



Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
Pharmacy Phone: _____

Complete the Clinical Assessment:

Please attach all relevant medical records and test results.

STEP
2

Underlying Diagnosis	<input type="checkbox"/> Breakthrough cancer pain <input type="checkbox"/> Other (please state): _____ _____	Diagnosis: ICD-9 Code #/ Description / J Code (required): _____								
Clinical Consideration	<p>MEDICATION HISTORY Is the patient opioid tolerant, defined as morphine 60mg/day or equi-analgesic dose of another opioid? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Please list current, chronic opioid therapy:</p> <table border="0"> <tr> <td>Drug</td> <td>Directions</td> </tr> <tr> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> </tr> </table> <p>If this request is for Fentora, has the patient already tried and failed fentanyl citrate lollipop (the generic form of Actiq)? This form of Transmucosal fentanyl must be used prior to approval of coverage for Fentora. <i>(Documentation Required)</i> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <p>Transmucosal fentanyl is only approvable for patients who have signed a pain/opioid contract with their physician. Is a pain contract in place? <i>Please provide a copy of the contract.</i> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><u>Documentation must be supplied</u> showing physician visits for pain management no less often than every three months. Is this patient being evaluated for pain control every three months or more frequently? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If all criteria are met, transmucosal fentanyl will <u>only be approved for 3 months at a time</u>. Each re-approval will only require documentation of office visits occurring no less often than every 3 months.</p> <p>Fentanyl citrate lollipop is approvable for ages ≥ 16 years old. Fentora® is approvable for ages ≥ 18 years old. Onsolis® and brand name Actiq® are NOT covered benefits.</p>		Drug	Directions	_____	_____	_____	_____	_____	_____
Drug	Directions									
_____	_____									
_____	_____									
_____	_____									
Provider Specialty	<input type="checkbox"/> Oncologist <input type="checkbox"/> Pain specialist <input type="checkbox"/> Other (please state): _____									

Confidentiality Notice:

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Supporting Documentation	Additional information for consideration of this request: _____ _____ _____ _____
	We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.

STEP 3 I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature

Date

STEP 4 Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____

Date Initiated _____

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RMHP Formulary Coverage Policy

Fentanyl citrate (Actiq[®], Fentora[®], Onsolis[®])

CLASSIFICATION

- Opioid analgesic

DESCRIPTION

- Oral/buccal transmucosal preparations of fentanyl citrate are only FDA approved in the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy.
- Patients considered opioid tolerant are those who are taking around-the-clock opioid consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients. For that reason, these products are contraindicated in the management of acute or postoperative pain including headache/migraine.
- Oral/buccal transmucosal preparations of fentanyl citrate are intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.
- Different oral/buccal transmucosal preparations of fentanyl citrate cannot be converted on a mcg per mcg basis one to another and are not substitutable. Substantial differences exist in the pharmacokinetic profiles of each product that results in clinically important differences in the extent of absorption of fentanyl. As a result of these differences, the substitution of one fentanyl product with any other fentanyl product may result in fatal overdose.
- Actiq is indicated for use in patients aged ≥ 16 years old. Other preparations are approved for use in patients aged ≥ 18 years old.
- Actiq is available as a cost-saving generic. There exists a huge cost disparity between this generic formulation and brand name counterparts.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Fentanyl lollipop (generic Actiq): Tier 1 Fentora: Tier 2 Actiq (brand name): Not covered Onsolis: Not covered
Legacy Commercial Formulary:	Fentanyl lollipop (generic Actiq): Tier 1 Fentora: Tier 2 Actiq (brand name): Not covered Onsolis: Not covered
Medicare Part D coverage:	Fentanyl lollipop (generic Actiq): Tier 2 Fentora: Tier 4 Actiq (brand name): Not covered Onsolis: Not covered

COVERAGE CRITERIA

Fentanyl citrate (oral/buccal transmucosal preparations) meets the definition of **medical necessity** for the following:

- Management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy
- Approval will be given in 3 month increments. Re-approval requires documentation showing physician visits for pain management no less often than every three months.

Fentanyl citrate (oral/buccal transmucosal preparations) is considered **experimental** for the following (requests will be individually reviewed for medical necessity):

- Treatment of other types of pain that are not breakthrough cancer pain
- Treatment of breakthrough cancer pain in patient 15 years of age and younger

For members previously established or maintained on fentanyl citrate for non-cancer breakthrough pain:

- A review of clinical documentation provided will be conducted.
- Consideration will be given to allow a 6 month period of coverage. This is to provide adequate time for the member to transition over to a different pain medication.
- After a period of 6 months, this medication will no longer be covered by RMHP for this indication.

Required Provider Specialty:

- Approval is limited to oncology or a pain specialist

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy in pediatric patients has not been established)

- Dosing should be individualized
- Dosing varies by preparation used (refer to corresponding prescribing information)

Dosing adjustments:

- Refer to corresponding prescribing information

PRECAUTIONS:

- **Contraindicated in opioid non-tolerant patients, or in the management of acute or postoperative pain including headache/migraines**
- Clinically significant respiratory and CNS depression can occur. Monitor patients accordingly.
- Full and partially consumed product contains medicine that can be fatal to a child. Ensure proper storage and disposal.
- Use with other CNS depressants and potent cytochrome P450 3A4 inhibitors may increase depressant effects including respiratory depression, hypotension, and profound sedation. Consider dosage adjustments if warranted.
- Titrate cautiously in patients with chronic obstructive pulmonary disease or preexisting medical conditions predisposing them to respiratory depression.
- Administer with extreme caution in patients susceptible to intracranial effects of CO₂ retention.

Billing/Coding information

- n/a

COST

- AWP (January 2011):
 - Actiq® (1): \$45.00 – \$132.56 (dosed up to 4 times daily)
 - One month of therapy averages \$6,000 - \$12,000
 - Fentora® (1): \$22.59 - \$66.30 (dosed up to 6 times daily)
 - One month of therapy averages \$7,000
 - Onsolis® (1): \$21.25 - \$61.25 (dosed up to 4 times daily)
 - *Fentanyl citrate oral transmucosal lollipop (generic Actiq): \$10.00 - \$24.00 per lollipop (based on estimated “maximum allowable cost”)*
- AWP (March 2012):
 - Fentora® (1): \$28.59 - \$83.87 (dosed up to 6 times daily)
 - *Fentanyl citrate oral transmucosal lollipop (generic Actiq): \$11.02 - \$19.33*

COMMITTEE APPROVAL:

January 2011 - Pharmacy and Therapeutic review of Fentora®, Actiq®, and Onsolis®

GUIDELINE UPDATE INFORMATION:

December 2010	Policy created
March 2012	Updated coverage criteria

REFERENCES:

- DRUGDEX®, accessed 12/28/2010, 03/07/2012.
- Product Information: ACTIQ® oral transmucosal, fentanyl citrate oral transmucosal. Cephalon Inc, Frazer, PA, 2006.
- Product Information: FENTORA™ oral tablets, fentanyl buccal oral tablets. Cephalon Inc, Frazer, PA, 2007.
- Product Information: ONSOLIS™ buccal, soluble film, fentanyl buccal, soluble film. Biodelivery Services International, Raleigh, NC, 2009.