Clinical Policy: extended-release oxycodone (OxyContin®) and oxymorphone (Opana® ER)

Reference Number: ERX.NSST.17
Effective Date: 06/15 Revision Log
Last Review Date: 09/16

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This policy is current at the time of approval, may be updated and therefore is subject to change. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Envolve Pharmacy Solutions for the use of extended-release oxycodone (OxyContin®) and oxymorphone (Opana® ER).

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that extended-release oxycodone (OxyContin®) and oxymorphone (Opana® ER) are **medically necessary** for members meeting the following criteria:

Initial Approval Criteria (must meet all)**:**

- **A.** Failure of an immediate-release (short-acting) narcotic analgesic;
- **B.** Failure of fentanyl patch and morphine extended-release tablets/capsules in the past 6 months, unless intolerant or contraindicated;
- **C.** Request does not exceed health plan approved daily quantity limit, unless both of the following are met:
  a. Dose cannot be adjusted within quantity limits using other dosage strengths;
  b. Prescribed by oncologist or pain management specialist.

Approval duration: 3 months

Continued Approval (must meet all)**:**

- **A.** Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
- **B.** If request is for a dose increase, request does not exceed health plan approved daily quantity limit, unless all of the following are met:
  a. Dose cannot be adjusted within quantity limits using other dosage strengths;
  b. Prescribed by oncologist or pain management specialist;
  c. Pharmacy claims history reflects gradual dose titration.

Approval duration: 6 months for requests within quantity limit,
3 months for requests exceeding quantity limit

Workflow Document

USS.NSST.17
extended-release ox

Background

Description/Mechanism of Action

Oxycodone and oxymorphone are opioid agonists and are relatively selective for the mu receptor, although they can bind to other opioid receptors at higher doses. The principal therapeutic action of oxycodone and oxymorphone is analgesia. There is no ceiling effect to analgesia; clinically, dosage is titrated to provide adequate analgesia and may be limited by adverse reactions, including respiratory and central nervous system (CNS) depression. The precise mechanism of the analgesic action is unknown. However, specific CNS opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and are thought to play a role in the analgesic effects of these drugs.

FDA Approved Indications

OxyContin and Opana ER are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. They are not indicated as as-needed analgesics.

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, they should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

References

1. OxyContin® prescribing information. Stamford, CT: Purdue Pharma L.P.; August 2015. Available at: www.oxycontin.com. Accessed July 2016.
2. Opana® ER prescribing information. Malvern, PA: Endo Pharmaceuticals, Inc; April 2014. Available at: www.opana.com. Accessed July 2016.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created.	06/15	06/15
Updated to new template (converted algorithm to bulleted criteria, added background and references). Changed policy title from "Long acting opioid analgesics" to "extended-release oxycodone (OxyContin) and oxymorphone (Opana ER)" as only two PDL long acting opioid analgesics are included in this policy.	09/16	09/16