Medical Policy:
APOKYN® (apomorphine)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.131	August 3, 2023	

Definitions

Apokyn (apomorphine) is indicated for the acute, intermittent treatment of hypomobility, "off"' episodes ("end of dose wearing off"' and unpredictable "on/off"' episodes) associated with advanced Parkinson's disease.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 4 boxes (60 ml) per month

Guideline

I. Initial Approval Criteria

Apokyn *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Parkinson's Disease**
    A. Patient is 18 years of age or older; **AND**
    B. Patient has a clinically documented diagnosis of advanced Parkinson's disease; **AND**
    C. Patient is currently receiving carbidopa/levodopa therapy; **AND**
    D. Patient has clinically documented acute, intermittent hypomobility, "off'' episodes; **AND**
    E. Patient has previously tried one other treatment for "off" episodes and meets **ONE** of the following criteria (i or ii):
        i. Patient had significant intolerance, according to the prescriber; **OR**
        ii. Patient had inadequate efficacy, according to the prescriber; **AND**

        Note: Examples of treatment for "off" episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Kynmobi™ (apomorphine hydrochloride sublingual film), Ongentys® (opicapone capsules), or Xadago® (safinamide tablets).
    F. Anti-emetic must be started 3 days prior to beginning treatment. Trimethobenzamide is the only antiemetic that has been studied and can be used with Apokyn.

Limitations/Exclusions

Based on the maximum daily dose (0.6 ml per dose, max of 2 ml per day) Apokyn will be limited to a quantity of 4 boxes (60ml) per month.

II. Renewal Criteria

Same as initial approval criteria.

Dosage/Administration

Indication	Dose
Parkinson's Disease	0.2 mL SC initial test dose. If patient tolerates and responds, starting dose should be 0.2 mL used on an as needed basis to treat "off" episodes. If needed, may increase dose by 0.1 mL (1 mg) increments every few days.

Applicable Procedure Codes

Code	Description
J0367	Injection, apomorphine, 1 mg, 1 billable unit = 1 mg

Applicable NDCs

Code	Description
27505-0004-xx	Apokyn 10mg/1ml solution in 3 ml (30 mg) glass cartridge

ICD-10 Diagnoses

Code	Description
G20	Parkinson's Disease

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/3/2023	Annual Review: Parkinson's Disease : Initial Criteria: Removed " A. Patient is using as an adjunct to other anti-parkinsonian medications and not as first line treatment; **AND** B. Patient must be on levodopa and at least one other agent (amantadine, entacapone, selegiline, or tolcapone); **AND"** Added "Patient is currently receiving carbidopa/levodopa therapy; **AND** C. Patient has previously tried one other treatment for "off" episodes and meets **ONE** of the following criteria (i or ii): i. Patient had significant intolerance, according to the prescriber; **OR** ii. Patient had inadequate efficacy, according to the prescriber; **AND** *Note: Examples of treatment for "off" episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Kynmobi™ (apomorphine hydrochloride sublingual film), Ongentys® (opicapone capsules), or Xadago® (safinamide tablets)."*
EmblemHealth & ConnectiCare	3/23/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	4/8/2020	Updated Age Restriction per FDA Label

References

1. Mylan Bertek. Apokyn (apomorphine hydrochloride injection) 10mg/ml for subcutaneous use only [package insert]. Research Triangle Park, NC: Mylan Bertek Pharmaceuticals.