

<b>Clinical Policy Title:</b>	apomorphine hydrochloride
<b>Policy Number:</b>	RxA.659
<b>Drug(s) Applied:</b>	Kynmobi®
<b>Original Policy Date:</b>	12/07/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Treatment of 'Off' Episodes with Parkinson's Disease (must meet all):

1. Diagnosis of Parkinson's Disease;
2. Member is experiencing 'off' episodes such as muscle stiffness, slow movements, or difficulty starting movements;
3. Member is currently receiving carbidopa/levodopa therapy;
4. Member has previously tried one other treatment for 'off' episodes (e.g., includes entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Apokyn, Ongentys, or Xadago, unless contraindicated or clinically side effects experienced);
5. Member is not concurrently taking a 5HT3 antagonist (e.g.e.g., ondansetron, granisetron, dolasetron, palonosetron and alosetron).

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. Treatment of 'Off' Episodes with Parkinson's Disease (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

1. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord* 2018; 33:1248. Available at: <https://pubmed.ncbi.nlm.nih.gov/29570866/>. Accessed August 28, 2024.
2. Sunovion. Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Examine the Efficacy, Safety and Tolerability of APL-130277 in Levodopa Responsive Patients with Parkinson's Disease Complicated by Motor Fluctuations ("OFF" Episodes). Available at: <https://www.clinicaltrials.gov/ct2/show/NCT02469090>. NLM identifier: NCT02469090. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	09/25/2020	12/07/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Policy title table updated to reflect accurate dates.</li> <li>2. Grammar and punctuation adjustments across document for clarity and consistency.</li> <li>3. Added requirement of concurrent carbidopa/levodopa use to background and indication.</li> <li>4. Added initial approval criteria I.A.3 to require approval by neurologist.</li> <li>5. Updated initial approval criteria I.A.6 to include antiemetic example used in clinical trials.</li> <li>6. Added initial approval criteria I.A.7 and continued therapy approval 3 to ensure contraindication to 5HT3 antagonists is considered.</li> </ol>	<p>01/20/2021</p>	<p>03/09/2021</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. References were reviewed and updated.</li> </ol>	<p>12/13/2021</p>	<p>01/17/2022</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.2: Updated diagnostic criteria from Documentation of number and frequency of “off” episodes to Member is experiencing “off” episodes such as muscle stiffness, slow movements, or difficulty starting movements.</li> <li>2. Initial Approval Criteria, I.A.4: Documentation that at least one (1) one other agent has been added to carbidopa/levodopa (e.g. dopamine agonist, COMT inhibitor, or MAO-B inhibitor) to reduce number and frequency of “off” episodes; was replaced with Member is currently receiving carbidopa/levodopa therapy;</li> <li>3. Initial Approval Criteria, I.A.5: "Treatment with a concomitant antiemetic such as trimethobenzamide (not including 5HT3 antagonists) beginning 3 days prior to initial dose" was replaced with Member has previously tried one other treatment for “off” episodes ( e.g., includes entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, Apokyn, Ongentys, or Xadago, unless contraindicated or clinically side effects experienced.</li> <li>4. Initial Approval Criteria, I.A.7: Updated combination therapy criteria from Member is not concurrently taking a 5HT3 antagonist</li> </ol>	<p>10/20/2022</p>	<p>01/17/2023</p>

<p>(e.g., ondansetron) to Member is not concurrently taking a 5HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron and alosetron).</p> <p>5. Continued Therapy Approval, II.A.3: Updated combination therapy criteria from Member is not concurrently taking a 5HT3 antagonist (e.g., ondansetron) to Member is not concurrently taking a 5HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron and alosetron).</p> <p>6. References were reviewed and updated.</p>		
Policy was reviewed.	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed prescriber restrictions.</li> <li>2. Removed dose restrictions.</li> <li>3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>4. Removed other reauthorization requirements including positive response to therapy.</li> <li>5. Updated approval duration verbiage.</li> <li>6. References were reviewed and updated.</li> </ol>	08/28/2024	09/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025