



## Prior Authorization Approval Criteria

### *Onsolis (fentanyl buccal soluble film)*

<b>Generic name:</b>	fentanyl buccal soluble film
<b>Brand name:</b>	Onsolis
<b>Medication class:</b>	Opioid analgesic
<b>FDA-approved uses:</b>	Management of breakthrough cancer pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for underlying persistent cancer pain
<b>Available dosage forms:</b>	200mcg, 400mcg, 600mcg, 800mcg, 1200mcg individually wrapped in a child resistant, protective foil package.
<b>Usual dose:</b>	<p>Initial starting dose of 200mcg in all patients. Titrate using 200mcg Onsolis film increments (up to a maximum of four 200mcg films or a single 1200mcg film) to adequate analgesia without undue side effects.</p> <p>*Maximum is one dose per episode; no more than four doses per day; separate by at least 2 hours.</p> <p>*Single doses above 1200mcg should not be used.</p> <p>If adequate pain relief is not achieved after one 200mcg Onsolis film, titrate using multiples of the 200mcg Onsolis film (for doses of 400, 600, or 800 mcg). Increase the dose by 200mcg in each subsequent episode until the patient reaches a dose that provides adequate analgesia with tolerable side effects.</p> <p><i>Patients switching from another oral transmucosal fentanyl product must be started on no greater than 200mcg of Onsolis. When prescribing, do not switch patients on a mcg per mcg basis from any other oral transmucosal fentanyl product to Onsolis as Onsolis is not equivalent on a mcg per mcg basis with any other fentanyl product.</i></p>
<b>Duration of therapy:</b>	Indefinite

<b>Approximate cost:</b> (based on AWP 2010)	<u>Strength</u>	<u>Cost per film</u>
	200mcg	21.25
	400mcg	31.25
	600mcg	41.25
	800mcg	51.25
	1200mcg	61.25

**Criteria for use** (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Only approved for management of breakthrough cancer pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for underlying persistent cancer pain
- Patients considered opioid-tolerant are those who are taking at least 60 mg morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for a week or longer.
- Must be 18 years of age or older.
- Must be prescribed by oncologist or pain specialist.
- Must be able to comply with instructions to keep medication out of the reach of children and to discard open units properly.
- Must try and fail an adequate dose of a formulary immediate release narcotic for breakthrough pain.
- Must be on an adequate dose of a long-acting (maintenance, around-the-clock) opioid.

**Caution:**

- Caution in patients with hepatic or renal impairment. The lowest possible dose should be used.
- Carefully monitor patients receiving medications that are CYP 3A4 inhibitors and increase dosage conservatively

**Contraindications:**

- Contraindicated in the management of acute or post-operative pain, including headache/migraine, dental pain, or use in the emergency room.
- Contraindicated in opioid non-tolerant patients.
- Patients with known intolerance or hypersensitivity to any of its components or the drug fentanyl.

**Not approved if:**

- Patient has any contraindications to the use of Fentanyl.
- Patient does not meet above requirements.
- Patient has known past or current substance abuse potential.
- Patient is on Suboxone or Subutex.

**Special Considerations:**

Patients will need to be enrolled in the FOCUS Program to receive Onsolis. The patient will receive their prescription via a traceable courier (with proof of delivery and adult signature required). The patient will receive a counseling call at the time of the first prescription to verify that they are opioid tolerant and discuss how to use the drug.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 03/10/10

