

PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease –Apomorphine Subcutaneous Prior Authorization Policy

- Apokyn® (apomorphine hydrochloride subcutaneous injection – US WorldMeds, generic)

REVIEW DATE: 03/13/2024

OVERVIEW

Apomorphine, 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, particularly for OFF periods that require rapid reversal.

The Academy of Family Physicians published recommendations for practice for the treatment of Parkinson's Disease (2020).³ The review recommends apomorphine subcutaneous and immediate release carbidopa/levodopa as treatment options for patients experiencing freezing episodes. Apomorphine subcutaneous will quickly resolve the freezing; however, it is poorly tolerated due to severe nausea, vomiting and orthostasis.

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of apomorphine subcutaneous 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 (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 (i or ii):
 - i. Patient had significant intolerance, according to the prescriber; **OR**

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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, 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 apomorphine subcutaneous is not recommended in the following situations:

1. **Concurrent Use with a Serotonin 5-HT₃ Antagonist.** Administration of apomorphine subcutaneous 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; June 2022.
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.
3. Halli-Tierney AD, Luker J and Carroll DG. Parkinson Disease. *Am Fam Physicians.* 2020;102(11):679-691.