Lazanda

Description

Lazanda (fentanyl intranasal spray)

Background
Lazanda 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. Lazanda 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 TIRF REMS Access (1).

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

Regulatory Status
FDA-approved indication: Lazanda is an opioid agonist indicated 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 (1).

Limitations of use:
Lazanda may be dispensed only to patients enrolled in the TIRF REMS Access program (1).

Lazanda has a boxed warning regarding the risk of fatal respiratory depression in patients treated with Lazanda, including following use in opioid non-tolerant patients and improper
dosing. Lazanda is contraindicated in the management of acute or postoperative pain, including headache/migraine and in opioid non-tolerant patients. Lazanda cannot be substituted mcg per mcg for other fentanyl products. The substitution of Lazanda 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 under the age of 18 have not been established (1).

Related policies
Abstral, Actiq, Butorphanol, Butrans, Duragesic, Extended Release Opioid Drugs, Fentanyl Powder, Fentora, Immediate Release Opioid Drugs, IR Opioid Combo Drugs, Methadone, Opioid Powders, Opioid Step Policy, Suboxone Drug Class, Subsys

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

Lazanda may be considered medically necessary for the management of breakthrough cancer pain in patients age 18 years old or older and if the conditions indicated below are met.

Lazanda is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age or older

Diagnosis
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 one week or longer. 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. Prescribing healthcare professional and patient are enrolled in the TIRF REMS Access program.

5. Initial dose of Lazanda must be for 100mcg, even if patient is already established on another fentanyl product.

Prior – Approval Renewal Requirements

Age 18 years of age or older

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**
100mcg up to 4 sprays / day – 1 unit / 2 days

**Duration**
6 months

#### Prior – Approval *Renewal* Limits

**Dosage**
- 100mcg / spray - up to 4 sprays/day – 1 unit / 2 days, or
- 100mcg / spray - up to 8 sprays/day – 1 unit / day, or
- 300mcg / spray - up to 4 sprays/day – 1 unit / 2 days, or
- 300mcg / spray - up to 8 sprays/day – 1 unit / day, or
- 400mcg / spray - up to 4 sprays/day – 1 unit / 2 days, or
- 400mcg / spray - up to 8 sprays/day – 1 unit / day, or

**Duration**
6 months

### Rationale

**Summary**
Lazanda, a short-acting opioid, is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. Lazanda should only be prescribed by health care professionals who are knowledgeable in the use of Schedule II opioids for cancer pain (1).

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

**References**
### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>January 2012</td>
<td>Decreased dosage allowance from 6 units/day to 4 units/day.</td>
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<tr>
<td>April 2012</td>
<td>Renal patients may require lower doses. Changed REMS to TIRF REMS.</td>
</tr>
<tr>
<td>September 2012</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>June 2013</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>April 2014</td>
<td>Annual editorial review and reference update, addition of type/location of cancer</td>
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<tr>
<td>June 2015</td>
<td>Annual editorial review and reference update. Addition of subject to secondary review by clinical specialist</td>
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<tr>
<td>March 2016</td>
<td>Annual editorial review, added limitation of use</td>
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<tr>
<td></td>
<td>Addition of 300mg spray to quantity limits</td>
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<tr>
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<td>Policy code changed from 5.02.15 to 5.70.15</td>
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<tr>
<td>March 2017</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td></td>
<td>Addition of age to renewal criteria.</td>
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<tr>
<td>March 2018</td>
<td>Annual editorial review</td>
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<tr>
<td>March 2019</td>
<td>Annual review and reference update</td>
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### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.