Fentanyl Powder

Description

Fentanyl Powder (fentanyl citrate)

Background

Fentanyl powder was added as a line extension to the commercially available fentanyl medications: Abstral, Actiq, Fentora, Onsolis, Lazanda and Subsys. Fentanyl powder can be compounded into the same immediate release dosage forms provided that the requested dose is not commercially available and does not exceed the FDA approved maximum strength for the equivalent commercially available product.

The commercially available immediate release medications have only one indication: the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain (1-6). They should only be prescribed by healthcare professionals who are knowledgeable in the use of Schedule II opioids for cancer pain (1-5).

Regulatory Status

FDA-approved indication: If the fentanyl powder will be compounded into an immediate release product: Fentanyl is an opioid analgesic indicated for the management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Fentanyl products have a boxed warning regarding the risk of fatal respiratory depression in patients treated with fentanyl, including following use in opioid non-tolerant patients and improper dosing. Fentanyl is contraindicated in the management of acute or postoperative pain,
including headache/migraine and in opioid non-tolerant patients. Fentanyl products have a high potential for abuse, addiction, and diversion (1-5).

The FDA has determined that a REMS is necessary for all opioid analgesics intended for outpatient use to ensure that the benefits of these drugs continue to outweigh the risks. The Opioid Analgesic REMS is a strategy to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics (6).

Off-Label Uses:
Off-label (non-FDA approved) compounded topical preparations such as creams, ointments, and gels have not been shown to be safe or effective.

Safety and effectiveness in pediatric patients under the age of 16 have not been established (2).

Related policies
Abstral, Actiq, Butorphanol, Butrans, Duragesic, Extended Release Opioid Drugs, Fentanyl Powder, Fentora, Immediate Release Opioid Drugs, IR Opioid Combo Drugs, Lazanda, Methadone, Opioid Powders, Opioid Step Policy, Suboxone Drug Class, Subsys

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Fentanyl powder compounded into immediate release products may be considered medically necessary for the management of breakthrough cancer pain in patients age ≥ 16 years old and if the conditions indicated below are met.

Fentanyl powder compounded into immediate release products is considered investigational in patients less than 16 years of age and for all other indications.

Prior-Approval Requirements
Age 16 years of age or older

Diagnoses
Patient must have ALL of the following diagnoses if fentanyl powder is being compounded into oral transmucosal lozenge, tablet, sublingual tablet or buccal film or a dosage form similar to Actiq, Fentora, Abstral and Onsolis or into any immediate release
dosage form such as nasal spray, sublingual spray, inhaler, suppository or solution for use in a nebulizer similar to Lazanda and Subsys.

1. Breakthrough cancer pain
   a. Patient is already receiving **around the clock** opioid therapy for underlying persistent cancer pain
   b. Patient is tolerant to opioid therapy.
      Patients are considered opioid tolerant if they are taking at least:
      i. 60mg of oral morphine/day
      ii. 25mcg of transdermal fentanyl/hr
      iii. 30mg of oral oxycodone daily
      iv. 25mg of oral oxymorphone daily
      v. 8 mg of hydromorphone daily
      vi. OR an equianalgesic dose of another opioid for a week or longer.
      *However, lower dosage requirements may achieve tolerance in renal impaired or elderly patients
   c. Prescribing healthcare professional is knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain
   d. Requested dosage form is commercially available
   e. Requested dose is not commercially available and does not exceed the FDA approved maximum strength for the equivalent commercially available product

OR

2. Patient must have following if fentanyl powder is being compounded into a sterile solution for intrathecal use:
   a. Intraoperative anesthesia and/or postoperative analgesia

AND

1. Prescriber agrees to participate in the Opioid Analgesic REMS program and to monitor for abuse, misuse, addiction, and overdose and discontinue if necessary
   (http://www.er-la-opioidrems.com/lwgUl/remS/home.action)

**Prior – Approval Renewal Requirements**

| Age          | 16 years of age or older |
Diagnoses

Patient must have **ALL** of the following:

1. Breakthrough cancer pain  
   a. Patient has remained on around-the-clock opioid therapy  
   b. Prescribing healthcare professional is knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain  
   c. Requested dosage form is commercially available  
   d. Requested dose is **not** commercially available and does not exceed the FDA approved maximum strength for the equivalent commercially available product

OR

2. Patient must have following if fentanyl powder is being compounded into a sterile solution for intrathecal use:  
   a. Intraoperative anesthesia and/or postoperative analgesia

AND

1. Prescriber agrees to participate in the Opioid Analgesic REMS program and to monitor for abuse, misuse, addiction, and overdose and discontinue if necessary  
   (http://www.er-la-opioidrems.com/lwgUI/remss/home.action)

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 6 months

Prior – Approval **Renewal** Limits

Duration 6 months
Summary
Fentanyl powder, when compounded into an immediate release short-acting opioid, is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. Fentanyl powder should only be prescribed by healthcare professionals, who are knowledgeable in the use of Schedule II opioids for cancer pain.

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of fentanyl powder while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2011</td>
<td>Criteria was updated to include any compounded immediate-release products and to identify those products that would be excluded from the PA process because they are not immediate release.</td>
</tr>
<tr>
<td>January 2012</td>
<td>Reduced dosage allowance from 6 units/day to 4 units/day.</td>
</tr>
<tr>
<td>April 2012</td>
<td>Renal patients may require lower dosages</td>
</tr>
<tr>
<td>September 2012</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2013</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>December 2013</td>
<td>Excluded topical compounds that do not have FDA equivalents</td>
</tr>
<tr>
<td>February 2014</td>
<td>Remove quantity limits from PA criteria</td>
</tr>
<tr>
<td></td>
<td>Addition for intrathecal use in renewal</td>
</tr>
<tr>
<td>June 2014</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>December 2016</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td></td>
<td>Added age limit to renewal section</td>
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<tr>
<td></td>
<td>Policy number change from 5.11.03 to 5.70.57</td>
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</table>
Section: Prescription Drugs  Effective Date: April 1, 2019
Subsection: Analgesics and Anesthetics  Original Policy Date: January 1, 2011
Subject: Fentanyl Powder  Page: 6 of 6

March 2017  Annual editorial review and reference update
March 2018  Annual editorial review and reference update
October 2018  Addition of Opioid Analgesic REMS requirement
November 2018  Annual review and reference update. Addition of Opioid Analgesic REMS link per SME
March 2019  Annual review and reference update

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.