

Specialty Guideline Management apomorphine-Apokyn

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Apokyn	apomorphine hydrochloride

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 Indications¹⁻³

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.

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

Documentation

Submission of the following information is necessary to initiation the prior authorization for review:

Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Reference number(s)
2258-A

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist or a specialist in the treatment of Parkinson's disease.

Coverage Criteria

Parkinson's Disease¹⁻⁶

Authorization of 12 months may be granted for acute, intermittent treatment of "off" episodes in members with Parkinson's disease when all of the following criteria are met:

- The member experiences at least 2 hours per day of "off" time.
- The member is currently being treated with carbidopa/levodopa.
- Attempts to manage "off" episodes by adjusting the dosing or formulation of carbidopa/levodopa were ineffective.
- The member must have had an inadequate response or intolerable adverse event with one of the following anti-Parkinson agents:
 - Dopamine agonist (e.g., pramipexole, ropinirole)
 - Monoamine oxidase-B (MAO-B) inhibitor (e.g., selegiline, rasagiline)
 - Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone)

Continuation of Therapy

Authorization of 12 months may be granted for continued acute, intermittent treatment of "off" episodes in members with Parkinson's disease when both of the following criteria are met:

- The member is currently being treated with carbidopa/levodopa.
- The member is experiencing improvement with the requested medication (e.g., reduction in daily "off" time, improvement in motor function post-administration).

References

1. Apokyn [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; June 2022.
2. Apomorphine hydrochloride injection [package insert]. Lee, MA: Berkshire Sterile Manufacturing, Inc.; February 2022.

Reference number(s)
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3. National Institute for Health and Care Excellence (NICE) guideline: Parkinson's disease in adults. Published July 19, 2017. Accessed August 7, 2025.
<https://www.nice.org.uk/guidance/ng71/resources/parkinsons-disease-in-adults-pdf-1837629189061>.
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 [published correction appears in *Mov Disord*. 2018 Dec;33(12):1992]. *Mov Disord*. 2018;33(8):1248-1266. doi:10.1002/mds.27372