BlueCross BlueShield
Federal Employee Program

ACTIQ
(oral transmucosal fentanyl citrate)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Actiq is indicated only for 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. Actiq should only be prescribed by oncologists and pain specialists who are knowledgeable in the use of Schedule II opioids for cancer pain (1).

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

Regulatory Status

FDA-approved indication: Actiq is an opioid agonist indicated for the management of breakthrough cancer pain in patients 16 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).

Actiq has a boxed warning regarding the risk of fatal respiratory depression in patients treated with Actiq, including following use in opioid non-tolerant patients and improper dosing. Actiq is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Actiq cannot be substituted mcg per mcg for other fentanyl products. The substitution of Actiq 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 Actiq in pediatric patients less than 16 years of have not been established (1).

Summary

Actiq, 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. Actiq should only be prescribed by oncologist and pain management specialists who are knowledgeable in the use of Schedule II opioids for cancer pain

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(1).

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

References

1. Actiq [package insert]. Parsippany, NJ: Cephalon, Inc; December 2023.