Medical Department Procedure Manual

Section: Chapter 7A Prescription Medications Prior Authorization

Title: Transmucosal Fentanyl products; fentanyl Nasal Spray (Lazanda), fentanyl buccal tablet (Fentora), fentanyl lozenge (Actiq)

<table>
<thead>
<tr>
<th>Approval: Robert Bonnell, M.D., Med. Dir.</th>
<th>DATES - Origination: 05/01/12</th>
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</thead>
<tbody>
<tr>
<td>Responsible Party: CPM Director</td>
<td>Revised: 11/11/14</td>
</tr>
<tr>
<td>Distribution: Medical Department</td>
<td>Effective: 11/14/14</td>
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<tr>
<td></td>
<td>P&amp;T Review: 11/16/16</td>
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<td></td>
<td>Annual Review: 08/23/17</td>
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</tbody>
</table>

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived:

3.1 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
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Background Information, continued:

Medication Summary

- Fentanyl nasal spray (Lazanda), fentanyl buccal tablet (Fentora), and fentanyl lozenge (Actiq) are pure opioid agonists (controlled substance in Schedule II of the Controlled Substances Act) indicated for the treatment of breakthrough pain in cancer. Members 18 years of age and older for Fentora and Lazanda and in cancer Members 16 years of age and older for Actiq, who are already receiving and who are tolerant to opioid therapy for their underlying cancer pain.

- Lazanda is supplied in glass bottles, containing eight (8) sprays of 100mcL containing 100mcg/100mcL or 400mcg/100mcL concentration solution. Lazanda is given as a single spray into one nostril or a single spray into each nostril (two [2] sprays).

- Fentora tablets are available in 100mcg, 200mcg, 400mcg, 600mcg and 800mcg strengths. Fentora is taken by placing the entire tablet in buccal cavity or under the tongue; tablet is not to be split, crushed, sucked, chewed or swallowed whole.

- Actiq lozenges are available in 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg and 1600mcg strengths. Actiq is taken by placing the lozenge unit in the mouth between the cheek and lower gum, occasionally moving the drug matrix from one side to the other using the handle; the lozenge should be sucked, not chewed.

- The dosage strength of one transmucosal fentanyl product is not the same dosage strength in other fentanyl-containing products. Transmucosal fentanyl products should not be substituted on a mcg per mcg basis.

Coverage Guidelines

- Member must be eligible and have applicable benefits.

- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.
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Background Information, continued:

Exclusion Criteria

- Members must be greater than eighteen (18) years old for Lazanda or Fentora, and greater than sixteen (16) years old for Actiq.
- Contraindicated in management of acute (headache or migraine pain) or post-operative pain.
- Contraindicated in opioid non-tolerant Members.
- Intolerance or hypersensitivity to fentanyl, Lazanda, Fentora, Actiq or their components.

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.

Procedure:

1.0 Request for initial therapy with a Transmucosal fentanyl product requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

1.1 Prescriber must be oncologist or pain specialist knowledgeable in the use of Schedule II narcotics to treat cancer pain; AND
1.2 Member must be diagnosed with cancer and experiencing breakthrough pain; AND
1.3 Member must already be receiving and tolerant (>60mg morphine sulfate or equianalgesic dose [see Appendix 1]) to other short-acting formulary opioid therapy (including, but not limited to: morphine sulfate, oxycodone, or hydromorphone);
1.4 Member must concurrently be on an adequate dose of long-acting (maintenance) opioid;
1.5 Breakthrough pain cannot be controlled by modifying the dose of the long-acting opioid;
1.6 If criteria are met, the requested transmucosal fentanyl product may be approved for up to six (6) months at a maximum of 4 doses per day.
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Procedure, continued:

2.0 Request for continuation of therapy beyond initial authorization period with a transmucosal fentanyl product requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying stabilization or reduction in the Member’s pain levels:

2.1 If criterion is met, the transmucosal fentanyl product may be approved for up to an additional six (6) months at a maximum of 4 doses per day:

Appendix 1: Equianalgesic dose chart

<table>
<thead>
<tr>
<th>Opioid</th>
<th>Equianalgesic Dose (per 24 hours unless specified)</th>
</tr>
</thead>
<tbody>
<tr>
<td>codeine</td>
<td>360-400mg</td>
</tr>
<tr>
<td>fentanyl *</td>
<td>25mcg/hr (TD)</td>
</tr>
<tr>
<td>hydrocodone</td>
<td>60mg</td>
</tr>
<tr>
<td>hydromorphone</td>
<td>15mg</td>
</tr>
<tr>
<td>levorphanol</td>
<td>2mg</td>
</tr>
<tr>
<td>meperidine</td>
<td>600mg</td>
</tr>
<tr>
<td>methadone</td>
<td>4-8mg</td>
</tr>
<tr>
<td>oxycodone</td>
<td>30-40mg</td>
</tr>
</tbody>
</table>

*All fentanyl products are not interchangeable on a mcg per mcg basis.

References: