Abstral
(fentanyl sublingual tablets)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Abstral 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. Abstral 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 Abstral TIRF REMS program (1).

Abstral has a high potential for abuse, addiction, and diversion. Abstral 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: Abstral is an opioid agonist indicated only for the management of breakthrough cancer pain in patients 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain (1).

Abstral has a boxed warning regarding the risk of neonatal opioid withdrawal syndrome and fatal respiratory depression in patients treated with Abstral, including following use in opioid non-tolerant patients and improper dosing. Abstral is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Abstral cannot be substituted mcg per mcg for other fentanyl products. The substitution of Abstral 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 Abstral in patients less than 18 years of age have not been established (1).

Summary

Abstral, a short-acting opioid, is indicated only for the management of breakthrough cancer pain in patients, 18 years of age or older, who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain. Abstral should only be prescribed by health care professionals who are knowledgeable in the use of Schedule II opioids for cancer pain (1).

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

References

1. Abstral [package insert]. Solana Beach, CA: Sentynl Therapeutics, Inc.; October 2019.