BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.75.021

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Neuromuscular Agents	**Original Policy Date:**	September 29, 2017
Subject:	Amantadine ER	**Page:**	1 of 6

Last Review Date: March 8, 2024

Amantadine Extended-Release

Description

Gocovri, Osmolex ER (amantadine 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 Parkinson's disease or drug induced extrapyramidal reactions in adult patients. 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 indications:

Gocovri is indicated: (1)

- For the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications
- As adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes

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 medications is contraindicated in patient with end-stage renal disease (eGFR below 15 mL/min/1.73 m^2) 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** if the conditions indicated below are met.

Gocovri and Osmolex ER may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

Gocovri

1. Parkinson's disease (PD)
    a. Patient is experiencing dyskinesia
    b. Currently receiving levodopa-based therapy
    c. Prescribing physician has attempted to adjust levodopa therapy to decrease dyskinesia

Osmolex ER

1. Parkinson's disease (PD)
2. Drug-induced EPS (extrapyramidal symptoms)

AND ALL of the following for **ALL** drugs:

1. Documented baseline evaluation of the patient's symptoms
2. Inadequate treatment response, intolerance, or contraindication to other adjunctive therapy
3. Inadequate treatment response or intolerance to short acting amantadine
4. **NO** end-stage renal disease (ESRD)

Gocovri ONLY

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Parkinson's disease (PD) experiencing "off" episodes
   a. Used in combination with levodopa/carbidopa
   b. Inadequate control of Parkinson's symptoms on maximum tolerated doses of oral levodopa/carbidopa
   c. **NO** end-stage renal disease (ESRD)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

Gocovri

1. Parkinson's disease (PD)

a. Patient is experiencing dyskinesia
b. Currently receiving levodopa-based therapy

Osmolex ER

1. Parkinson's disease (PD)
2. Drug-induced EPS (extrapyramidal symptoms)

AND ALL of the following for **ALL** drugs:

1. Documented improvement in symptoms from baseline
2. **NO** end-stage renal disease (ESRD)

Gocovri ONLY

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Parkinson's disease (PD) experiencing "off" episodes
   a. Used in combination with levodopa/carbidopa
   b. Improvement in Parkinson's symptoms
   c. **NO** end-stage renal disease (ESRD)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Gocovri

Quantity

Strength	Quantity
68.5 mg	180 capsules per 90 days **OR**
137 mg	180 capsules per 90 days

Maximum daily limit of any combination: 274 mg

OR

Osmolex ER

Quantity

Strength	Quantity
129 mg	90 tablets per 90 days **OR**
193 mg	90 tablets per 90 days **OR**
258 mg	90 tablets per 90 days **OR**
322 mg dosing kit (129 mg + 193 mg)	180 tablets per 90 days

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 Parkinson's disease or drug induced extrapyramidal reactions in adult patients. 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

1. Gocovri [package insert]. Emeryville, CA: Adamas Pharma, LLC.; January 2021.

2. Osmolex ER [package insert]. Bridgewater, NJ: Vertical Pharmaceuticals LLC.; March 2021.
3. Daniel Tarsy et al. Medical management of motor fluctuations and dyskinesia in Parkinson disease. UpToDate. September 30, 2021.

Policy History

Date	Action
February 2017	Addition to PA
December 2017	Annual review
June 2018	Annual editorial review and reference update Addition of Osmolex ER to criteria, Added "Patient is experiencing drug induced EPS (extrapyramidal symptoms)" to criteria Change in policy name from “Gocovri” to “Amantadine Extended-Release”
June 2019	Annual review and reference update
May 2020	Addition of Osmolex ER 322 mg dosing kit. Revised requirements: only Osmolex ER can be used for drug-induced EPS; changed to t/f other adjunctive therapy; levodopa requirements apply to Gocovri only; and simplified baseline and continuation evaluation requirements
June 2020	Annual review
February 2021	Addition of indication to Gocovri: Parkinson’s disease experiencing “off” episodes
March 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.75.021
December 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.