FORMULARY EXCEPTION POLICY

POLICY:  Opioids Transmucosal – Abstral® (fentanyl sublingual tablet – Novartis/ProStrakan)

DATE REVISED:  04/11/2019

Verification of Therapies Required:  Previous trials of other fentanyl transmucosal therapies are required to be verified by a clinician in the ESI Coverage Review Department when noted in the criteria as [verification of therapies required].

Approval Duration:  All approvals are provided for the duration noted below.

CRITERIA

1. Breakthrough Pain in Patients with Cancer:  Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient meets ONE of the following conditions (i or ii):
      i. Patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting (In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion); OR
      ii. Patient is unable to take two other short-acting narcotics (e.g., oxycodone, morphine sulfate, hydromorphone, etc.) secondary to allergy or severe adverse events (In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion); AND
   B) Patient is on or will be on an oral or transdermal long-acting narcotic (e.g., Duragesic, OxyContin, morphine extended-release), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (e.g., morphine sulfate, hydromorphone, fentanyl citrate).
   C) Patient meets ONE of the following conditions (i or ii):
      i. The patient has tried two of the following, if two are formulary (or one if only one is formulary or none if none are formulary): fentanyl citrate oral transmucosal lozenge (Actiq, generics), Fentora, Subsys, or Lazanda [verification of therapies required]; OR
      ii. In patients who cannot tolerate the sugar content of fentanyl citrate oral transmucosal lozenge (Actiq, generics) [e.g., patients who are glucose intolerant, diabetic, at high risk of dental caries], the patient has tried two of the following, if two are formulary (or one if only one is formulary or none if none are formulary): Fentora, Subsys, or Lazanda [verification of therapies required].

HISTORY

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes*</th>
<th>Date</th>
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<tbody>
<tr>
<td>New Policy</td>
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<td>03/02/2018</td>
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<tr>
<td>Annual revision</td>
<td>No changes to criteria.</td>
<td>04/11/2019</td>
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