Reference number(s)
2258-A

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.

FDA-Approved Indications
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 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

1. Apokyn [package insert]. Louisville, KY: US WorldMeds, LLC; April 2020.
2. Kynmobi [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; May 2022.
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 16, 2022.
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.
6. Apomorphine hydrochloride [package insert]. Lee, MA: Berkshire Sterile Manufacturing, Inc. February 2022.