PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ORAL FENTANYL PRODUCTS**
BRAND NAME (generic)	**ACTIQ (fentanyl citrate oral transmucosal lozenge)** **FENTORA (fentanyl citrate buccal tablet)** **SUBSYS (fentanyl sublingual spray)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

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.

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 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 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 fentanyl products may be dispensed only to outpatients enrolled in the program. For inpatient administration of oral 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.

QUANTITY FOR APPROVAL

Actiq (all strengths), Fentora (all strengths), Subsys (100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg): 120 units per 25 days* OR 360 units 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:
Actiq (all strengths), Fentora (all strengths), Subsys (100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg): 180 units per 25 days* OR 540 units 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. Actiq [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; March 2021.
2. Fentora [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; March 2021.
3. Subsys [package insert]. Northbrook, IL: West Therapeutic Development LLC.; April 2021.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed December 9, 2022.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed December 9, 2022.

6. Adult Cancer Pain. NCCN Guidelines version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed December 15, 2022.

