

**ABSTRAL, FENTORA, LAZANDA, ONSOLIS & SUBSYS
(Fentanyl)**

GPI CODING:

651000251007**
651000251003**
651000251020**
651000251082**
651000250009**

DESCRIPTION:

Fentanyl (sublingual tablet) is a short-acting opioid analgesic indicated only for the management of breakthrough pain (BTP) in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Safety and efficacy in patients less than 18 years of age have not been established. Fentanyl is a mu-opioid receptor agonist whose primary therapeutic action is analgesia. Fentanyl is approximately 80 times more potent than morphine. Fentanyl products are classified as schedule II controlled substances.

APPROVAL DURATION:

Initial approvals and renewals: 12 months
Quantity Limit: 4 units per day

CRITERIA FOR ABSTRAL, FENTORA, LAZANDA, ONSOLIS & SUBSYS

- I. Patient is 18 years of age or older **AND**
- II. Patient has a diagnosis of cancer and use is for breakthrough cancer pain **AND**
- III. Patient is opioid tolerant and 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 **AND**
- IV. Other formulary short-acting strong narcotic analgesic alternatives (other than fentanyl) have been ineffective, not tolerated, or contraindicated. Examples of short-acting strong narcotics include, but are not limited to, concentrated morphine oral solution, oxycodone or hydromorphone **AND**
- V. The prescriber is registered in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access program www.tirfremssaccess.com/TirfUI/remss/home.action [866-822-1483](tel:866-822-1483) **AND**
- VI. Fentanyl is not being used for the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room; opioid non-tolerant patients.

Authorization for continued use shall be reviewed at least every 12 months to confirm the following: patient has experienced an objective response to therapy