Washington State Health Care Authority

# Transmucosal Fentanyl Products

## Medical policy no. 65.10.00.25-3 Effective: August 1, 2026

### Related medical policies:

| Policy Number | Policy Name |
|---|---|
| 65.10.00 | Analgesics: Opioid Agonists |

***Note:*** *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

*To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx*

## Medical necessity

| Drug | Medical Necessity |
|---|---|
| Fentanyl sublingual tablet (Abstral)<br>Fentanyl lozenge/troche (Actiq)<br>Fentanyl buccal tablet (Fentora)<br>Fentanyl nasal spray (Lazanda)<br>Fentanyl buccal soluble film (Onsolis)<br>Fentanyl sublingual spray (Subsys) | Transmucosal fentanyl products may be considered medically necessary when approved under prior authorization for the treatment of breakthrough cancer pain for patients receiving around-the-clock opioid therapy for persistent cancer pain. |

## Clinical policy:

| Clinical Criteria | |
|---|---|
| **Initial authorization criteria** | Patients who meet the following criteria may be considered for authorization of transmucosal fentanyl products.<br><br>1. Chronic, long-acting opioid criteria authorized under Policy 65.10.00 (see **Policy 65.10.00** for more information)<br>a. Patient is currently receiving around-the-clock long-acting opioids for persistent cancer pain<br>b. Patient is tolerant on at least 60 MME per day of chronic, long-acting opioids.<br>2. Criteria for appropriate use of transmucosal fentanyl products:<br>a. Patient has confirmed diagnosis of cancer; **AND**<br>b. Patient is using transmucosal fentanyl for the treatment of breakthrough cancer pain; **AND** |

| | |
|---|---|
| | c. Patient has a history of failure to **TWO** oral immediate-release opioid products (e.g., morphine, hydromorphone, oxycodone); **AND**<br>d. Patient is greater than or equal to 16 years of age; **AND**<br>e. Patient is currently:<br>i. Tolerant to opioids; **AND**<br>ii. Taking a long-acting opioid for the treatment of cancer pain; **AND**<br>f. Any of patient's non-cancer related pain, including acute or postoperative pain not related to cancer treatment, headache/migraine, dental pain, or others, will not be managed with the use of transmucosal fentanyl; **AND**<br>g. Prescribed by or in consultation with a specialist in oncology or pain management related to oncology, unless enrolled in or eligible for hospice care; **AND**<br>h. Dose limit does not exceed the limits in the **Dosage and quantity limits** table below.<br><br>**If all of the criteria above are met, then the authorization can be approved for 6 months.** |
| **Reauthorization criteria** | 1. Continue to meet initial authorization criteria; **AND**<br>2. Cancer-related pain for the patient is controlled and titrated appropriately as to minimize the use of the transmucosal fentanyl products.<br><br>**If all of the criteria above are met, then the authorization can be approved for 6 months.** |

## Dosage and quantity limits

| Drug Name | Dose and Quantity Limits |
|---|---|
| **Fentanyl sublingual tablet (Abstral)** | #120 sublingual tablet per 30-days |
| **Fentanyl lozenge/troche (Actiq)** | #120 lozenges per 30-days |
| **Fentanyl buccal tablet (Fentora)** | #120 buccal tablet per 30-days |
| **Fentanyl nasal spray (Lazanda)** | #30 bottles per 30-days |
| **Fentanyl buccal soluble film (Onsolis)** | #120 unit dose-systems per 30-days |
| **Fentanyl sublingual spray (Ssubsys)** | #120 unit-dose systems per 30-days |

## Background:

The opioid agonists is a class of medications that is reserved for the treatment of severe pain that cannot be managed by non-pharmacologic therapies or other pharmacologic treatments. Transmucosal fentanyl is a strong opioid agonist that is only approved for breakthrough cancer pain for patients receiving around-the-clock opioid therapy for persistent cancer pain. Transmucosal fentanyl products should only be used in accordance to their REMS programs, known as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access program.

## References

1. US Food and Drug Administration (FDA): Drug Safety Communications: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning. US Food and Drug Administration (FDA). Silver Spring, MD. 2016.

## History

| Approved Date | Effective Date | Version | Action and Summary of Changes |
|---|---|---|---|
| 03/20/2026 | 08/01/2026 | 65.10.00.25-3 | -Updated criteria to remove attestation requirement for doses between 120 and 200 MME daily.<br>-Reformatted throughout for clarity and consistency |

| Date | Action and Summary of Changes |
|---|---|
| **12/13/2024** | Note and AHPDL link updated to reflect current language and formatting |
| **10/14/2019** | Updated language on clinical criteria 2e and 2f |
| **09/18/2019** | Updated to match other opioid policies |
| **07/29/2019** | New Policy |