

Medical Policy: APOKYN[®] (apomorphine)

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG[™] Care Guidelines, to assist us in administering health benefits. The MCG[™] Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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	<p>Annual Review:</p> <p><u>Parkinson’s Disease</u> : Initial Criteria:</p> <p>Removed “</p> <ul style="list-style-type: none"> 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” <p>Added “Patient is currently receiving carbidopa/levodopa therapy; AND</p> <ul style="list-style-type: none"> C. Patient has previously tried one other treatment for “off” episodes and meets ONE of the following criteria (i <u>or</u> ii): <ul style="list-style-type: none"> i. Patient had significant intolerance, according to the prescriber; OR ii. Patient had inadequate efficacy, according to the prescriber; AND <p><i>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).”</i></p>
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.