Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 17, 2010 April 5, 2012; July 13, 2012, March 24, 2016, March 12, 2018

ABSTRAL®/ACTIQ®/FENTORA®/LAZANDA®/ONSOLIS®/SUBSYS®

(fentanyl sublingual tablet /oral transmucosal lozenge/ buccal tablet/ nasal spray/ buccal soluble film /sublingual spray)

LENGTH OF AUTHORIZATION: UP TO 3 MONTHS

CLINICAL NOTES:
Abstral, Actiq, Fentora, Lazanda, Onsolis, and Susbsys are opioid analgesics indicated for management of breakthrough pain in patients with cancer, who are already receiving and are tolerant to opioid therapy. In order to avoid potential life-threatening side effects only patients who are tolerant to the effects of narcotics should use fentanyl transmucosal products. These drugs are available only through a restricted program called the Transmucousal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program. Outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors are required to enroll in the program. The doses of these fentanyl products vary depending upon the individual being treated and the strengths of the medications are not interchangeable.

APPROVAL INDICATIONS: (Must meet all criteria for approval.)

1. Must be greater than or equal to 18 years of age.

2. Must have a confirmed diagnosis of cancer. *(Confirmed by supporting documentation or "health conditions").*

3. Must be opioid tolerant and currently receiving around the clock opioids for background pain (over the past 30 days). These opioids must include a minimum of one long-acting narcotic and one short-acting narcotic.

4. Patients are considered opioid tolerant if they are taking at least 60 mg morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose of another opioid for at least a week.

5. Patient must have had a 30 day minimum trial and failure of an oral immediate-release formulation of morphine, hydromorphone, or oxycodone.
    a. Failure is defined as an allergy, intolerance or hypersensitivity.
    b. If the prescriber or patient indicates that these medications were ineffective, the reviewer must first evaluate for use of optimal dose.

6. Prescribing practitioner specialty must be Oncology or Pain Management related to oncology.

7. Request must be submitted with a copy of the patient prescriber agreement form verifying enrollment in the TIRF REMS Access Program for either product.

DENIAL INDICATIONS:

1. Abstral, Actiq, Fentora, Lazanda, Onsolis and Subsys is not covered for the management of acute or postoperative pain; or for patients who are not tolerant to and are not on opioid therapy.

2. **Nursing home patients should not (for any reason) receive an approval override for these medications.**

DOSAGE AND ADMINISTRATION:

ABSTRAL

- Initial dose of ABSTRAL: 100 mcg.
- Individually titrate to a tolerable dose that provides adequate analgesia.
- No more than two doses can be taken per breakthrough pain episode.
- Wait at least 2 hours before treating another episode of breakthrough pain with ABSTRAL.
- Limit consumption to treat four or fewer breakthrough pain episodes per day once a successful dose is found.
- Administer on the floor of the mouth directly under the tongue and allow to completely dissolve.
- **Dosage forms and strengths**: Sublingual tablet in 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg and 800 mcg strengths.

ACTIQ

- Initial dose: 200 mcg. Prescribe an initial supply of six 200 mcg Actiq units.
- Individually titrate to a tolerable dose that provides adequate analgesia using a single Actiq dosage unit per breakthrough cancer pain episode.
- No more than two doses can be taken per breakthrough pain episode. The second dose may be administered 15 minutes after completion of the first Actiq unit.
- Four hours must elapse before treating another episode of breakthrough pain with Actiq.
- Consumption should be limited to four or fewer units per day once a successful dose is found.
- **Dosage form and strengths**: Solid oral transmucosal lozenge in 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg dosage strengths.

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FENTORA

- Initial dose: 100 mcg.
- Dosing may be repeated once during a single episode of breakthrough pain if pain is not adequately relieved by one Fentora dose. Re-dosing may occur 30 minutes after the start of administration of Fentora and the same dosage strength should be used.
- At least 4 hours must elapse before treating the next breakthrough pain episode with Fentora. If treatment of several consecutive breakthrough pain episodes requires more than 1 dose, the dose should be increased.
- Titration should be initiated using multiples of the 100 mcg Fentora tablet. Patients needing to titrate above 100 mcg can be instructed to use two 100 mcg tablets (one on each side of the mouth in the buccal cavity.) If this dose is not successful in controlling the breakthrough pain episode, the patient may be instructed to place two 100 mcg tablets on each side of the mouth in the buccal cavity (total of four 100 mcg tablets).
- Use of more than 4 tablets simultaneously has not been studied and it is important to minimize the number of strengths available to patients at any time to prevent confusion and possible overdose.
- **Dosage forms and strengths**: buccal tablets in 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg dosage strengths.

LAZANDA

- Initial dose of Lazanda for all patients is 100 mcg.
- Individually titrate to an effective dose, from 100 mcg to 200 mcg to 400 mcg, and up to a maximum of 800 mcg, that provides adequate analgesia with tolerable side effects.
- Dose is a single spray into one nostril or a single spray into each nostril (2 sprays).
- Maximum dose is a single spray into one nostril or single spray into each nostril per episode; no more than four doses per 24 hours.
- Wait at least 2 hours before treating another episode of breakthrough pain with Lazanda.
- **Dosage forms and strengths**: Nasal spray; each spray delivers 100 mcL of solution containing either 100 mcg or 400 mcg fentanyl base. Supplied in a 5 mL bottle containing 8 sprays.

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ONSOLIS

- Initial starting dose of 200 mcg Onsolis in all patients.
- Titrate using 200 mcg Onsolis film increments (up to a maximum of four 200 mcg films or a single 1200 mcg film) to adequate analgesia without undue side effects.
- Maximum is one dose per episode; no more than four doses per day; separate by at least 2 hours.
- **Dosage forms and strengths**: Buccal soluble film in 200 mcg, 400 mcg, 600 mcg, 800 mcg, and 1200 mcg dosage strengths.

SUBSYS

- Initial dose of Subsys: 100 mcg.
- Individually titrate to a tolerable dose that provides adequate analgesia using a single Subsys dose per breakthrough cancer pain episode.
- No more than two doses can be taken per breakthrough pain episode.
- Wait at least 4 hours before treating another episode of breakthrough pain with Subsys.
- Limit consumption to four or fewer doses per day once successful dose is found.
- **Dosage forms and strengths:** Sublingual spray in 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg dosage strengths.

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