## PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>ORAL/INTRANASAL FENTANYL PRODUCTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAND NAME (generic)</td>
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</tr>
<tr>
<td>ABSTRAL</td>
<td>(fentanyl citrate sublingual tablet)</td>
</tr>
<tr>
<td>ACTIQ</td>
<td>(fentanyl citrate oral transmucosal lozenge)</td>
</tr>
<tr>
<td>FENTORA</td>
<td>(fentanyl citrate buccal tablet)</td>
</tr>
<tr>
<td>LAZANDA</td>
<td>(fentanyl nasal spray)</td>
</tr>
<tr>
<td>ONSOLIS</td>
<td>(fentanyl buccal soluble film)</td>
</tr>
<tr>
<td>SUBSYS</td>
<td>(fentanyl sublingual spray)</td>
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</tbody>
</table>

**Status:** CVS Caremark Criteria  
**Type:** Initial Prior Authorization

### POLICY

#### COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient does not have significant respiratory depression or known or suspected paralytic ileus **AND**
- The patient has CANCER related pain. This drug is indicated for the treatment of breakthrough CANCER related pain only **AND**
- Chart notes or other documentation supporting a diagnosis of cancer related pain have been submitted to CVS Health by fax **AND**
- The drug is being prescribed for the management of breakthrough pain in a CANCER patient who is currently receiving around-the-clock opioid therapy for underlying CANCER pain **AND**
- The patient can safely take the requested dose based on their current opioid use history  
  [Note: The TIRF (Transmucosal Immediate-Release Fentanyl) products (Abstral, Actiq, Fentora, Lazanda, Onsolis, and Subsys) are indicated for opioid- tolerant patients. Patients considered opioid tolerant are those who are taking at least: 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for a week or longer.] **AND**
  - The patient does not require **MORE** than 120 units per month of Abstral, Actiq, Fentora, Onsolis, Subsys, or 240 sprays per month (i.e., 30 bottles per month) of Lazanda **OR**
  - The patient requires **MORE** than 120 units per month of Abstral, Actiq, Fentora, Onsolis, Subsys, or 240 sprays per month (i.e., 30 bottles per month) of Lazanda **AND**
  - The patient is **NOT** requesting Abstral 600 mcg, Abstral 800 mcg, Lazanda 300 mcg or 400 mcg, Onsolis 800 mcg, or Onsolis 1200 mcg **AND**
- The patient’s pain does not require use of MORE than 180 units per month of Abstral 100 mcg, 200 mcg, 300 mcg, 400 mcg, Actiq (all strengths), Fentora (all strengths), Subsys (all strengths), Onsolis 200 mcg, 400 mcg, 600 mcg, or 360 sprays per month (i.e., 45 bottles per month) of Lazanda 100 mcg AND
  - The patient’s dose of a concomitant long-acting analgesic is being increased
  OR
  - 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 Limit applies.

**QUANTITY FOR APPROVAL**
Abstral, Actiq, Fentora, Onsolis, Subsys: 120 units per 25 days* OR 360 units per 75 days*
Lazanda: 30 bottles per 25 days* OR 90 bottles per 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:
Abstral (100, 200, 300, 400 mcg), Actiq (all strengths), Fentora (all strengths), Onsolis 200, 400, 600 mcg, Subsys (all strengths): 180 units per 30 days* OR 540 units per 75 days*
Lazanda 100 mcg: 45 bottles per 25 days* OR 135 bottles per 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.

**REFERENCES**