Effective Date.....**06/15/2025**
Coverage Policy Number.....**IP0403**

Amantadine Extended-Release

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

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

- **Gocovri®** (amantadine extended-release capsules)

Medical Necessity Criteria

Coverage criteria are listed for product **in below table(s):**

Employer Group Non-Covered Product and Criteria:

Non-Covered Product	Criteria
Gocovri extended-release capsule (amantadine)	**Gocovri extended-release capsule** (amantadine) **is considered medically necessary when the following are met:** **Parkinson's disease.** Individual meets **ALL** of the following criteria: A. Documentation of **ONE** of the following: i. Experiencing dyskinesia ii. Experiencing "off" episodes B. Individual is currently receiving levodopa-based therapy C. Documentation of failure, contraindication or intolerance to **ONE** of the following: i. Amantadine immediate-release capsules, tablets or oral solution ii. Osmolex® ER (amantadine extended-release tablet) D. Medication is prescribed by, or in consultation with, a neurologist

Individual and Family Plan Non-Covered Product and Criteria:

Non-Covered Product	Criteria
Gocovri extended-release capsule (amantadine)	**Gocovri extended-release capsule** (amantadine) **is considered medically necessary when the following are met:** **Parkinson's disease.** Individual meets **ALL** of the following criteria: A. Documentation of **ONE** of the following: i. Experiencing dyskinesia ii. Experiencing "off" episodes B. Individual is currently receiving levodopa-based therapy C. Documentation of failure, contraindication or intolerance to amantadine immediate-release capsules, tablets or oral solution D. Medication is prescribed by, or in consultation with, a neurologist

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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.

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

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:[1]

- **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:[2]

- **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.[3-5] 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.

The Academy of Family Physicians published recommendations for practice for the treatment of Parkinson's Disease (2020).[7] Amantadine is addressed; however, specific formulations are not. The review recommends amantadine for treatment of dyskinesias in patients with advanced disease (B recommendation). It is noted that amantadine may be most helpful for dyskinesias and as an add on to levodopa therapy.

References

1. Gocovri® extended-release capsules [prescribing information]. Emeryville, CA: Adamas; January 2021.
2. Osmolex® ER extended-release tablets [prescribing information]. Emeryville, CA: Adamas; March 2021.
3. Amantadine capsules [prescribing information]. Bridgewater, NJ: Alembic; April 2023.

4. Amantadine tablets [prescribing information]. Sunrise, FL: Cipla; August 2019.
5. Amantadine oral solution [prescribing information]. Gurnee, IL: Akorn, July 2022.
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.
7. Halli-Tierney AD, Luker J and Carroll DG. Parkinson Disease. *Am Fam Physicians.* 2020;102(11):679-691.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	06/15/2025

The policy effective date is in force until updated or retired.