MEDICAL MUTUAL®

Drug Policy

Policy:	Apokyn (apomorphine hydrochloride) Subcutaneous solution Kynmobi (apomorphine hydrochloride) Sublingual film	Annual Review Date: 06/20/2024 Last Revised Date: 06/20/2024

OVERVIEW

Apokyn and Kynmobi are non-ergoline dopamine agonists indicated for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease. Apokyn and Kynmobi have been studied as adjunct therapy to other medications.

POLICY STATEMENT

This policy involves the use of Apokyn and Kynmobi. Prior authorization is recommended for pharmacy benefit coverage of Apokyn and Kynmobi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Apokyn or Kynmobi is recommended in those who meet the following criteria:

1. **Acute intermittent episodes of Hypomobility ("off" episodes) associated with advanced Parkinson's disease**
   Criteria. *Patient must meet the following criteria (A, B, C, D, E and F):*
   - A. Diagnosis of advanced Parkinson's disease; AND
   - B. The patient experiences intermittent hypomobility or "off" episodes; AND
   - C. The patient is currently receiving carbidopa/levodopa therapy; AND
   - D. The patient is not concurrently taking a serotonin 5HT3 antagonist (such as: ondansetron, granisetron, etc.).
   - E. Apokyn or Kynmobi is being prescribed by, or in consultation with, a neurologist or prescriber specializing in the treatment of Parkinson's disease.
   - F. If request is for Apokyn, the patient meets one of the following (a or b):
     - a. Patient has tried Kynmobi; OR
     - b. Patient has a severe intolerance to oral medications;

2. **Patient has been started on Apokyn or Kynmobi**
   Criteria. *Patient must meet the following criteria (A, B, C, and D):*

A. The patient is diagnosed with acute intermittent episodes of Hypomobility ("off" episodes) associated with advanced Parkinson's disease; AND
B. The patient has experienced a positive clinical response to therapy; AND
C. The patient is not concurrently taking a serotonin 5HT3 antagonist (such as: ondansetron, granisetron, etc.).
D. Apokyn or Kynmobi is being prescribed by, or in consultation with, a neurologist or prescriber specializing in the treatment of Parkinson's disease.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Apokyn or Kynmobi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Erectile dysfunction

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Apokyn [package insert]. Brisbane, CA: Tercica, Inc; April 2020.
2. Kynmobi [package insert]. Marlborough, MA: Sunovion Pharmaceutical Inc.; May 2020
3. Rao SS, Hofmann LA, Shakil A. Parkinson's Disease: Diagnosis and Treatment. Am Fam Physician. 2006 Dec 15;74(12):2046-2054.
4. Gazewood JD1, Richards DR, Clebak K. Parkinson disease: an update. Am Fam Physician. 2013 Feb 15;87(4):267-73.
5. DeMaagd G, Philip A. Part 2: Introduction to the Pharmacotherapy of Parkinson's Disease, With a Focus on the Use of Dopaminergic Agents. P&T. 2015 Sept; 40(9):590-600.

6. Apomorphine. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 14 June 2019. Accessed on 18 June 2019.