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5.70.007

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	October 1, 2007
Subject:	Fentora	**Page:**	1 of 5

Last Review Date: March 8, 2024

Fentora

Description

Fentora (fentanyl buccal tablet)

Background
Fentora has one indication, the management of breakthrough cancer pain in patients with malignancies, who are already receiving, and are tolerant to, opioid therapy for their underlying persistent cancer pain. Fentora should only be prescribed by health care professionals who are knowledgeable in the use of Schedule II opioids for cancer pain and are registered in the Fentora TIRF REMS program (1).

Fentora has a high potential for abuse, addiction, and diversion. Fentora prescribing guidelines indicate that if more than 4 units are required per day, the dosage of the underlying opioid therapy should be titrated (1).

Regulatory Status
FDA-approved indication: Fentora is an opioid agonist indicated for the 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 (1).

Limitations of Use:
Fentora may be dispensed only to patients enrolled in the TIRF REMS Access program (1).

Fentora has a boxed warning regarding the risk of fatal respiratory depression in patients treated with Fentora, including following use in opioid non-tolerant patients and improper dosing. (1).

Fentora is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Fentora cannot be substituted mcg per mcg for other fentanyl products. The substitution of Fentora for any other fentanyl product may result in fatal overdose. Outpatients, prescribers and distributers must be enrolled in the TIRF REMS Access program (1).

Safety and effectiveness of Fentora in pediatric patients less than 18 years of age have not been established (1).

Related policies
Abstral, Actiq, Buprenorphine and Methadone Powders, Fentanyl Powder, Methadone, Opioid Drugs, Suboxone Drug Class, Subsys

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Fentora may be considered **medically necessary** if the conditions indicated below are met.

Fentora may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:

1. Patient is already receiving around the clock opioid therapy for underlying persistent cancer pain.
2. Patient is tolerant to opioid therapy.
   Patients are considered opioid tolerant if they are taking at least:
   a. 60mg of oral morphine/day
   b. 25mcg of transdermal fentanyl/hour
   c. 30mg of oral oxycodone daily
   d. 8 mg of oral hydromorphone daily
   e. 25mg of oral oxymorphone daily
   f. or an equianalgesic dose of another opioid for a week or longer
   However, lower dosage requirements may achieve tolerance in renal impaired or elderly patients.
3. Prescribing healthcare professional should be knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.
4. Patient and prescribing healthcare professional are enrolled in TIRF REMS Access program.
5. **Initial dose** of Fentora must be for 100mcg, even if patient is already established on another fentanyl product unless the conversion is from Actiq
   a. Actiq doses less than or equal to 400mcg – initial dose is Fentora 100mcg
   b. Actiq does greater than 400mcg – initial dose is Fentora 200mg

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:

1. Patient has remained on around-the-clock opioid therapy.
2. Prescriber is knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.
3. Prescriber and patient are enrolled in TIRF REMS program.

All requests are subject to approval by a secondary review by a clinical specialist for final coverage determination.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Dosage Fentora 100mcg – up to 4 units/day
Fentora 200mcg – up to 4 units/day

Duration 6 months

Prior - Approval *Renewal* Limits

Dosage Fentora 100mcg – up to 4 units/day, or
Fentora 200mcg – up to 4 units/day, or
Fentora 400mcg – up to 4 units/day, or
Fentora 600mcg – up to 4 units/day, or
Fentora 800mcg – up to 4 units/day

Duration 6 months

Rationale

Summary

Fentora, a short-acting opioid, is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. Fentora should only be prescribed by health care professionals who are knowledgeable in the use of Schedule II opioids for cancer pain (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Fentora while maintaining optimal therapeutic outcomes.

References

1. Fentora [package insert], North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2023.

Policy History

Date	Action
October 2007	New strength of Fentora tablets approved by FDA and released to the market. Added to the FEP PA Program as an extension of existing criteria.
November 2009	Criteria was updated to include the definition of opioid tolerant per the prescribing information. The time frame for initiation and renewal was changed to be consistent for all fentanyl products (2).
October 2011	Decreased dosage allowance from 6 units/day to 4 units/day. Required enrollment in REMS program.
September 2013	Annual editorial review and reference update
June 2013	Annual editorial review and reference update
June 2014	Annual editorial review and reference update and addition of type/location of cancer
June 2015	Annual editorial review and addition of subject to secondary review by clinical specialist
March 2016	Annual editorial review Policy code changed from 5.02.07 to 5.70.07
March 2017	Annual editorial review Addition of age to renewal criteria
March 2018	Annual editorial review and reference update
March 2019	Annual editorial review
March 2020	Annual review and reference update
March 2021	Annual editorial review and reference update
March 2022	Annual review and reference update
March 2023	Annual review. Changed policy number to 5.70.007
December 2023	Annual review
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.