



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Oral/Intranasal Fentanyl Products

Page: 1 of 4

Effective Date: 5/28/2025

Last Review Date: 5/2025

|             |   |  |  |
|-------------|---|--|--|
| 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 checked="" 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.



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Oral/Intranasal Fentanyl Products

Page: 2 of 4

Effective Date: 5/28/2025

Last Review Date: 5/2025

|             |   |  |  |
|-------------|---|--|--|
| 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 checked="" type="checkbox"/> Florida Kids |
|             | <input checked="" type="checkbox"/> Pennsylvania Kids | <input checked="" type="checkbox"/> Virginia | <input type="checkbox"/> Texas                   |

- 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:**

**Coverage Criteria**

Cancer-Related Pain

Authorization may be granted when the requested drug is being prescribed for the management of breakthrough pain in a CANCER patient with underlying CANCER pain. The requested drug is indicated for the treatment of breakthrough CANCER-related pain only. [ACTION REQUIRED: Documentation is required for approval. The prescriber must submit chart notes or other documentation supporting a diagnosis of cancer-related pain and list the type of cancer. For drug coverage approval, ICD diagnosis code provided MUST support the CANCER-RELATED DIAGNOSIS.] In addition, ALL of the following criteria are met:



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

|                 |   |  |   |
|-----------------|---|--|---|
| Name:           | Oral/Intranasal Fentanyl Products   | Page:  | 3 of 4  |
| Effective Date: | 5/28/2025   | Last Review Date:  | 5/2025  |
| Applies to:     | <input checked="" type="checkbox"/> Illinois<br><input checked="" type="checkbox"/> New Jersey<br><input checked="" type="checkbox"/> Pennsylvania Kids | <input type="checkbox"/> Florida<br><input checked="" type="checkbox"/> Maryland<br><input checked="" type="checkbox"/> Virginia | <input type="checkbox"/> Michigan<br><input checked="" type="checkbox"/> Florida Kids<br><input type="checkbox"/> Texas |

- The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying CANCER pain.
- The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their current opioid use history. [NOTE: Ensure that the patient can safely take the requested dose based on their current opioid use history. These drugs should be prescribed only by healthcare professionals who are knowledgeable about the use of opioids and how to mitigate the associated risks. 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 of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid.]
- If additional quantities are being requested, then the patient must meet ONE of the following:
  - The patient's dose of a concomitant long-acting analgesic is being increased.
  - 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.
- 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.

#### 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.



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Oral/Intranasal Fentanyl Products Page: 4 of 4

Effective Date: 5/28/2025 Last Review Date: 5/2025

|                |   |  |  |
|----------------|---|--|--|
| Applies<br>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 checked="" type="checkbox"/> Florida Kids |
|                | <input checked="" type="checkbox"/> Pennsylvania Kids | <input checked="" type="checkbox"/> Virginia | <input type="checkbox"/> Texas                   |

- Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed December 20, 2024.
- Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 12/20/2024).
- Adult Cancer Pain. NCCN Guidelines version 3.2024. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/pain.pdf](https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf). Accessed December 9, 2024.