PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/20/2022

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 International Parkinson and Movement Disorder Society published an evidence-based review for treatment for motor symptoms of Parkinson's disease (2018).[2] The review categorically divides treatment recommendations by Parkinson's disease characteristics. Apomorphine subcutaneous is noted to be efficacious and clinically useful in treatment for motor fluctuations.

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 Indication

1. **Parkinson's Disease.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements; AND
   - **B)** Patient is currently receiving carbidopa/levodopa therapy; AND
   - **C)** 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 treatments for "off" episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Kynmobi (apomorphine hydrochloride sublingual film), Ongentys (opicapone capsules), or Xadago (safinamide tablets).
   - **D)** The medication is 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-HT_3 Antagonist.** Administration of Apokyn in conjunction with a serotonin 5-HT_3 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. 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. *Mov Disord*. 2018;33(8):1248-1266.