PRIOR AUTHORIZATION POLICY

POLICY: Opioids – Fentanyl Transmucosal Drugs Prior Authorization Policy

- Actiq® (oral transmucosal fentanyl citrate – Teva, generic)
- Fentora® (fentanyl buccal tablet – Teva, authorized generic [brand obsolete])
- Lazanda® (fentanyl nasal spray – West Therapeutic Development [obsolete as of 12/30/2022])
- Subsys® (fentanyl sublingual spray – West Therapeutic Development [obsolete as of 6/1/2024])

REVIEW DATE: 11/13/2024

OVERVIEW

The transmucosal immediate-release fentanyl (TIRF) 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.[1-5]

Actiq (generic), Fentora, and Subsys are immediate-release oral transmucosal formulations of fentanyl citrate.[1-4] Lazanda is a nasal spray intended for intranasal transmucosal administration.[5] 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 Fentora, Subsys, and Lazanda have not been established in pediatric patients below 18 years of age.[2,4,5]

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.[1-5] 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[1-4] (oncologists and pain specialists)[2,3,5] 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 TIRF REMS ACCESS program. Under the TIRF REMS ACCESS program, outpatients, prescribers who prescribe to outpatients, pharmacies, and distributors must enroll in the program.

On September 16, 2024, the FDA stated that according to manufacturers of TIRF medicines, **production of all TIRF medicines will be discontinued on September 30, 2024**. Due to this discontinuation, the TIRF REMS will no longer accept new enrollments for patients, prescribers, or pharmacies. As of September 16, 2024, there were fewer than 150 patients receiving treatment with TIRF medicines. Patients who are currently on a TIRF medicine may continue treatment under the REMS while TIRF medicine supply remains available. Prescribers should work with their patients to transition to other non-TIRF treatment. The TIRF REMS will remain in place as long as the manufacturers' new drug applications or abbreviated new drug applications are approved, regardless of the marketing status of the products. Of note, **the FDA did not request this discontinuation**.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of fentanyl transmucosal drugs. All approvals are provided for the duration noted below.

Automation: If the patient has a prescription for a cancer medication (see Appendix A) within a 180-day period, the claim will adjudicate. When available, the ICD-10 codes for cancer will be used as part of automation to allow approval of the requested medication (see Appendix B).

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of fentanyl transmucosal drugs is recommended for those who meet the following criteria:

FDA-Approved Indication

1. **Breakthrough Pain in a Patient with Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** 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 secondary to allergy or severe adverse events; AND
       Note: Examples of short-acting narcotics include immediate-release formulations of oxycodone, morphine sulfate, hydromorphone, etc.
   - **B)** Patient is on or will be on an oral or transdermal long-acting narcotic, or the patient is on an intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotic.
     Note: Examples of long-acting narcotics include Duragesic (fentanyl transdermal system), OxyContin (oxycodone extended-release tablets), and morphine extended-release. Examples of intravenous, subcutaneous, or spinal narcotics include morphine sulfate, hydromorphone, and fentanyl citrate.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of fentanyl transmucosal drugs is not recommended in the following situations:

1. **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), Fentora, Lazanda, and Subsys are contraindicated for use in the management of acute or postoperative pain, including migraine headache pain.[1-5]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Actiq® oral transmucosal [prescribing information]. Parsippany, NJ: Teva; December 2023.
2. Fentora® buccal tablet [prescribing information]. Parsippany, NJ: Teva; December 2023.
3. Oral Transmucosal Fentanyl Citrate (OTFC) [prescribing information]. Parsippany, NJ: Teva; January 2024.
4. Subsys® sublingual spray [prescribing information]. Northbrook, IL: West Therapeutic Development; March 2021.
5. Lazanda® nasal spray [prescribing information]. Northbrook, IL: West Therapeutic Development; March 2021.

APPENDIX A

Note: This list is not inclusive. As new STCs become available, they will roll into this policy and the list will be updated periodically.

* Excluding topical products

APPENDIX B

*Indicates the inclusion of subheadings.