## Pharmacy Pre-authorization Criteria

<table>
<thead>
<tr>
<th>Drug(s)</th>
<th>Fentanyls</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Abstral (fentanyl sublingual tabs)</td>
</tr>
<tr>
<td></td>
<td>Actiq (fentanyl oral transmucosal lozenges)</td>
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<tr>
<td></td>
<td>Fentora (fentanyl buccal tablets)</td>
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<tr>
<td></td>
<td>Lazanda (fentanyl nasal spray)</td>
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<tr>
<td></td>
<td>Subsys (fentanyl sublingual spray)</td>
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### Policy #
12108

### Indications

**Abstral** (fentanyl) sublingual tablets are indicated only for the management of breakthrough pain in cancer patients 18 years of age and older 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 around-the-clock medicine consisting of at least 60 mg of oral morphine daily, or at least 25 mcg of transdermal fentanyl/hour, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid medication daily for a week or longer.

**Actiq** is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Actiq is contraindicated in the management of acute or postoperative pain. Actiq must not be used in opioid non-tolerant patients (contraindicated). Actiq is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

**Fentora** is indicated for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Fentora is contraindicated in the management of acute or postoperative pain. Fentora must not be used in opioid non-tolerant patients. Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

**Lazanda and Subsys** are opioid analgesics indicated only for the management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.
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### Drug(s)

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### Criteria

ConnectiCare considers **Abstral, Actiq and Fentora** to be medically necessary for patients who are being treated for breakthrough cancer pain and meet the following criteria:

1. Must be prescribed by an oncologist, hematologist or palliative care
2. Patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting.

OR

3. Patient is unable to take two other short-acting narcotics (e.g., oxycodone, morphine sulfate, hydromorphone, etc.) secondary to allergy or severe adverse events.

AND

4. Patient is on or will be on a long-acting narcotic or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (e.g., morphine sulfate, hydromorphone, fentanyl citrate).

ConnectiCare considers **Lazanda and Subsys** to be medically necessary for patients who are being treated for breakthrough cancer pain and meet the following criteria:

1. Must be prescribed by an oncologist, hematologist or palliative care
2. Patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting.

OR

3. Patient is unable to take two other short-acting narcotics (e.g., oxycodone, morphine sulfate, hydromorphone, etc.) secondary to allergy or severe adverse events.

AND

4. Patient is on or will be on a long-acting narcotic (e.g., Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (e.g., morphine sulfate, hydromorphone, fentanyl citrate)

AND

5. Patient has had an intolerance to, or treatment failure of, Actiq (fentanyl citrate lollipops)

### Limitations

If the above criteria are met initial authorizations is 3 months.

**Abstral, Actiq and Fentora**: In accordance with the manufacturers recommended dosage guidelines, the maximum quantity allowed per day is four (4) units.
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<tr>
<td>Lazanda:</td>
<td>A quantity limit of 15 bottles (120 doses) will be in place per prescription/30 days Subsys: A quantity limit of 120 doses will be in place per prescription/30 days</td>
</tr>
</tbody>
</table>

**References**
- Abstral full prescribing information. Bedminster, NJ. ProStrakan Inc
- Actiq® oral transmucosal [package insert]. Salt Lake City, UT: Cephalon, Inc.; #1598.02
- Fentora™ buccal tablets [package insert] Salt Lake City, UT: Cephalon, Inc.
- Lazanda full prescribing information. Bedminster, NJ. Archimedes
- Subsys full prescribing information. Lakewood, NJ. INSYS Therapeutics, Inc.

**P&T Review History**
- 9/05, 12/06, 6/07, 6/08, 9/09, 9/10, 9/11, 12/11, 5/12, 10/12, 10/13, 10/14, 11/15, 8/16, 11/16, 5/17, 5/18

**Revision Record**
- 7/15, 9/15, 11/16, 5/17