BlueCross BlueShield
Federal Employee Program

FENTORA
(fentanyl buccal tablet)

RATIONALE FOR INCLUSION IN PA PROGRAM

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. 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).

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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.