



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 18, 2012

## Apokyn<sup>®</sup> (apomorphine)

**LENGTH OF AUTHORIZATION:** UP TO ONE YEAR

**REVIEW CRITERIA:**

- Patient must be  $\geq 18$  years of age.
- Must have diagnosis of Parkinson's disease.
- The individual dose must not exceed 0.6 ml (6 mg) and total daily dose not to exceed 2.0 mL (20mg).

**DOSING & ADMINISTRATION:**

- The prescribed dose of APOKYN should always be expressed in mL to avoid confusion and doses greater than 0.6 mL (6 mg) are not recommended.
- APOKYN is indicated for subcutaneous administration only. APOKYN should not be initiated without use of a concomitant antiemetic (see WARNINGS: Nausea and Vomiting). Most antiemetic experience is with trimethobenzamide and this should generally be used. Trimethobenzamide (300 mg three times daily orally) should be started 3 days prior to the initial dose of apomorphine and continued at least during the first two months of therapy.
- Based on reports of profound hypotension and loss of consciousness when apomorphine was administered with ondansetron, the concomitant use of apomorphine with drugs of the 5HT<sub>3</sub> antagonist class (including, for example, ondansetron, granisetron, dolasetron, palonosetron, and alosetron) is contraindicated.
- The dose of APOKYN must be titrated on the basis of effectiveness and tolerance, starting at 0.2 mL (2 mg) and up to a maximum recommended dose of 0.6 mL (6 mg) as follows:
- The average frequency of dosing was 3 times per day in the development program, and there is limited experience with single doses greater than 0.6 mL (6 mg), dosing more than 5 times per day and with total daily doses greater than 2.0 mL (20 mg).
- The general principle guiding dosing (described in detail below) is to determine a dose (0.3 mL or 0.4 mL) that the patient will tolerate as a test dose under monitored conditions, and then begin an outpatient dosing trial (periodically assessing both efficacy and tolerability)



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using a dose 0.1 mL (1 mg) lower than the tolerated test dose. For example, if the patient tolerates a test dose of 0.4 mL (4 mg) the starting dose should be 0.3 mL (3 mg) used on an as needed basis to treat existing “off” episodes. If needed, the dose can be increased in 0.1 mL (1 mg) increments every few days on an outpatient basis. If a patient does not tolerate a test dose of 0.4 mL (4 mg), a test dose of 0.3 mL (3 mg) may be administered during a separate “off” period, no sooner than 2 hours after the test dose of 0.4 mL (4 mg). Both supine and standing blood pressure should be checked predose and at 20, 40, and 60 minutes post dose.

- If a single dose of apomorphine is ineffective for a particular “off” period, a second dose should not be given for that “off” episode. The efficacy of a second dose for a single “off” episode has not been systematically studied and the safety of redosing has not been characterized.
- Patients who have a significant interruption in therapy (more than a week) should be restarted on a 0.2 mL (2 mg) dose and gradually titrated to effect.