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Coverage Policy Number IP0381

Fentanyl Transmucosal Products

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following non-covered fentanyl transmucosal products:

- **Actiq®** (oral transmucosal fentanyl citrate lozenge)
- **fentanyl citrate oral transmucosal lozenge** (Actiq generic)
- **fentanyl citrate buccal tablet** (Fentora® generic)
- **Fentora** (fentanyl buccal tablet)
- **Lazanda®** (fentanyl nasal spray)
- **Subsys®** (fentanyl sublingual spray)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Product	Criteria
Actiq (fentanyl 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg oral transmucosal lozenge)	**Actiq** is considered medically necessary when the following are met: **Treatment of Breakthrough Pain in an Individual with Cancer.** Individual meets **ALL** of the following criteria: A. Age 16 years or older B. **ONE** of the following conditions is met: i. Continuation of fentanyl transmucosal therapy ii. Inability to swallow, has dysphagia, esophagitis, mucositis or uncontrollable nausea/vomiting iii. Unable to take two other short-acting narcotics secondary allergy or severe adverse events C. On oral or transdermal long-acting narcotic or on an intravenous, subcutaneous or spinal narcotic D. Documented trial of **fentanyl citrate oral transmucosal lozenge** (the bioequivalent [Actiq] generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
fentanyl citrate oral transmucosal lozenge (fentanyl 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg)	**Fentanyl citrate oral transmucosal lozenge** is considered medically necessary when the following are met: **Treatment of Breakthrough Pain in an Individual with Cancer.** Individual meets **ALL** of the following criteria: A. Age 16 years or older B. **ONE** of the following conditions is met: i. Continuation of fentanyl transmucosal therapy ii. Inability to swallow, has dysphagia, esophagitis, mucositis or uncontrollable nausea/vomiting iii. Unable to take two other short-acting narcotics secondary allergy or severe adverse events C. On oral or transdermal long-acting narcotic or on an intravenous, subcutaneous or spinal narcotic
fentanyl citrate buccal tablet (fentanyl 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg buccal tablet)	**Fentanyl citrate buccal tablet (Fentora generic)** is considered medically necessary when the following are met: **Treatment of Breakthrough Pain in an Individual with Cancer.** Individual meets **ALL** of the following criteria: A. Age 18 years or older B. **ONE** of the following conditions is met: i. Continuation of fentanyl transmucosal therapy ii. Inability to swallow, has dysphagia, esophagitis, mucositis or uncontrollable nausea/vomiting iii. Unable to take two other short-acting narcotics secondary allergy or severe adverse events C. On oral or transdermal long-acting narcotic or on an intravenous, subcutaneous or spinal D. Documentation of **ONE** of the following: i. Continuation of fentanyl citrate buccal tablet (Fentora generic) ii. Failure, contraindication or intolerance to fentanyl citrate oral transmucosal lozenge (Actiq generic)
Fentora (fentanyl 100 mcg, 200 mcg, 400 mcg,	**Fentora** is considered medically necessary when the following are met:

Product	Criteria
600 mcg and 800 mcg buccal tablet)	**Treatment of Breakthrough Pain in an Individual with Cancer.** Individual meets **ALL** of the following criteria: A. Age 18 years or older B. **ONE** of the following conditions is met: i. Continuation of fentanyl transmucosal therapy ii. Inability to swallow, has dysphagia, esophagitis, mucositis or uncontrollable nausea/vomiting iii. Unable to take two other short-acting narcotics secondary allergy or severe adverse events C. On oral or transdermal long-acting narcotic or on an intravenous, subcutaneous or spinal narcotic D. Documentation of **ONE** of the following: i. Continuation of Fentora ii. Failure, contraindication or intolerance to fentanyl citrate oral transmucosal lozenge (Actiq generic)
Lazanda (fentanyl 100 mcg, 300 mcg and 400 mcg nasal spray)	**Lazanda is** considered medically necessary when the following are met: **Treatment of Breakthrough Pain in an Individual with Cancer.** Individual meets **ALL** of the following criteria: A. Age 18 years or older B. **ONE** of the following conditions is met: i. Continuation of fentanyl transmucosal therapy ii. Inability to swallow, has dysphagia, esophagitis, mucositis or uncontrollable nausea/vomiting iii. Unable to take two other short-acting narcotics secondary allergy or severe adverse events C. On oral or transdermal long-acting narcotic or on an intravenous, subcutaneous or spinal narcotic D. Documentation of **ONE** of the following: i. Continuation of Lazanda ii. Has cancer and mucositis iii. Failure, contraindication or intolerance to fentanyl citrate oral transmucosal lozenge (Actiq generic)
Subsys (fentanyl 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg sublingual spray)	**Subsys is** considered medically necessary when the following are met: **Treatment of Breakthrough Pain in an Individual with Cancer.** Individual meets **ALL** of the following criteria: A. Age 18 years or older B. **ONE** of the following conditions is met: i. Continuation of fentanyl transmucosal therapy ii. Inability to swallow, has dysphagia, esophagitis, mucositis or uncontrollable nausea/vomiting iii. Unable to take two other short-acting narcotics secondary allergy or severe adverse events C. On oral or transdermal long-acting narcotic or on an intravenous, subcutaneous or spinal narcotic D. Documentation of **ONE** of the following: i. Continuation of Subsys ii. Failure, contraindication or intolerance to fentanyl citrate oral transmucosal lozenge (Actiq generic)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of fentanyl transmucosal products is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

> **Acute and/or Postoperative Pain.** This includes surgery/post-surgery, trauma/post-trauma, acute medical illness (acute abdominal pain, pelvic pain, muscle spasm). Actiq (generic), Abstral, Fentora, Lazanda, and Subsys are contraindicated for use in the management of acute or postoperative pain, including migraine headache pain.[1-6]

Background

OVERVIEW
The transmucosal fentanyl drugs are indicated only for the management of **breakthrough pain in patients with cancer** who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.[1-6]

Actiq (generic), Abstral (obsolete as of 12/2016), Fentora, and Subsys are immediate-release oral transmucosal formulations of fentanyl citrate.[1-5] Lazanda (obsolete as of 12/30/2022) is a nasal spray intended for intranasal transmucosal administration.[6] Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily, at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid for one week or longer. The appropriate dosing and safety of Actiq (generic) in opioid-tolerant children with breakthrough cancer pain have not been established in those below 16 years of age.[1,3] The safety and efficacy of Abstral, Fentora, Subsys, and Lazanda have not been established in pediatric patients below 18 years of age.[2,4-6]

The transmucosal fentanyl drugs are contraindicated in the management of acute or postoperative pain and in patients with known intolerance or hypersensitivity to any components or the drug fentanyl.[1-6] In addition, these products must not be used in patients who are not opioid tolerant (contraindicated). The transmucosal fentanyl drugs are approved for use only in the care of cancer patients and only by healthcare professionals[1-5] (oncologists and pain specialists)[2,3,6] who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Because of the risk of misuse, abuse, addition, and overdose, these products are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS program. Under the TIRF REMS ACCESS program, outpatients, prescribers who prescribe to outpatients, pharmacies, and distributors must enroll in the program.

References

1. Actiq® oral transmucosal [prescribing information]. Parsippany, NJ: Teva; November 2022.
2. Fentora® buccal tablet [prescribing information]. Parsippany, NJ: Teva; November 2022.

3. Oral Transmucosal Fentanyl Citrate (OTFC) [prescribing information]. Parsippany, NJ: Teva; December 2022.
4. Abstral® sublingual tablets [prescribing information]. Solana Beach, CA: Sentynl; October 2019.
5. Subsys® sublingual spray [prescribing information]. Northbrook, IL: West Therapeutic Development; March 2021.
6. Lazanda® nasal spray [prescribing information]. Northbrook, IL: West Therapeutic Development; March 2021.