

SPECIALTY GUIDELINE MANAGEMENT

APOKYN (apomorphine)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Acute, intermittent treatment of hypomobility, “off” episodes (“end-of-dose wearing off” and unpredictable “on/off” episodes) in patients with advanced Parkinson’s disease.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for the treatment of acute, intermittent treatment of hypomobility, “off” episodes (“end-of-dose wearing off” and unpredictable “on/off” episodes) for members with advanced Parkinson’s disease when all of the following criteria are met:

- A. The member experiences at least 2 hours per day of off time
- B. The member is currently being treated with carbidopa/levodopa
- C. Attempts to manage off episodes by adjusting the dosing or formulation of carbidopa/levodopa were ineffective
- D. Treatment with carbidopa/levodopa plus one of the following therapies was ineffective at managing off episodes:
 1. Dopamine agonist (e.g., pramipexole, ropinirole)
 2. Monoamine oxidase B (MAO-B) inhibitor (e.g., selegiline, rasagiline)
 3. Catechol-O-methyl transferase (COMT) inhibitor (e.g., entacapone, tolcapone)

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment of acute, intermittent treatment of hypomobility “off” episodes (“end-of-dose wearing off” and unpredictable “on/off” episodes) for members with advanced Parkinson’s disease when both of the following criteria are met:

- A. The member is currently being treated with carbidopa/levodopa
- B. The member is experiencing improvement on Apokyn therapy (e.g. reduction in daily off time, improvement in motor function post-administration)

IV. REFERENCES

1. Apokyn [package insert]. Louisville, KY: US WorldMeds, LLC; May 2019.
2. Miyasaki JM, Martin W, Suchowersky O, et al. Practice parameter: Initiation of treatment for Parkinson’s disease: An evidence-based review. *Neurology* Jan 2002, 58 (1) 11-17.

3. National Institute for Clinical Excellence: Parkinson's disease in adults. July 2017.
<https://www.nice.org.uk/guidance/ng71/resources/parkinsons-disease-in-adults-pdf-1837629189061>.
Accessed August 15, 2019.
4. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord*. 2018; 33(8):1248-1266.