



Policy #:113

Original policy date: 9/1/09  
Revised date: 10/8/09

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**Title**

**Fentanyl, oral/transmucosal**

Actiq<sup>®</sup> lozenge  
fentanyl lozenge  
Fentora<sup>®</sup> buccal tablet

**Note:** Prescription drugs are covered to the extent that these types of services are generally covered by each member's benefit design. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for review. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally.

Non formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and criteria below are met.

**Description**

Actiq<sup>®</sup> (fentanyl lozenge) and Fentora<sup>®</sup> (fentanyl buccal tablet) are potent, short-acting schedule II narcotic products that contain fentanyl as their active ingredient. They are indicated for the management of breakthrough cancer pain in patients who are already receiving and who are tolerant to opioid therapy for the underlying persistent cancer pain. Actiq<sup>®</sup> and Fentora<sup>®</sup> are rapid-acting narcotics that generally take less than 10 minutes to enter the bloodstream. Because of their potency, potential for abuse and safety concerns, these drugs carry a black box warning emphasizing the following:

- These products should only be used in breakthrough cancer pain.
- These products should only be used in patients who are already receiving and who are tolerant to opioid therapy for underlying cancer pain (opioid tolerance is defined as those patients taking at least 60mg morphine/day, 25 mcg transdermal fentanyl/hour or an equianalgesic dose of another opioid for a week or longer).
- These products are contraindicated in management of acute or postoperative pain
- These products should only be used 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.

**When services are covered for Commercial products (excluding Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx plans; see below for coverage for these products)**

We cover Actiq<sup>®</sup>, fentanyl lozenge and Fentora<sup>®</sup> when all of the following criteria are met:

- There is a diagnosis of breakthrough pain due to cancer
- The patient is already receiving and is tolerant to other opioids
  - Opioid tolerance is defined as patients who are taking one of the following medications at or above the dose listed for at least one week or longer
    - Oral morphine 60mg/day
    - Transdermal fentanyl 25mcg/hour
    - Oxycodone 30mg/day
    - Oral hydromorphone 8mg/day

- Equianalgesic dose of any other opioid

Requests meeting the above criteria will also be subject to a quantity limit of up to 120 units per 30 days.

#### **When services are not covered for Commercial Products (excluding Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx products)**

We do not cover the above drugs for acute pain or other conditions not listed above.

#### **When services are covered for Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS PlusRx Products**

For Medicare Advantage members, please refer to Medical Policy #023.

#### **Individual consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

Blue Cross Blue Shield of Massachusetts  
Clinical Pharmacy Department  
25 Technology Place  
Hingham, MA 02043  
Tel: 1-800-366-7778  
Fax: 1-800-583-6289

#### **Managed care, Indemnity and PPO guidelines**

- Prior Authorization is required for all plans as these drugs are processed as a Pharmacy benefit.
- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do meet the above criteria.  
Pharmacy Operations: (800)366-7778
- Physicians may fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who meet the above criteria.

#### **Coding information**

Physician billing is not applicable as these medications are billed through the pharmacy benefit.

#### **Policy update history**

New Policy, effective 9/1/09. Reviewed 9/2009 MPG-Hematology and Oncology, no changes in coverage were made.

#### **Footnotes**

<sup>1</sup>Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 2/10/09 and 5/12/09.

#### **References**

1. Actiq<sup>®</sup> [package insert]. Salt Lake City, UT; 2007.
2. Fentora<sup>®</sup> [package insert]. Frazer, PA: Cephalon, Inc.; 2007.
3. Farrar JT, Cleary J, Rauck R, et al. Oral transmucosal fentanyl citrate: randomized, double-blinded, placebo-controlled trial for treatment of breakthrough pain in cancer patients. J Natl Cancer Inst. 1998 Apr 15; 90(8):611-6.

This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

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**Request for Outpatient Retail Pharmacy Prior Authorization**

**Phone Authorization (800)366-7778**

**Fax to: Clinical Pharmacy Program (800) 583-6289**

**We plan to respond to your request within two business days of our receipt. To ensure that we can confirm your request (required by NCQA), please be sure to include your fax number.**

<b>We cannot process requests unless they contain all of the information requested below:</b>	
<b>Patient Information (REQUIRED)</b>	
Name	
BCBSMA ID number	
Is the patient a BCBSMA employee? If yes, please fax request to: (617) 246-4013	Yes                      No
Date of Birth	
Patient's Diagnosis or ICD-9-CM code	
<b>Physician Information (REQUIRED)</b>	
Name	
Medical Specialty	
BCBSMA Provider number/NPI number	
Telephone Number	
Fax Number	
Contact Name (if different from physician)	
Please select one of the three following sections to complete, depending on the nature of your request for the above-named patient.	
<b>Formulary Exception Request</b>	
Name of non-covered drug you want to prescribe	
Reason for Individual Consideration Request (please check one): <input type="checkbox"/> Treatment failure with the following covered drugs in class <input type="checkbox"/> Documented adverse reaction to the following covered drugs <input type="checkbox"/> Other clinical reason (please specify) _____	
<b>Quality Care Dosing Override Request</b>	
Drug name, strength and quantity requested:	
Clinical reason for override (please specify)	
<b>Outpatient Retail Pharmacy Prior Authorization Request</b>	
Drug name:	
Start/End date (must be one year or less):	
Associated Co-morbid diagnosis:	
MD Signature:	Date: