Pharmacy Policy Bulletin: J-0108 Immediate Release Fentanyl Citrate – Commercial and Healthcare Reform	
Number: J-0108	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0108-026	**Original Date:** 12/06/2006
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Fentanyl citrate (Actiq) transmucosal lozenge • Fentanyl citrate buccal tablet
FDA-Approved Indication(s):	• Management of breakthrough pain in cancer patients 18 years of age* and older who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent cancer pain. • Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, 60 mg of oral hydrocodone daily, or an equianalgesic dose of another opioid daily. Patients must remain on around-the-clock opioids while taking fentanyl citrate. • (*fentanyl citrate lozenges are indicated in patients 16 years of age and older.)

Background:	• Fentanyl is an opioid agonist whose principal therapeutic action is analgesia. • These medications should not be used in opioid non-tolerant patients. • NCCN recommends consideration of the use of rapidly acting transmucosal fentanyl in opioid-tolerant patients for brief episodes of incident pain not relieved by traditional immediate-release opioids and not attributable to inadequate dosing of around-the-clock opioid. Initiate transmucosal fentanyl with the lowest dose in the chosen formulation and titrate to effect. • If the member experiences more than 4 episodes of breakthrough cancer pain per day, the dose of the long-acting, maintenance narcotic should be re-evaluated. • All fentanyl products are subject to Black Box Warnings for life-threatening respiratory depression, accidental ingestion, cytochrome P450 3A4 interaction, risks from concomitant use with benzodiazepines or other CNS depressants, risk of medication errors, addiction, abuse and misuse, neonatal opioid withdrawal syndrome, and inclusion in a Risk Evaluation and Mitigation Strategy (REMS) Access Program

	• Discuss availability of naloxone with the patient and caregiver when initiating and renewing treatment with a fentanyl product. • The prescribing physician must be specifically certified to prescribe transmucosal immediate release fentanyl (TIRF) products for outpatient use as part of the TIRF risk evaluation and mitigation strategy (REMS) program. Patients receiving these medications must be enrolled in the TIRF REMS program by a certified doctor. • Pharmacies must be specifically certified to receive and dispense transmucosal immediate release fentanyl products as part of the TIRF risk evaluation and mitigation strategy (REMS) program. • Immediate release fentanyl citrate should not be used for acute or postoperative pain conditions (including headache/migraine, dental pain, or in the emergency room), chronic pain conditions which are not related to cancer, or in situations involving chronic pain in which the patient is not receiving maintenance doses of long acting opioid analgesics and is not considered opioid tolerant.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of an immediate release fentanyl product may be approved when the following criteria are met **(A., B., and C.)**:

A. The immediate release fentanyl is being used for the management of breakthrough cancer pain in patients with malignancies

B. The member is currently receiving and is tolerant to long-acting narcotic therapy (e.g., Oxycontin, morphine sulfate sustained release, fentanyl transdermal patch, etc.)

C. The member meets one (1) of the following criteria **(1. or 2.)**:

1. The member has difficulty or discomfort while swallowing (dysphagia), esophagitis, or uncontrolled nausea and vomiting

2. The member is unable to take one (1) short-acting single-entity narcotic (oxycodone, hydromorphone, morphine sulfate, etc.)

II. Reauthorization

When a benefit, reauthorization of an immediate release fentanyl product may be approved when all of the following criteria are met **(A. through D.)**:

A. The immediate release fentanyl is being used for the management of breakthrough cancer pain in patients with malignancies

B. The member is currently receiving and tolerant to long-acting narcotic therapy (e.g., Oxycontin, morphine sulfate sustained release, fentanyl transdermal patch, etc.)

C. The member meets one (1) of the following criteria **(1. or 2.)**:

1. The member has difficulty or discomfort while swallowing (dysphagia), esophagitis, or uncontrolled nausea and vomiting

2. The member is unable to take one (1) short-acting single-entity narcotic (oxycodone, hydromorphone, morphine sulfate, etc.)

D. The prescriber provides documentation that the medication is effective in treating the member's breakthrough pain and the benefits outweigh harms of continued opioid therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Immediate release fentanyl citrate should not be used for acute or postoperative pain, including headache/migraine, or dental pain, chronic pain conditions which are not related to cancer, or in situations involving chronic pain in which the patient is not receiving maintenance doses of long acting opioid analgesics and is not considered opioid tolerant.

II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Fentanyl citrate [package insert]. Parsippany, NJ: Teva Pharmaceuticals, USA, Inc.; January 2024.
2. Fentora [package insert]. Parsippany, NJ: Teva Pharmaceuticals, USA, Inc.; December 2023.
3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Adult Cancer Pain Version 1.2025. March 12, 2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed May 7, 2025.