UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Short-Acting Opioid Products- OHIO

Program	Prior Authorization/Medical Short-Acting Necessity – Short-Acting Opioid Products- OHIO
Medication	**Short-Acting Opioids:** **Includes both brand and generic versions of the listed products unless otherwise noted:** All salt forms, single and combination ingredient products, and all brand and generic formulations of the following: Butorphanol nasal spray, codeine, morphine, hydrocodone, hydromorphone, oxycodone, oxymorphone, pentazocine, tramadol, tapentadol, meperidine, levorphanol tartrate, dihydrocodeine
Markets in Scope	Ohio

(i) Background:

The CDC and the American Academy of Neurology recommends the following best practices in the prescription of opioids:

- Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain.
- Before starting opioid therapy, treatment goals should be established with patients that include realistic goals for pain and function and should consider how therapy will be discontinued if benefits do not outweigh risks. Track pain and function at every visit (at least every 3 months) using a brief, validated instrument. Continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended release/long-acting opioids.
- Document the daily morphine equivalent dose (MED) in mg/day from all sources of opioids. Access the state prescription drug monitoring program (PDMP) data at treatment initiation and periodically during treatment. Currently all states except for Missouri have a PDMP.
- To avoid increased risk of respiratory depression, long-acting opioids should not be prescribed concurrently with benzodiazepines. Screen for past and current substance abuse and for severe depression, anxiety, and PTSD prior to initiation.
- Use random urine drug screening prior to initiation and periodically during treatment with a frequency according to risk.
- Use a patient treatment agreement, signed by both the patient and prescriber that addresses risks of use and responsibilities of the patient.
- Methadone should not be the first choice for a long-acting opioid. Only clinicians who are familiar with methadone's unique risk profile and who are prepared to

educate and closely monitor their patients should consider prescribing methadone for pain.

- CDC recommends avoiding escalating doses above 50-90 mg/day MED unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist. A list of MED for the long-acting opioids is available in Table 1.
- The American Academy of Neurology recommends avoiding escalating doses above 80-120 mg/day MED unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist. A list of MED for the long-acting opioids is available in Table 1.
- Clinicians should evaluate benefits and harms of continued therapy at least every 3 months. If benefits do not outweigh harms, opioids should be tapered and discontinued. Evaluation should include assessment of substance use disorder/opioid dependence. Validated scales (such as the DAST-10) are available at www.drugabuse.gov.

Table 1. CDC Recommended Opioid Maximum Morphine Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses	60 MED equivalent (mg/day) (non treatment naïve)
Morphine	None	60mg
Hydromorphone	None	15mg
Hydrocodone	None	60mg
Tapentadol	600mg IR products	149mg
Tramadol IR	400mg IR products	600mg
Oxymorphone	None	20mg
Oxycodone	Xtampza Only =288mg	40mg
Codeine	360mg	396mg
Pentazocine	None	161mg
Meperidine	600mg	594mg
Butorphanol	None	8.5mg

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

Max MED is the maximum dose per day based on morphine equivalent dose allowed without consultation or prescription by a pain specialist. Max MED is based upon the CDC guidelines and adjusted for currently available product strengths. Fentanyl is dosed in mcg/hr rather than mg/day.

(ii) Short Acting Opioids: Criteria for Quantity Limits and Days Supply Limits for New Patients

NOTE: A new patient is defined as a patient with a claim history showing less than 90 days cumulative supply of opioids in the last 120 days. Prior authorization will be required for any of the following:

- **Prescription is greater than a 7 days supply**
- **The patient has exceeded 14 days of total opioid therapy in a rolling 45-day window**

A. <u>ONE</u> of the following:

1. **BOTH** <u>of the following:</u>
   a. Patient has one of the following conditions: active cancer treatment, palliative care, end-of-life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, or major orthopedic surgery.

   -AND-

   b. If the request is for a non-preferred medication the patient must have a history of failure, contraindication or intolerance to a trial of at least **<u>three</u>** preferred short-acting opioids.

   Authorization will be issued for the requested duration of therapy, not to exceed 90 days.

   -OR-

2. **ALL** <u>of the following:</u>
   a. Prescriber has attested that the patient is not opioid naïve.

   -AND-

   b. Non-pharmacologic treatment and/or non-opioid analgesics are ineffective or contraindicated.

   -AND-

   c. Diagnosis of somatic or visceral type pain.

   -AND-

   d. Benefits and risks of opioid therapy have been discussed with patient.

   -AND-

   e. Prescriber has attested that he/she has checked Ohio Automated Rx Reporting System (OARRS).

   -AND-

f. If the request is for a non-preferred medication the patient must have a history of failure, contraindication or intolerance to a trial of at least **three** preferred short-acting opioids.

Authorization will be issued for the requested duration of therapy, not to exceed 90 days.

(iii) Short Acting Opioids: Criteria for Quantity Limits

- **Maximum dose per day exceeding 60 MED per product**

A. ONE of the following:

1. **ALL** of the following:
   a. Patient has one of the following conditions: active cancer treatment, palliative care, end-of-life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, or major orthopedic surgery.

-AND-

   b. The requested dose cannot be achieved by moving to a higher strength of the product.

-AND-

   c. The requested dose is within FDA maximum dose per day, where an FDA maximum dose per day exists (see table).

-AND-

   d. If the requested drug contains acetaminophen, the requested dose does not exceed four grams of acetaminophen per day.

-AND-

   e. If the requested drug contains ibuprofen, the requested dose does not exceed 3200mg of ibuprofen per day.

-AND-

   f. If the requested drug contains aspirin, the requested dose does not exceed 2080mg of aspirin per day.

-AND-

g. If the request is for a non-preferred medication the patient must have a history of failure, contraindication or intolerance to a trial of at least **three** preferred short-acting opioids.

Authorization will be issued for the requested duration of therapy, not to exceed 90 days.

-OR-

2. **ALL** of the following:
   a. Prescriber has attested that the patient is not opioid naïve.

-AND-

   b. Non-pharmacologic treatment and/or non-opioid analgesics are ineffective or contraindicated.

-AND-

   c. Diagnosis of somatic or visceral type pain.

-AND-

   d. Benefits and risks of opioid therapy have been discussed with patient.

-AND-

   e. Prescriber has attested that he/she has checked Ohio Automated Rx Reporting System (OARRS).

-AND-

   f. The requested dose cannot be achieved by moving to a higher strength of the product.

-AND-

   g. The requested dose is within FDA maximum dose per day, where an FDA maximum dose per day exists (see table).

-AND-

   h. If the requested drug contains acetaminophen, the requested dose does not exceed four grams of acetaminophen per day.

-AND-

i. If the requested drug contains ibuprofen, the requested dose does not exceed 3200mg of ibuprofen per day.

-AND-

j. If the requested drug contains aspirin, the requested dose does not exceed 2080mg of aspirin per day.

-AND-

k. If the request is for a non-preferred medication the patient must have a history of failure, contraindication or intolerance to a trial of at least **three** preferred short-acting opioids.

Authorization will be issued for the requested duration of therapy, not to exceed 90 days.

(iv) References:

1. Avinza Prescribing Information. Pfizer, Inc. April 2014.
2. Embeda Prescribing Information. Pfizer Inc. October 2014
3. Exalgo Prescribing Information. Mallinckrodt, Inc. June 2014.
4. Hysingla ER Prescribing Information. Purdue Pharma. February 2015.
5. Kadian Prescribing Information. Actavis Elizabeth LLC. April 2014.
6. MS Contin Prescribing Information. Purdue Pharma. June 2014.
7. Nucynta ER Prescribing Information. Janssen Pharmaceuticals. April 2014.
8. Opana ER Prescribing Information. Endo Pharmaceuticals. April 2014.
9. OxyContin Prescribing Information. Purdue Pharma, August 2015.
10. Zohydro ER Prescribing Information. Zogenix Inc. August 2014.
11. Martell, Bridget A., Patrick G. O'Connor, Robert D. Kerns, William C. Becker, Knashawn H. Morales, Thomas R. Kosten, and David A. Fiellin. Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction. Annals of Internal Medicine 2007;146: 116-127.
12. Kalso, Eija. Opioids for Persistent Non-Cancer Pain. Editorial. BMJ 22 Jan. 2005.
13. "Low Back Pain Guidelines." Pharmacist's Letter/Prescriber's Letter 2007; 23(12):2312009.
14. Chou, Roger, Amir Quaseem, Vincenza Snow, Donald Casey, Thomas Cross Jr., Paul Shekelle, and Douglas Owens. Clinical Guidelines: Diagnosis and Treatment of Low Back Pain: a Joint Clinical Practice Guideline From the American College

of Physicians and the American Pain Society. Annals of Internal Medicine 2007;147: 478-491. 20 May 2008 <www.annals.org>.
15. "WHO's Pain Ladder." World Health Organization Cancer. World Health Organization. 30 May 2008 <www.who.int/cancer/palliative/painladder/en/>.
16. "NCCN Practice Guidelines in Oncology." NCCN Practice Guidelines in Oncology -V.1.2008 Adult Cancer Pain. 6 May 2008. National Comprehensive Cancer Network. 02 June 2008 <http://www.nccn.org/professionals/physician_gls/PDF/pain.pdf>.
17. Marcus DA. Treatment of Nonmalignant Chronic Pain. Am Fam Physician. 2000;61:1331-8, 1345-6.
18. Zenz M, Strumpf M, Tryba M. Long-term oral opioid therapy in patients with chronic nonmalignant pain. J Pain Symptom Manage. 1992;7:69-77.
19. Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for management of opioid therapy for chronic pain. Washington (DC): Veterans Health Administration, Department of Defense;2003.
20. Trescot AM, Boswell MV, Atluri SL, Hansen HC, et al. Opioid Guidelines in the management of Chronic Non-Cancer Pain. Pain Physician. 2006;9:1-40.
21. Franklin GM. Opioids for chronic noncancer pain. A position paper of the American Academy of Neurology. Neurology. 2014;83:1277-1284.
22. Rosenquist EWK. Overview of the treatment of chronic pain. UptoDate. October 2014. http://www.uptodate.com/contents/overview-of-the-treatment-of-chronic-pain?source=search_result&search=long+acting+opioids&selectedTitle=1%7E150#H1
23. Dworkin RH, O'Connor AB, Backonja M, et al. Pharmacologic management of neuropathic pain: evidence-based recommendations. Pain. 2007;5;132(3):237-251.
24. Argoff CE, Silvershein DI. A Comparison of Long- and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet Patient Needs. Mayo Clin Proc. 2009;84(7):602-612.
25. Mercadante S, et al. Opioid switching from and to tapentadol extended release in cancer patients: conversion ratio with other opioids. Curr Med Res Opin. 2013 Jun;29(6):661-6. doi: 10.1185/03007995.2013.791617
26. Hale ME, et al. Efficacy and Safety of OPANA ER (Oxymorphone Extended Release) for Relief of Moderate to Severe Chronic Low Back Pain in Opioid-Experienced Patients: A 12-Week, Randomized, Double-blind, Placebo-controlled Study. J Pain. 2007. 8(2):175-184.
27. Palermo T, et al. Assessment and management of children with chronic pain. A position statement from the American Pain Society. 2012. Available at: http://americanpainsociety.org/uploads/get-involved/pediatric-chronic-pain-statement.pdf
28. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. Published online March 15, 2016.
29. Methadone prescribing information. CorePharma, LLC. June, 2015.
30. Fentanyl transdermal prescribing information. Mallinckrodt, Inc. October, 2014.
31. Xtampza ER prescribing information. Collegium Pharmaceuticals, Inc. April 2016.

32. Franklin GM. Opioids for chronic non-cancer pain. A position paper of the American Academy of Neurology. Neurology. 2014;83: 1277-1284.
33. Rosenquist EWK. Overview of the treatment of chronic pain. UptoDate. October 2014. http://www.uptodate.com/contents/overview-of-the-treatment-of-chronic-pain?source=search_result&search=long+acting+opioids&selectedTitle=1%7E150#H1
34. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. Published online March 15, 2016.
35. Mercadante S, et al. Opioid switching from and to tapentadol extended release in cancer patients: conversion ratio with other opioids. Curr Med Res Opin. 2013 Jun;29(6):661-6. doi: 10.1185/03007995.2013.791617
36. Hale ME, et al. Efficacy and Safety of OPANA ER (Oxymorphone Extended Release) for Relief of Moderate to Severe Chronic Low Back Pain in Opioid-Experienced Patients: A 12-Week, Randomized, Double-blind, Placebo-controlled Study. J Pain. 2007. 8(2):175-184.

Program	Prior Authorization - Short-Acting Opioid Pain Medications-OHIO
Change Control	
Date	Change
10/2017	Created Ohio specific policy since they will not be going live with the UPC 90 MED edit on 10/1/17. Updated methadone max daily MED. Added Ohio specific criteria for short-acting opioids.
10/2017	Updated methadone daily max MED in background. Updated SAO and LAO Max MED for certain products that either do not have long or short acting MED requirements.
1/2018	Separated short-and long-acting opioids into individual policies. Updated background. Added butorphanol to medications section and MED table.
3/2018	Updated background and references.