Prior Authorization DRUG Guidelines

**ACTIQ® (fentanyl lozenge)**

Effective Date: 10.27.05  
Date Developed: 07.02.05 by C. Wilhelmy MD  
Last Approval Date: 1.26.16, 1.24.17

Actiq is an oral transmucosal preparation of the narcotic analgesic fentanyl citrate.

**Pre-Authorization Criteria:** treatment of breakthrough cancer pain in patients > 16 years old who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

VCHCP will authorize its use for patients who have failed treatment with oxycodone, oral morphine, oral dilaudid, fentanyl patches, and liquid morphine.

**Note:** "Opioid-tolerant" patients are defined as patients who are taking at least:
- Oral morphine 60 mg/day, or
- Transdermal fentanyl 25 mcg/hour, or
- Oral oxycodone 30 mg/day, or
- Oral hydromorphone 8 mg/day, or
- Oral oxymorphone 25 mg/day, or
- Equianalgesic dose of another opioid for at least 1 week

**DOSING: ADULTS** — initial starting dose of 200 mcgs; a second dose may be started 15 minutes after completion of the first dose, if needed to satisfactorily relieve pain, then titrated so that the patient's pain can be treated with one single dose. Generally, 1-2 days is required to determine this dose. Consumption should be limited to 4 units/day or less.

**How Supplied:** individually wrapped blister pack (30 per carton) in the following microgram doses: 200, 400, 600, 800, 1200 and 1600

**PRECAUTIONS** — Actiq® should be used only for the care of cancer patients and is intended for use by specialists who are knowledgeable in treating cancer pain. For patients who have received transmucosal product within 6-12 hours, it is recommended that if other narcotics are required, they should be used at starting doses 1/4 to 1/3 those usually recommended. Actiq® preparations contain an amount of medication that
can be fatal to children. Safety and efficacy have not been established in children <16 years of age; Do not convert a patient to ACTIQ from any other fentanyl product on a mcg per mcg basis (there are no safe conversion directions available for patients on any other fentanyl products); Respiratory depression is the chief hazard of fentanyl (as with all opioids).

**Drug Interactions:** use caution with concomitant use of ACTIQ with other CNS depressants; concomitant use with potent inhibitors of cytochrome P450 3A4 isoform (e.g., erythromycin, ketoconazole, grapefruit and grapefruit juice and certain protease inhibitors) may increase fentanyl levels, resulting in increased depressant effects

**REFERENCES**

13. Select Drug Information from Lexi-CompOnline
14. [www.uptodate.com](http://www.uptodate.com) Fentanyl Drug Information
15. Epocrates 2013 www.epocrates.com
**Revision History:**
Date Revised: 10.04.11 by A. Reeves, MD
Date Reviewed/No Updates: 04.02.12; 01.16.13 by A. Reeves, MD
Date Approved by P&T Committee: 10-27-05; 10.25.11; 04.24.12; 01.29.13
Date Reviewed/No Updates: 01.28.14 by C. Sanders MD
Date Approved by P&T Committee: 01.28.14
Date Reviewed/No Updates: 01.13.15 by C. Sanders, MD
Date Approved by P&T Committee: 01.27.15
Date Reviewed/Updated: 01.14.15 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 01.26.16
Date Reviewed/No Updates: 01.24.17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 01.24.17

<table>
<thead>
<tr>
<th>Revision Date</th>
<th>Content Revised (Yes/No)</th>
<th>Contributors</th>
<th>Review/Revision Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/24/17</td>
<td>No</td>
<td>Catherine Sanders, MD; Robert Sterling, MD</td>
<td>Annual review</td>
</tr>
</tbody>
</table>