



Horizon BCBSNJ  
Medical Necessity Guideline

<b>Section</b>	Drugs
<b>Policy Number</b>	
<b>Effective Date</b>	5/12/09
<b>Review Date</b>	9/8/09

**DRUG CLASS** Oral Fentanyl Products

**BRAND NAME (generic)** Actiq  
(oral transmucosal fentanyl citrate)

Fentora  
(fentanyl citrate buccal tablet)

Onsolis  
(fentanyl buccal soluble film)

**IMPORTANT NOTE:**

*The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. **Outpatient prescription drugs are not covered under all Horizon benefit plans.** If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

**Horizon BCBSNJ pharmacy guidelines do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.**

**BLACK BOX WARNINGS**

Fentanyl is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to other opioid analgesics. Fentanyl can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing fentanyl in situations in which the health care provider or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. Schedule II opioid substances, which include morphine, oxycodone, hydromorphone, oxymorphone, and methadone, have the highest potential for abuse and risk of fatal overdose due to respiratory depression.

The fentanyl lozenge and buccal tablet are indicated only for the management of breakthrough cancer pain in patients with cancer already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid-tolerant are those who are taking oral morphine 60 mg/day or more, transdermal fentanyl 25 mcg/h, oxycodone 30 mg/day, oral hydromorphone 8 mg/day, or an equianalgesic dose of another opioid for a week or longer.

Because life-threatening respiratory depression could occur at any dose in patients not taking chronic opiates, it is contraindicated in the management of acute or postoperative pain. This product is not indicated for use in opioid-intolerant patients.

Instruct patients and their caregivers that this drug contains a medicine in an amount that can be fatal to a child. Keep all units out of the reach of children, and discard opened units properly.

This medicine should be used only in the care of cancer patients and only by health care providers who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

**Tablet:** Because of the higher bioavailability of fentanyl in the buccal tablet, when converting patients from other oral fentanyl products (including the fentanyl lozenge) to the buccal tablet, do not substitute the buccal tablet on a mcg per mcg basis. Adjust dosage as appropriate

**Onsolis** is available only through a restricted distribution program called the FOCUS Program and requires prescriber, pharmacy, and patient enrollment.

## **FDA-APPROVED INDICATIONS**

### **Actiq:**

Actiq is indicated **ONLY** for the management of breakthrough cancer pain in patients 16 and older with malignancies who are **already receiving around-the-clock opioid therapy and who are tolerant to their existing opioid therapy for their underlying persistent cancer pain**. Patients considered opioid tolerant are those who are taking at least 60 mg morphine per day, at least 25 mcg transdermal fentanyl per hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or equianalgesic dose of another opioid for a week or longer.

This product **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates. For this reason, Actiq is contraindicated in the management of acute or postoperative pain.

Actiq is 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.

### **Fentora:**

Fentora is indicated only for the management of breakthrough pain in patients with cancer who are **already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain**. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

This product **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation could occur at any dose in patients not on a chronic regimen of opiates. For this reason, Fentora is contraindicated in the management of acute or postoperative pain.

Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

### **Onsolis:**

Onsolis (fentanyl buccal soluble film) is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, **who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain**. Patients considered opioid tolerant are those who are taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

This product **must not** be used in opioid non-tolerant patients because life-threatening respiratory depression could occur in patients not taking chronic opiates. For this reason, Onsolis is contraindicated in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room.

Onsolis is intended to be used only in the care of opioid tolerant patients with cancer and only by healthcare professionals who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.

## **CRITERIA FOR APPROVAL**

- |  |     |     |
|--|-----|-----|
| 1. Will the oral fentanyl product (e.g., Actiq, Fentora, Onsolis) be used to manage No breakthrough pain due to a current cancer condition or complication?<br>[If the answer to this question is no, then no further questions are required.]   | Yes |     |
| 2. Is a long-acting opioid being prescribed for around-the-clock treatment of the cancer pain?   | Yes | No  |
| 3. Is the patient opioid tolerant? (Patients are considered opioid tolerant if they are taking at least 60 mg of morphine per day, or an equianalgesic dose of another opioid, for a week or longer.)  | Yes | No  |
| 4. Is the patient taking a strong or moderate cytochrome P450 3A4 inhibitor(s) (e.g., ritonavir, ketoconazole, itraconazole, troleandomycin, clarithromycin, nelfinavir, nefazodone or amprenavir, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, or verapamil)?<br>[If the answer to this question is no, then skip to question 6.] | Yes | No  |
| 5. Will the patient be carefully monitored and will dosage adjustments be made if necessary?   | Yes | No  |
| 6. Will the oral fentanyl product (e.g., Actiq, Fentora, Onsolis) be used to manage acute or No postoperative pain, headache and/or migraine pain?   |     | Yes |
| 7. Is the patient 16 years of age or older?<br>[If the answer to this question is no, then no further questions required.]   | Yes | No  |
| 8. Is the prescription request for Actiq?<br>[If the answer to this question is no, then skip to question 10.]   | Yes | No  |
| 9. Is the patient 18 years of age or older?<br>[If the answer to this question is no, then no further questions are required.]   | Yes | No  |
| 10. Is the prescription request for more than 120 units per month?   | Yes | No  |

Guidelines for Approval							
Duration of Approval				3 months			
Quantity for Approval				120 units / 25 days			
Set 1		Set 2		Set 3		Set 4	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	4	1	6	1	4	1	6
2	6	2	10	2	6	2	8
3	10	3		3	8	3	10
7		4		7	10	4	
8		5		9		5	
		7				7	
		8				9	

**Horizon BCBSNJ Pharmacy Guideline Development Process:** This Horizon BCBSNJ Pharmacy Guideline (the "Pharmacy Guideline") has been developed by Horizon BCBSNJ's Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type,

frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

## **RATIONALE**

The intent of the criteria is to ensure that patients follow selection elements established by Horizon BCBS New Jersey's medical policies.

## **REFERENCES**

1. Actiq product information. Cephalon, Inc. February 2007.
2. Fentora product information. CIMA Labs, Inc. and Cephalon, Inc. October 2007.
3. Onsolis product information. BIODELIVERY SCIENCES INTL INC. July 2009.
4. Drugdex® System. Thomson Micromedex. <http://www.thomsonhc.com>. (accessed July 25, 2008).
5. McEvoy GK (ed), *AHFS Drug Information*. [online] Bethesda, MD: American Society of Health-System Pharmacists <<http://www.medicinescomplete.com/>> (Accessed on July 25, 2008).
6. Jost L, Roila F. Management of cancer pain: ESMO clinical recommendations. *Annals of Oncology* 2008;19:ii119-ii121.
7. FDA Postmarket Drug Safety Information for Patients and Providers. *Questions and Answers about Onsolis (fentanyl buccal soluble film)*. Food and Drug Administration Website. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm172039.htm>. Accessed July 28, 2009.

*Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.*

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