

Reference number(s)
2258-A

## SPECIALTY GUIDELINE MANAGEMENT

### APOKYN (apomorphine hydrochloride injection) KYNMOBI (apomorphine hydrochloride)

#### 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

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

Kynmobi is indicated for the acute, intermittent treatment of “off” episodes in patients with Parkinson’s disease (PD).

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 “off” episodes for members with Parkinson’s disease when all of the following criteria are met:

- A. The member experiences at least 1 hour 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 “off” episodes for members with 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 with the requested medication (e.g. reduction in daily off time, improvement in motor function post-administration)

##### IV. REFERENCES

Apokyn-Kynmobi 2258-A SGM P2020

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1. Apokyn [package insert]. Louisville, KY: US WorldMeds, LLC; April 2020.
2. Kynmobi [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; May 2020.
3. 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.
4. 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.
5. 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.