



**Policy Title** Controlled Substance Prior Authorization

**Policy Number** FS.CLIN.55

*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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.*

## Policy

**Fentanyl (Fentora®)/ oral transmucosal fentanyl citrate (Actiq®)/Fentanyl buccal soluble film (Onsolis™)** are Schedule II opioid analgesics indicated for the management of breakthrough pain in individuals with cancer who are already receiving and are tolerant to opioid therapy for underlying persistent cancer pain. Individuals who are considered opioid-tolerant adhere to at least one of the following regimens for one week or longer:

- 25 mcg of transdermal fentanyl hourly
- 30 mg of oxycodone daily
- 60 mg of oral morphine daily
- 8 mg of oral hydromorphone daily
- An equianalgesic dose of another opioid

**Oxycodone/acetaminophen (Magnacet®)** is indicated for the treatment of pain.

The use of fentanyl (Fentora®)/oral transmucosal fentanyl citrate (Actiq®)/fentanyl buccal soluble film (Onsolis™) and oxycodone/acetaminophen (Magnacet®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

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## Policy Description

**Fentanyl (Fentora®)/oral transmucosal fentanyl citrate (Actiq®)/Fentanyl buccal soluble film (Onsolis™)** are pure opioid agonists whose principal therapeutic action is analgesia. Other opioid agonists include morphine, oxycodone, hydromorphone, codeine, hydrocodone, and tramadol. In addition to analgesia, other pharmacological effects of opioid agonists include anxiolysis, euphoria, feelings of relaxation, respiratory depression, constipation, miosis, and cough suppression. With pure opioid agonists, there is increased analgesia with increased doses, but with mixed opioid agonists/antagonists or non-opioid agonists, there is a limit to the analgesic effect with increased doses. There is no defined maximum dose with pure opioid agonists; the ceiling to analgesic effectiveness is imposed only by side effects, the most serious of which may include somnolence and respiratory depression.

**Oxycodone/acetaminophen (Magnacet®)** is a combination of oxycodone and acetaminophen. Oxycodone is a semi-synthetic narcotic analgesic with pharmacologic properties similar to those of morphine. Oxycodone binds to opioid receptors in the central nervous system, thereby altering the perception of pain. Acetaminophen works by inhibiting prostaglandin synthesis.

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## Policy Guideline Inclusion

Fentanyl (Fentora®) is limited to 120 tablets per 30 days, oral transmucosal fentanyl citrate (Actiq®) to 120 units per 30 days, fentanyl buccal soluble film (Onsolis™) to 120 units per 30 days and oxycodone/acetaminophen (Magnacet®) to 180 tablets per 30 days.

Refer to the Quantity Level Limits for Pharmaceuticals Covered Under the Pharmacy Benefit 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™) and Fentora. Authorizations for Magnacet will be indefinite.

**FENTANYL (FENTORA®) (FOR INITIAL REQUESTS)**

**Fentanyl (Fentora®)** is 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 (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
  - 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

**FENTANYL (FENTORA®) (FOR REAUTHORIZATION REQUESTS)**

**Fentanyl (Fentora®)** is re-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
  - 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
  - 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)

**FENTANYL BUCCAL SOLUBLE FILM (ONSOLIS™) (FOR INITIAL REQUESTS)**

**Fentanyl buccal soluble film (Onsolis™)** 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 18 and older
- 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
- 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
  - An equianalgesic dose of another opioid

**FENTANYL BUCCAL SOLUBLE FILM (ONSOLIS™) (FOR REAUTHORIZATION REQUESTS)**

**Fentanyl buccal soluble film (Onsolis™)** is 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)

OXYCODONE/ACETAMINOPHEN (MAGNACET®)  
**Oxycodone/acetaminophen (Magnacet®)** is approved when **all** of the following inclusion criteria are met:

- Documentation of the trial and failure/intolerance to an oxycodone/acetaminophen-containing product with 325 mg of acetaminophen
- Documentation of the reason why an oxycodone/acetaminophen-containing product with greater than 400 mg of acetaminophen would not be appropriate

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## Policy Guideline Exclusion

FENTANYL (FENTORA®) (**FOR INITIAL REQUESTS**)  
**Fentanyl (Fentora®)** is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of breakthrough pain in individuals with cancer who are already receiving opioid therapy
- No documentation of age 18 and older
- No 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
  - An equianalgesic dose of another opioid
- No 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

FENTANYL (FENTORA®) (**FOR REAUTHORIZATION REQUESTS**)  
**Fentanyl (Fentora®)** is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of breakthrough pain in individuals with cancer who are already receiving opioid therapy
- No 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 denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of breakthrough pain due to/associated with cancer
- No documentation of age 16 and older
- No 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
  - An equianalgesic dose of another opioid
- No 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 denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of breakthrough pain due to/associated with cancer
- No documentation of age 16 and older
- No 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
- An equianalgesic dose of another opioid

#### ORAL TRANSMUCOSAL FENTANYL CITRATE

#### **(FOR REAUTHORIZATION REQUESTS)**

**Oral transmucosal fentanyl citrate (generic and brand Actiq)** are denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of breakthrough pain due to/associated with cancer
- No documentation to support the efficacy associated with the current regimen (eg pain scores, clinical response)

#### FENTANYL BUCCAL SOLUBLE FILM (ONSOLIS™) **(FOR INITIAL REQUESTS)**

**Fentanyl buccal soluble film (Onsolis™)** is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of breakthrough pain due to/associated with cancer
- No documentation of age 18 and older
- No 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
- No 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
  - An equianalgesic dose of another opioid

#### FENTANYL BUCCAL SOLUBLE FILM (ONSOLIS™)

#### **(FOR REAUTHORIZATION REQUESTS)**

**Fentanyl buccal soluble film (Onsolis™)** is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of breakthrough pain due to/associated with cancer
- No documentation to support the efficacy associated with the current regimen (eg pain scores, clinical response)

**OXYCODONE/ACETAMINOPHEN (MAGNACET®)**  
**Oxycodone/acetaminophen (Magnacet®)** is denied when **any** of the following exclusion criteria are present:

- No documentation of the trial and failure/intolerance to an oxycodone/acetaminophen-containing product with 325 mg of acetaminophen
- No documentation of the reason why an oxycodone/acetaminophen-containing product with greater than 400 mg of acetaminophen would not be appropriate

## Policy List of Applicable Drugs

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

## Dosing and Administration

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

## Policy 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 October 18, 2010.

Facts and Comparisons. Magnacet. [Facts and Comparisons Web site]. Available at:  
<http://online.factsandcomparisons.com> [via subscription only]. Accessed October 18, 2010.

Fentora® (fentanyl) [package insert]. Frazer, PA:

Cephalon, Inc.; 2007. Also available online at:  
<http://www.fentora.com/2000-hcp-homepage.aspx>. [Link  
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Mallinckrodt Inc. Brand pharmaceuticals. Magnacet.  
[Mallinckrodt Web site]. Available at:  
<http://www.mallinckrodt.com>. Accessed October 18,  
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Micromedex. Oxycodone/acetaminophen. [Micromedex  
Web site]. Available at: <http://www.micromedex.com> [via  
subscription only]. Accessed October 18, 2010.

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

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## Policy Link to Related Policies

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