PRIOR APPROVAL CRITERIA for fentanyl citrate lozenges (Actiq and generics) and buccal tablets (Fentora):

**Effective 7/1/09**

Coverage of these drugs is limited to the following FDA-approved indication: for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy.

1) Patients must have breakthrough pain due to cancer.

2) Patients must be receiving chronic opioid therapy, preferably with a long-acting opioid formulation.

3) Patients are considered opioid tolerant when the following doses are used, for one week or longer:
   - at least 60 mg morphine/day, or
   - at least 25 mcg transdermal fentanyl/hour, or
   - at least 30 mg of oxycodone daily, or
   - at least 8 mg oral hydromorphone daily, or
   - an equianalgesic dose of another opioid.

4) Patients must be 16 years of age or older.

5) When patients are able to take other oral immediate-release opioids for management of breakthrough pain, **at least one** other short-acting, immediate-release opioid must have been tried and failed or not tolerated. Other short-acting opioids include:
   - Immediate-release morphine (tablet, solution, suppository)
   - Immediate-release oxycodone and combinations (e.g., Roxicodone, OxyFast, OxylIR, Combunox, Percocet, Roxicet, Percodan, generics)
   - Hydromorphone (e.g., Dilaudid, generics)
   - Hydrocodone-containing products (e.g., Vicodin, Lorcet, Lortab, Xodol, Zydone, Norco, Anexsia, Vicoprofen, Reprexain, generics)

6) Use of fentanyl is contraindicated for:
   - treatment of acute or postoperative pain
   - patients who are not taking chronic opiates
   - patients who are not opioid-tolerant
   - patients with hypoxia or hypercarbia
   - patients with intolerance or hypersensitivity to fentanyl

7) The quantity requested cannot exceed 4 units per day (120 lozenges or tablets per 30 days or less). For patients who are still in the titration process of determining their effective dose, larger quantities of up to 180 units per 30 days may be approved.