



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Oral/Intranasal Fentanyl Products Page: 1 of 3

Effective Date: 6/26/2024 Last Review Date: 6/5/2024

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> Texas

**Intent:**

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for oral and intranasal fentanyl products under the patient's prescription drug benefit.

**Description:**

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 (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 (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 (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 (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.



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- 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.

**Applicable Drug List:**

**Preferred Drug:**

fentanyl citrate oral transmucosal lozenge

**Non-Preferred Drugs:**

Abstral  
fentanyl buccal tablet  
Lazanda  
Subsys

**Policy/Guideline:**

**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  
**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



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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**

- For all non-formulary agents, the patient is unable to take generic fentanyl citrate lozenge for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

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

Quantity Limits apply.

**Approval Duration and Quantity Restrictions:**

**Approval:** 12 months

**Quantity Level Limit:** Reference Formulary for drug specific quantity level limits

- fentanyl citrate oral transmucosal lozenge: 4 lozenges/day
- Abstral: 4 tablets/day
- fentanyl buccal tablets: 4 tablets/day
- Lazanda: 1 bottle/day
- Subsys: 8 sprays/day

**References:**

1. Actiq [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
2. Fentora [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
3. Subsys [package insert]. Northbrook, IL: West Therapeutic Development LLC.; March 2021.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed December 5, 2023.
5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 12/05/2023).
6. Adult Cancer Pain. NCCN Guidelines version 2.2023. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/pain.pdf](https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf). Accessed December 5, 2023.