

The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: Fentanyl Policy

Drug(s): ACTIQ LOZ (fentanyl), Fentanyl OT LOZ, FENTORA (fentanyl)

Covered Uses: Fentanyl buccal solid dosage and fentanyl oral transmucosal solid dosage forms are indicated specifically for breakthrough cancer pain.

Actiq® and Fentora® package Black box warning states:

- 1) Indicated only for the management of breakthrough cancer pain in patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oxycodone daily, 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- 2) Contraindicated in the management of acute or postoperative pain.
- 3) Intended to be used only in the care of cancer patients only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

All criteria in "other criteria" section must be met for coverage.

Required Medical Information: Chart notes supporting diagnosis and medication history identifying chronic pain extended release formulations currently being used. Treatment plan for fentanyl including dose and frequency.

Age Restrictions: Transmucosal solid dosage form restricted to 16 and older. All other forms restricted to 18 years and older.

Prescriber Restrictions: Restricted to oncologists and pain management specialists

Other Criteria: Fentanyl oral transmucosal or buccal solid dosage forms require prior authorization (for all quantities) and may be considered medically necessary when all of the following criteria are met:

- Breakthrough cancer pain,
- Ordered by or pursuant to the consult of an oncologist or pain management specialist,
- Claims history and/or documentation identifies at least one prescription for a chronic pain extended release formulation such as a morphine derivative, fentanyl patch or an equianalgesic dose of another opioid, and at least one prescription oral immediate release narcotic within the preceding 90 days
- All requests for fentanyl oral transmucosal or buccal solid dosage forms must be supported by prescription history of chronic pain medications (to support use for breakthrough pain).

Initial coverage will be for up to a maximum of 3 months for 120 doses per 30 days.

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Extensions of therapy will be approved for a maximum of 6 months if documentation provided identifies continued benefit from therapy and “rescue” doses used in a 24-hour period and dosing of long-acting product has been evaluated and is appropriate.

Exclusion Criteria:

- Fentanyl oral transmucosal and buccal solid dosage forms used as monotherapy for chronic pain are excluded unless available chronic pain formulations are contraindicated.
- Increased strength and/or frequency other than approved dosing are excluded.
- Diagnosis other than cancer pain is excluded.
- More than 120 doses per 30 days requires prior authorization.
- Coverage for fentanyl oral or buccal solid dosage forms are excluded if not currently on chronic pain extended release formulation.
- Coverage for fentanyl oral or buccal solid dosage forms are excluded if member has not failed or is intolerant to immediate-release narcotics.

Coverage Duration: Initial 3 months approval followed by 6-month intervals.