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| **Clinical Policy Title:** | apomorphine hydrochloride |
| **Policy Number:** | RxA.659 |
| **Drug(s) Applied:** | Kynmobi® |
| **Original Policy Date:** | 12/07/2020 |
| **Last Review Date:** | 08/28/2024 |
| **Line of Business Policy Applies to:** | 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 |
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| Policy established. | 09/25/2020 | 12/07/2020 |

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| Policy was reviewed:<br>1. Policy title table updated to reflect accurate dates.<br>2. Grammar and punctuation adjustments across document for clarity and consistency.<br>3. Added requirement of concurrent carbidopa/ levodopa use to background and indication.<br>4. Added initial approval criteria I.A.3 to require approval by neurologist.<br>5. Updated initial approval criteria I.A.6 to include antiemetic example used in clinical trials.<br>6. Added initial approval criteria I.A.7 and continued therapy approval 3 to ensure contraindication to 5HT3 antagonists is considered. | 01/20/2021 | 03/09/2021 |
| Policy was reviewed:<br>1. References were reviewed and updated. | 12/13/2021 | 01/17/2022 |
| Policy was reviewed:<br>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.<br>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;<br>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.<br>4. Initial Approval Criteria, I.A.7: Updated combination therapy criteria from Member is not concurrently taking a 5HT3 antagonist | 10/20/2022 | 01/17/2023 |

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| (e.g., ondansetron) to Member is not concurrently taking a 5HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron and alosetron).<br>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).<br>6. References were reviewed and updated. | | |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |
| Policy was reviewed:<br>1. Removed prescriber restrictions.<br>2. Removed dose restrictions.<br>3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.<br>4. Removed other reauthorization requirements including positive response to therapy.<br>5. Updated approval duration verbiage.<br>6. References were reviewed and updated. | 08/28/2024 | 09/13/2024 |