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5.70.001

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	January 1, 2012
Subject:	Abstral	**Page:**	1 of 5

Last Review Date: March 7, 2025

Abstral

Description

Abstral (fentanyl sublingual tablets)

Background
Abstral 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. Abstral 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 Abstral TIRF REMS program (1).

Abstral has a high potential for abuse, addiction, and diversion. Abstral prescribing guidelines indicate that if more than 4 units are required per day, the dosage of the underlying opioid therapy should be titrated (1)**.**

Regulatory Status
FDA-approved indication: Abstral 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).

Abstral has a boxed warning regarding the risk of neonatal opioid withdrawal syndrome and fatal respiratory depression in patients treated with Abstral, including following use in opioid non-tolerant patients and improper dosing. Abstral is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Abstral cannot be substituted mcg per mcg for other fentanyl products. The substitution of

Abstral for any other fentanyl product may result in fatal overdose. Outpatients, prescribers, and distributers must be enrolled in the TIRF REMS Access program (1).

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

Related policies
Actiq, Buprenorphine and Methadone Powders, Fentanyl Powder, Fentora, Methadone, Opioid Drugs, 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.

Abstral may be considered **medically necessary** if the conditions indicated below are met.

Abstral may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:

1. Patient is already receiving around the clock opioid therapy for underlying persistent cancer pain
2. Patient is tolerant to opioid therapy.
   Patients are considered opioid tolerant if they are taking at least:
   a. 60mg of oral morphine/day
   b. 25mcg transdermal fentanyl/hour
   c. 8mg oral hydromorphone/day
   d. 25mg oral oxymorphone/day
   e. 30mg oral oxycodone/day
   f. or an equianalgesic dose of another opioid for a week or

longer

g. However, lower dosage requirements may achieve tolerance in renal impaired or elderly patients.

3. Prescribing healthcare professional should be knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain

4. Patient and prescribing healthcare professional are enrolled in TIRF REMS Access program.

5. **Initial dose** of Abstral must be for 100mcg, even if patient is already established on another fentanyl product other than Actiq
   a. Actiq 200mcg converts to Abstral 100mcg
   b. Actiq 400mcg converts to Abstral 200mcg
   c. Actiq 600mcg converts to Abstral 200mcg
   d. Actiq 800mcg converts to Abstral 200mcg
   e. Actiq 1200mcg converts to Abstral 200mcg
   f. Actiq 1600mcg converts to Abstral 400mcg

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:

1. Patient has remained on around-the-clock opioid therapy
2. Prescriber is knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain
3. Prescriber and patient are enrolled in TIRF REMS program

All requests are subject to approval by a secondary review by a clinical specialist for final coverage determination

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Dosage 100 mcg: Up to 4 units / day

Duration 6 months

Prior – Approval *Renewal* Limits

Dosage 100 mcg: Up to 4 units / day or
200 mcg: Up to 4 units / day or
300 mcg: Up to 4 units / day or
400 mcg: Up to 4 units / day or
600 mcg: Up to 4 units / day or
800 mcg: Up to 4 units / day

Duration 6 months

Rationale

Summary

Abstral, a short-acting opioid, is indicated only for the management of breakthrough cancer pain in patients, 18 years of age or older, who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain. Abstral 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 Abstral while maintaining optimal therapeutic outcomes.

References

1. Abstral [package insert]. Solana Beach, CA: Sentynl Therapeutics, Inc.; October 2019.

Policy History

Date	Action
January 2012	Decreased the dosage allowance from 6 units/day to 4 units/day.
April 2012	Renal patients may require lower doses. REMS changed to TIRF REMS
September 2012	Annual editorial review and reference update
June 2013	Annual editorial review and reference update

June 2014	Annual editorial review and reference update and addition of type/location of cancer
June 2015	Annual editorial review and reference update. Addition of subject to secondary review by clinical specialist and Actiq conversion chart
March 2016	Annual editorial review Policy number changed from 5.02.01 to 5.70.01
March 2017	Annual editorial review Addition of age to renewal criteria
March 2018	Annual editorial review and reference update
March 2019	Annual editorial review
March 2020	Annual review
March 2021	Annual editorial review and reference update
March 2022	Annual review
March 2023	Annual review. Changed policy number to 5.70.001
March 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.