

## Pharmacy Policy Bulletin

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**Title:** Controlled Substance Prior Authorization

**Policy #:** Rx.01.15

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### ▸ Intent:

N/A

### ▸ Description:

N/A

### ▸ Policy:

Controlled substances are subject to quantity limits. Refer to the controlled substances quantity limit policy for specific quantity limits.

Authorizations will be granted for a period of one year for Actiq, Fentanyl citrate otfc, fentanyl buccal soluble film (Onsolis™), fentanyl (Abstral) and Fentora and Lazanda.

## INITIAL REQUESTS

Fentanyl (Fentora), Fentanyl buccal soluble film (Onsolis™), Fentanyl (Abstral), Fentanyl (Lazanda) are approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of breakthrough pain in individuals with cancer who are already receiving opioid therapy
- Documentation of age 18 and older
- Documentation of tolerance to current opioid therapy (i.e. adherence to one of the following regimens for one week or longer):
  - At least 60mg of oral morphine daily
  - At least 25mcg of transdermal fentanyl/hour
  - At least 30mg of oral oxycodone daily
  - At least 8mg of oral hydromorphone daily
  - At least 25mg of oral oxymorphone daily
  - An equianalgesic dose of another opioid medication
- Documentation of a trial and failure of generic oral transmucosal fentanyl citrate (generic oral

transmucosal fentanyl citrate requires prior authorization) for at least one week or longer

## **REAUTHORIZATION REQUESTS**

Fentanyl (Fentora), Fentanyl buccal soluble film (Onsolis™), Fentanyl (Abstral), Fentanyl (Lazanda) are approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of breakthrough pain in individuals with cancer who are already receiving opioid therapy
- Documentation to support the efficacy associated with the current regimen (eg pain scores, clinical response)

## **ORAL TRANSMUCOSAL FENTANYL CITRATE (ACTIQ®) (FOR INITIAL REQUESTS)**

Oral transmucosal fentanyl citrate (Actiq®) is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of breakthrough pain due to/associated with cancer
- Documentation of age 16 and older
- Documentation of tolerance to current opioid therapy (ie, adherence to one of the following regimens for one week or longer):
  - At least 25 mcg of transdermal fentanyl hourly
  - At least 30 mg of oxycodone daily
  - At least 60 mg of oral morphine daily
  - At least 8 mg of oral hydromorphone daily
  - At least 25mg of oral oxymorphone daily
  - An equianalgesic dose of another opioid
- Documentation of a trial and failure of generic oral transmucosal fentanyl citrate (generic oral transmucosal fentanyl citrate requires prior authorization) for at least one week or longer

## **ORAL TRANSMUCOSAL FENTANYL CITRATE (GENERIC) (FOR INITIAL REQUESTS)**

Generic oral transmucosal fentanyl citrate is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of breakthrough pain due to/associated with cancer
- Documentation of age 16 and older
- Documentation of tolerance to current opioid therapy (ie, adherence to one of the following regimens for one week or longer):
  - At least 25 mcg of transdermal fentanyl hourly
  - At least 30 mg of oxycodone daily
  - At least 60 mg of oral morphine daily
  - At least 8 mg of oral hydromorphone daily
  - At least 25mg of oral oxymorphone daily
  - An equianalgesic dose of another opioid

## **ORAL TRANSMUCOSAL FENTANYL CITRATE (FOR REAUTHORIZATION REQUESTS)**

Oral transmucosal fentanyl citrate (generic and brand Actiq) are re-approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of breakthrough pain due to/associated with cancer
- Documentation to support the efficacy associated with the current regimen (eg pain scores, clinical response)

#### Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

#### BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

#### References:

Actiq® (oral transmucosal fentanyl citrate) [package insert]. Salt Lake City, UT: Cephalon, Inc.; 2007. Also available online at: [http://www.actiq.com/pdf/actiq\\_package\\_insert\\_4\\_5\\_07.pdf](http://www.actiq.com/pdf/actiq_package_insert_4_5_07.pdf). Accessed April 8, 2011.

Facts and Comparisons. Magnacet. [Facts and Comparisons Web site]. Available at: <http://online.factsandcomparisons.com> [via subscription only]. Accessed April 8, 2011.

Fentora® (fentanyl) [package insert]. Frazer, PA: Cephalon, Inc.; 2007. Also available online at: <http://www.fentora.com/2000-hcp-homepage.aspx>. [Link no longer active]

Mallinckrodt Inc. Brand pharmaceuticals. Magnacet. [Mallinckrodt Web site]. Available at: <http://www.mallinckrodt.com>. Accessed April 8, 2011.


Micromedex. Oxycodone/acetaminophen. [Micromedex Web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed April 8, 2011.

Product Information: ONSOLIS(TM) buccal, soluble film, fentanyl buccal, soluble film. Biodelivery Services International, Raleigh, NC, July 2009.

Facts and Comparisons website [Abstral]. Available at [www.factsandcomparisons.com](http://www.factsandcomparisons.com). Accessed April 8, 2011.

Lazanda [package insert]. Bedminster NJ. Archimedes Pharma US Inc. 2011.

#### Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Fentora	fentanyl
Actiq	oral transmucosal fentanyl citrate
Magnacet	oxycodone/acetaminophen
Onsolis	Fentanyl buccal soluble film
Lazanda	Fentanyl
Abstral	fentanyl

#### Cross References:

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<b>Policy Version Number:</b>	1.00
<b>P&amp;T Approval Date:</b>	March 08, 2012
<b>Policy Effective Date:</b>	June 01, 2012
<b>Next Required Review Date:</b>	March 08, 2013

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