

Actiq®, Fentora®, Fentanyl Powder and Onsolis® To Initiate a Coverage Review, Call 1 800 753-2851

Covered Medications	
Oral transmucosal fentanyl citrate (Actiq®) Fentanyl buccal tablets (Fentora®)	Fentanyl buccal soluble film (Onsolis®) Fentanyl powder

What They Do and How They Are Used
<ul style="list-style-type: none"> ➤ Actiq®, Fentora® and Onsolis® are potent narcotics used to relieve breakthrough pain in patients who are already receiving longer-acting narcotics. Patients can experience breakthrough pain when the analgesic effects of the longer-acting narcotic wear off. ➤ Actiq® comes in the form of a lozenge on a stick, Fentora® is a buccal tablet, and Onsolis® is a buccal soluble film. These medications are slowly dissolved in the mouth, between the cheek and the upper or lower gum. Actiq® and Fentora® should be sucked, not chewed. Onsolis® should be applied to the side of the cheek until it dissolves, not chewed or swallowed. ➤ In order to avoid potential life-threatening side effects, such as a reduced rate of breathing, only patients who are tolerant to (and used to) the effects of narcotics should use fentanyl transmucosal products. ➤ Actiq®, Fentora®, and Onsolis® are used to manage breakthrough pain in patients who are in constant pain with chronic pain conditions such as cancer, neuropathic pain or chronic back pain. Onsolis® is specifically indicated for patients who are 18 years of age and older. Fentanyl transmucosal products are not to be used for acute or postoperative pain. ➤ Onsolis® is available only through a restricted distribution program called FOCUS. Under this program only prescribers, pharmacies, and patients registered with the program are able to prescribe, dispense, and receive Onsolis®. ➤ Less-costly narcotics (available as generics) that can be used for the control of breakthrough pain include immediate-release morphine- or oxycodone-containing drugs (Percocet®, Percodan®), hydromorphone (Dilaudid®), and hydrocodone-containing drugs (Vicodin®, Lortab®). ➤ The doses of the three fentanyl products vary depending upon the individual being treated and strengths of the medications are not interchangeable. For example, due to its greater bioavailability, lower doses of Fentora® may achieve the same results as higher doses of Actiq®. ➤ When and if patients are changed from one product to another, the doses cannot be converted on a mcg basis from any other oral fentanyl transmucosal product. Treatment must begin with titration from the 200-mcg dose; differences in the product's extent of absorption may result in fatal overdose. ➤ Once a successful dose is established, up to 4 units may be consumed per day. If more than 4 units per day are required, the dose of the long-acting narcotic used for maintaining relief of chronic pain should be reconsidered. ➤ In the event that a patient needs to use more than one unit for a single breakthrough pain episode, he/she may take another unit 30 minutes after the start of the first unit. However, single doses of Onsolis® should be separated by at least 2 hours. ➤ Fentanyl powder may be compounded or reconstituted and should be used only when there are no other options available due to increased risk of death.

Rationale for Coverage Authorization
To provide coverage for Actiq®, Fentora® or Onsolis® for the management of breakthrough pain where the use of other less-costly narcotics is not an option.

Benefit Design:
<p>Coverage is provided for Fentora®, Onsolis® or Actiq® <u>without</u> a coverage authorization process when a prescription for a ≥ 60-day supply of a long-acting narcotic analgesic [ex: methadone, sustained-release morphine, oxycodone controlled-release tablets (OxyContin®), or fentanyl transdermal system (Duragesic®)] exists in claims history during the previous 90 days (retail or home delivery channel) AND a prescription for a short acting narcotic analgesic exists in claim history during the previous 720 days.</p> <p>1. In situations where there is no prescription for a short-acting and a long-acting narcotic analgesic in claim history to indicate chronic narcotic use/opioid tolerance, coverage for fentanyl transmucosal products will be determined through prior authorization.</p>

Coverage Authorization Criteria
<p>1. Coverage is provided for Actiq®, Fentora®, and Onsolis® for use in the management of breakthrough pain that cannot be managed successfully with other oral immediate-release narcotics in patients who have chronic persistent pain who are already receiving and who are tolerant to long-acting narcotic analgesics.</p> <p>AND</p>

2. Coverage for Onsolis[®] is provided for patients age 18 years and older.

Coverage is provided for 6 months and can be renewed.

References

- Actiq[®] (oral transmucosal fentanyl citrate). Prescribing information. Cephalon. Salt Lake City, UT: February 2007.
- Fentora[®] (fentanyl buccal tablet). Prescribing information. Cephalon. Salt Lake City, UT: October 2007.
- Onsolis[®] (fentanyl buccal soluble film). Prescribing information. Meda Pharmaceuticals Inc: Somerset, NJ: July 2009.