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5.70.073

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	August 16, 2019
Subject:	Dsuvia	**Page:**	1 of 7

Last Review Date: December 13, 2024

Dsuvia

Description

Dsuvia (sufentanil sublingual tablet)

Background
Dsuvia (sufentanil) is an opioid agonist indicated for the treatment of acute pain in adults, of which the severity is great enough to require the use of an opioid analgesic. Additionally, Dsuvia should only be reserved for use in patients who are intolerant or who have not received an adequate response to alternative treatment options. Dsuvia should only be administered by a healthcare provider in a supervised healthcare setting that is medically certified (1).

Regulatory Status
FDA-approved indication: Dsuvia is an opioid agonist indicated for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate (1).

Dsuvia has boxed warnings for the following (1):

- Respiratory depression is the chief hazard of opioid agonists, which if not immediately recognized and treated, may lead to respiratory arrest and death. Risk is increased in patients receiving concurrent CNS depressants (including alcohol), patients with chronic obstructive pulmonary disease, orthostatic hypotension, increased intracranial pressure, biliary tract diseases, and seizure disorders. In order to reduce the risk of respiratory depression, proper dosing, titration, and monitoring are essential.

- All patients treated with opioids require careful monitoring for signs of abuse and addiction, as the use of opioid analgesic products carries the risk of addiction even under appropriate medical use.
- Accidental ingestion of immediate-release opioids, especially in children, can result in fatal opioid overdose.
- Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of sufentanil.
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

Due to the high risk of addiction, abuse, misuse and fatal respiratory depression, this medication is strictly for use in a healthcare setting, in which a patient can be closely monitored, and adverse events rapidly treated. Dsuvia should be discontinued upon discharge or transfer from this setting (1).

The CDC guidelines find that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents (2).

Dsuvia is only available via a REMS program, due to the potentially fatal risk of respiratory depression with accidental exposures and ingestion. Healthcare settings and wholesalers must be enrolled in this program prior to dispensation (1).

Dsuvia is contraindicated for use in patients: with significant respiratory depression; whom have bronchial asthma (acute and severe) in a setting that is unmonitored or in the absence of resuscitative equipment; or with known or suspected gastrointestinal obstructions, including paralytic ileus (1).

Safety and effectiveness of Dsuvia in pediatric patients have not been established (1).

Related policies
Abstral, Actiq, Buprenorphine and Methadone Powders, Fentanyl Powder, Fentora, Methadone, Olinvyk, Onsolis, 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.

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

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

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Severe acute pain

AND ALL of the following:

1. Alternative treatment options have been ineffective, not tolerated or inadequate for controlling the pain
    a. These include: non-opioid analgesics and other treatment modalities
2. Prescriber agrees to assess patient for signs and symptoms of serotonin syndrome
3. **NO** other opioid at prior authorization limits
4. **NO** dual therapy with opioid addiction treatment or methadone
5. **NO** dual therapy with anti-anxiety benzodiazepine(s)
    a. Alprazolam (Xanax)
    b. Clonazepam (Klonopin)
    c. Diazepam (Valium)
    d. Lorazepam (Ativan)
    e. Oxazepam (Serax)
    f. Chlordiazepoxide (Librium)
    g. Clorazepate dipotassium (Tranxene)
6. Patient is under supervision by a healthcare provider in a medically certified healthcare setting such as:
    a. Emergency department
    b. Surgical center

c. Hospital
7. Treatment duration will be limited to 72 hours
8. Healthcare setting is certified in the Dsuvia REMS program

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 36 tablets

Duration 3 days

Prior – Approval *Renewal* Limits

Same as above

*Maximum of 1 PA and 1 renewal per 365 days

Rationale

Dsuvia (sufentanil), a short-acting opioid, is indicated only for the management of severe, acute pain in patients aged 18 years and older, who are intolerant or achieved an inadequate response to alternative treatment options. Dsuvia should only be prescribed and administered by healthcare professionals who are knowledgeable with the administration processes and risks of Dsuvia. Treatment duration should be limited to 72 hours and should be discontinued upon discharge or transfer from approved medical facility. Safety and effectiveness of Dsuvia in pediatric patients have not been established (1).

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

References

1. Dsuvia [package insert]. Redwood City, CA: AcelRx Pharmaceuticals, Inc.; December 2023.
2. Dowell D, Haegerich T, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain. CDC Guidelines 2016.

Policy History

Date	Action
August 2019	Addition to PA
September 2019	Annual review
March 2020	Annual review and reference update
March 2021	Annual review
June 2021	Annual review
March 2022	Annual review and reference update
March 2023	Annual review. Changed policy number to 5.70.073
December 2023	Annual review
March 2024	Annual review
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.

Appendix 1 - List of Serotonergic Medications

Selective Serotonin Reuptake Inhibitors (SSRIs)

paroxetine	Paxil, Paxil CR, Pexeva, Brisdelle
fluvoxamine	Luvox, Luvox CR
fluoxetine	Prozac, Prozac Weekly, Sarafem, Selfemra, Symbyax
sertraline	Zoloft
citalopram	Celexa
escitalopram	Lexapro

Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)

venlafaxine	Effexor XR
desvenlafaxine	Pristiq, Khedezla
duloxetine	Cymbalta
milnacipran	Savella

Tricyclic Antidepressants (TCAs)

amitriptyline	No brand name currently marketed
desipramine	Norpramin
clomipramine	Anafranil
imipramine	Tofranil, Tofranil PM
nortriptyline	Pamelor, Aventyl
protriptyline	Vivactil
doxepin	Zonalon, Silenor
trimipramine	Surmontil

Monoamine Oxidase Inhibitors (MAOIs)

isocarboxazid	Marplan
phenelzine	Nardil
selegiline	Emsam, Eldepryl, Zelapar
tranylcypromine	Parnate

Other Psychiatric Medicines

amoxapine	No brand name currently marketed
maprotiline	No brand name currently marketed
nefazodone	No brand name currently marketed
trazodone	Oleptro
buspirone	No brand name currently marketed
vilazodone	Viibryd
mirtazapine	Remeron, Remeron Soltab
lithium	Lithobid

Migraine Medicines

almotriptan	Axert
frovatriptan	Frova
naratriptan	Amerge
rizatriptan	Maxalt, Maxalt-MLT
sumatriptan	Imitrex, Imitrex Statdose, Alsuma, Sumavel Dosepro, Zecuity, Treximet
zolmitriptan	Zomig, Zomig-ZMT

Antiemetics

ondansetron	Zofran, Zofran ODT, Zuplenz
granisetron	Kytril, Sancuso
dolasetron	Anzemet
palonosetron	Aloxi

Other Serotonergic Medicines

dextromethorphan	Bromfed-DM, Delsym, Mucinex DM, Nuedexta
linezolid	Zyvox
cyclobenzaprine	Amrix
methylene blue	
St. John’s wort	
tryptophan	