BlueCross BlueShield Federal Employee Program

OXYCODONE IR (oxycodone)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Oxycodone hydrochloride, a pure opioid agonist, is used in the treatment of moderate to severe pain (1-2). The precise mechanism of action is unknown; however, specific opioid receptors in the CNS have been identified and are considered to play a role in the therapeutic effects of the drug (3).

Oxycodone is a Schedule II controlled substance and can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing oxycodone in a situation where misuse, abuse, or diversion are a concern (1).

Regulatory Status

FDA-approved indications:
Oxycodone IR tablets and capsules are immediate-release (IR) oral formulations of oxycodone hydrochloride indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. Oxycodone hydrochloride oral solution 100 mg/5 mL (20 mg/mL) is an opioid analgesic indicated for the management of moderate to severe acute and chronic pain in opioid-tolerant patients (1-3).

Limitations of use: (1)
Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Oxycodone IR for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or non-opioid combination products):

- Have not been tolerated, or are not expected to be tolerated
- Have not provided adequate analgesia or are not expected to provide adequate analgesia

The Oxycodone IR has boxed warnings for the following (1-6):

- Respiratory depression is the chief hazard of opioid agonists, including morphine sulfate, which if not immediately recognized and treated, may lead to respiratory arrest and death. Risk is increased in patients receiving concurrent CNS depressants (including alcohol), patients with chronic obstructive pulmonary disease, orthostatic hypotension,

increased intracranial pressure, biliary tract diseases, and seizure disorders. To reduce the risk of respiratory depression, proper dosing, titration, and monitoring are essential.

- All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use. The risk for opioid abuse increases in patients with a personal or family history of substance abuse or mental illness. Patients should be assessed for the risk of developing abuse prior to the start of treatment and should be routinely monitored during therapy

- Prolonged use of opioid agonists during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening.

- Patients should not consume alcohol or any products containing alcohol while taking.

Oxycodone IR is contraindicated in patients who have significant respiratory depression, paralytic ileus, acute or severe bronchial asthma and hypersensitivity to any of its components or the active ingredient, oxycodone. Usual therapeutic doses of immediate-release oxycodone hydrochloride may decrease respiratory drive to the point of apnea. In these patients, alternative non-opioid analgesics should be considered, and opioids should be employed only under careful medical supervision at the lowest effective dose (1-3).

CDC guidelines find that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents (5)

CDC guidelines finds that given uncertain benefits and substantial risks that opioids should not be considered first-line or routine therapy for chronic pain (i.e., pain continuing or expected to continue longer than 3 months or past the time of normal tissue healing) outside of active cancer, palliative, and end-of-life care (5).

The FDA warns that opioids can interact with antidepressants and migraine medicines to cause a serious central nervous system reaction called serotonin syndrome, in which high levels of the

chemical serotonin build up in the brain and cause toxicity (see Appendix 1 for list of drugs) (5).

The FDA requires healthcare providers to go through the REMS program before prescribing OxyContin / long acting opioids (1).

Summary

Oxycodone hydrochloride is used in the treatment of moderate to severe pain. Oxycodone hydrochloride oral solution is also an opioid analgesic indicated for the management of moderate to severe pain. Both formulations have the potential for developing substance abuse and addiction. It is necessary to monitor the patient for these behaviors. Patients should be assessed for their risk of developing substance abuse prior to being prescribed oxycodone. They should be routinely monitored for signs of misuse, abuse and addiction during therapy (1-6).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of oxycodone while maintaining optimal therapeutic outcomes.

References

1. Oxycodone [package insert]. North Wales, PA: Teva Pharmaceuticals; December 2016.
2. Oxycodone HCl oral solution (oxycodone) [prescribing information]. Greenville, NC: Mayne Pharma; December 2016.
3. Roxybond [package insert]. Valley Cottage, NY: Inspirion Delivery Sciences, LLC.; April 2017.
4. Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic non-cancer pain. *J Pain* 2009; 10:113-30.
5. Dowell D, Haegerich T, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain. CDC Guidelines 2016.
6. FDA Safety Release. FDA Drug Safety Communication: FDA warns about several safety issues with opioid pain medicines; requires label changes. March 22, 2016.