



Prior Authorization Approval Criteria

Actiq (fentanyl citrate)

Generic name:	fentanyl citrate
Brand name:	Actiq
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:	200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg transmucosal lozenges
Usual dose:	<p>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</p> <p>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.</p>
Duration of therapy:	Indefinite
Cost (based on AWP 2006):	<p>Actiq: \$2510.40 to \$7400.40*</p> <p>Fentora: \$1569.60 to \$4623.60*</p> <p><i>* Based on 1 dosage unit per episode and max of 4 episodes per day</i></p>

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

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must be cancer patient with malignancies experiencing breakthrough pain who is already receiving and is tolerant to opioid therapy for underlying persistent cancer pain.
- Must have tried and failed an adequate dose of a formulary immediate release narcotic for breakthrough pain.
- Must be on adequate dose of a long-acting opioid.
- Must be 16 years of age or older
- Must be prescribed by oncologist or pain specialist.

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