BlueCross BlueShield Federal Employee Program

FENTANYL POWDER (fentanyl citrate)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Fentanyl powder was added as a line extension to the commercially available fentanyl medications: Abstral, Actiq, Fentora, Onsolis, Lazanda and Subsys. Fentanyl powder can be compounded into the same immediate release dosage forms provided that the requested dose is not commercially available and does not exceed the FDA approved maximum strength for the equivalent commercially available product.

The commercially available immediate release medications have only one indication: the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain (1-6). They should only be prescribed by healthcare professionals who are knowledgeable in the use of Schedule II opioids for cancer pain (1-5).

Regulatory Status

FDA-approved indication: If the fentanyl powder will be compounded into an immediate release product: Fentanyl is an opioid analgesic 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.

Fentanyl products have a boxed warning regarding the risk of fatal respiratory depression in patients treated with fentanyl, including following use in opioid non-tolerant patients and improper dosing. Fentanyl is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Fentanyl products have a high potential for abuse, addiction, and diversion (1-5).

The FDA has determined that a REMS is necessary for all opioid analgesics intended for outpatient use to ensure that the benefits of these drugs continue to outweigh the risks. The Opioid Analgesic REMS is a strategy to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics (6).

<u>Off-Label Uses</u>:

Off-label compounded topical preparations such as creams, ointments, and gels have not been

shown to be safe or effective.

Safety and effectiveness in pediatric patients less than 16 years of age have not been established (2).

Summary

Fentanyl powder, when compounded into an immediate release 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. Fentanyl powder should only be prescribed by healthcare professionals, who are knowledgeable in the use of Schedule II opioids for cancer pain.

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

References

1. Abstral [package insert]. Solana Beach, CA: Sentynl Therapeutics, Inc.; October 2019.
2. Actiq [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2023.
3. Fentora [package insert], North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2023.
4. Lazanda [package insert]. Northbrook, IL: West Therapeutic Development, LLC.; March 2021.
5. Subsys [package insert], Northbrook, IL: West Therapeutic Development, LLC.; March 2021.
6. Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS). Drug Safety and Availability: U.S. Food & Drug Administration. September 19, 2018.