ONSOLIS
(fentanyl buccal soluble film)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Onsolis 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. Onsolis 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 TIRF REMS Access program (1).

Onsolis has a high potential for abuse, addiction, and diversion. Because of the risk for misuse, abuse and overdose, Onsolis is available only through the TIRF REMS program, which is a restricted distribution program that requires prescribers, pharmacies and patients to be enrolled (1).

Regulatory Status

FDA-approved indication: Onsolis 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).

Limitations of use:

Onsolis may be dispensed only to patients enrolled in the TIRF REMS Access program (1).

Onsolis has a boxed warning regarding the risk of fatal respiratory depression in patients treated with Onsolis, including following use in opioid non-tolerant patients and improper dosing. Onsolis is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Onsolis cannot be substituted mcg per mcg for other fentanyl products. The substitution of Onsolis for any other fentanyl product may result in fatal overdose (1).

Safety and effectiveness in pediatric patients under the age of 18 have not been established (1).

Summary

Onsolis, 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. Onsolis 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 Onsolis while maintaining optimal therapeutic outcomes.

References

1. Onsolis [package insert].Somerset, NJ: Meda Pharmaceuticals; December 2011.