

Blue Cross Blue Shield of Vermont and The Vermont Health Plan Prior Approval Guidelines Oral Transmucosal Fentanyl (Actiq® and Fentora®)

Description: Fentanyl, a Schedule II controlled substance, is a pure opioid agonist used for analgesia. Other agents in this class include substances such as morphine, oxycodone, hydromorphone, codeine and hydrocodone.

FDA Indications: **ACTIQ®** is indicated only for the management of breakthrough cancer pain in patients 16 and older with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

FENTORA® is indicated only for the management of breakthrough pain in patients 18 years and older with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

**Warning/
Precautions:**

- Serious CNS depression can occur. Concomitant use with other CNS depressants and/or potent CYP P450 3A4 inhibitors may increase CNS depressant effects and can cause fatal respiratory depression.
- Ingestion of either product can be fatal to a child. These products must be kept out of reach of children.
- To be used with caution in patients with COPD or other conditions causing hypoventilation.
- Fentora® and Actiq® are NOT interchangeable. Because of substantial pharmacokinetic differences between the products, substitution of the same dose may result in a fatal overdose.

**Reasons for Prior
Authorization:**

- Cost Potential for misuse Toxicity

**Criteria for
Approval:**

- 1) Diagnosis is an FDA-Labeled Indication **and**
- 2) Patient is tolerant to opioid treatment and is currently on an around-the-clock opioid regimen **and**
- 3) Patient has no contraindications to treatment **and**
- 4) Patient is at least 16 years of age or older for Actiq® coverage requests and at least 18 years of age or older for Fentora® coverage requests
- 5) Patient has failed at least TWO short acting as needed (PRN) opioid break through pain management trials.

Initial Approvals:

Initial approval will be for 3 months patient should be evaluated for response to therapy. If patient is responding to therapy, an additional 9 months will be approved. Dispensed in ONLY 30-day supplies.

**Reasons for Denial
of Benefit:**

- 1) Patient has the following **contraindication(s)**
 - a) Patient is opioid non-tolerant
 - b) History of hypersensitivity to transmucosal fentanyl or any of its components
 - c) Patient has acute or postoperative pain (including headache/migraine)
- 2) Patient does not meet above criteria

References:

- 1) Actiq® (fentanyl citrate oral transmucosal lozenge). Product Information. Cephalon, Inc. 2007, Salt Lake City, UT.
- 2) Fentora® (fentanyl buccal tablet). Product Information. Cephalon Inc. 2007, Salt Lake City, UT.