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: 12/14/2022

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.

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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of Gocovri is recommended in those who meet the following criteria:

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 the following criteria (i, ii, iii , and iv):
     - **i.** Patient meets ONE of the following criteria (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 criteria (a or b):
       - **a)** Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber; OR
       - **b)** Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber; AND
     - **iv.** The medication is prescribed by or in consultation with a neurologist.
   - **B)** Patients is Currently Receiving Gocovri. Approve for 1 year if the patient meets the following criteria (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 criteria (a or b):
       - **a)** Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber; OR
       - **b)** Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber; 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.

II. Coverage of Osmolex ER is recommended in those who meet one of the following criteria:

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 the following criteria (i and ii):
     - **i.** Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following criteria (a or b):
       - **a)** Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber; OR
       - **b)** Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber; AND
     - **ii.** The medication is prescribed by or in consultation with a neurologist.
   - **B)** Patient is Currently Receiving Osmolex ER. Approve for 1 year if the patient meets the following criteria (i, ii, and iii):

i. Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following criteria (a or b):
  a) Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber; OR
  b) Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber; 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 the following criteria (i and ii):
  i. Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following criteria (a or b):
    a) Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber; OR
    b) Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber; AND
  ii. The medication is prescribed by or in consultation with a neurologist.
B) Patient is Currently Receiving Osmolex ER. Approve for 1 year if the patient meets the following criteria (i, ii, and iii):
  i. Patient has tried immediate-release amantadine capsules, tablets, or oral solution and meets ONE of the following criteria (a or b):
    a) Patient derived benefit from immediate-release amantadine but had intolerable adverse events, as determined by the prescriber; OR
    b) Patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber; 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 RECOMMENDED FOR APPROVAL

Coverage of amantadine extended-release products is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.