Fentora

Description

Fentora (fentanyl buccal tablet)

Background
Fentora has one indication, the management of breakthrough cancer pain in patients with malignancies, who are already receiving, and are tolerant to, opioid therapy for their underlying persistent cancer pain. Fentora should only be prescribed by health care professionals who are knowledgeable in the use of Schedule II opioids for cancer pain and are registered in the Fentora TIRF REMS program (1).

Fentora has a high potential for abuse, addiction, and diversion. Fentora prescribing guidelines indicate that if more than 4 units are required per day, the dosage of the underlying opioid therapy should be titrated (1).

Regulatory Status
FDA-approved indication: Fentora is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 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 (1).

Limitations of use:
Fentora may be dispensed only to patients enrolled in the TIRF REMS Access program (1).
Fentora has a boxed warning regarding the risk of fatal respiratory depression in patients treated with Fentora, including following use in opioid non-tolerant patients and improper dosing. (1).

Fentora is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Fentora cannot be substituted mcg per mcg for other fentanyl products. The substitution of Fentora for any other fentanyl product may result in fatal overdose. Outpatients, prescribers and distributors must be enrolled in the TIRF REMS Access program (1).

Safety and effectiveness in pediatric patients under the age of 18 have not been established (1).

Related policies
Abstral, Actiq, Butrans, Duragesic, Extended Release Opioid Drugs, Fentanyl Powder, 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.

Fentora may be considered medically necessary for the management of breakthrough cancer pain in patients age 18 years old or older and if the conditions indicated below are met.

Fentora is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age or older

Diagnosis
Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:
1. Patient is already receiving around the clock opioid therapy for underlying persistent cancer pain.
2. Patient is tolerant to opioid therapy. Patients are considered opioid tolerant if they are taking at least:
   a. 60mg of oral morphine/day
   b. 25mcg of transdermal fentanyl/hour
   c. 30mg of oral oxycodone daily
   d. 8 mg of oral hydromorphone daily
   e. 25mg of oral oxymorphone daily
   f. 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.

3. Prescribing healthcare professional should be knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.

4. Patient and prescribing healthcare professional are enrolled in TIRF REMS Access program.

5. Initial dose of Fentora must be for 100mcg, even if patient is already established on another fentanyl product unless the conversion is from Actiq
   a. Actiq doses less than or equal to 400mcg – initial dose is Fentora 100mcg
   b. Actiq does greater than 400mcg – initial dose is Fentora 200mcg

Prior – Approval Renewal Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:

   Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:
1. Patient has remained on around-the-clock opioid therapy.
2. Prescriber is knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.
3. Prescriber and patient are enrolled in TIRF REMS program.

All requests are subject to approval by a secondary review by a clinical specialist for final coverage determination.

**Policy Guidelines**

**Pre-PA Allowance**
None

**Prior Approval Limits**

**Dosage**
- Fentora 100mcg – up to 4 units/day
- Fentora 200mcg – up to 4 units/day

**Duration**
6 months

**Prior Approval Renewal Limits**

**Dosage**
- Fentora 100mcg – up to 4 units/day, or
- Fentora 200mcg – up to 4 units/day, or
- Fentora 400mcg – up to 4 units/day, or
- Fentora 600mcg – up to 4 units/day, or
- Fentora 800mcg – up to 4 units/day

**Duration**
6 months

**Rationale**

**Summary**
Fentora, a 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. Fentora should only be prescribed by health care professionals who are knowledgeable in the use of Schedule II opioids for cancer pain (1).

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

**References**
1. Fentora [package insert], North Wales, PA: Cephalon, Inc; December 2016.
Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>October 2007</td>
<td>New strength of Fentora tablets approved by FDA and released to the market. Added to the FEP PA Program as an extension of existing criteria.</td>
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<tr>
<td>November 2009</td>
<td>Criteria was updated to include the definition of opioid tolerant per the prescribing information. The time frame for initiation and renewal was changed to be consistent for all fentanyl products (2).</td>
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<tr>
<td>October 2011</td>
<td>Decreased dosage allowance from 6 units/day to 4 units/day. Required enrollment in REMS program.</td>
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<tr>
<td>September 2013</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>June 2013</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2014</td>
<td>Annual editorial review and reference update and addition of type/location of cancer</td>
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<tr>
<td>June 2015</td>
<td>Annual editorial review and addition of subject to secondary review by clinical specialist</td>
</tr>
<tr>
<td>March 2016</td>
<td>Annual editorial review Policy code changed from 5.02.07 to 5.70.07</td>
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<tr>
<td>March 2017</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>March 2018</td>
<td>Addition of age to renewal criteria</td>
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<tr>
<td>March 2019</td>
<td>Annual editorial review and reference update</td>
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Keywords

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