UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2077-12
Program	Prior Authorization/Medical Necessity - Fentanyl Transmucosal
Medication	Actiq® (brand only)* (fentanyl transmucosal lozenge), Fentora®* (fentanyl buccal tablet), and fentanyl citrate bulk powder*
P&T Approval Date	2/2016, 9/2016, 9/2017, 10/2018, 10/2019, 10/2020, 2/2022, 4/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Actiq, Fentora and fentanyl citrate lozenges (generic Actiq) are rapid-acting opioid analgesics indicated for the management of breakthrough cancer pain in patients who are already receiving and have developed tolerance to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine daily, at least 25 mcg/hour of transdermal fentanyl, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg of oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids while taking a rapid-acting fentanyl product. Actiq, Fentora, and fentanyl citrate lozenges (generic Actiq) must not be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not on a chronic regimen of opiates.

Compounded fentanyl preparations may provide a unique delivery for certain patient-specific conditions and administration requirements. Compounded fentanyl preparations should be made for a single individual and not produced on a large scale. Compounded fentanyl preparations should not be covered if it is being prescribed as an alternative for a commercially available fentanyl product. Therefore, additional criteria will be provided for fentanyl citrate compounds.

2. Coverage Criteria[a, b]:

A. Actiq* (brand only), or Fentora*will be approved based on **one** of the following criteria:

1. Submission of medical records demonstrating **all** of the following:

   a. Use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented in the medical records).

   -AND-

   b. Patient must have at least a **one** week history of **one** of the following medications to demonstrate tolerance to opioids:

      1) Oral morphine sulfate at a doses of greater than or equal to 60 mg/day
      2) Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr
      3) Oral oxycodone at a dose of greater than or equal to 30 mg/day
      4) Oral hydromorphone at a dose of greater than or equal to 8 mg/day
      5) Oral oxymorphone at a dose of greater than or equal to 25 mg/day
      6) Oral hydrocodone at a dose of greater than or equal to 60 mg/day

7) An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

-AND

c. The patient is currently taking a long-acting opioid around the clock for cancer pain

-AND-

d. The patient has a history of failure, contraindication, or intolerance to fentanyl citrate lozenges (generic Actiq)

-AND-

e. The patient has a history of failure, contraindication, or intolerance to Lazanda

-AND-

f. **One** of the following:

1) The patient is not concurrently receiving an alternative transmucosal fentanyl product.

-OR-

2) The patient is currently receiving an alternative transmucosal fentanyl product **AND** the prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication. Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied.

-OR-

2. The patient is currently taking Actiq (brand only)* or Fentora*, and does not meet the medical necessity criteria requirements based on the FDA-approved indication for breakthrough cancer pain (a one-time fill may be approved for transition to an alternative treatment).

Authorization will be approved for 12 months.

C. Fentanyl citrate bulk powder* or compounded fentanyl will be approved based on **one** of the following criteria:

1. Submission of medical records demonstrating **all** of the following:

a. Use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented in the medical records).

-AND-

b. Patient must have at least a **one** week history of **one** of the following medications to demonstrate tolerance to opioids:

1) Oral morphine sulfate at a doses of greater than or equal to 60 mg/day
2) Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr
3) Oral oxycodone at a dose of greater than or equal to 30 mg/day
4) Oral hydromorphone at a dose of greater than or equal to 8 mg/day
5) Oral oxymorphone at a dose of greater than or equal to 25 mg/day
6) Oral hydrocodone at a dose of greater than or equal to 60 mg/day
7) An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

-AND

c. The patient is currently taking a long-acting opioid around the clock for cancer pain

-AND-

d. A unique dosage form is required for a product that is not commercially available due to patient's age or weight.

-AND-

e. **One** of the following:

1) The patient is not concurrently receiving an alternative transmucosal fentanyl product.

-OR-

2) The patient is currently receiving an alternative transmucosal fentanyl product **AND** the prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication. Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied.

-OR-

2. The patient is currently taking a compounded fentanyl citrate product and does not meet the medical necessity criteria requirements based on the FDA-approved indication for breakthrough cancer pain (a one-time fill may be approved for transition to an alternative treatment).

Authorization will be approved for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] Coverage of medications to treat conditions associated with cancer may be approved based on state mandates.

* Actiq (Brand ONLY), fentanyl bulk powder and Fentora are typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine coverage status.

3. Additional Clinical Programs:

- Supply limits may be in place.
- Prior Authorization/Notification may be in place.
- Compound and Bulk powder notification may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Actiq [package insert]. Parsippany, NJ: Cephalon; December 2023.
2. Fentora [package insert]. Parsippany, NJ: Cephalon; December 2023.

Program	Prior Authorization/Medical Necessity – Fentanyl Transmucosal
Change Control	
Date	Change
2/2016	New program.
7/2016	Added Indiana and West Virginia coverage information.
9/2016	Added requirement that patients cannot be receiving concurrent fentanyl products.
11/2016	Administrative change. Added California coverage information.
9/2017	Added criteria for Abstral, Actiq, Fentora, Subsys and bulk or compounded fentanyl citrate. Updated state mandate language.
10/2018	Updated formatting and references.
10/2019	Updated references; added automation language; added clarifier for transition of care fill.
10/2020	Annual review. Clarified submission of cancer diagnosis. Updated references.
2/2022	Updated references.
4/2022	Added cancer medications state mandate note.
7/2023	Removed Abstral as it is no longer on the market. Updated references. Removed Arkansas footnote, refer to general state mandate footnote.
7/2024	Removed Lazanda and Subsys as they are no longer on the market. Added opioid tolerate dose for oral hydrocodone. Updated references.