



Effective Date..... 1/15/2024
Next Review Date..... 1/15/2025
Coverage Policy Number ..... IP0403

Amantadine Extended-Release

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Overview

This policy supports medical necessity review for formulary exceptions to the following Parkinson's disease non-covered product:

- Gocovri® (amantadine extended-release capsules)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for product in below table:

Employer Group Non-Covered Product and Criteria:

Non-Covered Product	Criteria
<b>Gocovri extended-release capsule</b> (amantadine)	<p><b>Gocovri extended-release capsule (amantadine) is considered medically necessary when the following are met:</b></p> <p><b>Parkinson’s disease.</b> Individual meets <b>ALL</b> of the following criteria:</p> <ul style="list-style-type: none"> <li>A. Documentation of <b>ONE</b> of the following:             <ul style="list-style-type: none"> <li>i. Experiencing dyskinesia</li> <li>ii. Experiencing “off” episodes</li> </ul> </li> <li>B. Individual is currently receiving levodopa-based therapy</li> <li>C. Documentation of failure, contraindication or intolerance to <b>ONE</b> of the following:             <ul style="list-style-type: none"> <li>i. Amantadine immediate-release capsules, tablets or oral solution</li> <li>ii. Osmolex® ER (amantadine extended-release tablet)</li> </ul> </li> <li>D. Medication is prescribed by, or in consultation with, a neurologist</li> </ul>

**Individual and Family Plan Non-Covered Product and Criteria:**

Non-Covered Product	Criteria
<b>Gocovri extended-release capsule</b> (amantadine)	<p><b>Gocovri extended-release capsule (amantadine) is considered medically necessary when the following are met:</b></p> <p><b>Parkinson’s disease.</b> Individual meets <b>ALL</b> of the following criteria:</p> <ul style="list-style-type: none"> <li>A. Documentation of <b>ONE</b> of the following:             <ul style="list-style-type: none"> <li>i. Experiencing dyskinesia</li> <li>ii. Experiencing “off” episodes</li> </ul> </li> <li>B. Individual is currently receiving levodopa-based therapy</li> <li>C. Documentation of failure, contraindication or intolerance to amantadine immediate-release capsules, tablets or oral solution</li> <li>D. Medication is prescribed by, or in consultation with, a neurologist</li> </ul>

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Reauthorization Criteria

Continuation of Gocovri (amantadine extended-release capsules) is considered medically necessary for Parkinson’s disease when the above medical necessity criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

## Background

### OVERVIEW

Gocovri, an extended-release capsule formulation of amantadine, is indicated for patients with **Parkinson's disease** for the following uses:<sup>1</sup>

- **Dyskinesia**, in patients receiving levodopa-based therapy, with or without concomitant dopaminergic medications.
- **“Off” episodes**, as adjunctive treatment to levodopa/carbidopa.

Osmolex ER, an extended-release tablet formulation of amantadine, is indicated for the following uses:<sup>2</sup>

- **Drug-induced extrapyramidal reactions**, in adult patients.
- **Parkinson's disease**, in adult patients.

Amantadine hydrochloride is available as immediate-release capsules, tablets, and oral solution.<sup>3-5</sup> The amantadine immediate-release products are indicated for the prophylaxis and treatment of signs and symptoms of infection caused by various strains of influenza A virus; idiopathic Parkinson's disease (paralysis agitans), post-encephalitic parkinsonism, symptomatic parkinsonism which may follow injury to the nervous system by carbon monoxide intoxication, and in those elderly patients believed to develop parkinsonism in association with cerebral arteriosclerosis; and drug-induced extrapyramidal reactions.

### Guidelines

The International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018). Amantadine is addressed; however, specific formulations are not. The review categorically divides treatment recommendations by Parkinson's disease characteristics. Amantadine was noted to be likely efficacious and possibly useful in treatment for symptomatic monotherapy and symptomatic adjunct therapy in early or stable Parkinson's disease. For treatment of dyskinesia, amantadine was identified to be efficacious and clinically useful.

## References

1. Gocovri® extended-release capsules [prescribing information]. Emeryville, CA: Adamas; February 2021.
2. Osmolex® ER extended-release tablets [prescribing information]. Emeryville, CA: Adamas; March 2021.
3. Amantadine capsules [prescribing information]. Bridgewater, NJ: Alembic; September 2021.
4. Amantadine tablets [prescribing information]. Sunrise, FL: Cipla; August 2019.
5. Amantadine oral solution [prescribing information]. Amityville, NY: Hi-Tech; October 2020.
6. 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.

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