



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** Fentanyl Citrate

**Brand Name:** Actiq, Fentora

**Medication Class:** opioid analgesic

**FDA Approved Uses:** management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

**Available Dosage Forms:** Actiq: 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, 1600mcg transmucosal lozenges  
Fentora: 100mcg, 200mcg, 400mcg, 600mcg, 800mcg buccal tablets

**Usual Dose:** Actiq: varies; titration begins with the 200mcg strength, patient should be prescribed only 6 units of each new dose of Actiq during titration period; no more than 4 units per day  
  
Fentora: varies; starting dose 100mcg, patient should be prescribed only one strength of Fentora at a time; max 4 tablets simultaneously  
  
Both: Generally if a patient requires more than 1 dosage unit per breakthrough episode for several consecutive episodes, the fentanyl dose should be increased; If a patient experiences more than 4 breakthrough episodes per day, the dose of the maintenance (around-the-clock) opioid should be re-evaluated.

Dose conversion Actiq to Fentora: (Due to higher bioavailability of fentanyl in Fentora, when converting patients from other fentanyl products, including Actiq, to Fentora, do not substitute Fentora on a mcg per mcg basis.)

<u>Current Actiq dose (mcg)</u>	<u>Initial Fentora dose (mcg)</u>
200	100
400	100
600	200
800	200
1200	400
1600	400

**Duration of Therapy:** indefinite



**Approximate monthly cost** (based on AWP 2006):

Actiq: \$2510.40 to \$7400.40\*

Fentora: \$1569.60 to \$4623.60\*

\*Based on 1 dosage unit per episode and max of 4 episodes per day.

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

- Only approved for management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain
- Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day or an equianalgesic dose of another opioid for a week or longer.
- Must be 18 years of age or older (16 or over for Actiq)
- Must be prescribed by oncologist or pain specialist
- Must be able to comply with instructions to keep medication out of the reach of children and to discard open units properly.
- Maximum of 6 units of each new strength allowed during titration period for Actiq; maximum of 1 strength allowed at a time for titration of Fentora.
- Must try and fail an adequate dose of a formulary immediate release narcotic for breakthrough pain.
- Must be on an adequate dose of a long-acting (maintenance, around-the-clock) opioid.

**Cautions:**

- Caution in patients with hepatic or renal impairment. The lowest possible dose should be used.
- Carefully monitor patients receiving medications that are CYP 3A4 inhibitors and increase dosage conservatively.

**Contraindications:**

- Contraindicated in the management of acute or post-operative pain
- Contraindicated in opioid non-tolerant patients.

**Not Approved if:**

- Patient has any contraindications to the use of Actiq or Fentora
- Patient does not meet above requirements
- Patient has received an MAO-I within 14 days.
- Patient is on Suboxone or Subutex.
- Patient has known past or current substance abuse potential.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_