

## 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 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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Reference number(s)
2258-A

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