SPECIALTY GUIDELINE MANAGEMENT

APOKYN (apomorphine hydrochloride injection)
KYNMOBI (apomorphine hydrochloride)
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.

<u>FDA-Approved Indications</u>
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

Parkinson's disease
Authorization of 6 months may be granted for the acute, intermittent treatment of "off" episodes in members with 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 "off" episodes in 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

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1. Apokyn [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; June 2022.
2. Kynmobi [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; May 2022.
3. Apomorphine hydrochloride [package insert]. Lee, MA: Berkshire Sterile Manufacturing, Inc.; February 2022.
4. Miyasaki JM, Martin W, Suchowersky O, et al. Practice parameter: Initiation of treatment for Parkinson's disease: An evidence-based review: report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology.* Jan 2002, 58 (1) 11-17. doi:10.1212/wnl.58.1.11
5. 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 1, 2023.
6. 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 [published correction appears in *Mov Disord.* 2018 Dec;33(12):1992]. *Mov Disord.* 2018; 33(8):1248-1266. doi:10.1002/mds.27372

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