MEDICAL MUTUAL®

Drug Policy

Policy:	**20260101**	**Initial Effective Date:** 01/15/2026
Code(s):	**HCPCS J3490, J3590 or J9999**	**Annual Review Date:** 01/15/2026
SUBJECT:	**Onapgo™ (apomorphine subcutaneous injection – Supernus)**	**Last Revised Date:** 01/15/2026

☐Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Onapgo, a dopaminergic agonist continuous subcutaneous infusion, is indicated for the treatment of motor fluctuations in adults with advanced **Parkinson's disease**.[1]

POLICY STATEMENT

This policy involves the use of Onapgo. Prior authorization is recommended for pharmacy and medical benefit coverage of Onapgo. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Onapgo as well as the monitoring required for AEs and long-term efficacy, initial approval requires Onapgo be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

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.

Dosing in Onapgo. *Dosing must meet the following (medical benefit only):*

- ONAPGO (apomorphine hydrochloride) is administered as a subcutaneous infusion with the ONAPGO pump.
- The daily dosage is determined by individualized patient titration and is composed of a continuous dosage and as needed extra dose(s).
- The maximum recommended total daily dosage of ONAPGO, including the continuous dosage and any extra dose(s), is 98 mg per day, generally administered over the waking day (e.g., 16 hours).
- Continuous Dosage
- The recommended initial continuous dosage (continuous infusion) of ONAPGO is 1 mg/hr. Titrate the continuous dosage, as needed, in 0.5 mg/hr to 1 mg/hr increments. Dose adjustments may be made daily, or at longer intervals, through the titration process. Patients in clinical studies used a mean of 4 mg/hr of ONAPGO. The maximum continuous dosage is 6 mg/hour administered over the waking day (e.g., 16 hours).

Extra Dose

- Extra doses of ONAPGO may be used:
  - Upon starting in the morning; or
  - When restarting the continuous dosage after a 1-hour or longer break in use (i.e., as a loading dose); or
  - As a supplement to the continuous dosage to manage acute OFF symptoms that are not controlled
- The extra dose may be titrated to clinical response and tolerability with adjustments in increments of 0.5 mg or 1 mg. Subsequent extra doses may be between 0.5 mg and 2 mg.
- Administer no more than 3 extra doses per day over 16 hours with at least 3 hours between extra doses.
- If 3 extra doses are routinely required during daily infusion, consider further adjustment of the continuous dosage.
- The maximum recommended total daily dosage, including extra doses, is 98 mg during the waking day (e.g., 16 hours).

Other Apomorphine Medications

- ONAPGO is not substitutable for apomorphine products intended for intermittent use. There is insufficient information about concomitant use of other apomorphine containing products with ONAPGO.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Onapgo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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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.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3490 and J3590 or J9999

†When *unclassified drugs* (J3490) or *unclassified biologics* (J3590) or *unclassified antineoplastics* (J9999) is determined to be Onapgo

Edits and Denials:

Prior approval: Prior approval is required for Onapgo **(HCPCS Codes J3490 , J3590, J9999)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

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Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3490, J3590, J9999** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3490	Unclassified drugs
J3590	Unclassified biologics
J9999	Unclassified antineoplastics