

Clinical Policy: Amantadine ER (Gocovri, Osmolex ER)

Reference Number: MDN.CP.PMN.89

Effective Date: 4.22

Last Review Date: 2.20.24

Line of Business: IL MeridianMedicaid

[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 (PD) receiving levodopa-based therapy, with or without concomitant dopaminergic medications;
- As adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes.

Osmolex ER is indicated for the treatment of PD 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 PD;
2. Age \geq 18 years;
3. Member is receiving levodopa-based therapy;
4. Member must use immediate-release amantadine, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 274 mg (2 capsules) per day for Gocovri or 322 mg (2 tablets) per day for Osmolex ER.

Approval duration:

Medicaid – 12 months

B. Parkinson's Disease With "Off" Episodes (must meet all):

1. Diagnosis of PD;
2. Request is for Gocovri;
3. Age \geq 18 years;

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4. Member is experiencing “off” time (*see Appendix D*) on levodopa/carbidopa therapy;
5. Failure of two of the following adjunct drugs prescribed in combination with levodopa/carbidopa, each from different classes, unless clinically significant adverse effects are experienced or all are contraindicated: *
 - a. MAO-B inhibitor: selegiline ;
 - b. COMT inhibitor: entacapone;
 - c. Dopamine agonist: ropinirole, pramipexole;
6. Member must use immediate-release amantadine, unless contraindicated or clinically significant adverse effects are experienced;
7. Prescribed in combination with levodopa/carbidopa;
8. Dose does not exceed 274 mg (2 capsules) per day.

Approval duration:**Medicaid/HIM** – 12 months**Commercial** – 12 months or duration of request, whichever is less**C. Drug Induced Extrapyrimal Reactions (must meet all):**

1. Diagnosis of a drug induced extrapyramidal reaction;
2. Request is for Osmolex ER;
3. Age \geq 18 years;
4. Member must use immediate-release amantadine, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 322 mg (2 tablets) per day.

Approval duration:**Medicaid/HIM** – 12 months**Commercial** – 12 months or duration of request, whichever is less**D. Other diagnoses/indications**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
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 (2 capsules) per day for Gocovri or 322 mg (2 tablets) per day for Osmolex ER.

Approval duration:**Medicaid** – 12 months**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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 –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

PD: Parkinson's disease

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.

Drugs	Dosing Regimen	Dose Limit/ Maximum Dos
amantadine immediate-release	Titrated up to 100 mg PO QID	400 mg/day
COMT Inhibitors		
entacapone	PO: 200 mg with each dose of levodopa/carbidopa	1,600 mg/day (divided doses)
MAO-B Inhibitors		
Selegiline	PO: 5 mg twice daily with breakfast and lunch with concomitant carbidopa/levodopa therapy	10 mg/day
Dopamine Agonists		
pramipexole	PO: Initial dose: 0.125 mg 3 times daily, increase gradually every 5 to 7 days; maintenance (usual): 0.5 to 1.5 mg 3 times daily	4.5 mg/day (divided doses)
ropinirole	PO: Recommended starting dose: 0.25 mg 3 times/day. Based on individual patient response, the dosage should be titrated with weekly increments: Week 1: 0.25 mg 3 times/day; total daily dose: 0.75 mg; week 2: 0.5 mg 3 times/day; total daily dose: 1.5 mg; week 3: 0.75 mg 3 times/day; total daily dose: 2.25 mg; week 4: 1 mg 3 times/day; total daily dose: 3 mg. After week 4, if necessary, daily dosage may be increased by 1.5 mg/day on a weekly basis up to a dose of 9 mg/day, and then by up to 3 mg/day weekly to a total of 24 mg/day.	24 mg/day (divided doses)

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

Appendix D: General Information

- Off time/episodes represent a return of PD symptoms (bradykinesia, rest tremor or rigidity) when the L-dopa treatment effect wears off after each dosing interval.
- Parkinson's disease symptoms, resulting from too little levodopa (L-dopa), are in contrast with dyskinesia which typically results from too much L-dopa. The alterations between

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“on” time (the time when Parkinson’s disease symptoms are successfully suppressed by L-dopa) and “off” time is known as “motor fluctuations”.

- The addition of carbidopa to L-dopa prevents conversion of L-dopa to dopamine in the systemic circulation and liver.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Amantadine ER (Gocovri)	Dyskinesia or “off” episodes in PD	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 PD; 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, 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; January 2021. Available at: <https://www.gocovrihcp.com>. Accessed October 19, 2023.
2. Osmolex ER Prescribing Information. Bridgewater, NJ: Vertical Pharmaceuticals, LLC; January 2020. Available at: www.osmolex.com. Accessed October 19, 2023.
3. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	9.22	
1Q2024 Annual Review: Template changes applied to other diagnoses/indications and continued therapy section.References reviewed and updated.	2.20.24	

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

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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.

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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.

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