PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Amantadine Extended-Release Drugs Prior Authorization with Step Therapy Policy
- Gocovri® (amantadine extended-release capsules – Adamas)
- Osmolex® ER (amantadine extended-release tablets – Adamas)

REVIEW DATE: 03/12/2025

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of amantadine extended-release products. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with amantadine extended-release products as well as the monitoring required for adverse events and long-term efficacy, approval requires amantadine extended-release products to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required for use of Gocovri and Osmolex ER as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. For patient cases in which documentation is required, if this documentation has been previously received upon a prior coverage review, the documentation requirement is considered to be met.

- **Gocovri® (amantadine extended-release capsules – Adamas)**
- **Osmolex® ER (amantadine extended-release tablets – Adamas)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Parkinson's Disease.** Approve if patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii , and iv):
     - **i.** Patient meets ONE of the following (a or b):
       - **a)** Patient is experiencing dyskinesia; OR
       - **b)** Patient is experiencing "off" episodes; AND
         Note: Examples of "off" episodes include muscle stiffness, slow movements, or difficulty starting movements.
     - **ii.** Patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa); AND
     - **iii.** Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following (a or b):
       - **a)** Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber **[documentation required]**; OR
       - **b)** Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber **[documentation required]**; AND
     - **iv.** The medication is prescribed by or in consultation with a neurologist; OR
   - **B)** Patients is Currently Receiving Gocovri. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa); AND
     - **ii.** Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following (a or b):
       - **a)** Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber **[documentation required]**; OR
       - **b)** Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber **[documentation required]**; AND
     - **iii.** Patient has had a response to therapy (e.g., decrease in dyskinesia, decrease in "off" episodes), as determined by the prescriber; AND
       Note: Examples of "off" episodes include muscle stiffness, slow movements, or difficulty starting movements.
     - **iv.** The medication is prescribed by or in consultation with a neurologist.

FDA-Approved Indications

1. **Drug-Induced Extrapyramidal Reactions.** Approve if patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following (i and ii):

i. Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following (a or b):
- **a)** Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber **[documentation required]**; OR
- **b)** Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber **[documentation required]**; AND

ii. The medication is prescribed by or in consultation with a neurologist; OR

B) Patient is Currently Receiving Osmolex ER. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following (a or b):
- **a)** Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber **[documentation required]**; OR
- **b)** Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber **[documentation required]**; AND

ii. Patient has had a response to therapy (e.g., decrease in extrapyramidal reactions), as determined by the prescriber; AND

iii. The medication is prescribed by or in consultation with a neurologist.

2. Parkinson's Disease. Approve if patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets BOTH of the following (i and ii):

i. Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following (a or b):
- **a)** Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber **[documentation required]**; OR
- **b)** Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber **[documentation required]**; AND

ii. The medication is prescribed by or in consultation with a neurologist; OR

B) Patient is Currently Receiving Osmolex ER. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following (a or b):
- **a)** Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber **[documentation required]**; OR
- **b)** Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber **[documentation required]**; AND

ii. Patient has had a response to therapy (e.g., decrease in dyskinesia), as determined by the prescriber; AND

iii. The medication is prescribed by or in consultation with a neurologist.

CONDITIONS NOT COVERED

- **Gocovri® (amantadine extended-release capsules – Adamas)**
- **Osmolex® ER (amantadine extended-release tablets – Adamas)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following; criteria will be updated as new published data are available

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	For all conditions of approval in the policy, documentation requirements were added for the requirements that the patient has tried immediate-release amantadine capsules, tablets, or oral solution and that the patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber. There were no other changes to the criteria.	11/15/2023
Annual Revision	No criteria changes.	03/14/2024
Annual Revision	No criteria changes.	03/12/2025