PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ORAL/INTRANASAL FENTANYL PRODUCTS**
BRAND NAME (generic)	**ABSTRAL (fentanyl citrate sublingual tablet)** **ACTIQ (fentanyl citrate oral transmucosal lozenge)** **FENTORA (fentanyl citrate buccal tablet)** **LAZANDA (fentanyl nasal spray)** **ONSOLIS (fentanyl buccal soluble film)** **SUBSYS (fentanyl sublingual spray)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Abstral

Abstral (fentanyl citrate sublingual tablets) are 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. Patients must remain on around-the-clock opioids when taking Abstral. Abstral is contraindicated for patients who are not already tolerant to opioids because life-threatening respiratory depression and death could result at any dose in patients not on a chronic regimen of opioids. For this reason, Abstral is contraindicated in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room. Abstral is intended to be prescribed only by healthcare professionals who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat 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. Patients must remain on around-the-clock opioids when taking Actiq. This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Actiq is contraindicated in the management of acute or postoperative pain, including headache/migraine, and dental 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. Patients must remain on around-the-clock opioids while taking Fentora. This product must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Fentora is contraindicated in the management of acute or postoperative pain, including headache/migraine, and dental pain.

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. Patients must remain on around-the-clock opioids when taking Lazanda. Lazanda is contraindicated for patients who are not already tolerant to opioids because life-threatening respiratory depression and death could occur in patients not taking chronic opioids. For this reason, Lazanda is contraindicated in the management of acute or postoperative pain, including headache/migraine, or dental pain. Lazanda is intended to be prescribed only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

Onsolis
Onsolis (fentanyl buccal soluble film) is an opioid analgesic 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. Patients must remain on around-the-clock opioids while taking Onsolis. This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression could occur in patients not taking chronic opiates. For this reason, Onsolis is contraindicated in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room.

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. Patients must remain on around-the-clock opioids when taking Subsys. This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Subsys is contraindicated in the management of acute or postoperative pain, including headache/migraine, dental pain, or in the emergency room.

For All Oral/Intranasal Fentanyl Products:
Patients considered opioid tolerant are those who are taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

Oral/Intranasal Fentanyl Products are intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

Limitations of Use:
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 patient has CANCER related pain. This drug is indicated for the treatment of breakthrough CANCER related pain only. Prescriber must submit chart notes or other documentation supporting a diagnosis of cancer related pain and list 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**
- The 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 **AND**
- The patient can safely take the requested dose based on their current opioid use history
  AND
  - The patient does not require MORE than 120 units per month of Abstral, Actiq, Fentora, Onsolis, Subsys, or 240 sprays per month (i.e., 30 bottles per month) of Lazanda

OR

- The patient requires MORE than 120 units per month of Abstral, Actiq, Fentora, Onsolis, Subsys, or 240 sprays per month (i.e., 30 bottles per month) of Lazanda **AND**
- The patient is NOT requesting Abstral 600 mcg, Abstral 800 mcg, Lazanda 300 mcg or 400 mcg, Onsolis 800 mcg, or Onsolis 1200 mcg **AND**
- The patient's pain does not require use of MORE than 180 units per month of Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg, Actiq (all strengths), Fentora (all strengths), Subsys (all strengths), Onsolis 200 mcg, 400 mcg, 600 mcg, or 360 sprays per month (i.e., 45 bottles per month) of Lazanda 100 mcg
  AND
  - 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

Quantity Limit applies.

QUANTITY FOR APPROVAL

Abstral, Actiq, Fentora, Onsolis, Subsys: 120 units per 25 days* OR 360 units per 75 days*
Lazanda: 30 bottles per 25 days* OR 90 bottles 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 (all strengths): 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*
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]. Lake Oswego, OR: Galena Biopharma, Inc.; November 2014.
2. Actiq [package insert]. Salt Lake City, Utah: Cephalon, Inc.; December 2016.
3. Fentora [package insert]. Salt Lake City, Utah: Cephalon, Inc.; December 2016.
4. Lazanda [package insert]. Newark, CA: Depomed, Inc.; March 2015.
5. Subsys [package insert]. Chandler, AZ: Insys Therapeutics, Inc; December 2016.
6. Onsolis [package insert]. Somerset, NJ: MEDA Pharmaceuticals; August 2015.
7. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed January 2017.
8. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed January 2017.