

Exhibit 1030

Coalition For Affordable Drugs V. HHS



Prior Authorization Approval Criteria

Subsys (fentanyl sublingual spray)

Generic name:	fentanyl
Brand name:	Subsys
Medication class:	Opioid analgesic
FDA-approved uses:	Management of breakthrough cancer pain in patients who are receiving and who are tolerant to opioid therapy for underlying persistent cancer pain
Available dosage forms:	Sublingual Spray-100, 200, 400, 600 and 800mcg single spray units.
Usual dose:	Individually titrate to an effective dose starting at 100mcg to 200mcg to 400mcg, and up to a <u>maximum of 1600mcg</u> . If pain is not relieved after 30 minutes, patients may take only one additional dose of the same strength for that episode. No more than two Subsys doses should be used per episode. Patients must wait at least 4 hours before treating another episode.
Duration of therapy:	Indefinite

Cost (based on AWP 2012): based on 100mcg qid- 800mcg qid: \$102.88-\$300/day

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 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.
- 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.

Criteria for continuation of therapy:

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication

Contraindications:

- Contraindicated in the management of acute or post-operative pain
- Contraindicated in opioid non-tolerant patients.
- Intolerance or hypersensitivity to fentanyl, Subsys, or its components.

Not approved if:

- Patient has any contraindications to the use of fentanyl.
- Patient does not meet above requirements.
- Patient has received an MAO-I within 14 days.
- Patient has known past or current substance abuse potential.
- Patient is being treated for substance abuse (including treatment with buprenorphine or buprenorphine-naloxone).

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 03/14/12

Revised 12/18/12