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5.70.57

Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	January 1, 2011
Subject:	Fentanyl Powder	**Page:**	1 of 6

Last Review Date: March 12, 2021

Fentanyl Powder

Description

Fentanyl Powder (fentanyl citrate)

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).

Off-Label Uses:
Off-label (non-FDA approved) 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).

Related policies
Abstral, Actiq, Butrans, Duragesic, Extended Release Opioid Drugs, Fentora, Immediate Release Opioid Drugs, IR Opioid Combo Drugs, Methadone, Opioid Injectables, Opioid Powders, Suboxone Drug Class, Subsys

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Fentanyl powder compounded into immediate release products may be considered **medically necessary** for the management of breakthrough cancer pain in patients age 16 years of age or older and if the conditions indicated below are met.

Fentanyl powder compounded into immediate release products may be considered **investigational** in patients less than 16 years of age and for all other indications.

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
    a. 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
    c. 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
    e. 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

1. 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* 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
    b. 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

1. 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*)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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.; October 2019.
3. Fentora [package insert], North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2019.
4. Lazanda [package insert]. Northbrook, IL: West Therapeutic Development, LLC.; October 2019.
5. Subsys [package insert], Northbrook, IL: West Therapeutic Development, LLC.; February 2020.
6. Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS). Drug Safety and Availability: U.S. Food & Drug Administration. September 19, 2018.

Policy History

Date	Action
January 2011	Criteria was updated to include any compounded immediate- release products and to identify those products that would be excluded from the PA process because they are not immediate release.
January 2012	Reduced dosage allowance from 6 units/day to 4 units/day.
April 2012	Renal patients may require lower dosages
September 2012	Annual editorial review and reference update
June 2013	Annual editorial review and reference update
December 2013	Excluded topical compounds that do not have FDA equivalents
February 2014	Remove quantity limits from PA criteria Addition for intrathecal use in renewal
June 2014	Annual editorial review and reference update
March 2015	Annual editorial review and reference update
December 2016	Annual editorial review and reference update Added age limit to renewal section

	Policy number change from 5.11.03 to 5.70.57
March 2017	Annual editorial review and reference update
March 2018	Annual editorial review and reference update
October 2018	Addition of Opioid Analgesic REMS requirement
November 2018	Annual review and reference update. Addition of Opioid Analgesic REMS link per SME
March 2019	Annual review and reference update
March 2020	Annual editorial review and reference update. Updated Opioid Analgesic REMS link
March 2021	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.