UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2020 P 2228-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Prior Authorization/Medical Necessity</td>
</tr>
<tr>
<td>Medication</td>
<td>Apokyn® (apomorphine) injection</td>
</tr>
<tr>
<td>P&amp;T Approval Date</td>
<td>12/2020</td>
</tr>
<tr>
<td>Effective Date</td>
<td>5/1/2021; Oxford only: 5/1/2021</td>
</tr>
</tbody>
</table>

1. **Background:**
   Apokyn is a non-ergoline dopamine agonist 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.

   Coverage will be provided for members who meet the following criteria.

2. **Coverage Criteriaa:**

   **A. Initial Authorization**

   1. **Apokyn** will be approved based on all of the following criteria:

   a. Diagnosis of Parkinson’s disease

   -AND-

   b. Apokyn will be used as intermittent treatment for OFF episodes

   -AND-

   c. Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson’s disease

   -AND-

   d. Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

   -AND-

   e. Patient continues to experience ≥ 2 hours of OFF time per day despite optimal management of carbidopa-levodopa therapy including both of the following:

© 2020 UnitedHealthcare Services, Inc.
(1) Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet

-AND-

(2) Dose and dosing interval optimization

-AND-

f. History of failure, contraindication, or intolerance to two anti-Parkinson’s disease therapy from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

(1) Dopamine agonists (e.g., pramipexole, ropinirole)
(2) Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
(3) Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

-AND-

g. History of failure, contraindication, or intolerance to both of the following:

(1) Kynmobi (apomorphine) sublingual film
(2) Inbrija (levodopa) inhalation powder

Authorization will be issued for 6 months.

B. Reauthorization

1. Apokyn will be approved based on the following criterion:

   a. Documentation of positive clinical response to Apokyn therapy

   -AND-

   b. Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

   Authorization will be issued for 12 months.

a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
3. **Additional Clinical Rules:**
   - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   - Supply limits may be in place.

4. **References:**

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Medical Necessity – Apokyn (apomorphine) injection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Change Control</strong></td>
</tr>
<tr>
<td>12/2020</td>
<td>New program.</td>
</tr>
</tbody>
</table>

© 2020 UnitedHealthcare Services, Inc.