UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Apokyn

Program	Prior Authorization
Medication	Apokyn (apomorphine HCl injection)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2013
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

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. Apokyn has been studied as an adjunct to other medications.

2. Coverage Criteria:

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

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-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)

Authorization will be issued for 12 months.

B. Reauthorization

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

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.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-

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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 Prescribing Information. Louisville, KY: US WorldMeds, LLC. April 2020.
2. National Institute of Health and Clinical Excellence of England (NICE). Parkinson's disease in adults. 07/2017. Accessed August 14, 2020.
3. Liang, TW, Tarsy D. UpToDate. Medical management of motor fluctuations and dyskinesia in Parkinson's disease. 2020 Sept. 17. Accessed October 15, 2020.
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.

Program	Prior Authorization –Apokyn (apomorphine HCl injection)
Change Control	
Date	Change
12/2013	New criteria
12/2015	Added requirement #4 of "for intermittent subcutaneous injection only"
10/2016	Updated clinical criteria to align with Optum Rx policy and updated policy template
10/2017	Updated references and policy template
10/2018	Annual review. Updated references.
8/2019	Removed criteria for not using with 5-HT3 antagonists since this will be evaluated using DUR edits. Updated references.
9/2020	Annual review. Updated references.
12/2020	Updated language within clinical criteria to align with E&I medical necessity policy without addition of step through preferred drugs. Did not revise initial auth period.

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