



# apomorphine (Apokyn®)

## EOCCO POLICY



Policy Type: PA/SP

Pharmacy Coverage Policy: EOCCO087

### Description

Apomorphine (Apokyn), a non-ergoline dopamine agonist, is administered as a subcutaneous injection. It possesses an unknown mechanism in the treatment of Parkinson's disease, but it is suggested that its effects are attributed to stimulation of post-synaptic D(2)-type receptors within the brain.

### Length of Authorization

- Initial: Three months
- Renewal: 12 months

### Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
Apomorphine (Apokyn)	10 mg/mL Subcutaneous Injection	Parkinson's Disease	20 mL/30 days

### Initial Evaluation

- I. Apomorphine (Apokyn) may be considered medically necessary when the following criteria below are met:
  - A. Member must 18 years of age or older; **AND**
  - B. Must be prescribed by or in consultation with a neurologist; **AND**
  - C. Not used in combination with a 5-HT<sub>3</sub> receptor antagonist (e.g. ondansetron, granisetron, dolasetron, etc.); **AND**
  - D. A diagnosis of **Parkinson's disease** when the following are met:
    1. Provider must attest that the first dose will be done in office and the member will be monitored; **AND**
    2. Treatment with the following has been ineffective, contraindicated, or not tolerated:
      - i. Carbidopa/levodopa IR up to five times a day; **OR**
      - ii. Carbidopa/levodopa XR; **AND**
      - iii. One of the following:
        - a. Dopamine agonist (e.g. pramipexole, ropinirole, rotigotine)
        - b. Monoamine oxidase-B (MAO-B) inhibitor (e.g. selegiline, rasagiline)
        - c. Catechol-O-methyl transferase (COMT) inhibitors (e.g. entacapone, tolcapone)



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- II. Apomorphine (Apokyn) is considered investigational when used for all other conditions, including but not limited to:
  - A. Erectile dysfunction

### Renewal Evaluation

- I. Member has demonstrated benefit through reduction of “off” episodes/hypomobility; **AND**
- II. Absence of unacceptable toxicity (e.g. coronary events, QTc prolongation, serious hypotension, etc.)

### Supporting Evidence

- I. Apomorphine (Apokyn) was studied in three randomized controlled trials. All patients in the studies were on L-dopa, 86% of patients were on oral dopaminergic agonists, 31% were on catechol-ortho-methyl transferase inhibitors, and 10% were on monoamine B oxidase inhibitors.
  - Study one was a randomized, double-blind, placebo-controlled, parallel-group trial evaluating 29 patients with advanced Parkinson’s disease who had at least two hours of “off” time per day. Apomorphine (Apokyn) demonstrated a statistically significant decrease in the Unified Parkinson’s Disease Rating Scale (UPDRS) compared to placebo, with a mean change from baseline of -23.9 and -0.1 ( $p<0.001$ ) respectively.
  - Study two was a randomized, placebo-controlled crossover trial evaluating 17 patients with Parkinson’s disease who had been using apomorphine (Apokyn) for at least three months. Apomorphine (Apokyn) demonstrated a statistically significant decrease in UPDRS compared to placebo, with a mean change from baseline of -20 and -3 respectively.
  - Study three was a randomized, double-blind, placebo-controlled, trial evaluating 62 patients with Parkinson’s disease who had been using apomorphine (Apokyn) for at least three months. Apomorphine (Apokyn) demonstrated a statistically significant decrease in UPDRS at 20 minutes compared to placebo, with a mean change from baseline of -24.2 vs -7.4 ( $p<0.0001$ ) respectively.
- II. Use of apomorphine (Apokyn) with 5-HT<sub>3</sub> antagonists (e.g. ondansetron, granisetron, dolasetron, or alosetron) is contraindicated. There have been reports of profound hypotension and loss of consciousness when administered together.

### Investigational or Not Medically Necessary Uses

- I. Apomorphine (Apokyn) has not been adequately studied in patients with erectile dysfunction.



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## References

1. Apokyn [prescribing information]. USWorldMeds: Louisville, KY; November 2019.
2. Pfeiffer RF, Gutmann L, Hull KL, Bottini PB, Sherry JH. Continued efficacy and safety of subcutaneous apomorphine in patients with advanced Parkinson's disease. *Parkinsonism Relat Disord.* 2007;13(2):93-100.
3. Dewey RB, Hutton JT, Lewitt PA, Factor SA. A randomized, double-blind, placebo-controlled trial of subcutaneously injected apomorphine for parkinsonian off-state events. *Arch Neurol.* 2001;58(9):1385-92.
4. Uptodate, Inc. Medical management of motor fluctuations and dyskinesia in Parkinson disease [database online]. Waltham, MA. Updated 09/16/19. Available at: <http://www.uptodate.com/home/index.html>. [Accessed 11/04/19]

## Policy Implementation/Update:

Date Created	September 2005
Date Effective	October 2019
Last Updated	October 2019
Last Reviewed	09/08, 12/08, 11/14, 10/19

Action and Summary of Changes	Date
Criteria transitioned to policy	10/2019