

Medical Drug Clinical Criteria

Subject: Onapgo (apomorphine subcutaneous solution)
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Overview

This document addresses the use of Onapgo (apomorphine subcutaneous solution), a continuous subcutaneous apomorphine infusion that is FDA approved for the treatment of advanced Parkinson's disease. Apomorphine is a dopamine agonist that is thought to stimulate specific postsynaptic dopamine receptors within the brain.

Parkinson's disease (PD) is a progressive neurodegenerative disorder associated with motor complications such as tremor, bradykinesia, and rigidity. The decision to initiate pharmacologic therapy for the management of symptoms associated with PD is determined by the degree to which the individual is functionally impaired and influenced by a variety of individual and medication-related factors. Treatment is individualized and combination therapy is often employed to manage symptoms and reduce "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes).

Levodopa and dopamine agonists are approved as first-line treatment options for early PD. Dopamine agonists, MAO B inhibitors, COMT inhibitors, or adenosine receptor antagonist can be used as adjunct therapy to levodopa in individuals who have continued motor symptoms despite optimal levodopa therapy. Rasagiline is also approved as a monotherapy option for those with early PD. At least one agent from each drug class is available as a generic agent.

Advanced therapies include device assisted therapies (e.g. foscarnidopa-foslevodopa subcutaneous infusion, levodopa-carbidopa intestinal gel, apomorphine subcutaneous solution) and neurosurgery (deep brain stimulation).

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Onapgo (apomorphine subcutaneous solution)

Initial requests for Onapgo (apomorphine subcutaneous solution) may be approved if the following criteria are met:

- I. Individual has a diagnosis of advanced Parkinson's disease; **AND**
- II. Individual will be using for treatment of motor fluctuations; **AND**
- III. Requested drug will be used as a continuous infusion (not intermittent use); **AND**
- IV. Documentation is provided that individual has motor symptoms inadequately controlled by current therapy.

Continuation requests for Onapgo (apomorphine subcutaneous solution) may be approved if the following criteria are met:

- I. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Onapgo (apomorphine subcutaneous solution) may not be approved for:

- I. Individual is using in combination with 5HT3 antagonists, including antiemetics (e.g., ondansetron, granisetron, dolasetron, palonosetron) and alosetron; **OR**
- II. Request is for erectile dysfunction (ED).

Quantity Limits

Onpago (apomorphine subcutaneous solution) Quantity Limit

Drug	Limit
Onpago 98 mg/20 mL (4.9 mg/mL) subcutaneous solution	1 vial (20 mL) per day

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Onpago (apomorphine hydrochloride)]
J3490	Unclassified drugs [when specified as Onpago (apomorphine hydrochloride)]

ICD-10 Diagnosis

All diagnosis pend

Document History

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Document History:

- 03/10/2025 – Select Review: Add new criteria and quantity limits for Onpago. Administrative addition for documentation. Coding Reviewed: Added HCPCS NOC C9399, J3490 and all diagnosis pend for Onpago.

References

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- 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. doi:10.1016/S1474-4422(18)30239-4.
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- Pringsheim T, Day GS, Smith DB, et al. Dopaminergic Therapy for Motor Symptoms in Early Parkinson Disease Practice Guideline Summary: A Report of the AAN Guideline Subcommittee. *Neurology*. 2021;97(20):942-957. doi:10.1212/WNL.00000000000012868.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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