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)

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, 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.

*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

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**Age Restrictions:** 16 years of age or older

**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.

**Policy Revision history**

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<tr>
<th>Rev #</th>
<th>Type of Change</th>
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|   | New Policy       | New Policy       | All     | 01/01/2019 |
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