Washington State Health Care Authority

Transmucosal Fentanyl Products

Medical policy no. 65.10.00.25 Effective: November 1, 2019

Note:

- *For non-preferred agents in this class/category, patients must have had an inadequate response or have had a 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/category documentation of inadequate response to ONE preferred agent is needed*
- *If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria*

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.

Medical necessity

Drug	Medical Necessity
Fentanyl sublingual tablet (Abstral) Fentanyl lozenge/troche (Actiq) Fentanyl buccal tablet (Fentora) Fentanyl nasal spray (Lazanda) Fentanyl buccal soluble film (Onsolis) 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. 1. Chronic, long-acting opioid criteria authorized under Policy 65.10.00 (see **Policy 65.10.00** for more information) a. Patient is currently receiving around-the-clock long-acting opioids for persistent cancer pain b. Patient is tolerant on at least 60 MME per day of chronic, long-acting opioids as demonstrated by: i. Doses less than 120 MME approved through cancer-pain expedited authorization ii. Doses between 120 MME and 200 MME require a signed and approved Opioid High Dose form iii. Doses above 200 MME have an approved prior authorization on file. 2. Criteria for appropriate use of transmucosal fentanyl products:

	a. Patient has confirmed diagnosis of cancer; **AND** 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** d. Patient is greater than or equal to 16 years of age; **AND** e. Patient is currently: i. Tolerant to opioids; **AND** ii. Taking a long-acting opioid for the treatment of cancer pain; **AND** 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** 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** h. Dose limit does not exceed the limits in the **Dosage and quantity limits** table below. **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** 2. Cancer-related pain for the patient is controlled and titrated appropriately as to minimize the use of the transmucosal fentanyl products. **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

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

Date	Action and Summary of Changes
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