



Fentanyl Oral Prior Authorization Criteria

NOTE: This prior authorization (PA) criteria program contains a quantity limit of 4 units total for any combination of oral fentanyl products.

Brand	Generic	Dosage Form
Actiq [®]	fentanyl	transmucosal lozenge ^{ab}
Fentora [®]	fentanyl	buccal tablet
Onsolis [™]	fentanyl	buccal soluble film

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

b – generic fentanyl citrate lollipop FDA approved, expected to be available in 2010; will be included in program when marketed

PROGRAM OBJECTIVES

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.

Table 1: Targeted Agents for Fentanyl Oral Prior Authorization

Agent	GPI (multisource code)
Actiq (fentanyl transmucosal lozenge)^{ab}	
200 mcg	65100025108450 (M, N, O, or Y)
400 mcg	65100025108455 (M, N, O, or Y)
600 mcg	65100025108460 (M, N, O, or Y)
800 mcg	65100025108465 (M, N, O, or Y)
1200 mcg	65100025108475 (M, N, O, or Y)
1600 mcg	65100025108485 (M, N, O, or Y)
Fentora (fentanyl buccal tablet)	
100 mcg	65100025100310 (M, N, O, or Y)
200 mcg	65100025100320 (M, N, O, or Y)
300 mcg	65100025100325 (M, N, O, or Y)
400 mcg	65100025100330 (M, N, O, or Y)
600 mcg	65100025100340 (M, N, O, or Y)
800 mcg	65100025100350 (M, N, O, or Y)
Onsolis (fentanyl buccal soluble film)	
200 mcg	65100025108220 (M, N, O, or Y)
400 mcg	65100025108230 (M, N, O, or Y)
600 mcg	65100025108240 (M, N, O, or Y)
800 mcg	65100025108250 (M, N, O, or Y)
1200 mcg	65100025108260 (M, N, O, or Y)

a – fentanyl citrate lollipop (not a generic) included in program

b – generic fentanyl citrate lollipop FDA approved, expected to be available in 2010; will be included in program when marketed

Table 2: FDA-Approved Dosing and Program Quantity Limits

Agent	Recommended Dosage	Quantity per Day Limit	
Actiq (fentanyl oral transmucosal lozenge)			
200 mcg, 400mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg lollipop	<ul style="list-style-type: none"> ●Initial dose of Actiq: 200 mcg. Prescribe an initial supply of six 200 mcg units ●Individually titrate to a tolerable dose that provides adequate analgesia using a single unit per breakthrough cancer pain episode ●Limit consumption to four or fewer units per day once successful dose is found 		
Fentora (fentanyl buccal tablet)			
100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg buccal tablet	<ul style="list-style-type: none"> ●For opioid-tolerant patients not being converted from Actiq, the initial dose is always 100 mcg ●Once titrated, patients should use only one tablet of the appropriate strength per breakthrough pain episode ●If greater than 4 breakthrough pain episodes occur per day, the of the maintenance opioid used for persistent pain should be re-evaluated 	4 units total (cumulative for ALL agents and strengths)	
Onsolis (fentanyl buccal soluble film)			
200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg buccal soluble film	<ul style="list-style-type: none"> ●All patients must begin treatment with one 200 mcg film; patients switching from another oral fentanyl product should not be started on a dose greater than 200 mcg ●Titrate by increasing the dose by 200 mcg in each subsequent episode ●Once titrated, patients should use only one film of the appropriate strength per breakthrough pain episode ●Consider increasing dose of maintenance opioid in patients with greater than 4 breakthrough pain episodes daily 		

Prior Authorization (PA) Criteria for Approval

No claims for fentanyl oral agents will be automatically paid at the point of sale. The Prior Authorization (PA) Criteria for Approval provide the manual review process for all claims for targeted agents in this PA program.

Quantity limits for fentanyl oral will be set at four units per day, including any combination of oral fentanyl products. Use of quantities greater than four units per day will be reviewed through the clinical review process. Use above the set limit may be considered only 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.

Fentanyl Oral Agents (Actiq, Fentora, Onsolis)

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.)

NOTE: PA criteria will approve a quantity of 4 units total for any combination of fentanyl oral products.

4. Can the requested dose be achieved using a lesser quantity of a higher strength (e.g., Fentora 10 x 100 mcg could be accommodated with 5 x 200 mcg)?

If yes, approve the lesser quantity of the higher strength for 12 months (requested quantity and strength are denied).

If no, continue to 5.

NOTE: PA criteria will approve a quantity of 4 units total for any combination of fentanyl oral products.

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 increased quantity is denied).

If no, continue to 6.

NOTE: PA criteria will approve a quantity of 4 units total for any combination of fentanyl oral products.

6. Has the prescriber submitted and the pharmacist reviewed documentation in support of the higher quantity requested?

If yes, the pharmacist must review and may approve the requested quantity (approve for quantities greater than 4 units per day) for 12 months.

If no, deny.

CLINICAL RATIONALE FOR PRIOR AUTHORIZATION

Chronic Pain

Due to fentanyl's characteristics of rapid onset of action and short duration of effect, Actiq, Fentora, and Onsolis were developed and licensed for treatment of breakthrough pain in cancer patients.¹⁻³ The current labeled use of Actiq, Fentora, and Onsolis is in opioid-tolerant patients who are taking longer acting opioids for persistent cancer pain.¹⁻⁵ Chronic cancer pain is treated with long-acting opioids for persistent pain and a short-acting opioid for breakthrough pain.^{5,7}

Table 2: Available Opioids with Equianalgesic Doses^{12,13}

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 SC 2	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

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.⁸⁻¹¹ 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.⁵ The PA criteria for fentanyl oral will not allow use of the agent for noncancer, episodic or acute pain.

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.^{1-3,5} Actiq, Fentora, and Onsolis product labeling recommend limiting consumption to four or fewer units per day once titration to an effective dose has been accomplished.¹⁻³ If patients consistently use more than four units per day, adjustment of the around-the-clock opioid is indicated.¹⁻⁴ 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 will be reviewed 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.

FDA APPROVED INDICATIONS¹⁻³

The following information is taken from individual drug prescribing information and is provided here as background information only. Not all FDA-approved indications may be considered medically necessary. All criteria are found in the section "Prior Authorization (PA) Criteria for Approval."

Actiq¹, Fentora²

Actiq[®] (fentanyl) oral transmucosal lozenge and Fentora[®] (fentanyl) buccal tablet are indicated only for the management of breakthrough pain in patients (for Actiq, patients sixteen years of age or older) with cancer who are **already receiving and who are tolerant to around-the-clock 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 and Fentora are 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

Onsolis³

Onsolis (fentanyl buccal soluble film) is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

REFERENCES

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Document History

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