Policies Repository

Independence Blue Cross

Policy Title	Controlled Substance Prior Authorization
Policy Number	FS.CLIN.16

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

Oxymorphone (Opana®) is indicated for the relief of moderate-to-severe acute pain where the use of an opioid is appropriate.

Oxymorphone extended-release (ER) (Opana ER®) is indicated for the relief of moderate-to-severe pain in individuals requiring continuous, around-the-clock opioid treatment for an extended period of time.

Fentanyl (Fentora®)/ oral transmucosal fentanyl citrate (Actiq®) is 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 oxymorphone (Opana®), oxymorphone ER (Opana ER®), fentanyl (Fentora®)/oral transmucosal fentanyl citrate (Actiq®), and oxycodone/acetaminophen (Magnacet®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Oxymorphone (Opana®) and fentanyl (Fentora®)/oral transmucosal fentanyl citrate (Actiq®) 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.

Policy Guideline Inclusion

Oxymorphone (Opana®) is limited to 180 tablets per 30 days, oxymorphone ER (Opana ER®) to 90 tablets per 30 days, fentanyl (Fentora®) to 120 tablets per 30 days, oral transmucosal fentanyl citrate (Actiq®) to 120 units per 30 days, and oxycodone/acetaminophen (Magnacet®) to 180 tablets per 30 days.

Specific drugs have quantity limits to comply with manufacturer and US Food and Drug Administration (FDA) guidelines. 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 and Fentora. Authorizations for Opana, Opana ER, and Magnacet will be indefinite.

OXYMORPHONE IMMEDIATE-RELEASE (IR) (OPANA®)
Oxymorphone (Opana®) is approved when **one** of the following inclusion criteria is met:

- Documentation of the trial and failure of or contraindication/allergy/intolerance to **two** of the following:
  - Oxycodone IR-containing product
  - Hydromorphone
  - Morphine sulfate IR
- Authorization for oxymorphone extended-release (ER) (Opana ER®)

OXYMORPHONE ER (OPANA ER®)
Oxymorphone ER (Opana ER®) is approved when **one** of the following inclusion criteria is met:

- Documentation of the trial and failure of or contraindication/allergy/intolerance to both of the following:
  - Oxycodone ER
  - Morphine sulfate sustained-release (SR)
- Authorization for oxymorphone IR (Opana®)

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 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)

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

Policy Guideline Exclusion

OXYMORPHONE IR (OPANA®)
Oxymorphone (Opana®) is denied when **both** of the following exclusion criteria are present:

- No documentation of the trial and failure of or contraindication/allergy/intolerance to two of the following:
  - Oxycodone IR-containing product
  - Hydromorphone
  - Morphine sulfate IR
- No authorization for oxymorphone ER (Opana ER®)

OXYMORPHONE ER (OPANA ER®)
Oxymorphone ER (Opana ER®) is denied when **both** of the following exclusion criteria are present:

- No documentation of the trial and failure of or contraindication/allergy/intolerance to both of the following:
  - Oxycodone ER
  - Morphine sulfate SR
- No authorization for oxymorphone IR (Opana®)

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 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)

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
Opana	oxymorphone
Opana ER	oxymorphone ER
Fentora	fentanyl
Actiq	oral transmucosal fentanyl citrate
Magnacet	oxycodone/acetaminophen

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. Accessed July 28, 2009.

Facts and Comparisons. Magnacet. [Facts and Comparisons Web site]. Available at: http://online.factsandcomparisons.com [via subscription only]. Accessed July 28, 2009.

Fentora® (fentanyl) [package insert]. Frazer, PA: Cephalon, Inc.; 2007. Also available online at: http://www.fentora.com/2000-hcp-homepage.aspx. Accessed July 28, 2009.

Mallinckrodt Inc. Brand pharmaceuticals. Magnacet. [Mallinckrodt Web site]. Available at: http://www.mallinckrodt.com. Accessed July 28, 2009.

Micromedex. Oxycodone/acetaminophen. [Micromedex Web site]. Available at: http://www.micromedex.com [via subscription only]. Accessed July 28, 2009.

Opana® (oxymorphone) [package insert]. Chadds Ford, PA: Endo Pharmaceuticals; 2006. Also available online at: http://www.endo.com/pdf/Opana_IR_PI.pdf. Accessed July 28, 2009.

Opana ER® (oxymorphone ER) [package insert]. Chadds Ford, PA: Endo Pharmaceuticals; 2008. Also available online at: http://www.opana.com/hcp/. Accessed July 28, 2009.

Policy Link to Related Policies

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