



Prior Authorization Approval Criteria

Abstral (fentanyl)

Generic name:	fentanyl
Brand name:	Abstral
Medication class:	Opioid analgesic
FDA-approved uses:	Management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain
Available dosage forms:	100mcg, 200mcg, 300mcg, 400mcg, 600mcg, 800mcg sublingual tablet
Usual dose:	<p>Starting dose 100 mcg; patient should be prescribed a maximum of two strengths of Abstral at a time; maximum of 4 tablets taken simultaneously</p> <p>If a patient requires more than 1 dose per breakthrough episode for several consecutive episodes, the fentanyl dose should be increased; If a patient experiences more than 4 breakthrough episodes per day, the dose of the maintenance (around-the-clock) opioid should be re-evaluated.</p> <p><i>Dose conversion:</i> Abstral is not equivalent on a mcg per mcg basis with other fentanyl products</p>
Approximate monthly cost: (based on AWP 2011)	<p>\$2016 to \$5760</p> <p><i>* Based on 1 dosage unit per episode and max of 4 episodes per day</i></p>
Duration of therapy:	Indefinite

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 malignancies 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 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
- Maximum of 6 units/day of each strength allowed during titration period
- Maximum of 2 strengths allowed at a time
- 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
- Contraindicated in opioid non-tolerant patients

Not approved if:

- Patient has any contraindications to the use of Abstral
- Patient does not meet above requirements
- Patient has received an MAO-I within 14 days

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 09/07/2011