

Connecticare Commercial & Healthcare Exchange PA Criteria Effective: January 1, 2019

Prior Authorization: Transmucosal Immediate Release Fentanyl (TIRF) Products

Products Affected:

- Abstral® (fentanyl sublingual tablet – Novartis/ProStrakan)
- Actiq® (oral transmucosal fentanyl citrate – Cephalon, generics)
- Fentora® (fentanyl buccal tablet – Cephalon, authorized generic)
- Lazanda® (fentanyl nasal spray – Depomed)
- Subsys® (fentanyl sublingual spray – Insys)
- Fentanyl citrate buccal tablet, effervescent

Medication Description:

Transmucosal Immediate Release Fentanyl (TIRF) products contain fentanyl citrate, a pure opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. TIRF products 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. Due to the highly addictive and dangerous nature of the TIRF products, prescribing should be limited to healthcare professionals (oncologists and pain specialists) who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

TIRF products are contraindicated in opioid non-tolerant patients and are contraindicated in the management of acute or postoperative pain, including headache/migraine and dental pain, or use in the emergency room. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients treated with some TIRF products. Because of the risk of misuse, abuse, addiction, 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 TIFR REMS ACCESS program, outpatients, prescribers who prescribe to outpatients, pharmacies, and distributors must enroll in the program.

*Patients considered opioid-tolerant are those who are taking:

- at least 60 mg of oral morphine/daily
- at least 25 mcg transdermal fentanyl/hour
- at least 30 mg of oral oxycodone daily
- at least 8 mg oral hydromorphone daily
- at least 25 mg oral oxymorphone daily
- or an equianalgesic dose of another opioid daily for a week or longer.

Covered Uses: Breakthrough cancer pain in opioid-tolerant patients

Exclusion Criteria:

1. Patients who are not opioid-tolerant.
2. Acute or postoperative pain including headache/migraine and dental pain, or acute pain in the emergency department.

Required Medical Information:

1. Diagnosis
2. Previous medications tried and failed
3. Current medication regimen

Age Restrictions:

- 16 years of age or older: Actiq
- 18 years of age or older: Abstral, Fentora, Lazanda, Subsys

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist or pain specialist.

Coverage Duration: 12 months

Other Criteria:

Approve if the patient meets the following criteria (A, B and C):

- A. Patient has a documented diagnosis of breakthrough pain in cancer patients; **AND**
- B. Patient meets **ONE** of the following conditions (i or ii):
 - i. Patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting; **OR**
 - ii. Patient is unable to take two other short-acting narcotics (e.g., oxycodone, morphine sulfate, hydromorphone, etc.) secondary to allergy or severe adverse events (including treatment failure); **AND**
- C. Patient is on or will be on an oral or transdermal long-acting narcotic (e.g., Duragesic, morphine extended-release).

References:

1. Product Information: ACTIQ(R) oral transmucosal lozenge, fentanyl citrate oral transmucosal lozenge. Teva Pharmaceuticals USA, Inc. (per FDA), North Wales, PA, 2016.
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3. Collado F, Torres LM. Association of transdermal fentanyl and oral transmucosal fentanyl citrate in the treatment of opioid naïve patients with severe chronic noncancer pain. *J Opioid Manag*. 2008;4(2):111-115.
4. Tennant F, Hermann L. Self-treatment with oral transmucosal fentanyl citrate to prevent emergency room visits for pain crises: patient self-reports of efficacy and utility. *J Pain Palliat Care Pharmacother*. 2002;16:37-44.
5. Shaiova L, Wallenstein D. Outpatient management of sickle cell pain with chronic opioid pharmacotherapy. *J Natl Med Assoc*. 2004;96:984-986.
6. Guarino AH, Myers J, Cornell ME. A descriptive case series: oral transmucosal fentanyl use in patients with noncancerous pain. *J Opioid Manag*. 2006;2(2):81-87.
7. Taylor DR, Webster LR, Chun SY, et al. Impact of breakthrough pain on quality of life in patients with chronic, noncancer pain: patient perceptions and effect of treatment with oral transmucosal fentanyl citrate (OTFC[®], ACTIQ[®]). *Pain Med*. 2007;8(3):281-288.
8. Simpson DM, Messina J, Xie F, Hale M. Fentanyl buccal tablet for the relief of breakthrough pain in opioid-tolerant adult patients with chronic neuropathic pain: a multicenter, randomized, double-blind, placebo-controlled study. *Clin Ther*. 2007;29(4):588-601.
9. Portenoy RK, Messina J, Xie F, Peppin J. Fentanyl buccal tablet (FBT) for relief of breakthrough pain in opioid-treated patients with chronic low back pain: a randomized, placebo-controlled study. *Curr Med Res Opin*. 2007;23(1):223-233.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date

Last Res. January 1, 2019

1	New Policy	New Policy	All	01/01/2019
2	Policy Revision	Updated Age Indications Annual P&T Review	Age Restrictions	5/2019
3	Policy Update	Added new branded product Fentanyl buccal tablet, effervescent	Products affected	7/1/2019