

## PRIOR AUTHORIZATION CRITERIA

<b>DRUG CLASS</b>	<b>ORAL/INTRANASAL FENTANYL PRODUCTS</b>
<b>BRAND NAME (generic)</b>	<p><b>ABSTRAL</b> (fentanyl citrate sublingual tablet)</p> <p><b>ACTIQ</b> (fentanyl citrate oral transmucosal lozenge)</p> <p><b>FENTORA</b> (fentanyl citrate buccal tablet)</p> <p><b>LAZANDA</b> (fentanyl nasal spray)</p> <p><b>ONSOLIS</b> (fentanyl buccal soluble film)</p> <p><b>SUBSYS</b> (fentanyl sublingual spray)</p>
<b>Status: CVS Caremark Criteria</b>	
<b>Type: Initial Prior Authorization</b>	

**POLICY**

**FDA-APPROVED INDICATIONS**

**Abstral**

Abstral (fentanyl citrate sublingual tablet) is indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent cancer pain.

**Actiq**

Actiq (fentanyl citrate oral transmucosal lozenge) is indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

**Fentora**

Fentora (fentanyl citrate buccal tablet) is indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Oral-Intranasal Fentanyl Products Policy 288-C 01-2018

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**Lazanda**

Lazanda (fentanyl nasal spray) is indicated for the 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.

**Onsolis**

Onsolis (fentanyl buccal soluble film) is indicated for the 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.

**Subsys**

Subsys (fentanyl sublingual spray) is indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

**For All Oral/Intranasal Fentanyl Products:**

Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer. Patients must remain on around-the-clock opioids when taking the requested oral/intranasal fentanyl product.

**Limitations of Use:**

- Not for use in opioid non-tolerant patients.
- Not for use in the management of acute or postoperative pain, including headache/migraine, dental pain, or in the emergency department.
- As a part of the TIRF REMS Access program, oral/intranasal fentanyl products may be dispensed only to outpatients enrolled in the program. For inpatient administration of oral/intranasal fentanyl products (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

**COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is indicated for the treatment of breakthrough CANCER related pain only. The requested drug is being prescribed for the management of breakthrough pain in a CANCER patient who is currently receiving around-the-clock opioid therapy for underlying CANCER pain. The prescriber must submit chart notes or other documentation supporting a diagnosis of cancer related pain and list the type of cancer  
**AND**
- Chart notes or other documentation supporting a diagnosis of cancer related pain have been submitted to CVS Health by fax  
**AND**
- If additional quantities are being requested, then:
  - The patient's dose of a concomitant long-acting analgesic is being increased  
**OR**
  - Additional quantities of the requested drug are needed for breakthrough pain because the dose of the patient's long-acting analgesic is unable to be increased

[Note: Ensure that the patient can safely take the requested dose based on their history of opioid use.]

Quantity Limits apply.

### **QUANTITY FOR APPROVAL**

Abstral (all strengths), Actiq (all strengths), Fentora (all strengths), Onsolis (all strengths), Subsys (200 mcg, 400 mcg, 600 mcg, 800 mcg): 120 units per 25 days\* OR 360 units per 75 days\*

Lazanda (all strengths): 30 bottles per 25 days\* OR 90 bottles per 75 days\*

Subsys (1200 mcg, 1600 mcg): 240 sprays (i.e., 120 blisters) per 25 days\* or 720 sprays (i.e., 360 blisters) per 75 days\*

For patients undergoing dose titration (increase) of their concomitant long-acting analgesic or in situations where it is not clinically appropriate to increase the dose of the long-acting analgesic, an additional quantity may be available:

Abstral (100, 200, 300, 400 mcg), Actiq (all strengths), Fentora (all strengths), Onsolis 200, 400, 600 mcg, Subsys (200 mcg, 400 mcg, 600 mcg, 800 mcg): 180 units per 25 days\* OR 540 units per 75 days\*

Lazanda 100 mcg: 45 bottles per 25 days\* OR 135 bottles per 75 days\*

Subsys (1200 mcg, 1600 mcg): 360 sprays (i.e., 180 blisters) per 25 days\* or 1080 sprays (i.e., 540 blisters) per 75 days\*

*\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

### **REFERENCES**

1. Abstral [package insert]. Hunt Valley, MD: Pharmaceuticals International, Inc.; May 2017.
2. Actiq [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; January 2018.
3. Fentora [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; February 2017.
4. Lazanda [package insert]. Newark, CA: Depomed, Inc.; December 2017.
5. Onsolis [package insert]. Somerset, NJ: MEDA Pharmaceuticals; December 2016.
6. Subsys [package insert]. Chandler, AZ: Insys Therapeutics, Inc; December 2016.
7. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed January 2018.
8. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed January 2018.