



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy

Fentanyl, oral-transmucosal

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Policy Number: 113

BCBSA Reference Number: None

Related Policies

- Quality Care Dosing guidelines may apply to these medications and can be found in Medical Policy [#621A](#).

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

We may cover **Fentanyl lozenge** 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.

We may cover **Abstral®** (fentanyl), **Actiq®** (fentanyl), **Fentora®** (fentanyl), **Fentanyl Buccal (fentanyl citrate)**, **Lazanda®** (fentanyl), and **Subsys®** (fentanyl) when **ALL** of the following criteria are met:

- There is a diagnosis of breakthrough pain due to cancer, AND
- 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, or
- Equianalgesic dose of any other opioid.

AND

- There has been previous treatment failure with or a contraindication to **Fentanyl lozenge**.

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

Description

Abstral® (fentanyl sublingual tablet), **Actiq®** (fentanyl lozenge) **Fentora®** (fentanyl buccal tablet), **Lazanda®** (fentanyl intranasal solution), **Onsolis™** (fentanyl buccal film) and **Subsys®** (fentanyl sublingual spray) 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.

Abstral®, Actiq®, Fentora®, and Onsolis™ (fentanyl buccal film) 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.

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. Physicians may send relevant clinical information for individual patients for consideration to:

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

Managed Care Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale. Pharmacy Operations: (800) 366-7778
- Physicians may also 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 do not meet the step therapy criteria at the point of sale.

PPO and Indemnity Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale. Pharmacy Operations: (800) 366-7778

- Physicians may also 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 do not meet the step therapy criteria at the point of sale.

Policy History

Date	Action
2/2020	Updated to add FENTA Fentanyl Buccal to the policy.
6/2017	Updated address for Pharmacy Operations.
1/2014	Updated ExpressPath language.
1/2013	Updated to require use of generic fentanyl lozenges prior to use of brand name formulations.
4/2012	Updated to include new FDA approved medications Lazanda® and Subsys®.
11/2011- 4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
3/2011	Updated to include new FDA approved product Abstral®.
9/2010	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
4/2010	Updated to include coverage criteria for Onsolis™ and to include Express PA information.
9/2009	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
9/1/2009	New policy, effective 9/1/2009, describing covered and non-covered indications.

References

- Actiq® [package insert]. Salt Lake City, UT; 2007.
- Fentora® [package insert]. Frazer, PA: Cephalon, Inc.; 2007.
- Onsolis™ [package insert]. Somerset, NJ: Meda Pharmaceuticals; 2009.
- 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.
- Abstral® [package insert]. Bedminster, NJ: ProStraken, Inc.; 2010

Endnotes

- Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 2/10/2009 and 5/12/2009.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

<http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>