



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Oxycodone (OxyContin®)**

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## Hyperlink to Related Coverage Policies

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

## Coverage Policy

**CIGNA covers oxycodone (OxyContin®) as medically necessary for EITHER of the following indications:**

- management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time
- postoperative use **ONLY** if the individual is already receiving oxycodone prior to surgery or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

### AND when the dosage is:

- two tablets per day of oxycodone 10 mg, 15mg, 20 mg, 30mg, 40 mg or 60 mg strength
  - \* four tablets per day of oxycodone 80 mg strength
- \*to accommodate dosing of 320 mg/day, since the manufacturer no longer produces 160 mg strength tablets**

(**Note:** 60 mg and 80 mg tablets ARE FOR USE IN OPIOID-TOLERANT INDIVIDUALS ONLY. This tablet strength may cause fatal respiratory depression when administered to individuals not previously exposed to opioids.)

**CIGNA does not cover oxycodone (OxyContin®) for any of the following indications because it is considered experimental, investigational, or unproven (this list may not be all-inclusive):**

- mild pain or pain not expected to persist for an extended period of time
  - pain in the immediate postoperative period (the first 12–24 hours following surgery)
  - mild pain or pain not expected to persist for an extended period of time
  - use on an as-needed (pro re nata [p.r.n.]) basis
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## FDA Approved Indications

OxyContin tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. OxyContin is NOT intended for use as a prn analgesic. Physicians should individualize treatment in every case, initiating therapy at the appropriate point along a progression from non-opioid analgesics, such as non-steroidal anti-inflammatory drugs and acetaminophen to opioids in a plan of pain management such as outlined by the World Health Organization, the Agency for Healthcare Research and Quality (formerly known as the Agency for HealthCare Policy and Research), the Federation of State Medical Boards Model Guidelines, or the American Pain Society. OxyContin is not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. OxyContin is only indicated for postoperative use if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate.

## FDA Recommended Dosing

Patients should be started on the lowest appropriate dose. In treating pain it is vital to assess the patient regularly and systematically. Therapy should also be regularly reviewed and adjusted based upon the patient's own reports of pain and side effects and the health professional's clinical judgment. OxyContin tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the The controlled-release nature of the formulation allows OxyContin to be effectively administered every 12 hours. Whilee symmetric (same dose AM and PM), around-the-clock, q12h dosing is appropriate for the majority of patients, some patients may benefit from asymmetric (different dose given in AM than in PM) dosing, tailored to their pain pattern. It is usually appropriate to treat a patient with only one opioid for around-the-clock therapy.

Controlled-release oxycodone is formulated to deliver the opioid analgesic oxycodone over twelve hours, which facilitates convenient dosing, steady blood levels, and consistent pain control. The safety and clinical benefit of dosing controlled-release oxycodone more frequently than every 12 hours is currently not known. Controlled-release oxycodone has not demonstrated a superior clinical benefit over immediate-release opioid analgesics or other long-acting narcotics in chronic pain, and it has not been proven to improve the quality of life in patients suffering from chronic pain. The safety and efficacy of daily doses greater than 80 mg of controlled-release oxycodone in patients with chronic non-cancer pain is not known.

## Black Box Warning

**OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. OxyContin Tablets are not intended for use on an as needed basis. Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. All patients receiving opioids should be routinely monitored for signs of misuse, abuse and addiction. OxyContin must be swallowed whole and must not be cut, broken, chewed, crushed or dissolved. Taking cut, broken, chewed, crushed or dissolved OxyContin tablets leads to rapid release and absorption of a potentially fatal dose of oxycodone. The concomitant use of OxyContin with all cytochrome P450 3A4 inhibitors such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole), and protease inhibitors (e.g., ritonavir) may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse effects and may cause potentially fatal respiratory depression.**

## Drug Availability

OxyContin tablets 10 mg are round, unscored, white-colored, convex tablets imprinted with OC on one side and 10 on the other. They are supplied in bottles of 100 or in unit dose packaging with 10 individually numbered tablets per card; two cards per glue end carton.

OxyContin tablets 15 mg are round, unscored, gray-colored, convex tablets imprinted with OC on one side and 15 on the other. They are supplied in bottles of 100.

OxyContin tablets 20 mg are round, unscored, pink-colored, convex tablets imprinted with OC on one side and 20 on the other. They are supplied in bottles of 100 or in unit dose packaging with 10 individually numbered tablets per card; two cards per glue end carton.

OxyContin tablets 30 mg are round, unscored, brown-colored, convex tablets imprinted with OC on one side and 30 on the other. They are supplied in bottles of 100.

OxyContin tablets 40 mg are round, unscored, yellow-colored, convex tablets imprinted with OC on one side and 40 on the other. They are supplied in bottles of 100 or in unit dose packaging with 10 individually numbered tablets per card; two cards per glue end carton.

OxyContin tablets 60 mg are round, unscored red-colored, convex tablets imprinted with OC on one side and 60 on the other. They are supplied in bottles of 100.

OxyContin tablets 80 mg are round, unscored, green-colored, convex tablets imprinted with OC on one side and 80 on the other. They are supplied in bottles of 100 or in unit dose packaging with 10 individually numbered tablets per card; two cards per glue end carton.

OxyContin tablets 160 mg are caplet-shaped, unscored, blue-colored, convex tablets imprinted with OC on one side and 160 on the other. They are supplied in bottles of 100 or in unit dose packaging with 10 individually numbered tablets per card; two cards per glue end carton.

## General Background

### Pharmacology

Oxycodone is a pure agonist opioid whose principal therapeutic action is analgesia. Pharmacological effects of opioid agonists include anxiolysis, euphoria, feelings of relaxation, respiratory depression, constipation, miosis, and cough suppression, as well as analgesia. Like all pure opioid agonist analgesics, with increasing doses there is increasing analgesia, unlike mixed agonist/antagonists or non-opioid analgesics, where there is a limit to the analgesic effect with increasing doses. With pure opioid agonist analgesics, there is no defined maximum dose; the ceiling to analgesic effectiveness is imposed only by side effects, the more serious of which may include somnolence and respiratory depression.

The precise mechanism of the analgesic action is unknown. However, specific central nervous system (CNS) opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and play a role in the analgesic effects of this drug. Oxycodone produces respiratory depression by direct action on brain stem respiratory centers. The respiratory depression involves a reduction in the responsiveness of the brain stem respiratory centers to both increases in carbon dioxide tension and electrical stimulation.

About 60–87% of an oral dose of oxycodone reaches the central compartment in comparison to a parenteral dose. This high oral bioavailability is due to low pre-systemic and/or first-pass metabolism. In normal volunteers, the half-life of absorption is 0.4 hours for immediate-release oral oxycodone. In contrast, oxycodone tablets exhibit a biphasic absorption pattern with two apparent absorption half-times of 0.6 and 6.9 hours, which describes the initial release of oxycodone from the tablet followed by a prolonged release. Pharmacokinetic studies sponsored by the manufacturer of controlled-release oxycodone support the feasibility of 12-hour dosing.

## Guidelines

The National Comprehensive Cancer Network (NCCN) recommends Oxycontin for maintenance therapy for the management of chronic persistent pain in cancer patients when 24-hr opioid requirement is stable - used in conjunction with specific treatment for oncologic emergency as clinically indicated.

The American Pain Society recommends OxyContin for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

## Clinical Efficacy

In comparison with other opioids, controlled-release oxycodone has not demonstrated a consistent clinical benefit over immediate-release oxycodone in chronic pain in five clinical studies. All studies have proven equal effectiveness and, in most of the studies, there were no differences in adverse effects. Four studies that compared multiple doses of controlled-release oxycodone with other long-acting opioids have not demonstrated a clinical difference, and all four studies have shown equal effectiveness. One study found controlled-release oxycodone to have fewer adverse effects, while another favored the comparator.

## Adverse Reactions

Numerous reports of inappropriate use, abuse, and diversion (some of which resulted in death) led the FDA to strengthen the warnings and precautions in the labeling of oxycodone in the form of the following Black Box Warning as described in the Black Box Warning section.

Serious adverse reactions which may be associated with use of oxycodone include respiratory depression, apnea, respiratory arrest, and (to an even lesser degree) circulatory depression, hypotension, or shock.

Oxycodone has emerged as one of the most problematic, abused opiate agonists in the United States; therefore, patients should be advised about the risk of theft and clinicians should be informed about abuse and diversion issues.

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## Coding/Billing Information

**Note:** This section not in use.

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.