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)**
	SUBSYS **(fentanyl sublingual spray)**
Status: CVS Caremark Criteria	
Type: Initial Prior Authorization*	***Ref # 288-C***

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*
*** No Tech Approval; criteria requires a pharmacist to approve.*

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.

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 around-the clock 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 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 with 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. [Note: For drug coverage approval, ICD diagnosis code provided MUST support the CANCER-RELATED DIAGNOSIS.]
  AND
- Chart notes or other documentation supporting a diagnosis of cancer-related pain have been submitted to CVS Health
  AND
- The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying CANCER pain
  AND
- The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their history of opioid use. [Note: Patients considered opioid tolerant are those who are taking 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.]
  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.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Abstral, Actiq, Fentora, Lazanda, and Subsys are indicated for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. 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. Oral/intranasal fentanyl products are not for use in opioid non-tolerant patients. Oral/intranasal fentanyl products are 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 Transmucosal Immediate-Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategies (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.[1-7]

For patients who are tolerant to and currently receiving opioid therapy for persistent cancer pain, dosing should be individually titrated to provide adequate analgesia with minimal side effects. Oral/intranasal fentanyl products should be limited to four or fewer doses per day. When the breakthrough pain episode is not relieved after administration of one dose, an additional dose may be necessary. If the patient requires more than 1 dose per breakthrough pain episode for several consecutive episodes, dose titration may be necessary. Patients experiencing >4 breakthrough pain episodes/day should have the dose of their long-term opioid re-evaluated.[1-8] Prescribers should ensure that the patient can safely take the requested dose based on their history of opioid use.

Based on this information, a limit of four units per day, or 120 units per month, will be placed on Abstral, Actiq, Fentora, and Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg. A limit of 240 sprays per month (i.e., 120 blisters per month) will be placed on Subsys 1200 mcg and 1600 mcg since two sprays of 600 mcg are needed to achieve the 1200 mcg dose and two sprays of 800 mcg are needed to achieve the 1600 mcg dose. A limit of 30 bottles per month will be placed on the Lazanda products since each bottle provides 8 sprays.

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. This additional quantity will provide coverage for an amount sufficient for up to 4 episodes of breakthrough pain per day plus two additional doses per day. A limit of 6 units per day, or 180 units per month, will be placed on Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg, Actiq (all strengths), Fentora (all strengths), and Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg. For Subsys 1200 mcg and 1600 mcg, a higher limit of 12 sprays per day (i.e., 6 blisters), or 360 sprays per month (i.e., 180 blisters), will be in place. For Lazanda 100 mcg, a higher limit of 12 sprays per day, or 45 bottles per month, will be in place.

Coverage for Abstral 600 mcg or 800 mcg and Lazanda 300 mcg or 400 mcg, is only provided for up to 4 units (Abstral,) or 8 sprays (Lazanda) per day to avoid exceeding the labeled maximum dose.

REFERENCES

1. Abstral [package insert]. Solana Beach, CA: Sentynl Therapeutics, Inc.; October 2019.
2. Actiq [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2019.
3. Fentora [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2019.
4. Lazanda [package insert]. Northbrook, IL: West Therapeutic Development LLC; October 2019.
5. Subsys [package insert]. Northbrook, IL: West Therapeutic Development LLC.; February 2020.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed December 2020.
7. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 2020.

Written by: UM Development (JG)

Date Written:	04/2002
Revised:	(MB) 08/2004; (NB) 08/2005; (CT) 08/2006; (NB) 11/2006 (Added Fentora); (RP) 03/2007 (update label); (CT) 07/2007; (AM) 08/2008; (SE) 08/2009; (RB/AH/SE) 06/2010; (SE) 01/2011 (Added Abstral; Clarified age restriction question), 08/2011, 01/2012 added Subsys (08-2011 (2)), 03/2012, 03/2013, 07/2013 (changed to commercial reference number); (SE/MT) 01/2014; (SE) 06/2014, 01/2015; (CF) 08/2015 (added Onsolis, additional cancer question, documentation/tech notes), 10/2015 (added questions for additional quantities), 01/2016 (added Lazanda questions for macro compatibility, no clinical changes), 06/2016 (new strength of Lazanda – 300 mcg), 12/2016 (updated denial reasons, no clinical changes); (JH/CF) 01/2017, 07/2017 (clarified qty for Subsys 1200 mcg and 1600 mcg), 01/2018, 06/2018 (added note); (CF/DS) 01/2019 (no clinical changes), 01/2020 (removed Onsolis); (DS) 01/2021 (updated questions to reflect updated REMS; updated document title); (PM) 08/2021 (updated denial verbiage)
Reviewed:	Medical Affairs: 04/2002; (MM) 08/2004, 08/2005, 08/2006; (WF) MD 07/2007, 08/2008, 08/2009; (KP) 06/2010, 01/2011, 08/2011, 01/2012, 03/2012; (DNC) 03/2013; (LMS) 07/2013; (KP) 01/2014; (SES) 06/2014, 01/2015; (ADA) 08/2015; (DNC) 10/2015; (ME) 06/2016; (DNC) 01/2017, 07/2017, 01/2018; (MC) 06/2018; (CHART) 01/30/2020, 01/28/2021
External Review:	12/2004, 12/2006, 02/2008, 12/2008, 09/2009, 12/2010, 10/2011, 1/2012, 02/2012, 08/2012, 06/2013, 06/2014, 04/2015, 12/2015, 04/2016, 04/2017, 08/2017, 04/2018, 04/2019, 04/2020, 04/2021

CRITERIA FOR APPROVAL

1	The requested drug is indicated for the treatment of breakthrough CANCER-related pain only. Is the requested drug being prescribed for the management of breakthrough pain in a CANCER patient with underlying CANCER pain? If yes, then prescriber MUST submit chart notes or other documentation supporting a diagnosis of cancer-related pain AND list type of cancer_____ [Note: For drug coverage approval, ICD diagnosis code provided MUST support the CANCER-RELATED DIAGNOSIS.] [If no, then no further questions.]	Yes	No
2	Have chart notes or other documentation supporting a diagnosis of cancer-related pain been submitted to CVS Health? [If no, then no further questions.] [Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes or other documentation.] [RPh Note: MUST obtain a physical copy of chart notes or other documentation supporting a diagnosis of cancer-related pain AND verify that the prescriber has listed the type of cancer. If a physical copy of documentation of a diagnosis of cancer-related pain is not received, then the PA should be denied.]	Yes	No
3	Is the patient currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying CANCER pain? [If no, then no further questions.]	Yes	No
4	The requested drug is intended only for use in opioid tolerant patients. Can the patient safely take the requested dose based on their current opioid use history? [Note: Patients considered opioid tolerant are those who are taking 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.] [If no, then no further questions.]	Yes	No
5	Which drug is being requested? Please check the drug being requested.		

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

[] Abstral 600 mcg or 800 mcg (if checked, then go to 6)
[] Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg (if checked, then go to 8)
[] Actiq (all strengths) (if checked, then go to 8)
[] Fentora (all strengths) (if checked, then go to 8)
[] Lazanda 100 mcg (if checked, then go to 9)
[] Lazanda 300 mcg or 400 mcg (if checked, then go to 7)
[] Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg (if checked, then go to 8)
[] Subsys 1200 mcg, 1600 mcg (if checked, then go to 10)

6	Coverage is provided for up to 120 units per month of Abstral 600 mcg, 800 mcg. Is MORE than this quantity needed to manage the patient's pain? [No further questions.] [RPh Note: If yes, then deny and enter a partial approval for up to 120 units per month of Abstral 600 mcg, 800 mcg.]	Yes	No
7	Coverage is provided for up to 240 sprays per month (i.e., 30 bottles per month) of Lazanda 300 mcg, 400 mcg. Is MORE than this quantity needed to manage the patient's pain? [No further questions.] [RPh Note: If yes, then deny and enter a partial approval for 240 sprays per month (i.e., 30 bottles per month) of Lazanda 300 mcg, 400 mcg.]	Yes	No
8	Coverage is provided for up to 120 units per month of the following: A) Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg, B) Actiq (all strengths), C) Fentora (all strengths), D) Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg. If higher quantities are needed, then additional questions are required. Is MORE than this quantity needed to manage the patient's pain? [Note Subsys packaging: Supplied as 1 spray per blister for Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg.] [If no, then no further questions.] [If yes, then skip to question 11.]	Yes	No
9	Coverage is provided for up to 240 sprays per month (i.e., 30 bottles per month) of Lazanda 100 mcg. If higher quantities are needed, then additional questions are required. Is MORE than this quantity needed to manage the patient's pain? [If no, then no further questions.] [If yes, then skip to question 11.]	Yes	No
10	Coverage is provided for up to 240 sprays per month (i.e., 120 blisters per month) of Subsys 1200 mcg or 1600 mcg. If higher quantities are needed, then additional questions are required. Is MORE than this quantity needed to manage the patient's pain? [Note Subsys packaging: Supplied as 2 sprays per blister for Subsys 1200 mcg and 1600 mcg.] [If no, then no further questions.]	Yes	No
11	Is the patient's dose of a concomitant long-acting analgesic being increased? [If yes, then skip to question 13.]	Yes	No

12	Are additional quantities of the requested drug needed for breakthrough pain because the dose of the patient's long-acting analgesic is unable to be increased? [If no, then no further questions.] [RPh Note: If no, then deny and enter a partial approval for the following: A) 120 units per month of Abstral, Actiq, Fentora, or Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg, B) 240 sprays per month (i.e., 30 bottles per month) of Lazanda 100 mcg, C) 240 sprays per month (i.e., 120 blisters per month) of Subsys 1200 mcg or 1600 mcg.]	Yes	No
13	Which drug is being requested? Please check the drug being requested. [Note: Ensure that the patient can safely take the requested dose based on their history of opioid use.] [] Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg (if checked, then go to 14) [] Actiq (all strengths) (if checked, then go to 14) [] Fentora (all strengths) (if checked, then go to 14) [] Lazanda 100 mcg (if checked, then go to 15) [] Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg (if checked, then go to 14) [] Subsys 1200 mcg, 1600 mcg (if checked, then go to 16)		
14	Does the patient's pain require use of MORE than 180 units per month of any of the following: A) Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg, B) Actiq (all strengths), C) Fentora (all strengths), D) Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg? [Note Subsys packaging: Supplied as 1 spray per blister for Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg.] [No further questions.] [RPh Note: If yes, then deny and enter a partial approval for 180 units per month of the following: A) Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg, B) Actiq (all strengths), C) Fentora (all strengths), D) Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg.]	Yes	No
15	Does the patient's pain require use of MORE than 360 sprays per month (i.e., 45 bottles per month) of Lazanda 100 mcg? [No further questions.] [RPh Note: If yes, then deny and enter a partial approval for 360 sprays per month (i.e., 45 bottles per month) of Lazanda 100 mcg.]	Yes	No
16	Does the patient's pain require use of MORE than 360 sprays per month (i.e., 180 blisters per month) of Subsys 1200 mcg or 1600 mcg? [Note Subsys packaging: Supplied as 2 sprays per blister for Subsys 1200 mcg and 1600 mcg.] [RPh Note: If yes, then deny and enter a partial approval for 360 sprays per month (i.e., 180 blisters per month) of Subsys 1200 mcg or 1600 mcg.]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are using it to manage your breakthrough cancer pain. Your request has been denied based on the information we have.

			[Short Description: No approvable diagnosis.]
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when your prescriber submits your chart notes or other documentation that supports that you have pain due to cancer to CVS Health. Your request has been denied based on the information we have. [Short Description: Prescriber did not fax documentation to confirm cancer-related pain.]
3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are currently taking, and will continue to take, opioid drugs around-the-clock for cancer pain. Your request has been denied based on the information we have. [Short Description: Not on around-the-clock opioids.]
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you can safely take the drug based on your history of opioid use. Your request has been denied based on the information we have. [Short Description: Patient cannot safely take requested dose.]
5.	1=6; 2=8; 3=8; 4=8; 5=9; 6=7; 7=8; 8=10	N/A	
6.	Deny	Approve, 12 months 120 units per 25 days or 360 units per 75 days* of: Abstral 600 mcg, 800 mcg No Tech Approval	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 120 units per month of the requested drug and strength. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity.]
7.	Deny	Approve, 12 months 30 bottles per 25 days or 90 bottles per 75 days* of: Lazanda 300 mcg, 400 mcg No Tech Approval	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 240 sprays per month (i.e., 30 bottles per month) of the requested drug and strength. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity.]
8.	Go to 11	Approve, 12 months 120 units per 25 days OR 360 units per 75 days* of: Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg Actiq (all strengths) Fentora (all strengths)	

		Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg No Tech Approval	
9.	Go to 11	Approve, 12 months 30 bottles per 25 days or 90 bottles per 75 days* of: Lazanda 100 mcg No Tech Approval	
10.	Go to 11	Approve, 12 months 240 sprays (i.e., 120 blisters) per 25 days or 720 sprays (i.e., 360 blisters) per 75 days* of Subsys 1200 mcg or 1600 mcg No Tech Approval	
11.	Go to 13	Go to 12	
12.	Go to 13	Deny RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.	You have requested more than the quantity allowed by your plan. Current plan approved criteria cover up to: - 120 units per month of Abstral, Actiq, Fentora, or Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg - 240 sprays per month (i.e., 30 bottles per month) of Lazanda 100 mcg - 240 sprays per month (i.e., 120 blisters per month) of Subsys 1200 mcg or 1600 mcg Your request has been partially approved. You have been approved for the quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. Your plan covers additional quantities of this drug when you meet any of these conditions: - The dose of your long-acting opioid drug is being increased - The dose of your long-acting opioid drug is unable to be increased and you need more of the requested drug to manage your breakthrough pain Your use of this drug does not meet the requirement. This is based on the information we have. [Short Description: Over max quantity and patient does not meet requirements for additional quantities.]
13.	1=14; 2=14; 3=14; 4=15; 5=14; 6=16	N/A	
14.	Deny	Approve, 12 months 180 units per 25 days OR 540 units per 75 days* of:	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 180 units/month of the requested drug and strength. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 12

		Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg Actiq (all strengths) Fentora (all strengths) Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg No Tech Approval	months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity.]
15.	Deny	Approve, 12 months 45 bottles per 25 days or 135 bottles per 75 days* of: Lazanda 100 mcg No Tech Approval	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 45 bottles/month of the requested drug and strength. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity.]
16.	Deny	Approve, 12 months 360 sprays (i.e., 180 blisters) per 25 days or 1080 sprays (i.e., 540 blisters) per 75 days* of Subsys 1200 mcg or 1600 mcg No Tech Approval	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 360 sprays (i.e., 180 blisters)/month of the requested drug and strength. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity.]

**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.*