PRIOR AUTHORIZATION POLICY

POLICY: Parkinson's Disease – Onapgo Prior Authorization Policy
- Onapgo™ (apomorphine subcutaneous injection – Supernus)

REVIEW DATE: 05/28/2025; selected revision 06/11/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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

Onapgo, a dopaminergic agonist continuous subcutaneous infusion, is indicated for the treatment of motor fluctuations in adults 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. Onapgo is not addressed in current guidelines.

Clinical Efficacy

The efficacy of Onapgo for the treatment of motor fluctuations in adults with advanced Parkinson's disease has been evaluated in one pivotal study.[1,3] The study included patients ≥ 30 years of age with idiopathic and levodopa-responsive Parkinson's Disease. An open-label trial followed patients for up to 52 weeks.[4] The

key efficacy endpoints evaluated changes from baseline in daily "off" and the change in daily "on" time without troublesome dyskinesia.[1,3] From baseline to Week 12, the change in "off" time was -2.55 hours for Onapgo vs. -0.9 hours for placebo (P = 0.0114). The change in "on" time without troublesome dyskinesias from baseline to Week 12 was 2.76 hours for Onapgo vs. 1.12 hours for placebo (P = 0.0188). The pooled results for Onapgo at Week 64, showed "off" time decreased by -3.66 hours and "on" time increased by 3.31 hours.[4]

POLICY STATEMENT

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

- **Onapgo™ (apomorphine subcutaneous injection – Supernus) 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, D, and E):
   - **A)** Patient is diagnosed with advanced Parkinson's disease; AND
   - **B)** Patient is experiencing "off" episodes; AND
     Note: Examples of "off" episodes include muscle stiffness, slow movements, or difficulty starting movements.
   - **C)** Patient has tried an oral carbidopa/levodopa therapy and meets ONE of the following (i or ii):
     - **i.** According to the prescriber, patient had significant intolerance; OR
     - **ii.** According to the prescriber, patient had inadequate efficacy; AND
   - **D)** Patient has previously tried or is currently receiving ONE other treatment for "off" episodes; AND
     Note: Examples of treatment for "off" episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Ongentys (opicapone capsules), or Xadago (safinamide tablets).
   - **E)** The medication is prescribed by or in consultation with a neurologist.

CONDITIONS NOT COVERED

Onapgo™ (apomorphine subcutaneous injection – Supernus)

is(are) considered not medically necessary 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. Onapgo™ subcutaneous injection [prescribing information]. Rockville, MD: Supernus; February 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. Katzenschlager R, Poewe W, Rascol O, et al. Apomorphine subcutaneous infusion in patients with Parkinson's disease with persistent motor fluctuations (TOLEDO): A multicentre, double-blind, randomised, placebo-controlled trial. *Lancet Neurol*. 2018;17(9):749-759.
4. Katzenschlager R, Poewe W, Rascol O, et al. Long-term safety and efficacy of apomorphine infusion in Parkinson's disease patients with persistent motor fluctuations: Results of the open-label phase of the TOLEDO study. *Parkinsonism Relat Disord*. 2021;83:79-85.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/28/2025
Selected Revision	Concurrent Use with a Serotonin 5-HT_3 Antagonist was added under "Conditions Not Covered ".	06/11/2025