

New Hampshire Medicaid Fee-for-Service Program

Short-Acting Fentanyl Analgesic Criteria

Approval Date: June 10, 2024

Pharmacology

Fentanyl is a pure opioid agonist whose principal therapeutic action is analgesic with activity as a mu opioid receptor agonist.

Indications

Actiq®, Fentora®, and the generics are indicated 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.

Medications

| Brand Names | Generic Names | Dosage |
|-------------|--|--|
| Actiq® | Oral transmucosal fentanyl citrate lozenge | 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,200 mcg, 1,600 mcg |
| Fentora® | Oral transmucosal fentanyl buccal tablet | 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg |

Criteria for Approval

- The treatment of breakthrough cancer pain where patient is already receiving and is tolerant to opioid therapy; **AND**
 - Note:** The FDA defines a patient as *opioid tolerant* if for at least one week he or she has been receiving oral morphine 60 mg/day; transdermal fentanyl 25 mcg/hour; oral oxycodone 30 mg/day; oral hydromorphone 8 mg/day; oral oxymorphone 25 mg/day; or an equianalgesic dose of any other opioid.
- Patient must have tried and failed immediate release narcotics for breakthrough pain; **AND**
- An oncologist, pain specialist, palliative care specialist, or hospice specialist has been consulted on this case; **AND**
- Prescribers, pharmacies, and patients need to be enrolled in TIRF REMS ACCESS program for all fentanyl products; **AND**

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5. Attestation that the New Hampshire Prescription Drug Monitoring Program (PDMP) has been reviewed within the last 60 days; **AND**
6. Attestation that the prescriber has reviewed with the patient the risks associated with continuing high-dose opioids; **AND**
7. Confirmation that patient has a written pain agreement; **AND**
8. Attestation that the prescriber has discussed with the patient to attempt to taper the dose slowly at an individualized pace; **AND**
9. Attestation that the prescriber is monitoring the patient to mitigate overdose risk; **AND**
10. Confirmation that the patient will be prescribed concurrent naloxone.

Length of Approval: 6 months

Criteria for Denial

1. Failure to meet criteria for authorization; **OR**
2. Treatment of acute or postoperative pain, including headache/migraine and dental pain; **OR**
3. Treatment of types of pain other than breakthrough cancer pain; **OR**
4. Use in opioid non-tolerant patients; **OR**
5. Patient is less than 18 years of age for Fentora® **OR**
6. Patient is less than 16 years of age for Actiq®.

References

Available upon request.

Revision History

| Reviewed by | Reason for Review | Date Approved |
|----------------------------------|-----------------------------------|---------------|
| Pharmacy & Therapeutic Committee | New | 11/02/2006 |
| Commissioner | New | 11/16/2006 |
| DUR Board | Revision | 10/25/2010 |
| Commissioner | Revision | 02/10/2011 |
| DUR Board | Newly available drugs to category | 10/19/2011 |
| Commissioner | Approval | 04/12/2012 |
| N/A | Newly rebateable drug to category | 07/10/2014 |
| DUR Board | Name change/New drug to market | 05/12/2015 |
| Commissioner | Approval | 06/30/2015 |

| Reviewed by | Reason for Review | Date Approved |
|-----------------------|-------------------|---------------|
| DUR Board | Revision | 10/24/2017 |
| Commissioner | Approval | 12/05/2017 |
| DUR Board | Revision | 03/12/2019 |
| Commissioner Designee | Approval | 04/05/2019 |
| DUR Board | Revision | 06/30/2020 |
| Commissioner Designee | Approval | 08/07/2020 |
| DUR Board | Revision | 06/08/2021 |
| Commissioner Designee | Approval | 08/13/2021 |
| DUR Board | Revision | 12/13/2022 |
| Commissioner Designee | Approval | 01/26/2023 |
| DUR Board | Revision | 05/07/2024 |
| Commissioner Designee | Approval | 06/10/2024 |