PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/12/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

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

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Parkinson's Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is experiencing "off" episodes; AND
     Note: Examples of "off" episodes include muscle stiffness, slow movements, or difficulty starting movements.
   - **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
     - **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 COVERED

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is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent Use with a Serotonin 5-HT_3 Antagonist.** Administration of apomorphine subcutaneous 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]

REFERENCES

1. Apokyn® subcutaneous injection [prescribing information]. Louisville, KY: US WorldMeds; January 2025.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/26/2023
Update	Policy name changed from Parkinson's Disease – Apokyn Prior Authorization Policy to Parkinson's Disease – Apomorphine Subcutaneous Prior Authorization Policy. The generic apomorphine was added, where relevant, throughout the policy.	09/06/2023
Annual Revision	No criteria changes.	3/13/2024
Annual Revision	**Parkinson's Disease:** Examples of evidence of "off" episodes were moved to a Note.	3/12/2025