-2).

Related policies

Policy

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

Gocovri and Osmolex ER may be considered medically necessary for patients 18 years of age or older with Parkinson’s disease (PD) and when the conditions indicated below are met.

Gocovri and Osmolex ER may be considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:

Parkinson’s disease (PD)

AND ONE of the following:

a. Patient is experiencing dyskinesia
b. Patient is experiencing drug induced EPS (extrapyramidal symptoms)

AND ALL of the following:

1. Currently receiving levodopa-based therapy
2. Documented baseline evaluation of dyskinesia/drug induced EPS
3. Prescribing physician has attempted to adjust levodopa therapy to decrease dyskinesia or drug induced EPS
4. Inadequate treatment response, intolerance, or contraindication to ONE of the following adjunctive pharmacotherapy options:
   a. Dopamine agonists
   b. COMT inhibitors
   c. MAO B inhibitors
5. Inadequate treatment response or intolerance to short acting amantadine
6. NO end-stage renal disease (ESRD)

**Prior – Approval Renewal Requirements**

**Age**
18 years of age or older

**Diagnosis**

Patient must have the following:

Parkinson’s disease (PD)

AND ONE of the following:
   a. Patient is experiencing dyskinesia
   b. Patient is experiencing drug induced EPS (extrapyramidal symptoms)

AND ALL of the following:
   1. Currently receiving levodopa-based therapy
   2. Documented improvement in dyskinesia or drug induced EPS from baseline
   3. NO end-stage renal disease (ESRD)

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**
Gocovri

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
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<tbody>
<tr>
<td>68.5 mg</td>
<td>180 capsules per 90 days OR</td>
</tr>
<tr>
<td>137 mg</td>
<td>180 capsules per 90 days</td>
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</tbody>
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Maximum daily limit of any combination: 274 mg

OR

Osmolex ER

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
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<tbody>
<tr>
<td>129 mg</td>
<td>90 tablets per 90 days OR</td>
</tr>
<tr>
<td>193 mg</td>
<td>90 tablets per 90 days OR</td>
</tr>
<tr>
<td>258 mg</td>
<td>90 tablets per 90 days</td>
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Maximum daily limit of any combination: 322 mg

Duration

12 months

Prior – Approval Renewal Limits

Same as above

Rationale

Summary

Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy with or without concomitant dopaminergic medications. Osmolex ER is another formulation of extended release amantadine, and similarly can be used to treat drug induced extrapyramidal reactions in adult patients (including those with Parkinson’s disease). Motor problems and dyskinesia are significant complications of levodopa therapy used to treat patients with Parkinson’s disease (PD), and increases in frequency the longer patients are treated with levodopa for Parkinson’s disease. Adverse reactions reported include: falling asleep during activities of daily living and somnolence, suicidality and depression, hallucinations/psychotic behavior, dizziness and orthostatic hypotension, and impulse control/compulsive behaviors (1-3).
Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Gocovri and Osmolex ER while maintaining optimal therapeutic outcomes.

References


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>February 2017</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>December 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td></td>
<td>Addition of Osmolex ER to criteria, Added &quot;Patient is experiencing drug</td>
</tr>
<tr>
<td></td>
<td>induced EPS (extrapyramidal symptoms)&quot; to criteria</td>
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<tr>
<td></td>
<td>Change in policy name from “Gocovri” to “Amantadine Extended-Release”</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review and reference update</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.