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Fentanyl Oral Prior Authorization Criteria

Brand	generic	Dosage Form
Actiq®	fentanyl	transmucosal lozenge*
Fentora™	fentanyl	buccal tablet

* product is available from distributors as fentanyl citrate lollipop (not a generic)

FDA APPROVED INDICATIONS

Actiq®¹, Fentora™²

Actiq® (fentanyl) oral transmucosal lozenge and Fentora™ (fentanyl) buccal tablet are indicated only for the management of breakthrough cancer pain in patients with malignancies who are **already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.** Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer [use of oral fentanyl does not require continued use of prior opioid (text added for clarification)].

These products must not be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates. For this reason, Actiq and Fentora are contraindicated in the management of acute or postoperative pain.

Actiq is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.¹

Actiq should be individually titrated to a dose that provides adequate analgesia and minimizes side effects. If signs of excessive opioid effects appear before the unit is consumed, the dosage unit should be removed from the patient's mouth immediately, disposed of properly, and subsequent doses should be decreased.¹

Patients and their caregivers must be instructed that Actiq contains a medicine in an amount that can be fatal to a child. Patients and their caregivers must be instructed to keep all units out of the reach of children and to discard opened units properly in a secured container.¹

RATIONALE

The intent of the Fentanyl Oral Prior Authorization (PA) Criteria is to appropriately select patients for the treatment of chronic cancer pain in appropriate quantities according to product labeling and/or clinical guidelines and/or clinical studies.

Chronic Pain

Due to fentanyl's characteristics of rapid onset of action and short duration of effect, Actiq and Fentora were developed and licensed for treatment of breakthrough pain in cancer patients.¹⁻³ The current labeled use of Actiq and Fentora is in opioid-tolerant patients who are taking longer acting opioids for persistent cancer pain.^{1,2,4} Chronic cancer pain is treated with long-acting opioids for persistent pain and a short-acting opioid for breakthrough pain.⁴⁻⁶

Table, Available Opioids with Equianalgesic Doses ^{11,12}

Drug	Onset (min)	Peak (hours)	Duration ^a (hours)	T _{1/2} (hours)	Equianalgesic doses ^b (mg)	
					Parenteral	Other
Codeine	10-30	0.5-1	4-6	3	IM 120-130 SC 120	Oral 200 ^d
Fentanyl	7-8	No data ^c	1-2	1.5-6	IM 0.1-0.2	Transdermal 25mcg/hr
Hydrocodone	No data ^c	No data ^c	4-6	3.3-4.5	No data ^c	Oral 5-10
Hydromorphone	15-30	0.5-1	4-5	2-3	IM 1.3-1.5 SC 1-1.5	Oral 7.5
Levorphanol	30-90	0.5-1	6-8	11-16	IM 2 SC2	Oral 4
Meperidine	10-45	0.5-1	2-4	3-4	IM 75 SC 75-100	Oral 300 ^d
Methadone	30-60	0.5-1	4-6 ^e	15-30	IM 10 SC 8-10	Oral 10-20
Morphine	15-60 ^f	0.5-1	3-7	1.5-2	IM 10 SC 10	Oral 30-60
Oxycodone	15-60	1	4-6	No data ^c	IM 10-15 SC 10-15	Oral 30 ^d
Oxymorphone	5-10	0.5-1	3-6	No data ^c	IM 1 SC 1-1.5	Rectal 5, 10
Butorphanol	<10	30-60	3-4	2.5-4	2-3	No data

a=After IV administration, peak effects may be more pronounced but duration is shorter; Duration of action may be longer with the oral route.

b=Based on morphine 10mg IM or SC

c=No data available

d=Starting doses lower (codeine 30mg, oxycodone 5mg; meperidine 50mg

e=Duration and half-life increase with repeated used because of cumulative effects

f=Data based on intrathecal or epidural administration

Quantity Limit for Chronic Pain

Addition of fentanyl oral to a long-acting opioid regimen involves titration of the dose until one unit gives adequate pain relief with acceptable side effects.^{1,2,4} Actiq and Fentora product labeling recommend limiting consumption to four or fewer units per day once titration to an effective dose has been accomplished.^{1,2} If patients consistently use more than four units per day, adjustment of the around-the-clock opioid is indicated.¹⁻³ Quantity limits for fentanyl oral will be set at four units per day. Use of quantities greater than four units per day, if appropriate, may be approved through the clinical review process. Use above the set limit may be considered if the patient requires doses higher than the maximum strength supplied and long-acting opioid dosage cannot be increased or if the patient experiences more than four episodes per day of breakthrough pain despite appropriate long-acting opioid use.

Acute or Episodic Pain

Case reports and small studies evaluating the use of fentanyl oral in acute and episodic pain, some in nonmonitored settings, include the treatment of migraine headache pain that does not respond to traditional migraine agents, treatment of frequent episodes of moderate-to-severe pain from sickle cell disease, as analgesia for postoperative pain, and as a component of burn wound care in children.⁷⁻¹⁰ There are currently no large, randomized, controlled trials supporting the use of fentanyl oral for acute pain for these indications and safety in patients that are not opioid tolerant in nonmonitored settings is a concern.⁴ The PA criteria for fentanyl oral will not allow use of the agent for noncancer, episodic or acute pain.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Fentanyl Oral

Initial and Renewal Evaluation

1. Does the patient require fentanyl oral for the treatment of chronic cancer pain?
If yes, continue to 2. If no, deny.

2. Is the patient taking a long-acting opioid concurrently with the oral fentanyl?
If yes, verify in claims history any long-acting opioid claim in the past 90 days.
 If not found, deny.
 If found, continue to 3.
If no, deny.
3. Is the requested quantity greater than four units per day?
If yes, continue to 4.
If no, approve the PA for a quantity of 4 units per day for 12 months
(quantities > 4 will reject.)
4. Can the requested dose be achieved using a lesser quantity of a higher strength (e.g., Fentora 10 x 100mcg could be accommodated with 5 x 200mcg)?
If yes, approve the lesser quantity of the higher strength for 12 months (requested quantity and strength are denied).
If no, continue to 5.
5. Can the episodes of breakthrough pain be controlled by modifying the dose of the long-acting opioid?
If yes, approve the PA at a quantity of 4 units per day for 12 months (requested quantity is denied).
If no, approve the PA for quantities greater than 4 units per day for 12 months.

REFERENCES

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Document History

Original Prime Standard Approved by External UM Committee 11/2006
 HCSC Client Specific Criteria approved by HCSC Corporate Clinical Committee 12/2006
 Administrative addition of Fentora 300 mcg, approved by HCSC Corporate Clinical Committee 10/2007