CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Parkinson's Disease – Onapgo Utilization Management Medical Policy
- Onapgo™ (apomorphine subcutaneous injection – Supernus)

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

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 medical benefit coverage of Onapgo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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, initial approval requires Onapgo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Onapgo is recommended in those who meet the following criteria:

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; the patient had significant intolerance; OR
     - **ii.** According to the prescriber; the 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.

   Dosing. Approve up to 98 mg administered as a subcutaneous infusion every day.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Onapgo is not recommended in the following situations:

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]

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. 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 Recommended for Approval".	06/11/2025