<table>
<thead>
<tr>
<th>Program Number</th>
<th>2016 P 1031-6</th>
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<tbody>
<tr>
<td>Program</td>
<td>Prior Authorization/Notification - Fentanyl</td>
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<tr>
<td>Medication</td>
<td>Abstral**, (fentanyl sublingual tablets), Actiq**, (fentanyl transmucosal lozenge), Fentora**, (fentanyl buccal tablet), Lazanda (fentanyl nasal spray), Subsys** (fentanyl sublingual spray), and fentanyl citrate**</td>
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<tr>
<td>Effective Date</td>
<td>12/1/2016</td>
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1. **Background:**
   Abstral, Actiq, Fentora, Lazanda, Subsys, and fentanyl citrate lozenges (generic Actiq) are opioid analgesics indicated for the management of breakthrough cancer pain in patients who are already receiving and have developed tolerance to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine daily, at least 25 mcg/hour of transdermal fentanyl, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg of oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids while taking one of these fentanyl products. Abstral, Actiq, Fentora, Lazanda, fentanyl citrate (generic Actiq) and Subsys must not be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not on a chronic regimen of opiates.

Compounded fentanyl preparations may provide a unique delivery for certain patient-specific conditions and administration requirements. Compounded fentanyl preparations should be made for a single individual and not produced on a large scale. Compounded fentanyl preparations should not be covered if it is being prescribed as an alternative for a commercially available fentanyl product. Therefore, additional criteria will be provided for fentanyl citrate compounds.

2. **Coverage Criteria:**

   **A. Abstral**, **Actiq**, fentanyl citrate lozenges (generic Actiq), **Fentora**, **Lazanda**, or **Subsys** will be approved based on one of the following criteria:

   1. **All** of the following:

      a. Submission of medical records demonstrating use is for the management of pain associated with a cancer diagnosis (cancer diagnosis must be documented).
b. Use is for the management of breakthrough cancer pain.
   -AND-

c. Patient must have at least a **one** week history of **one** of the following medications to demonstrate tolerance to opioids:

1) Morphine sulfate at a dose of greater than or equal to 60 mg/day
2) Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr
3) Oxycodone at a dose of greater than or equal to 30 mg/day
4) Oral hydromorphone at a dose of greater than or equal to 8 mg/day
5) Oral oxymorphone at a dose of greater than or equal to 25 mg/day
6) An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)
   -AND-

d. The patient is currently taking a long-acting opioid around the clock for cancer pain.
   -AND-

e. **One** of the following:

1) The patient is not concurrently receiving an alternative transmucosal fentanyl product.
   -OR-

2) The patient is currently receiving an alternative transmucosal fentanyl product **AND** the prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication. Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied.
   -OR-

2. The patient is currently taking fentanyl citrate lozenges (generic Actiq), Abstral**, Actiq**, Fentora**, Lazanda, or Subsys** and does not meet the notification criteria requirements based on the FDA-approved indication for breakthrough cancer pain (a one-time fill may be approved for transition to an alternative treatment).

**Authorization will be approved for 12 months.**
B. **Compounded fentanyl** will be approved based on **one** of the following criteria:

1. **All** of the following:
   
   a. Submission of medical records demonstrating use is for the management of pain associated with a cancer diagnosis (cancer diagnosis must be documented).
   
   b. For the management of breakthrough cancer pain
      
      -AND-
   
   c. Patient must have at least a **one** week history of **one** of the following medications to demonstrate tolerance to opioids:
      
      (1) Morphine sulfate at a dose of greater than or equal to 60 mg/day
      (2) Fentanyl transdermal patch at a dose of greater than or equal to 25 mcg/hr
      (3) Oxycodone at a dose of greater than or equal to 30 mg/day
      (4) Oral hydromorphone at a dose of greater than or equal to 8 mg/day
      (5) Oral oxymorphone at a dose of greater than or equal to 25 mg/day
      (6) An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)
      
      -AND-
   
   d. The patient is currently taking a long-acting opioid around the clock for cancer pain
      
      -AND-
   
   e. A unique dosage form is required for a product that is not commercially available due to patient’s age or weight.
      
      -AND-
   
   f. **One** of the following:
      
      1) The patient is not concurrently receiving an alternative transmucosal fentanyl product.
      
      -OR-
      
      2) The patient is currently receiving an alternative transmucosal fentanyl product **AND** the prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication. Only one transmucosal
fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied.

-OR-

2. The patient is currently taking a compounded fentanyl citrate product and does not meet the notification criteria requirements based on the FDA-approved indication for breakthrough cancer pain (a one-time fill may be approved for transition to an alternative treatment)

**Authorization will be approved for 12 months.**

**Abstral, Actiq (Brand ONLY), fentanyl bulk powder, Subsys and Fentora are typically excluded from coverage. Tried/failed criteria may be in place. Please refer to plan specifics to determine coverage status.**

a. Criteria is not applicable to groups situed in Arkansas when medication is being used for pain control in someone who is terminally ill (defined as no expectation of recovery and death as a result of the illness or disease is reasonably expected within six (6) months.)

3. **Additional Clinical Programs:**
   Supply limits may be in place.

4. **References:**

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<tr>
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<th>Prior Authorization/Notification - Fentanyl</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td>Date</td>
<td>Change</td>
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<tr>
<td>10/2013</td>
<td>Changed compounded fentanyl citrate powder to fentanyl. Added Subsys to background information. Noted that Abstral will typically be excluded from coverage as of 1/1/14.</td>
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<tr>
<td>10/2014</td>
<td>Removed Onsolis from criteria (obsolete). Noted that Brand ONLY Actiq and fentanyl bulk powder is typically excluded from coverage. Updated fentanyl transdermal to 25 mcg/hr. Updated references.</td>
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<tr>
<td>10/2015</td>
<td>Minor changes to background section. Added requirement for documentation of cancer diagnosis. Updated references.</td>
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<table>
<thead>
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<th>Date</th>
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<tbody>
<tr>
<td>2/2016</td>
<td>Added requirement for the provision of medical records to verify cancer diagnosis. Added clarification for patients not meeting notification criteria can have a one-time rather than one month approval for transition of care.</td>
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<tr>
<td>9/2016</td>
<td>Added requirement that patients cannot be receiving concurrent fentanyl products. Added clarification that prescriber requests the termination of all previous authorizations for transmucosal fentanyl products.</td>
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