Abstral

Description

Abstral (fentanyl sublingual tablets)

Background
Abstral has one indication, the management of breakthrough cancer pain in patients with malignancies, who are already receiving, and are tolerant to, opioid therapy for their underlying persistent cancer pain. Abstral should only be prescribed by health care professionals who are knowledgeable in the use of Schedule II opioids for cancer pain and are registered in the Abstral TIRF REMS program (1).

Abstral has a high potential for abuse, addiction, and diversion. Abstral prescribing guidelines indicate that if more than 4 units are required per day, the dosage of the underlying opioid therapy should be titrated (1).

Regulatory Status
FDA-approved indication: Abstral is an opioid agonist indicated only for the management of breakthrough cancer pain in patients 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain (1).

Abstral has a boxed warning regarding the risk of fatal respiratory depression in patients treated with Abstral, including following use in opioid non-tolerant patients and improper dosing. Abstral is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Abstral cannot be substituted mcg per mcg for other fentanyl products. The substitution of Abstral for any other fentanyl product may
result in fatal overdose. Outpatients, prescribers and distributors must be enrolled in the TIRF REMS Access program (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies
Actiq, Duragesic, Embeda, Fentanyl Powder, Fentora, Hysingla ER, Lazanda, Morphine drug class, Nucynta, Onsolis, Oxycodone, Subsys, Tramadol, Xartemis ER, Zohydro ER

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Abstral may be considered medically necessary for the management of breakthrough cancer pain in patients age 18 years old or older with malignancies who are already receiving and tolerant to around-the-clock opioid therapy for at least one week for their underlying persistent cancer pain, the prescribing healthcare professional is knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain, AND prescriber and patient are enrolled in the TIRF REMS Access program. Patients are considered opioid tolerant if they are taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hr, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer. However, lower dosage requirements may achieve tolerance in renal impaired or elderly patients.

Abstral is considered investigational in patients below 18 years of age, and in patients that do not have a diagnosis of breakthrough cancer pain or who are not opioid tolerant.

Prior-Approval Requirements

<table>
<thead>
<tr>
<th>Age</th>
<th>18 years of age or older</th>
</tr>
</thead>
</table>

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:

1. Patient is already receiving around the clock opioid therapy for underlying persistent cancer pain
2. Patient is tolerant to opioid therapy.
   Patients are considered opioid tolerant if they are taking at least:
   a. 60mg of oral morphine/day
   b. 25mcg transdermal fentanyl/hour
   c. 8mg oral hydromorphone/day
   d. 25mg oral oxymorphone/day
   e. 30mg oral oxycodone/day
   f. or an equianalgesic dose of another opioid for a week or longer
   g. However, lower dosage requirements may achieve
      tolerance in renal impaired or elderly patients.

3. Prescribing healthcare professional should be knowledgeable of, and
   skilled in, the use of Schedule II opioids to treat cancer pain

4. Patient and prescribing healthcare professional are enrolled in TIRF
   REMS Access program.

5. Initial dose of Abstral must be for 100mcg, even if patient is already
   established on another fentanyl product other than Actiq
   a. Actiq 200mcg converts to Abstral 100mcg
   b. Actiq 400mcg converts to Abstral 200mcg
   c. Actiq 600mcg converts to Abstral 200mcg
   d. Actiq 800mcg converts to Abstral 200mcg
   e. Actiq 1200mcg converts to Abstral 200mcg
   f. Actiq 1600mcg converts to Abstral 400mcg

Prior – Approval Renewal Requirements

Diagnosis

Patient must have the following:

Breakthrough cancer pain – type or location of cancer must be specified

AND ALL of the following:
1. Patient has remained on around-the-clock opioid therapy
2. Prescriber is knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.

3. Prescriber and patient are enrolled in TIRF REMS program

All requests are subject to approval by a secondary review by a clinical specialist for final coverage determination.

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Dosage**

100 mcg: Up to 4 units / day

**Duration**

6 months

**Prior – Approval Renewal Limits**

**Dosage**

100 mcg: Up to 4 units / day or
200 mcg: Up to 4 units / day or
300 mcg: Up to 4 units / day or
400 mcg: Up to 4 units / day or
600 mcg: Up to 4 units / day or
800 mcg: Up to 4 units / day

**Duration**

6 months

**Rationale**

**Summary**

Abstral, a short-acting opioid, is indicated only for the management of breakthrough cancer pain in patients, 18 years of age or older, who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain. Abstral should only be prescribed by health care professionals who are knowledgeable in the use of Schedule II opioids for cancer pain.

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Abstral while maintaining optimal therapeutic outcomes.
### References


### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2012</td>
<td>Decreased the dosage allowance from 6 units/day to 4 units/day.</td>
</tr>
<tr>
<td>April 2012</td>
<td>Renal patients may require lower doses. REMS changed to TIRF REMS</td>
</tr>
<tr>
<td>September 2012</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2013</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2014</td>
<td>Annual editorial review and reference update and addition of type/location of cancer</td>
</tr>
<tr>
<td>June 2015</td>
<td>Annual editorial review and reference update. Addition of subject to secondary review by clinical specialist and Actiq conversion chart</td>
</tr>
<tr>
<td>March 2016</td>
<td>Annual editorial review. Policy number changed from 5.02.01 to 5.70.01</td>
</tr>
</tbody>
</table>

### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 18, 2016 and is effective April 1, 2016.

Deborah M. Smith, MD, MPH