UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1031-14
Program	Prior Authorization/Notification - Fentanyl
Medication	Actiq®* (fentanyl transmucosal lozenge), Fentora®* (fentanyl buccal tablet), and fentanyl citrate*
P&T Approval Date	3/2006, 11/2006, 11/2007, 6/2008, 8/2009, 10/2009, 5/2010, 5/2011, 11/2011, 4/2012, 04/2013, 10/2013, 10/2014, 10/2015, 2/2016, 9/2016, 4/2018, 10/2018, 10/2019, 10/2020, 2/2022, 4/2023, 4/1/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Actiq, Fentora, and fentanyl citrate lozenges (generic Actiq) are 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 one of these fentanyl products. 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 required for fentanyl citrate compounds.

2. Coverage Criteria[a, b]:

A. Actiq*, fentanyl citrate lozenges (generic Actiq*) 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 dose 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. **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 fentanyl citrate lozenges (generic Actiq), Actiq*or Fentora*, and does not meet the notification 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

B. 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 medical record).

-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 dose 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 notification 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.

* 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 – Medical Necessity 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/Notification - Fentanyl
Change Control	
Date	Change
10/2013	Changed compounded fentanyl citrate powder to fentanyl. Added Subsys to background information. Noted that Abstral will typically be excluded from coverage as of 1/1/14.
9/2014	Administrative change – Tried/Failed exemption for State of New Jersey removed.
10/2014	Removed Onsolis from criteria (obsolete). Noted that Brand ONLY Actiq and fentanyl bulk powder is typically excluded from coverage. Updated fentanyl transdermal to 25 mcg/hr. Updated references.
10/2015	Minor changes to background section. Added requirement for documentation of cancer diagnosis. Updated references. Administrative changes.
2/2016	Added requirement for the provision of medical records to verify cancer diagnosis. Added clarification for patients not meeting notification criteria can have a one-time rather than one month approval for transition of care.
9/2016	Added requirement that patients cannot be receiving concurrent fentanyl products. Added clarification that prescriber requests the termination of all previous authorizations for transmucosal fentanyl products.
4/2018	Revised state mandate language. Updated background section. Updated references.
10/2018	Updated formatting and references. Added state mandate language.
10/2019	Annual review; updated references; added automation language.
10/2020	Annual review. Clarified submission of cancer diagnosis. Updated references.
2/2022	Updated references.
4/2023	Removed Abstral as it is no longer on the market. Updated references. Removed Arkansas footnote, refer to general state mandate footnote.
4/2024	Removed Lazanda and Subsys as they are no longer on the market. Added opioid tolerate dose for oral hydrocodone. Updated references.
5/2025	Annual review with no changes.