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

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Product Identifier(s)

Effective 1/1/23 to 2/27/23: 108310

Effective 2/28/23: 72310

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Cigna covers apomorphine hydrochloride (Apokyn®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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 individuals 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.

FDA Indication(s)

1. **Parkinson's Disease.** Approve for 1 year if the individual meets the following criteria (A, B, C, and D):
   A) Individual is experiencing "off" episodes such as muscle stiffness, slow movements, or difficulty starting movements; AND

B) Individual is currently receiving carbidopa/levodopa therapy; AND
C) Individual has previously tried one other treatment for "off" episodes and meets ONE of the following criteria (i or ii):
  i. Individual had significant intolerance, according to the prescriber; OR
  ii. Individual 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 Covered

Apomorphine hydrochloride (Apokyn®) is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

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]

Background

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.

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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	07/20/2022