# Clinical Policy: Opioid Analgesics

Reference Number: OH.PHAR.PPA.23
Effective Date: 01/01/2020 Revision Log
Last Review Date: 10/2019
Line of Business: Medicaid

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for narcotic analgesic use and the Ohio Governor's Cabinet Opiate Action Team.

## FDA approved indication

Opioid analgesics are indicated for the management and treatment of moderate to severe pain.

## FDA Safety Communication

Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants, including alcohol.

## Policy/Criteria

Acute opioid therapy: Prior authorization will be required for patients receiving short-acting opioids that are considered opioid naïve (defined as patients receiving less than a one day supply of opioids in the last 90 days) and exceed 30 MED (morphine equivalent dose) per prescription OR greater than 7 days supply per prescription.

Sub-acute therapy: Prior authorization will be required for patients receiving short-acting opioids that are considered opioid naïve (defined as patients with fewer than 90 days of opioid therapy in the previous 120 days) and exceed 60 MED (morphine equivalent dose) per prescription OR greater than 7 days supply per prescription.

Prior authorization will be required for all long-acting opioid analgesics.

A "soft stop" edit will be placed on concomitant opioid analgesics and benzodiazepine use that can be overridden by the Pharmacist at the local pharmacy if it is medically necessary the member be treated with both medications. Prior authorization will be required if the Pharmacist does not deem treatment is medically necessary for concomitant use of opioid analgesics and benzodiazepines.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation® that opioid analgesics are **medically necessary** for members meeting the following criteria:

*Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria.*

## I. Initial Approval Criteria

**A. Short-acting opioid analgesic** *(must meet all):*

1. Prescribed for the treatment of non-cancer/non-malignant pain outside of active cancer treatment, palliative care, end of life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery;
2. Diagnosis of moderate or severe pain (Prescriber must provide documentation specifying the associated diagnosis/rationale for use);
3. Member has failed at least TWO (2) non-opioid ancillary treatments (such as non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, anticonvulsants, antidepressants, etc.) at maximum tolerated doses, unless allergy, contraindicated; or clinically significant adverse effects are experienced;
4. If request is for a non-PDL drug, member must have failed a trial of One (1)* PDL short-acting opioid analgesic for at least ≥ ONE week trial of each, unless allergy,contraindicated or clinically significant adverse effects are experienced;
5. If provider indicates patient is not opioid-naïve, prior therapy on opioids must be provided, for example - patient is new to plan and has received opioids previously; or patient received opioids during a recent inpatient stay;
6. Member will be maintained on no more than TWO (2) opioid analgesics concurrently; **If member requires therapy with two opioid analgesics concurrently, regimen must consist of one immediate-release and one extended-release analgesic unless contraindicated**
7. Documentation that the provider has reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances;
8. Documentation that the provider has discussed the benefits and risks of opioid therapy with the patient.

**Provided TWO (2) agents exist in the therapeutic category with comparable labeled indications.*

**Approval Duration: Course of therapy OR up to 3 months**

**B. Long-acting opioid analgesic** *(must meet all):*

1. Prescribed for the treatment of non-cancer/non-malignant pain outside of active cancer treatment, palliative care, end of life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery;

2. Diagnosis of moderate to severe chronic pain (Prescriber must provide documentation specifying the associated diagnosis/rationale for use)
3. Member must have failed at least ≥ 60 day trial on a short-acting opioid analgesic
4. If request is for a non-PDL drug, member must have failed a trial of ONE (1)* PDL long-acting opioid analgesic for at least ≥ ONE week trial of each, unless allergy,contraindicated or clinically significant adverse effects are experienced;
5. Member will be maintained on no more than TWO (2) opioid analgesics concurrently; **If member requires therapy with two opioid analgesics concurrently, regimen must consist of one immediate-release and one extended-release analgesic unless contraindicated**
6. Documentation that the provider has reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances;
7. For initial therapy, cumulative opioid dose does NOT exceed 80 MED/day *(See appendix A)*

**Provided TWO (2) agents exist in the therapeutic category with comparable labeled indications.*

**Approval Duration: Course of therapy OR up to 3 months**

C. **Active cancer treatment, palliative care, end of life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery** *(must meet all):*
   1. Prescribed for pain associated with active cancer treatment, palliative care, end of life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery;
   2. For request for > TWO (2) agents concurrently, prescriber must submit supporting clinical rationale and the upward titration of existing opioid analgesics is inappropriate or contraindicated

   **Approval Duration: 6 months**

D. **Combination of opioid and benzodiazepine (must meet all):**
   1. Provider must state a diagnosis for each therapy.
   2. Provider is aware of concomitant opioid analgesics and benzodiazepine treatment
   3. Provides documentation that the provider has reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances.
   4. Provider is aware of the FDA black box warnings and is monitoring closely for the side effects of concomitant opioid analgesics and benzodiazepine use.

Approval Duration: Course of therapy OR up to 3 months (for non-cancer/non-malignant pain outside of active cancer treatment, palliative care, end of life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery) or 6 month (for active cancer treatment, palliative care, end of life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery)

**E. ADDITIONAL CRITERIA FOR TRANSMUCOSAL FENTANYL**

1. **Diagnosis of cancer pain; and**
2. **Prescription is from oncologist or pain specialist; and**
3. **Concurrently taking a long-acting opioid at therapeutic dose (any of the following for ≥1 week without adequate pain relief):**
   a) ≥ 60 mg oral morphine/day, or
   b) ≥ 25 mcg/hr transdermal fentanyl, or
   c) ≥ 30 mg oral oxycodone/day, or
   d) ≥ 8 mg oral hydromorphone/day, or
   e) ≥ 25 mg oral oxymorphone/day, or
   f) Equianalgesic dose of another opioid; and
4. Dose is </= 4 units per day

**Approval Duration: Course of therapy OR up to 3 months**

**F. Diagnoses/Indications for which coverage is NOT authorized:**

Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

*Requests for non-preferred medications are subject to policy "CP.PMN.16 - Request for Medically Necessary Drug not on the PDL" and this policy.*

**Background**

Opioid analgesics provide relief of acute or chronic pain symptoms. The most profound analgesic effects of opioids are mediated at the mu receptors. Within the central nervous system (CNS), mu receptors are found in large numbers in the midbrain and the in the dorsal horn of the spinal cord where they induce intense analgesia, and a number of other effects such as bradycardia, sedation, euphoria, physical dependence, and respiratory depression. Some common opioid analgesics include buprenorphine, butorphanol, butalbital combinations, codeine, dihydrocodeine, fentanyl,

hydrocodone, hydromorphone, methadone, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tramadol and tapentadol.
Benzodiazepines are a class of medicines that are widely used to treat conditions including anxiety, insomnia, and seizures. Since both opioid and benzodiazepines are depressants of the central nervous system, the combination may result in profound sedation, respiratory depression, coma, and/or death.

**Appendices/General Information**
*Appendix A: General Information*

Calculation of daily morphine equivalent dose (MED):
Strength per unit **X** (number of days/days supply) **X** MED conversion factor = **DAILY MED**

Online calculator available: www.pharmacy.ohio.gov/calculator

| Opioid Oral Morphine Equivalent Dose (MED) Conversion Factors | |
|---|---|
| **Type of Opioid (strength units)** | **MED Conversion Factor** |
| Buprenorphine, transdermal patch (mcg/hr) | 12.6 |
| Buprenorphine, tablet or film | 30 |
| Buprenorphine, film (mcg) | 0.03 |
| Codeine (mg) | 0.15 |
| Dihydrocodeine (mg) | 0.25 |
| Fentanyl buccal or SL tablets, or lozenge/troche (mcg) | 0.13 |
| Fentanyl film or oral spray (mcg) | 0.18 |
| Fentanyl nasal spray (mcg) | 0.16 |
| Fentanyl patch (mcg) | 7.2 |
| Hydrocodone (mg) | 1 |
| Hydromorphone (mg) | 4 |
| Levorphanol tartrate (mg) | 11 |
| Meperidine hydrochloride (mg) | 0.1 |
| Methadone (mg) | |
| >0, ≤ 20 | 4 |
| >20, ≤ 40 | 8 |
| >40, ≤ 60 | 10 |
| >60 | 12 |
| Morphine (mg) | 1 |
| Opium (mg) | 1 |
| Oxycodone (mg) | 1.5 |
| Oxymorphone (mg) | 3 |
| Pentazocine (mg) | 0.37 |
| Tapentadol (mg) | 0.4 |
| Tramadol (mg) | 0.1 |

## Appendix B – Preferred and non-preferred medications

### ANALGESIC AGENTS: OPIOIDS – Long-Acting Oral
### ALL LONG-ACTING OPIOIDS REQUIRE CLINICAL PRIOR AUTHORIZATION

| CLINICAL PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| **Extended Release Buprenorphine Products** | |
| | BELBUCA™ (Buprenorphine buccal film) |
| **Extended Release Hydrocodone Products** | |
| | HYSINGLA ER® (hydrocodone)<br>ZOHYDRO ER® (hydrocodone) |
| **Extended Release Morphine Products** | |
| MORPHINE SULFATE ER tablet (generic of MS Contin®) | ARYMO™ (morphine ER)<br>EMBEDA® (morphine sulfate/ naltrexone)<br>MORPHABOND™ ER (morphine ER)<br>MORPHINE SULFATE ER capsule (generic of Avinza®, Kadian®) |
| **Extended Release Oxycodone Products** | |
| | OXYCODONE ER (generic of Oxycontin®)<br>OXYCONTIN® (oxycodone)<br>XARTEMIS XR® (oxycodone/ acetaminophen)<br>XTAMPZA® ER (oxycodone) |
| **Extended Release Tramadol Products** | |
| | CONZIP® (tramadol)<br>TRAMADOL ER (generic of Ryzolt ER®, Ultram ER®) |
| **Extended Release Oxymorphone Products** | |
| | OXYMORPHONE HCL ER tablets (generic of Opana® ER non-abuse-deterrent) |
| **Extended Release Hydromorphone Products** | |
| | HYDROMORPHONE ER (generic of Exalgo® ER) |
| **Extended Release Tapentadol Products** | |
| | NUCYNTA® ER (tapentadol) |
| **Methadone Products** | |
| | METHADONE tablet (generic of Dolophine®)<br>METHADONE HCL oral concentrate 10mg/ml<br>METHADONE HCL SOLN 5mg/5ml, 10mg/5ml<br>METHADONE INTENSOL® 10mg/ml |

### ANALGESIC AGENTS: OPIOIDS – Long-Acting Transdermal

| CLINICAL PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| BUTRANS® patch (buprenorphine) | BUPRENORPHINE patch (generic for Butrans®)<br>FENTANYL PATCH (generic of Duragesic®)<br>FENTANYL patch 37.5mg/hr, 62.5mg/hr, 87.5mg/hr |

**ANALGESIC AGENTS: OPIOIDS – SHORT-ACTING ORAL SINGLE-ENTITY ***

Note: Effective July 1, 2018, patients with short acting opioid therapy will be limited to 30 MED per prescription and a maximum of 7 days per prescription. Prior authorization will be required to exceed these limits*

| NO PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| **Codeine Products** | |
| CODEINE SULFATE tablet | |
| **Hydromorphone Products** | |
| HYDROMORPHONE HCL tablet (generic of Dilaudid®) | |
| **Levorphanol Products** | |
| | LEVORPHANOL TABLETS (generic of Levo-Dromoran) |
| **Meperidine Products** | |
| | MEPERIDINE tablet (generic of Demerol®) |
| **Morphine Products** | |
| MORPHINE SULFATE: immediate-release tablets (generic of MSIR®) | |
| **Oxycodone Products** | |
| ROXICODONE® tablets (oxycodone)<br>OXYCODONE HCL capsules, tablets (generic of M-Oxy®, OxyIR®) | OXECTA® (oxycodone) |
| **Oxymorphone Products** | |
| | OXYMORPHONE HCL tablets (generic of Opana®) |
| **Tapentadol Products** | |
| | NUCYNTA® (tapentadol) |

**ANALGESIC AGENTS: OPIOIDS – Short-Acting Combination and tramadol**

| NO PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| **Codeine Combinations** | |
| ACETAMINOPHEN w/CODEINE TABLETS (generic of Tylenol® #2, #3, #4) | |
| **Dihydrocodeine Combinations** | |
| | DIHYDROCODEINE/ASPIRIN/CAFFEINE (generic of Synalgos-DC®) |
| **Hydrocodone Combinations** | |
| HYDROCODONE/ACETAMINOPHEN tablets containing 325mg acetaminophen (generic of Lorcet, Lortab, Norco) | BENZHYDROCODONE & ACETAMINOPHEN (generic for APADAZ™) |

| | |
|---|---|
| | HYDROCODONE/ IBUPROFEN (generic of Ibudone®, Vicoprofen®)<br>HYDROCODONE/ACETAMINOPHEN tablets containing 300mg acetaminophen (generic of Vicodin®, Xodol®) |
| **Oxycodone Combinations** | |
| OXYCODONE W/ ACETAMINOPHEN tablets (generic of Percocet®) | OXYCODONE W/ IBUPROFEN (generic of Combunox®)<br>PRIMLEV® (oxycodone/ acetaminophen) |
| **Pentazocine Combinations** | |
| *Not advocated for use* | PENTAZOCINE/NALOXONE (generic of Talwin NX®) |
| **Tramadol** | |
| TRAMADOL (generic of Ultram®)<br>TRAMADOL/ACETAMINOPHEN (generic of Ultracet®) | |
| **Carisoprodol Combinations** | |
| | CARISOPRODOL/ASPIRIN/CODEINE (generic of Soma Compound w/Codeine®) |

## ANALGESIC AGENTS: OPIOIDS –Liquids Immediate-Release (Single Entity)

| NO PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| HYDROMORPHONE 1mg/ml liquid (generic of Dilaudid-5® )<br>MORPHINE SULFATE solution: 10 mg/5ml, 20mg/5ml, 20mg/ml (generic of MSIR Soln®, Roxanol Soln®)<br>OXYCODONE oral solution 5mg/5ml, concentrate 20mg/1ml (generic of Oxydose®, Roxicodone Intensol®) | MEPERIDINE HCL SYRUP 50 mg/5ml (generic of Demerol Oral Syrup®) |

## ANALGESIC AGENTS: OPIOIDS – Liquids and Oral Syrup Immediate-Release (Combination)

| NO PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| ACETAMINOPHEN w/CODEINE ORAL SOLN 120mg-12mg/5ml (generic of Tylenol w/Codeine Elixir®)<br>HYDROCODONE BITARTRATE w/ ACETAMINOPHEN ELIXIR 2.5mg-167mg/5ml, 2.5mg-108mg/5ml (generic of Hycet®, Lortab Elixir®)<br>LORTAB® 10mg-300mg/15ml (hydrocodone/ acetaminophen)<br>ROXICET® ORAL SOLN (5mg Oxycodone-325mg APAP/5ml) | CAPITAL w/CODEINE® suspension 12mg codeine-120mg APAP/5ml<br>ZAMICET® 10mg-325mg/15ml (hydrocodone/ acetaminophen) |

## ANALGESIC AGENTS: OPIOIDS – Nasal Inhalers

| NO PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| BUTORPHANOL TARTRATE NS (generic of Stadol NS®) | |

## ANALGESIC AGENTS: OPIOIDS – Transmucosal System *

| NO PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|

| | |
|---|---|
| | ABSTRAL® (fentanyl)<br>FENTANYL CITRATE (generic of Actiq®)<br>FENTORA® (fentanyl)<br>SUBSYS® (fentanyl) |

* Note: Clinical criteria must be met for transmucosal systems

**Dosage and Administration**
There are numerous narcotic analgesics, please refer to the package insert of your drug of interest for information on appropriate dosage and administration.

**Product Availability**
There are numerous narcotic analgesics, please refer to the package insert of your drug of interest for product availability information.

**References**
1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. JAMA. 2016 Apr 19; 315(15):1624-45.
2. Initial and Continued Approval follow-up periods based on the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain – 2016. http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf
3. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. J Addict Med. 2015 Sep-Oct;9(5):358-67.
4. FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning: Issued 9/20/17.
5. Governor's Cabinet Opiate Action Team: Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point"
6. 131st General Assembly Senate Bill 319 amendments to ORC Section 1751.691 (November 2017)

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| New policy | 9/17 | |
| Added sections for Combination of opioid and benzodiazepine.<br>Added FDA Safety Communication | 1/18 | |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| Added to Policy/Criteria: A "soft stop" edit will be placed on concomitant opioid analgesics and benzodiazepine use that can be overridden by the Pharmacist at the local pharmacy if it is medically necessary the member be treated with both medications. Prior authorization will be required if the Pharmacist does not deem treatment is medically necessary for concomitant use of opioid analgesics and benzodiazepines.<br>Updated references. | | |
| Added description of acute and sub-acute therapy restrictions, including definitions of opioid naïve patients for acute and sub-acute therapy.<br>Removed limit of 14 day supply of short-acting opioids in a 45 day period.<br>For initial approval criteria, added requirement that provider indicate previous opioid therapy if patient is opioid naïve.<br>For initial and continued approval criteria, added requirement that provider discuss the risks and benefits of opioid therapy with the patient. | 6/18 | |
| Annual Review – no changes deemed necessary | 07/19 | |
| Policy revised and renamed per ODM for single PDL | 10/19 | |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory

requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.