

Proposed Actiq® (fentanyl citrate) Oral Transmucosal Lozenges PA Criteria

FDA-Approved Indication

Actiq® is indicated for the management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

- 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.

PA Criteria

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

- A. Covered for patients 16 years and older; **and**
- B. For pain due to malignant diagnosis only; **and**
- C. 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**
- D. Intolerant of two (2) other immediate-release opioids including morphine, hydrocodone, oxycodone, or hydromorphone.

Dose

Individually titrate to a dose that provides adequate analgesia and minimizes side effects. The initial dose of Actiq® to treat episodes of breakthrough cancer pain should be 200mcg.

From this initial dose, patients should be closely followed and the dosage level changed until the patient reaches a dose that provides adequate analgesia using a single oral transmucosal fentanyl dosage unit per breakthrough cancer pain episode.

Quantity Limit

120 lozenges

Authorization Period

Initial Approval: 6 months

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

Non-Coverage

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

- A. Non-malignant pain, including, but not limited to, fibromyalgia, migraines, headaches, peripheral neuropathy, chronic pain syndrome.
- B. Management of acute or postoperative or in patients not taking chronic opiates or not tolerant to opioid therapy.

References

1. Actiq® (fentanyl citrate transmucosal lozenges) prescribing information. Cephalon, 2007.
http://www.actiq.com/pdf/actiq_package_insert_4_5_07.pdf
2. WHO Pain Ladder Accessed June 2007 at
<http://www.who.int/cancer/palliative/painladder/en/>