UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2228-4
Program	Prior Authorization/Medical Necessity
Medication	Apokyn® (apomorphine) injection
P&T Approval Date	12/2020, 12/2021, 6/2023, 6/2024
Effective Date	9/1/2024

1. Background:

Apokyn is a non-ergoline dopamine agonist indicated for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease.

Coverage will be provided for members who meet the following criteria.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Apokyn** will be approved based on **all** of the following criteria:

   a. Diagnosis of Parkinson's disease

   -AND-

   b. Apokyn will be used as intermittent treatment for OFF episodes

   -AND-

   c. Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

   -AND-

   d. Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

   -AND-

   e. Patient continues to experience ≥ 2 hours of OFF time per day despite optimal management of carbidopa-levodopa therapy including **both** of the following:

      (1) Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet

      -AND-

(2) Dose and dosing interval optimization

-AND-

f. History of failure, contraindication, or intolerance to **two** anti-Parkinson's disease therapy from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

(1) Dopamine agonists (e.g., pramipexole, ropinirole)
(2) Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
(3) Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

-AND-

g. History of failure, contraindication, or intolerance to **both** of the following:

(1) Kynmobi (apomorphine) sublingual film
(2) Inbrija (levodopa) inhalation powder

Authorization will be issued for 12 months.

B. Reauthorization

1. **Apokyn** will be approved based on the following criterion:

a. Documentation of positive clinical response to **Apokyn** therapy

-AND-

b. Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Apokyn [package insert]. Rockville, MD: MDD US Operations; June 2022.
2. Carbone F, Djamshidian A, Seppi K, Poewe W. Apomorphine for Parkinson's Disease: Efficacy and Safety of Current and New Formulations. *CNS Drugs*. 2019;33(9):905-918.
3. Liang, TW, Tarsy D. UpToDate. Medical management of motor fluctuations and dyskinesia in Parkinson's disease.2024 Feb 26. Accessed May 3, 2024.
4. Olanow, CW et al. Apomorphine sublingual film for off episodes in Parkinson's disease: a randomized, double-blind, placebo-controlled phase 3 study. The Lancet Neurology. 2020; 19(2): 135-144.
5. Paik J. Levodopa Inhalation Powder: A Review in Parkinson's Disease. *Drugs*. 2020;80(8):821-828.

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Change Control	
12/2020	New program.
12/2021	Annual review with no changes to clinical criteria. Updated references.
6/2023	Annual review with no changes to clinical criteria. Updated references.
6/2024	Annual review. Updated initial authorization duration to 12 months. Updated references.