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## **SUBSYS (sublingual fentanyl spray)**

### **RATIONALE FOR INCLUSION IN PA PROGRAM**

#### **Background**

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

Subsys has a high potential for abuse, addiction, and diversion. Subsys 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: Subsys is an opioid agonist indicated for the management of breakthrough cancer pain in 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. Patients must remain on around-the-clock opioids when taking Subsys (1).

#### **Limitations of Use:**

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

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

Subsys is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Subsys cannot be substituted mcg per mcg for other fentanyl products. The substitution of Subsys for any other fentanyl product may result in fatal overdose (1).

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

#### **Summary**



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## **SUBSYS (sublingual fentanyl spray)**

Subsys, 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. Subsys should only be prescribed by oncologists and pain management specialists 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 Subsys while maintaining optimal therapeutic outcomes.

### **References**

1. Subsys [package insert], Northbrook, IL: West Therapeutic Development, LLC.; April 2021.