Pharmacy Management Drug Policy

SUBJECT: Parkinson's Disease
POLICY NUMBER: PHARMACY-129
EFFECTIVE DATE: 06/2025
LAST REVIEW DATE: 02/12/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Parkinson's disease (PD) is a progressive neurodegenerative disease that impacts dopaminergic neurons in the basal ganglia of the brain, particularly in the substantia nigra, leading to motor deficits. Movement related symptoms of PD include resting tremor, rigidity, bradykinesia, hypokinesia, and postural instability. Beyond motor dysfunction, additional disease manifestations may emerge such as neuropsychiatric symptoms (e.g., depression, dementia, psychosis), autonomic disturbances (e.g., orthostatic hypotension, urinary dysfunction, sialorrhea), and other non-movement related symptoms. Disease progression and symptomology may vary among individuals, making it difficult to accurately predict the disease course.

Parkinson's disease affects around one million people in the United States with approximately 90,000 individuals diagnosed each year.[1] The incidence of PD primarily increases with age and men are 1.5 times more likely to develop PD than women.[1] Diagnosis of PD is based on clinical presentation and the patient's medical history. Currently, there are no specific tests or biomarkers to diagnose PD, although there may be imaging and/or laboratory values that support a PD diagnosis or assist in ruling out other medical conditions that mirror PD.

Currently, there are no disease-modifying pharmacologic treatments for PD, therefore the primary goal of therapy is symptom management. Drugs used for PD motor symptoms mainly target the dopaminergic pathway. Levodopa, which is converted to dopamine in both the periphery and central nervous system, is the preferred and most effective initial therapy to improve motor symptoms in early PD patients. Levodopa is typically paired with carbidopa, a peripheral decarboxylase inhibitor, to ensure levodopa enters the central nervous system before it converts to dopamine. This reduces the dose of levodopa necessary to achieve a therapeutic effect and can also help diminish side effects of levodopa such as nausea. Several formulations (i.e., immediate release, controlled release) and dosage forms (i.e., capsule, tablet, orally disintegrating tablet, suspension, inhalation, infusion) are available.[2]

Over time, the effects of levodopa may wane, and patients experience "wearing off" episodes where symptoms return prior to the next levodopa dose. Initially these episodes may be managed by increasing the dose of levodopa, shortening the dosing interval, or switching to longer acting levodopa formulations. Moreover, the addition of agents such as dopamine agonists (i.e.,

pramipexole, ropinirole, and rotigotine), monoamine oxidase type B (MAO-B) inhibitors (i.e., selegiline and rasagiline), and catechol-O-methyltransferase (COMT) inhibitors (i.e., entacapone, opicapone, tolcapone) may help to extend "on" time and minimize motor fluctuation symptoms due to levodopa. Other therapies indicated as adjunctive treatment to levodopa for "off" episodes include amantadine and istradefylline. Anticholinergic agents such as trihexyphenidyl or benztropine may be useful for younger patients with PD related tremor.[3]

For more advanced disease, on-demand agents such as subcutaneous apomorphine or inhaled levodopa are indicated to manage sudden or prolonged "off" episodes. Device-assisted infusions are also available to provide continuous exposure to dopaminergic therapy for the treatment of motor fluctuations in advanced disease. These devices include levodopa-carbidopa intestinal gel (LCIG) administered through a percutaneous gastrojejunostomy tube and continuous subcutaneous infusions (CSIs) with foscarbidopa/foslevodopa or apomorphine.[3]

A common non-motor complication is Parkinson's disease psychosis (PDP), occurring in more than half of individuals with PD. The atypical antipsychotic pimavanserin is FDA approved to treat hallucinations and delusions associated with PDP.[4]

POLICY:

Apokyn and apomorphine hydrochloride injection (Rx)
1. Must be prescribed by a neurologist 2. Must have a diagnosis of Parkinson's disease 3. Must be experiencing "off" episodes ("wearing off symptoms") 4. Must be currently taking oral carbidopa/levodopa 5. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa 6. Must have attempted two other treatments used for "off" episodes from two different medication classes: a. Catechol-O-methyl transferase (COMT) inhibitors (such as entacapone and tolcapone) b. Oral dopamine agonists (such as pramipexole and ropinirole) c. Monoamine oxidase type B (MAO B) inhibitors (such as rasagiline and selegiline) 7. Requests for brand name Apokyn will require documentation of use of generic apomorphine injection that led to serious side effects or drug failure 8. Quantity Limit: 30 mL/30 days (1 mL [10 mg] per day) a. The recommended starting dose is 0.2 mL (2 mg) per dose with a max of 0.6 mL (6 mg) per dose b. Due to limited experience, dosing of Apokyn more than 5 times per day and with total daily doses greater than 2 mL (20 mg) is not recommended. c. Based on the maximum recommended dosing, patients who need more than 10 mg per day will be considered for approval up to 20 mg per day (60 mL/30 days) when clinically justified
Gocovri – amantadine ER capsules (Rx)
1. Must be prescribed by a neurologist 2. Must be prescribed for dyskinesia associated with a diagnosis of Parkinson's disease **AND** a. Member must be currently receiving levodopa-based therapy **AND** b. Must have had serious side effects or drug failure with generic amantadine at a total dose of at least 200 mg per day **OR** 3. Must have a diagnosis of Parkinson's disease with "wearing off symptoms" **AND** a. Must be currently taking oral carbidopa/levodopa **AND** b. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa **AND**

c. Must have had serious side effects or drug failure with TWO of the following: pramipexole, ropinirole, entacapone, tolcapone, selegiline, or rasagiline 4. Quantity Limit of 60 capsules/30 days
Inbrija – levodopa inhalation (Rx)
1. Must be prescribed by a neurologist 2. Must have a diagnosis of Parkinson's disease with "wearing off symptoms" 3. Must be currently taking oral carbidopa/levodopa at a minimum dosage of 100 mg of carbidopa 4. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa 5. Must have had serious side effects or drug failure with **TWO** of the following: pramipexole, ropinirole, entacapone, tolcapone, selegiline, or rasagiline 6. The Quantity Limit is 120 capsules for inhalation per 30 days. Based on the maximum recommended dosing, requests for up to 300 capsules per 30 days will be considered when clinically justified
Mirapex ER and pramipexole ER (Rx)
1. Must be 18 years of age or older 2. Must have a diagnosis of Parkinson's Disease 3. Must have had a trial and failure of immediate release pramipexole 4. Quantity limit: a. 30 tablets/30 days for 0.375 mg, 0.75 mg, 1.5 mg, 3 mg, 3.75 mg, and 4.5 mg strengths b. 60 tablets/30 days for 2.25 mg strength
Neupro – rotigotine patch (Rx)
1. Must have FDA-approved diagnosis of Parkinson disease or moderate to severe restless legs syndrome 2. Must have had serious side effects or drug failure with both oral pramipexole **AND** ropinirole. This requirement is waived upon documentation of an inability to swallow. 3. Quantity limit of 1 patch per day
Nourianz – istradefylline tablets (Rx)
1. Must be prescribed by a neurologist 2. Must have a diagnosis of Parkinson's disease with "wearing off symptoms" 3. Must be currently taking a regimen of oral carbidopa/levodopa 4. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa 5. Must have had serious side effects or drug failure with **TWO** of the following: pramipexole, ropinirole, entacapone, tolcapone, selegiline, or rasagiline 6. Quantity limit of 30 tablets per 30 days
Nuplazid – pimavanserin tablets and capsules (Rx)
1. Member must have a diagnosis of Parkinson's disease psychosis (PDP) 2. Nuplazid will not be approved for any other non-FDA approved indication, including dementia related psychosis. 3. Medication must be prescribed by a neurologist, psychiatrist, psychiatric nurse practitioner or geriatrician 4. Nuplazid is not recommended in patients with hepatic impairment or severe renal impairment (CrCL< 30ml/min) 5. Quantity limit is 30 tablets or capsules per 30 days
Onapgo (apomorphine)-Rx & Medical
1. Must be prescribed by a neurologist **AND** 2. Must have a diagnosis of advanced Parkinson's disease **AND** 3. Must be 18 years of age or older **AND** 4. Must be currently taking oral carbidopa/levodopa **AND** 5. Must be responsive to levodopa treatment (e.g., patient is experiencing some benefit from levodopa) **AND**

6. Must have inadequately controlled motor fluctuations ("off" periods) on current treatment **AND**
7. Prescriber must attest that the patient experiences a minimum of 3 hours of "off" time per day **AND**
8. Must have attempted increasing the dose and dosing frequency of oral levodopa/carbidopa **AND**
9. Must have attempted TWO other treatments used for "off" episodes from TWO different medication classes:
   a. Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone and tolcapone)
   b. Oral dopamine agonists (e.g., pramipexole and ropinirole)
   c. Monoamine oxidase type B (MAO B) inhibitors (e.g., rasagiline and selegiline)
10. Onapgo will not be authorized in combination with Apokyn, Vyalev, or Duopa
11. Quantity limit: 600 mL/30 days.
12. Approval for 12 months at a time. Continued approval for 12 months based on positive response/disease stability.

Osmolex – amantadine ER tablet (Rx)

1. Must be prescribed by a neurologist
2. Must be prescribed for either:
   a. Parkinson's disease **OR**
   b. Drug-induced extrapyramidal reactions **AND**
3. Must have had serious side effects or drug failure with generic amantadine

Rytary, Crexont, and carbidopa/levodopa ER capsule (Rx)

1. Must have a diagnosis of Parkinson's disease, post-encephalitic Parkinsonism, or Parkinsonism following carbon monoxide/manganese intoxication
2. Must have motor fluctuations despite carbidopa/levodopa with entacapone therapy
3. Quantity limit will vary by product and dosage strength:
   a. Rytary and carbidopa/levodopa ER:
      i. 23.75mg/95 mg: 150 capsules/30 days
      ii. 36.25mg/145mg: 300 capsules/30 days
      iii. 48.75mg/195 mg: 300 capsules/30 days
      iv. 61.25 mg/245mg: 300 capsules/30 days
   b. Crexont:
      i. 35mg/140mg: 60 capsules/30 days
      ii. 52.5mg/210mg: 180 capsules/30 days
      iii. 70mg/280mg: 180 capsules/30 days
      iv. 87.5mg/350mg: 180 capsules/30 days

Zelapar ODT – Selegiline Hydrochloride (L-Deprenyl) tablet (Rx)

1. Must have clinically documented Parkinson's disease
2. Must be currently receiving treatment with levodopa/carbidopa
3. Must be exhibiting deterioration in quality of response to levodopa/carbidopa therapy
4. Must be unable to swallow traditional tablets.
5. Quantity limit of 60 tablets per 30 days.

Vyalev (foscarbidopa/foslevodopa injection)- Rx & Medical

1. Must be prescribed by a neurologist **AND**
2. Must have a diagnosis of advanced Parkinson's disease **AND**
3. Must be 18 years of age or older **AND**
4. Must be taking a minimum of 400 mg/day of levodopa (Note: from levodopa-containing medications and catechol-O-methyl transferase (COMT) inhibitors. See Appendix to determine total daily levodopa dosage) **AND**
5. Must be responsive to levodopa treatment (e.g., patient is experiencing some benefit from levodopa) **AND**
6. Must have inadequately controlled motor fluctuations ("off" periods) on current treatment **AND**

7. Prescriber must attest that the patient experiences a minimum of 2.5 hours of "off" time per day **AND** 8. Must have attempted increasing the dose and dosing frequency of oral levodopa/carbidopa **AND** 9. Must have attempted TWO other treatments used for "off" episodes from TWO different medication classes: a. Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone and tolcapone) b. Oral dopamine agonists (e.g., pramipexole and ropinirole) c. Monoamine oxidase type B (MAO B) inhibitors (e.g., rasagiline and selegiline) 10. Vyalev will not be authorized for use in patients concomitantly receiving Duopa (carbidopa/levodopa enteral suspension) unless patient is being transitioned from Duopa to Vyalev. 11. Quantity limit: 42 vials/28 days 12. Approval for 12 months at a time. Continued approval for 12 months based on positive response/disease stability.
Xadago (safinamide mesylate)
1. Must have had serious side effects or drug failure with TWO of the following: pramipexole, ropinirole, entacapone, tolcapone, selegiline, or rasagiline

Appendix

Levodopa Formulation	**Dose Multiplication Factor**
Immediate release, including enteral suspension	1
Sustained-release tablets, controlled-release tablets, or prolonged-release tablets	0.75
Extended-release capsules (Rytary®) (mg)	
0-855	0.42
856-1755	0.48
1756-2340	0.56
2341 or above	0.67
If any COMT inhibitor is used, multiply sum of calculated total daily levodopa dosage from above by 1.33.*	

*For formulations containing carbidopa/levodopa/COMT inhibitors, count levodopa as immediate release and add to the total levodopa dosage from all other sources of levodopa before the sum is multiplied for the COMT inhibitor correction factor. Do not apply COMT inhibitor correction factor until all total levodopa dosages are summed.

Source: Soileau MJ, Aldred J, Budur K, et al. Safety and efficacy of continuous subcutaneous foslevodopa-foscarbidopa in patients with advanced Parkinson's disease: a randomised, double-blind, active-controlled, phase 3 trial. *Lancet Neurol.* 2022;21(12)(suppl):1-14.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key:
Experimental/Investigational = (E/I),
Not medically necessary/ appropriate = (NMN).

HCPCS:

Vyalev	J7356 (effective 7/1/2025)

POLICY GUIDELINES:

1. Unless otherwise stated above within the individual drug criteria, approval time-period will be for 2 years.
    a. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
2. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
    - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
3. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
4. Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent if the preferred drug is not found in claims history.
5. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
6. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
7. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
8. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;

- The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
- The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
- The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
- The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

9. This policy is applicable to drugs that are included on a specific drug formulary (Rx benefit only). If a drug referenced in this policy is non-formulary, please reference the Non-formulary Medication Exception Review Policy for review guidelines.
10. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
11. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
12. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

UPDATES:

Date	Revision
02/12/2026	P&T Committee Approval
01/01/2026	Revised
12/01/2025	Revised
11/19/2025	Revised
06/18/2025	Created and Implemented
02/06/2025	P&T Committee Approval

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4. Forsaa EB, Larsen JP, Wentzel-Larsen T, et al. A 12-year population-based study of psychosis in Parkinson's disease. *Arch* Neurol. 2010;67:996-1001