UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Fentanyl IR

Program	Prior Authorization
Medication	Abstral (fentanyl sublingual tablets), Actiq (fentanyl transmucosal lozenge), Fentora (fentanyl buccal tablet), Lazanda (fentanyl nasal spray), Subsys (fentanyl sublingual spray), and fentanyl citrate
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2012
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

1. Background:

Abstral, Actiq, Fentora, Lazanda, Subsys, 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. Abstral, Actiq, Fentora, Lazanda, Subsys, 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.

2. Coverage Criteria:

A. **Fentanyl citrate lozenges (generic Actiq),** will be approved based on the following criteria:

1. **All** of the following:

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

-AND-

b. Patient must have at least a **one** week history of **one** of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

1) 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) 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) 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. (Document drug)

-AND-

d. **One** of the following:

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

Authorization will be approved for 12 months.

B. **Abstral, Actiq, Fentora, Lazanda, or Subsys** will be approved based on the following criteria:

1. **All** of the following:

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

-AND-

b. Patient must have at least a **one** week history of **one** of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

1) 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) 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) 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. (Document drug)

-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.

-AND-

e. History of failure, contraindication, or intolerance to Fentanyl citrate lozenges (generic Actiq) (Document date of trial)

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Authorization will be approved for 12 months.

(3) Additional Clinical Rules:

- 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.
- Supply limits may be in place.

(4) References:

1. Abstral [package insert]. Lake Oswego, OR: Galena Biopharma; November 2014.
2. Actiq [package insert]. North Wales, PA: Cephalon; October 2019.
3. Fentora [package insert]. North Wales, PA: Cephalon; October 2019.
4. Lazanda [package insert]. Newark, CA: Depomed, Inc.; December 2017.
5. Subsys [package insert]. Chandler, AZ: Insys Therapeutics; February 2020.
6. Swarm R, Paice JA, Anghelescu DL, et al. NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain. Version 3.2019. <www.NCCN.org/professionals/physician_gls/pdf/pain.pdf>. Accessed September 5, 2019.

Program	Prior Authorization -Abstral (fentanyl sublingual tablets), Actiq (fentanyl transmucosal lozenge), Fentora (fentanyl buccal tablet), Lazanda (fentanyl nasal spray), Subsys (fentanyl sublingual spray), and fentanyl citrate
Change Control	
Date	Change
6/2012	New policy
6/2013	Changed policy name to “Oral Fentanyl Products” Converted policy to new UHC enterprise wide formatting No changes to clinical criteria
3/2015	Removed Onsolis from guideline and notification; Onsolis is no longer on the market. No clinical changes to criteria. Background revisions.
9/2015	Separated initial therapy criteria into preferred with prior authorization and non-preferred sections. Preferred, prior authorization criteria applies to Fentanyl Citrate and the new non-preferred section applies to Abstral, Brand Actiq, Fentora, Lazanda, and Subsys.

	Added prescriber requirement. Updated quantity limit criteria to simplify review criteria.
9/2016	Updated policy template. Updated clinical criteria to align with Employer & Individual's policy.
12/2016	Added clarification that prescriber requests the termination of all previous authorizations for transmucosal fentanyl products
8/2017	Added a step through fentanyl citrate lozenges for all branded products. Updated references.
4/2018	Updated background and references.
10/2019	Updated background and references. Minor language updates with no changes to clinical intent.
10/2020	Updated documentation requirements. Updated references.