

Proposed Fentora® (fentanyl) PA Criteria

FDA-Approved Indication

Fentora® is indicated for the management of breakthrough cancer pain in patients with cancer who are already receiving and are tolerant of opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking morphine 60mg/day or more, transdermal fentanyl 25mcg/hour, oxycodone 30mg/day, oral hydromorphone 8mg/day, or an equianalgesic dose of another opioid for 1 week or longer.

PA Criteria

Fentora® is covered for members who meet the following criteria:

- A. Have pain due to a malignancy, **AND**
- B. Are already receiving and who are tolerant to opioid therapy. Patients who are considered opioid tolerant are those who are taking at least 60mg morphine/day, 25mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for at least a week, **AND**
- C. Intolerant of two (2) other immediate-release opioids including morphine, hydrocodone, oxycodone, or hydromorphone.

Dose

The initial Fentora® dose should be 100mcg.

From an initial dose, patients should be closely followed and the dosage strength changed until the patient reaches a dose that provides adequate analgesia with tolerable adverse reactions using a single fentanyl buccal tablet.

Quantity Limit

120 tablets/month for all strengths and generic equivalents.

Authorization Period

Initial Approval: 6 months

Extended Approval: Requires continued pain from the malignancy and unable to use other oral dosage forms.

Non-Coverage

Fentora® is **NOT** covered for members with the following criteria:

- A. Patient with pain not related to malignancy.
- B. Patient is not opioid-tolerant.
- C. Patient diagnosis is for acute pain or chronic pain due to surgery or injury.
- D. Patient diagnosis is for migraine/headache pain relief or prevention.

References

1. Fentora® (fentanyl) prescribing information. Cephalon, Inc., 2007.
<http://www.fentora.com/HCP/pi.pdf>
2. WHO Pain Ladder. Accessed June 2007 at
<http://www.who.int/cancer/palliative/painladder/en/>