Reference number(s)
288-C

Initial Prior Authorization with Quantity Limit Oral Fentanyl Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

No Technician Approval; criteria requires a pharmacist to approve.

Brand Name	Generic Name	Dosage Form
Actiq	fentanyl citrate	oral transmucosal lozenge
Fentora	fentanyl citrate	buccal tablet

Indications

FDA-approved Indications

Actiq

Actiq is indicated for the management of breakthrough pain in cancer 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.

Fentora

Fentora is indicated for the management of breakthrough pain in cancer patients 18 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.

For All Oral Fentanyl Products:

Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid. Patients must remain on around-the-clock opioids when taking the requested oral fentanyl product.

Limitations of Use

- Not for use in opioid non-tolerant patients.
- Not for use in the management of acute or postoperative pain, including headache/migraine, dental pain, or in the emergency department.
- As a part of the TIRF REMS, oral fentanyl products may be dispensed by outpatient pharmacies only to outpatients enrolled in the program. For inpatient administration of oral fentanyl products, patient and prescriber enrollment is not required.

Coverage Criteria

Cancer-Related Pain

Authorization may be granted when the requested drug is being prescribed for the management of breakthrough pain in a CANCER patient with underlying CANCER pain. The requested drug is indicated for the treatment of breakthrough CANCER-related pain only. [ACTION REQUIRED: Documentation is required for approval. The prescriber must submit chart notes or other documentation supporting a diagnosis of cancer-related pain and list the type of cancer. For drug coverage approval, ICD diagnosis code provided MUST support the CANCER-RELATED DIAGNOSIS.] In addition, ALL of the following criteria are met:

- The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying CANCER pain.
- The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their current opioid use history. [NOTE: Ensure that the patient can safely take the requested dose based on their current opioid use history. These drugs should be prescribed only by healthcare professionals who are knowledgeable about the use of opioids and how to mitigate the associated risks. Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid.]
- If additional quantities are being requested, then the patient must meet ONE of the following:

- The patient's dose of a concomitant long-acting analgesic is being increased.
- Additional quantities of the requested drug are needed for breakthrough pain because the dose of the patient's long-acting analgesic is unable to be increased.

Quantity Limits Apply

120 units / 25 days OR 360 units / 75 days.

For patients undergoing dose titration (increase) of their concomitant long-acting analgesic or in situations where it is not clinically appropriate to increase the dose of the long-acting analgesic, an additional quantity may be available:

180 units / 25 days OR 540 units / 75 days.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 288-C: DOA: 12 months

References

1. Actiq [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
2. Fentora [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed December 20, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12/20/2024).
5. Adult Cancer Pain. NCCN Guidelines version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed December 9, 2024.