

FENTANYL POWDER (fentanyl citrate)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 16 years of age or older

Diagnoses

Patient must have **ALL** of the following diagnoses if fentanyl powder is being compounded into oral transmucosal lozenge, tablet, sublingual tablet or buccal film or a dosage form similar to Actiq, Fentora, Abstral and Onsolis or into any immediate release dosage form such as nasal spray, sublingual spray, inhaler, suppository or solution for use in a nebulizer similar to Lazanda and Subsys.

- 1. Breakthrough cancer pain
 - Patient is already receiving around the clock opioid therapy for underlying persistent cancer pain
 - b. Patient is tolerant to opioid therapy.

Patients are considered opioid tolerant if they are taking at least:

- i. 60mg of oral morphine/day
- ii. 25mcg of transdermal fentanyl/hr
- iii. 30mg of oral oxycodone daily
- iv. 25mg of oral oxymorphone daily
- v. 8 mg of hydromorphone daily
- vi. OR an equianalgesic dose of another opioid for a week or longer.
- *However, lower dosage requirements may achieve tolerance in renal impaired or elderly patients
- Prescribing healthcare professional is knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain
- d. Requested dosage form is commercially available
- Requested dose is **not** commercially available and does **not** exceed the FDA approved maximum strength for the equivalent commercially available product



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OR

- 2. Patient must have following if fentanyl powder is being compounded into a sterile solution for intrathecal use:
 - a. Intraoperative anesthesia and/or postoperative analgesia

AND

 Prescriber agrees to participate in the Opioid Analgesic REMS program and to monitor for abuse, misuse, addiction, and overdose and discontinue if necessary (https://opioidanalgesicrems.com)

Prior - Approval Limits

Duration 6 months

Prior - Approval Renewal Requirements

Age 16 years of age or older

Diagnoses

Patient must have **ALL** of the following:

- 1. Breakthrough cancer pain
 - a. Patient has remained on around-the-clock opioid therapy
 - Prescribing healthcare professional is knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain
 - c. Requested dosage form is commercially available
 - d. Requested dose is **not** commercially available and does not exceed the FDA approved maximum strength for the equivalent commercially available product

OR

- 2. Patient must have following if fentanyl powder is being compounded into a sterile solution for intrathecal use:
 - a. Intraoperative anesthesia and/or postoperative analgesia

AND



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Federal Employee Program.

 Prescriber agrees to participate in the Opioid Analgesic REMS program and to monitor for abuse, misuse, addiction, and overdose and discontinue if necessary (https://opioidanalgesicrems.com)

Prior - Approval Renewal Limits

Same as above