VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Apokyn Prior Authorization Policy
- Apokyn® (apomorphine hydrochloride for subcutaneous injection)

REVIEW DATE: 08/19/2020

OVERVIEW

Apokyn, a non-ergoline dopamine agonist, is 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.[1]

Guidelines

The American Academy of Neurology published guidelines in 2006 on the treatment of Parkinson's disease with motor fluctuations and dyskinesia.[2] The guidelines are dated and do not include more recently approved medications. It is recommended to offer entacapone and rasagiline to reduce "off" time (Level A). Pergolide (withdrawn from the market in 2007 due to risk of valvular fibrosis), pramipexole, ropinirole, and tolcapone (used with caution; requires monitoring for hepatotoxicity) should be considered to reduce "off" time (Level B). Apokyn® (apomorphine hydrochloride injection), cabergoline, and selegiline may be used to reduce "off" time (Level C). According to the guidelines, the available evidence does not establish superiority of one medication over another in reducing "off" time (Level B). Sustained-release levodopa/carbidopa and bromocriptine should not be considered to reduce "off" time (Level C). Amantadine may be used to reduce dyskinesia (Level C).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Apokyn. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Apokyn as well as the monitoring required for adverse events and long-term efficacy, approval requires Apokyn to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Parkinson's Disease.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is diagnosed with advanced Parkinson's disease; AND
   - **B)** Patient is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements; AND
   - **C)** Patient is currently receiving carbidopa/levodopa therapy; AND
   - **D)** Patient has previously tried one other treatment for "off" episodes and meets ONE of the following criteria (i or ii):

i. Patient had significant intolerance, according to the prescriber; OR

ii. Patient had inadequate efficacy, according to the prescriber; AND

Note: Examples of treatment for "off" episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Kynmobi™ (apomorphine hydrochloride sublingual film), Ongentys® (opicapone capsules), or Xadago® (safinamide tablets).

E) Apokyn is being prescribed by, or in consultation with, a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Apokyn is not recommended in the following situations:

1. **Concurrent Use with a Serotonin 5-HT3 Antagonist.** Administration of Apokyn in conjunction with a serotonin 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron) can result in extreme lowering of blood pressure and loss of consciousness and is considered an absolute contraindication.[1]

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

REFERENCES

1. Apokyn® subcutaneous injection [prescribing information] Louisville, KY: US WorldMeds; April 2020.
2. Pahwa R, Factor SA, Lyons KE, et al. Practice parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Report of the quality standards subcommittee of the American Academy of Neurology. Neurology. 2006;66:983-995.