SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Onapgo™ (apomorphine hydrochloride) **(J3490) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage:

- Initial continuous dosage is 1 mg/hr with a maximum of 6 mg/hr for up to 16 hours per day. An extra dose may be titrated in increments of 0.5 mg or 1 mg based on clinical response and tolerability. Subsequent extra doses are between 0.5 mg and 2 mg, with at least 3 hours between extra doses and a maximum of 3 extra doses per day.
- Maximum recommended total daily dosage of Onapgo, including the continuous dosage and any extra dose(s), is 98 mg (1 cartridge per day) generally administered over the waking day (e.g., 16 hours).

Quantity Limit: 6 cartons (30 cartridges; 600 mL) per 30 days

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Member must be 18 years of age or older
- ❑ Medication must be prescribed by, or in consultation with a neurologist
- ❑ Member has a diagnosis of advanced Parkinson's disease (PD) with complicated motor fluctuations
- ❑ Member does **NOT** have a diagnosis of atypical PD or secondary PD
- ❑ Member is experiencing "OFF" episodes such as muscle stiffness, slow movements, or difficulty starting movements
- ❑ Provider has submitted documentation which confirms member's symptoms have **NOT** been adequately controlled with optimal medical therapy using **ALL** the following agents:
  - ❑ Dopamine agonist (e.g., Apokyn® or apomorphine hydrochloride, Neupro®, pramipexole, ropinirole)
  - ❑ **ONE** agent from any of the following classes:
    - ❑ Catechol-0-methyl transferase (COMT) inhibitor (e.g., entacapone, Ongentys®, tolcapone)
    - ❑ Monoamine oxidase B (MAO-B) inhibitor (e.g., rasagiline, selegiline, Xadago®)
    - ❑ Adenosine receptor antagonist (e.g., Nourianz®)
- ❑ Member is receiving concurrent therapy with carbidopa/levodopa **within the past 30 days AND** will be used in combination with continuous carbidopa/levodopa treatment **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Provider has made adjustments to members carbidopa/levodopa dose in order to manage symptoms without success
- ❑ Member is **NOT** currently taking a 5-HT3 antagonist medication such as Zofran® (ondansetron), Kytril® (granisetron), Aloxi® (palonostron), Lotronex® (alosetron), or Anzemet® (dolasetron) which can result in profound hypotension and loss of consciousness **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Member has received a starting dose of requested medication and did **NOT** develop clinically significant orthostatic hypotension
- ❑ Member does **NOT** have hypersensitivity to apomorphine, its excipients or sodium metabisulfite

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Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Provider must submit chart notes confirming a positive clinical response to therapy, such as continued success in reversing "OFF" episodes, improved motor function, or clinically significant improvement or stabilization in the signs and symptoms of the disease
- ❑ Member continues to meet all initial criteria and has an absence of drug toxicity

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: ~~5/22/2025;~~ **11/20/2025**
REVISED/UPDATED/REFORMATTED: ~~6/18/2025,~~ **12/12/2025**