Clinical Policy: Amantadine ER (Gocovri, Osmolex ER)

Reference Number: CP.PMN.89
Effective Date: 10.10.17
Last Review Date: 02.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Amantadine extended-release (Gocovri™, Osmolex ER™) is a weak uncompetitive antagonist of the N-methyl-D-aspartate (NMDA) receptor.

FDA Approved Indication(s)

Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

Osmolex ER is indicated for the treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Gocovri and Osmolex ER are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Dyskinesia in Patients with Parkinson's Disease (must meet all)**:**

1. Diagnosis of dyskinesia in patients with Parkinson's disease;
2. Member is receiving levodopa-based therapy;
3. Meets one of the following (a or b):
   a. Failure of a 2-week trial of immediate-release amantadine unless contraindicated or clinically significant adverse effects are experienced;
   b. Medical justification supports inability to continue use of immediate-release amantadine (e.g., contraindications to excipients);
4. Dose does not exceed 274 mg per day for Gocovri or 322 mg per day for Osmolex ER.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Drug Induced Extrapyramidal Reactions (must meet all)**:**

1. Diagnosis of a drug induced extrapyramidal reaction;
2. Request is for Osmolex ER;
3. Meets one of the following (a or b):

a. Failure of a 2-week trial of immediate-release amantadine unless contraindicated or clinically significant adverse effects are experienced;
b. Medical justification supports inability to continue use of immediate-release amantadine (e.g., contraindications to excipients);

4. Dose does not exceed 274 mg per day.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., reductions in OFF time, improvement in dyskinesia symptoms);
3. If request is for a dose increase, new dose does not exceed 274 mg per day for Gocovri or 322 mg per day for Osmolex ER.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
amantadine immediate-release	Titrated up to 100 mg PO QID	400 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): end-stage renal disease
- Boxed Warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Amantadine ER (Gocovri)	Dyskinesia in Parkinson's disease	137 mg PO QHS for 1 week. After 1 week, increase to 274 mg (two 137 mg capsules) PO QHS	274 mg/day
Amantadine ER (Osmolex ER)	Dyskinesia in Parkinson's disease; drug induced extrapyramidal reaction	129 mg PO QAM, increase dose in weekly intervals	322 mg/day

VI. Product Availability

Drug Name	Availability
Amantadine ER (Gocovri)	Extended-release capsules: 68.5 mg and 137 mg
Amantadine ER (Osmolex ER)	Extended-release tablets: 129 mg, 193 mg, 258 mg

VII. References

1. Gocovri Prescribing Information. Emeryville, CA: Adamas Pharma, LLC; August 2017. Available at: https://www.gocovri.com/pdf/Gocovri_Prescribing_Information.pdf. Accessed October 30, 2019.
2. Osmolex ER Prescribing Information. Bridgewater, NJ: Vertical Pharmaceuticals, LLC; July 2018. Available at: www.osmolex.com. Accessed October 30, 2019.
3. Oertel W, Eggert Karla, Pahwa R, et al. Randomized, placebo-controlled trial of ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson's disease (EASE LID 3). Mov Disord. 2017 August 21. Available at: 10.1002/mds.27131.
4. Pahwa R, Tanner CM, Hauser RA, et al. ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson disease (EASE LID Study). JAMA Neurol. 2017;74(8):941-949. Doi:10.100/jamaneurol.2017.0943.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.10.17	01.18
Per SDC, added requirement for medical justification that supports inability to use immediate-release amantadine	04.12.18	
Added Osmolex ER per SDC based on approved clinical guidance; added criteria set for drug induced extrapyramidal reaction.	09.18.18	
1Q 2019 annual review; no significant changes; immediate-release amantadine two-week trial and medical justification requirements are edited to reflect either/or; references reviewed and updated.	11.13.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.30.19	02.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.