New Hampshire Medicaid Fee-for-Service Program

Short-Acting Fentanyl Analgesic Criteria

Approval Date: August 13, 2021

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

1. The treatment of breakthrough cancer pain where patient is already receiving and is tolerant to opioid therapy; **AND**
    a. **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.
2. Patient must have tried and failed immediate release narcotics for breakthrough pain; **AND**
3. An oncologist, pain specialist, palliative care specialist, or hospice specialist has been consulted on this case; **AND**
4. Prescribers, pharmacies, and patients need to be enrolled in TIRF REMS ACCESS program for all fentanyl products; **AND**
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 <18 years old for Fentora® **OR**
6. Patient is <16 years old 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
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