

### Clinical Pharmacy Program Guidelines for Kynmobi

Program	Prior Authorization
Medication	Kynmobi™ (apomorphine) sublingual film
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	12/2020
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	3/2021

#### 1. Background:

Kynmobi is a non-ergoline dopamine agonist indicated for the acute, intermittent treatment of “off” episodes in patients with Parkinson’s disease.

Coverage will be provided for members who meet the following criteria.

#### 2. Coverage Criteria:

##### A. Initial Authorization

1. **Kynmobi** will be approved based on **all** of the following criteria:

a. Diagnosis of Parkinson’s disease

**-AND-**

b. Kynmobi will be used as intermittent treatment for OFF episodes

**-AND-**

c. Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson’s disease

**-AND-**

d. Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

**-AND-**

- e. Patient continues to experience  $\geq 2$  hours of OFF time per day despite optimal management of carbidopa-levodopa therapy including **both** of the following:
- (1) Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet

**-AND-**

- (2) Dose and dosing interval optimization

**-AND-**

- f. History of failure, contraindication, or intolerance to **two** anti-Parkinson's disease therapy from the following adjunctive pharmacotherapy classes (trial must be from two different classes):
- (1) Dopamine agonists (e.g., pramipexole, ropinirole)
  - (2) Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
  - (3) Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

**Authorization will be issued for 6 months.**

**B. Reauthorization**

1. **Kynmobi** will be approved based on the following criterion:
  - a. Documentation of positive clinical response to **Kynmobi** therapy

**-AND-**

- b. Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis



**Community Plan**

codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

**4. References:**

1. Kynmobi [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; May 2020.
2. Liang, TW, Tarsy D. UpToDate. Medical management of motor fluctuations and dyskinesia in Parkinson’s disease. 2020 Sept. 17. Accessed October 15, 2020.
3. Olanow, CW et al. Apomorphine sublingual film for off episodes in Parkinson’s disease: a randomized, double-blind, placebo-controlled phase 3 study. The Lancet Neurology. 2020; 19(2): 135-144.

Program	Prior Authorization– Kynmobi
<b>Change Control</b>	
12/2020	New program