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.
Prior Authorization Information

☒ Prior Authorization
☐ Step Therapy
☒ Quality Care Dosing

Pharmacy Operations:
Tel: 1-800-366-7778
Fax: 1-800-583-6289
Policy last updated 7/1/2023

Policy applies to Commercial Members:
- Managed Care (HMO and POS),
- PPO and Indemnity
- MEDEX with Rx plan
- Managed Major Medical with Custom BCBSMA Formulary
- Comprehensive Managed Major Medical with Custom BCBSMA Formulary
- Managed Blue for Seniors with Custom BCBSMA Formulary

To request for coverage: Physicians may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043

Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration

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, hospice and palliative care specialists, 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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>7/2023</td>
<td>Reformatted Policy.</td>
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<tr>
<td>2/2020</td>
<td>Updated to add FENTA Fentanyl Buccal to the policy.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
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<tr>
<td>1/2014</td>
<td>Updated ExpressPAth language.</td>
</tr>
<tr>
<td>1/2013</td>
<td>Updated to require use of generic fentanyl lozenges prior to use of brand name formulations.</td>
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<tr>
<td>4/2012</td>
<td>Updated to include new FDA approved medications Lazanda® and Subsys®.</td>
</tr>
<tr>
<td>3/2011</td>
<td>Updated to include new FDA approved product Abstral®.</td>
</tr>
<tr>
<td>4/2010</td>
<td>Updated to include coverage criteria for Onsolis™ and to include Express PA information.</td>
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</tbody>
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References
Endnotes
1. 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: