



- Must be using a long-acting opioid analgesic and experiencing breakthrough cancer pain
  - Transmucosal fentanyl citrate is not approved for the treatment of acute or postoperative pain.
- Must be opioid tolerant as defined by requiring medication for one week or longer containing at least one of the following:
  - 60mg/day morphine
  - 50mcg/hour transdermal fentanyl

**2. For Abstral:**

- Must meet all criteria above for generic transmucosal fentanyl citrate
- Must have documentation of trial and failure or intolerance to generic transmucosal fentanyl citrate

**3. For formulary brand transmucosal fentanyl citrate (other than Abstral):**

- Must meet all criteria above for generic transmucosal fentanyl citrate
- Must have documentation of trial and failure or intolerance to both of the following:
  - Generic transmucosal fentanyl citrate
  - Abstral

**Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at one-year intervals based upon chart documentation from the prescriber that the member's condition has improved/stabilized based upon the prescriber's assessment while on therapy.

**Limitations:**

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

**REFERENCES**

1. Actiq® [package insert]. Cephalon, Inc., June 2000, 2001.
2. Shaiova L. Wallenstein D. Outpatient management of sickle cell pain with chronic opioid pharmacotherapy.] *Journal of the National Medical Association*. 96(7):984-6, 2004 Jul.
3. Coluzzi PH. Schwartzberg L. Conroy JD., et al. Breakthrough cancer pain: a randomized trial comparing oral transmucosal fentanyl citrate (OTFC) and morphine sulfate immediate release (MSIR). *Pain*. 91(1-2):123-30, 2001 Mar.
4. Portenoy RK. Payne R. Coluzzi P. Raschko JW., et al. Oral transmucosal fentanyl citrate (OTFC) for the treatment of breakthrough pain in cancer patients: a controlled dose titration study. *Pain*. 79(2-3):303-12, 1999 Feb.
5. Onsolis® [package insert]. Somerset, NJ: Meda Pharmaceuticals; July 2009.
6. Fentora® [package insert]. Salt Lake City, UT: Cephalon, Inc.; December 2009
7. Abstral [package insert]. Bedminster, NJ: Prostrakan, Inc.; January 2011



8. Lazanda® [package insert]. Bedminster, NJ: Archimedes Pharma US, Inc.; 2011.
9. Subsys™ [package insert]. Phoenix, AZ: Insys Therapeutics, Inc.; January 2012.

**RECORD RETENTION**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

**REVIEW HISTORY**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review</i>	<i>02/17, 02/18</i>

