



Prior Authorization Approval Criteria

Actiq (fentanyl citrate)

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 underlying persistent cancer pain														
Available dosage forms:	<i>Actiq:</i> 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg transmucosal lozenges <i>Fentora:</i> 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg buccal tablets														
Usual dose:	<i>Actiq:</i> Varies ; titration begins with the 200 mcg strength; patient should be prescribed only 6 units of each new dose of Actiq during titration period; no more than 4 units per day <i>Fentora:</i> Varies ; starting dose 100 mcg; patient should be prescribed only one strength of Fentora at a time; max. 4 tablets simultaneously <i>Both:</i> 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. <i>Dose conversion Actiq to Fentora:</i> 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. <table><thead><tr><th><i>Current Actiq dose (mcg)</i></th><th><i>Initial Fentora dose (mcg)</i></th></tr></thead><tbody><tr><td>200</td><td>100</td></tr><tr><td>400</td><td>100</td></tr><tr><td>600</td><td>200</td></tr><tr><td>800</td><td>200</td></tr><tr><td>1200</td><td>400</td></tr><tr><td>1600</td><td>400</td></tr></tbody></table>	<i>Current Actiq dose (mcg)</i>	<i>Initial Fentora dose (mcg)</i>	200	100	400	100	600	200	800	200	1200	400	1600	400
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200	100														
400	100														
600	200														
800	200														
1200	400														
1600	400														
Duration of therapy:	Indefinite														
Cost (based on AWP 2006):	<i>Actiq:</i> \$2510.40 to \$7400.40* <i>Fentora:</i> \$1569.60 to \$4623.60* <i>* Based on 1 dosage unit per episode and max of 4 episodes per day</i>														

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 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.

Caution:

- 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 has known past or current substance abuse potential.
- Patient is on Suboxone or Subutex.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 10/12/06
First revision: 12/13/06