

Clinical Policy: Parkinson's Agents

Reference Number: OH.PHAR.PPA.43 Effective Date: 01.01.2020 Last Review Date: Line of Business: Medicaid

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

Description

PARKINSON'S AGENTS – COMT INHIBITOR

NO PA REQUIRED "PREFERRED"	REFERRED" PA REQUIRED "NON-PREFERRED"	
ENTACAPONE (generic of Comtan [®])	TASMAR [®] (tolcapone)	
	TOLCAPONE (generic of Tasmar [®])	

PARKINSON'S AGENTS – DOPAMINERGIC AGENTS, ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"	
AMANTADINE	GOCOVRI™ (amantadine er)	
	OSMOLEX ER™ (amantadine er)	

PARKINSON'S AGENTS – DOPAMINE RECEPTOR AGONISTS FOR INTERMITTENT TREATMENT OF OFF EPISODES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"	
	APOKYN [®] (apomorphine)	
	INBRIJA™ (levodopa)	

PARKINSON'S AGENTS - DOPAMINE RECEPTOR AGONISTS, NON-ERGOT, ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"	
PRAMIPEXOLE (generic of Mirapex [®])	PRAMIPEXOLE ER (generic of Mirapex ER [®])	
ROPINIROLE (generic of Requip [®])	ROPINIROLE ER (generic of Requip XL [®])	



PARKINSON'S AGENTS – DOPAMINERGIC AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"	
CARBIDOPA†	AZILECT [®] (rasagiline)	
CARBIDOPA/LEVODOPA (generic of Sinemet [®])	CARBIDOPA/LEVODOPA dispersible tablets	
CARBIDOPA/LEVODOPA CR (generic of	(generic of Parcopa [®])	
Sinemet [®] CR)	CARBIDOPA/LEVODOPA/ENTACAPONE	
SELEGILINE (generic of Eldepryl [®])	(generic of Stalevo [®])	
	NEUPRO [®] patch (rotigotine)	
	RYTARY [®] (carbidopa/levodopa ER)	
	XADAGO [®] (safinamide)	
	ZELAPAR [®] ODT (selegiline)	

⁺Use not recommended as monotherapy; edit may ensure used concomitantly

FDA Approved Indication(s)

• Refer to Clinical Pharmacology or other appropriate clinical resource for FDA approved indications

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 the medications listed in the above tables are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Parkinson's disease (must meet all):

- 1. Diagnosis of Parkinson's disease;
- 2. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated;
- 3. Member has had a therapeutic failure to no less than a 30 day trial of at least one medication not requiring prior approval unless one of the following:
 - a. Allergy to medications not requiring prior approval
 - b. Contraindication to or drug interaction with medications not requiring prior approval
 - c. History of unacceptable/toxic side effects to medications not requiring prior approval
 - d. Member is unable to swallow (if requested medication is Neupro®)
- 4. If requested medication is Xadago or Inbrija:
 - a. Member must currently be taking carbidopa/levodopa
 - b. Member is experiencing "off" episode on levodopa/carbidopa therapy;
 - c. If medication is Inbrija there must be documentation of a trial of at least one other medication for the treatment of "off episodes" (dopamine agonist, COMT inhibitor, or MAO-B inhibitor).



Approval duration: 12 months

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

- 1. Diagnosis of dyskinesia in patients with Parkinson's disease;
- 2. Requested medication is Gocovri;
- 3. Member is receiving levodopa-based therapy;
- 4. Member has had a therapeutic failure to no less than a 30 day trial of immediate release amantadine unless contraindication or history of unacceptable/toxic side effects are experienced
- 5. Dose does not exceed 274 mg per day

Approval duration: 12 months

C. Drug Induced Extrapyramidal Reactions (must meet all):

- 1. Diagnosis of a drug induced extrapyramidal reaction;
- 2. Requested medication is for Osmolex ER;
- 3. Member has had a therapeutic failure to no less than a 30 day trial of immediate release amantadine unless contraindication or history of unacceptable/toxic side effects are experienced
- 4. Dose does not exceed 322 mg per day.

Approval duration: 12 months

II. 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.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

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

Appendix B: Therapeutic Alternatives

• Dosing varies by drug product. See FDA approved dosing and administration

Appendix C: Contraindications/Boxed Warnings

• Refer to Clinical Pharmacology or other appropriate clinical resource for contraindications or black box warnings

IV. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration



V. Product Availability

A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.2019	

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.

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