

### Clinical Pharmacy Program Guidelines for Apokyn

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| Program                                 | Prior Authorization                |
| Medication                              | Apokyn (apomorphine HCl injection) |
| Issue Date                              | 12/2013                            |
| Pharmacy and Therapeutics Approval Date | 10/2017                            |
| Effective Date                          | 12/2017                            |

**1. Background:**

Apokyn is 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:**

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| <p><b>A. <u>Initial Authorization</u></b></p> <p>1. Diagnosis of advanced Parkinson’s disease</p> <p style="text-align: center;"><b>-AND-</b></p> <p>2. Patient is experiencing acute intermittent hypomobility (defined as “off” episodes characterized by muscle stiffness, slow movements, or difficulty starting movements)</p> <p style="text-align: center;"><b>-AND-</b></p> <p>3. Patient is receiving Apokyn in combination with other medications for the treatment of Parkinson’s disease (e.g., carbidopa/levodopa, pramipexole, ropinirole, benzotropine, etc.)</p> <p style="text-align: center;"><b>-AND-</b></p> <p>4. Patient is not using Apokyn with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)</p> <p><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Reauthorization</u></b></p> |
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1. Documentation of positive clinical response to Apokyn therapy

**-AND-**

2. Patient is not using Apokyn with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)

**Authorization will be issued for 12 months.**

**3. References:**

1. Apokyn Prescribing Information. Louisville, KY: US WorldMeds, LLC. March 2017.
2. Dewey RB, Jr., 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;58:1385-1392.
3. Pahwa R, Factor SA, Lyons KE, et al.. Practice parameter: treatment for Parkinson's disease with motor fluctuations and dyskinesia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2006;66:983-995.
4. National Institute of Health and Clinical Excellence of England (NICE). Parkinson's disease in adults. 07/2017. Accessed September 15, 2017.

| Program               | Prior Authorization –Apokyn (apomorphine HCl injection)                             |
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| <b>Change Control</b> |   |
| 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  |