

## Fentanyl Transdermal Patch Drug Use Criteria

Created: March 2016

Reviewed: April 2019

Includes:

**Duragesic®** *Fentanyl Transdermal Patch*

### Guideline for Use:

1. Is the patient diagnosed and being treated for a funded condition?
  - a. If yes, go to 2
  - b. If no, deny as below the line
2. Is the member unable to take medications by mouth or G-tube if one is present?
  - a. If yes, go to 3
  - b. If no, deny as not meeting criteria. Recommend trial of formulary alternative.
3. Does the patient have any contraindications to therapy?
  - a. If yes, deny as meeting criteria. Off-label use of medication is not covered by OHP.
  - b. If no, go to 4
4. Is Dosing consistency with FDA approved prescribing information?
  - a. If yes, go to 5
  - b. If no, deny as not meeting criteria. Off-label use of medication is not covered by OHP.
5. Are all aspects of the Advanced Health Opioid Coverage Policy met?
  - a. If yes, approve for requested duration of therapy up to 3 months
  - b. If no, deny as not meeting criteria. Forward Advanced Health Opioid Coverage Policy and drug use criteria to requesting provider.

### **Rationale:**

Due to the high potential for misuse, diversion and adverse health outcomes associated with opioid use, this criteria was developed to promote safer, evidence based prescribing of fentanyl products, to ensure use of least costly formulary alternatives when medically appropriate and to ensure prescribing consistent with the FDA approved prescribing information.

### **FDA Approved Indication:**

Fentanyl patches are indicated for the management of pain in opioid tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Patients considered opioid tolerant are those taking, for one week or longer, at least 60mg of oral morphine per day, 25mcg of transdermal fentanyl per hour, 30mg of oral oxycodone per day, 8mg of oral hydromorphone per day, 25mg of oral oxymorphone per day, 60mg of hydrocodone per day, or an equianalgesic dose of another opioid.

**Mechanism of Action:**

Fentanyl is an opioid agonist. Fentanyl interacts predominately with the opioid mu-receptor. These mu-binding sites are distributed in the human brain, spinal cord, and other tissues.

**Contraindications:**

- Opioid non-tolerant patients.
- Acute or intermittent pain, postoperative pain, mild pain.
- Significant respiratory depression.
- Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment.
- Known or suspected gastrointestinal obstruction, including paralytic ileus.
- Known hypersensitivity to fentanyl or any of the components of the transdermal system.

**Dosing and Administration:**

- To be prescribed only by healthcare providers knowledgeable in use of potent opioids for management of chronic pain.
- Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.
- Individualize dosing based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse.
- Initial dose selection: consult conversion instructions in the prescribing information.
- Each transdermal system is intended to be worn for 72 hours.
- Adhere to instructions concerning administration and disposal of fentanyl.
- Mild to moderate hepatic and renal impairment: Initiate treatment with one half the usual starting dose, titrate slowly, and monitor for signs of respiratory and central nervous system depression.
- Do not abruptly discontinue fentanyl in a physically-dependent patient.

**References:**

1. Duragesic® package insert. <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/DURAGESIC-pi.pdf> Revised 9/2018
2. DOCS criteria dated February 7, 2000
3. Advanced Health Opioid Policy