Pharmacy Policy Bulletin: J-0680 Gocovri and Osmolex ER (amantadine ER) – Commercial and Healthcare Reform	
Number: J-0680	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0680-011	**Original Date:** 11/08/2017
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Gocovri (amantadine ER) • Osmolex ER (amantadine ER)

FDA-Approved Indication(s):	• Gocovri (amantadine ER)
	  ○ 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 (amantadine ER)
	  ○ Treatment of Parkinson's disease
	  ○ Treatment of drug-induced extrapyramidal reactions in adult patients

Background:	• The mechanism by which amantadine exerts efficacy in the treatment of Parkinson's disease (PD), dyskinesia in patients with PD, or drug-induced extrapyramidal reactions is unknown. Amantadine acts as an N-Methyl-D-aspartic acid (NMDA) receptor antagonist and may have indirect effects on dopamine neurons.
	• PD
	  ○ PD is a complex progressive disease characterized by the loss of nigrostriatal dopaminergic innervation. The symptoms of Parkinson's disease are tremor, rigidity, bradykinesia, and postural instability.
	  ○ Amantadine is most useful in treating younger patients with early or mild Parkinson's disease.
	• Dyskinesia
	  ○ Dyskinesia is a consequence of levodopa-based treatment in PD and is characterized by involuntary and non-rhythmic movements that are purposeless, unpredictable, and impact the activities of daily living.
	  ○ The 2018 International Parkinson and Movement Disorder Society (IPMDS) evidence-based medicine review states that amantadine is efficacious and clinically useful in treating dyskinesia in patients with PD.
	• Extrapyramidal reactions

	○ The most common adverse drug effect patients experience from dopamine-receptor blocking agents. A variety of movement phenotypes belong to the EPS spectrum, including dystonia, akathisia, and parkinsonism, which occur more acutely, as well as more chronic manifestations of tardive akathisia and tardive dyskinesia. • "Off" Episodes ○ "Off" episodes occur when carbidopa/levodopa has worn off and may consist of tremor, slowness, stiffness, difficulty walking or moving, and trouble getting around. For the treatment of motor fluctuations including "off" episodes, IPMDS recommends adjusting the timing of levodopa to a shorter time interval, improving absorption by taking levodopa on an empty stomach, and treating constipation to improve gastrointestinal transit. The guidelines also recommend addressing "off" episodes with adjunctive medications. For treating motor fluctuations, the guidelines state amantadine has insufficient evidence and is investigational. • Prescribing considerations: ○ Gocovri and Osmolex ER have warnings and precautions which include: falling asleep during activities of daily living, somnolence, suicidality and depression, hallucinations and psychotic behavior, dizziness and orthostatic hypotension, withdrawal-emergent hyperpyrexia and confusion, and impulse control/compulsive behaviors. ○ Immediate-release amantadine has been available commercially since 1966. ○ Gocovri and Osmolex ER are contraindicated in patients with end-stage renal disease.

Approval Criteria

I. Approval Criteria

A. Gocovri

1. Dyskinesia in PD

When a benefit, coverage of Gocovri may be approved when all of the following criteria are met **(a. through d.)**:

a. The member has a diagnosis of Parkinson's disease (ICD-10: G20).
b. The member is experiencing dyskinesia.
c. The member is receiving concurrent levodopa-based therapy.
d. The member has experienced therapeutic failure or intolerance to the plan-preferred product, immediate-release amantadine.

2. "Off" Episodes in PD

When a benefit, coverage of Gocovri may be approved when all of the following criteria are met **(a. through e.)**:

a. The member has a diagnosis of Parkinson's disease (ICD-10: G20).
b. The member is experiencing "off" episodes despite optimized levodopa/carbidopa therapy.
c. The member is receiving concurrent levodopa/carbidopa therapy.
d. The member has experienced therapeutic failure or intolerance to the plan-preferred product, immediate-release amantadine.
e. The member has experienced therapeutic failure, contraindication, or intolerance to two (2) of the following generic agents **(i. through v.):**
i. entacapone
ii. pramipexole
iii. rasagiline

iv. ropinirole
v. selegiline

B. Osmolex ER
When a benefit, coverage of Osmolex ER may be approved when all of the following criteria are met **(1. and 2.)**:
1. The member has a diagnosis of one (1) of the following **(a. or b.)**:
a. Parkinson's disease (ICD-10: G20)
b. Drug-induced extrapyramidal reactions (ICD-10: G21.1, G24.0, G25.1, G25.7) and meets the following criterion **(i.)**:
i. The member is 18 years of age or older.
2. The member has experienced therapeutic failure or intolerance to the plan-preferred product, immediate-release amantadine.

II. Reauthorization
When a benefit, reauthorization of Gocovri or Osmolex ER may be approved when the following criterion is met **(A.)**:
A. The prescriber attests that the member has experienced positive clinical response to therapy.

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. Gocovri [package insert]. Emeryville, CA: Adamas Pharma LLC; February 2021.
2. Osmolex ER [package insert]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC; February 2018.
3. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord.* 2018;33(8):1248-1266.
4. Miyasaki J, Martin W, Suchowersky O, et al. Practice Parameter: Initiation of Treatment for Parkinson's disease: An Evidence-Based Review: Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2002; 58:11-7.
5. Pringsheim T, Day G, Smith D, et al. Dopaminergic Therapy for Motor Symptoms in Early Parkinson Disease Practice Guideline Summary. *Neurology* 2021; 97:942-957.
6. D'Souza RS, Hooten WM. Extrapyramidal Symptoms. Available at: https://www.ncbi.nlm.nih.gov/books/NBK534115/. Accessed February 18, 2025.