

### Clinical Pharmacy Program Guidelines for Short-Acting Opioid Products –ARIZONA

Program	Prior Authorization/Medical Necessity – Short-Acting Opioid Products
Medication	<p><b><u>Short-Acting Opioids:</u></b>  <b>Includes both brand and generic versions of the listed products unless otherwise noted:</b></p> <p><b>Preferred products:</b> hydromorphone liquid/suppository/tablets, meperidine tablets, morphine sulfate solution/suppository/tablets, oxycodone capsules/concentrate/solution/tablets, tramadol tablets, acetaminophen with codeine solution/tablets/suspension, butalbital-acetaminophen-caffeine with codeine capsules, butalbital- aspirin- caffeine with codeine capsules, hydrocodone/acetaminophen solution/tablets, hydrocodone-ibuprofen tablets, oxycodone with acetaminophen solution/tablets, oxycodone-ibuprofen tablets, codeine tablets, pentazocine with naloxone tablets, oxycodone with aspirin tablets</p> <p><b>Non-preferred products:</b> levorphanol tablets, oxymorphone tablets, tapentadol tablets, acetaminophen-caffeine-dihydrocodeine capsules, aspirin-caffeine-dihydrocodeine capsules, meperidine with promethazine capsules, tramadol with acetaminophen tablets, meperidine oral solution, oxycodone abuse deterrent tablets, opium suppository, butorphanol nasal spray</p>
Markets in Scope	Arizona

**(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](http://www.drugabuse.gov).

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

Active Ingredient	FDA Label Max Daily Doses	90 MED equivalent (mg/day) (non treatment naïve)
Morphine	None	90mg
Opium	None	90mg
Hydromorphone	None	22.5mg
Hydrocodone	None	90mg

Tapentadol	600mg IR products	225mg
Oxymorphone	None	30mg
Oxycodone	None	60mg
Codeine	360mg	600mg
Pentazocine	None	243mg
Tramadol	400mg IR products	900mg
Meperidine	600mg	900mg
Butorphanol nasal	None	12.8mg

\*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.

Members under 18 years of age

A prescriber shall limit the **initial and refill** prescriptions for any short-acting opioid medication for a member under 18 years of age to no more than a 5-day supply.

An **initial** prescription for a short-acting opioid medication is one in which the member has not previously filled any prescription for a short-acting opioid medication within 60 days of the date of the pharmacy filling the current prescription as evidenced by the member’s Pharmacy Benefit Management (PBM) prescription profile.

Members 18 years of age and older

A prescriber shall limit the **initial** prescription for any short-acting opioid medication for a member 18 years of age and older to no more than a 5-day supply.

An **initial** prescription for a short-acting opioid medication is one in which the member has not previously filled any prescription for a short-acting opioid medication within 60 days of the date of the pharmacy filling the current prescription as evidenced by the member’s Pharmacy Benefit Management (PBM) prescription profile.

**Coverage Criteria:**

**(ii) Short-Acting Opioids: Criteria for Days Supply Limit Reviews**

**A. Members under 18 years of age- Exception Criteria for 5-day Initial and Refill Supply Limitation**

1. The **initial and refill** prescription 5-day supply limitation for short-acting opioid medications *does not* apply to prescriptions for the following conditions and care instances:

- a. Active oncology diagnosis
- b. Hospice care
- c. End-of-life care (other than hospice)

- d. Palliative care
- e. Children on opioid wean at time of hospital discharge
- f. Skilled nursing facility care
- g. Traumatic injury, excluding post-surgical procedures
- h. Chronic conditions for which the provider has received PA approval
- i. Post-surgical procedures

NOTE: If the short-acting opioid is being requested for post-surgical procedures, the initial prescription is limited to no more than a 14-day supply and refills are limited to no more than a 7-day supply.

**-AND-**

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

**Authorization will be issued for:**

- **12 months: Active Oncology Diagnosis, Skilled nursing facility care**
- **6 months: Hospice care, End-of-Life Care (other than hospice), Palliative care, Chronic conditions for which the provider has already received PA approval**
- **3 months: Traumatic injury, excluding post-surgical procedures**
- **1 month: Children on an opioid wean at time of hospital discharge**
- **Post-surgical procedures: Initial prescription is limited to no more than a 14-day supply and refills are limited to no more than a 7-day supply**

**B. Members 18 years of age and older- Exception Criteria for 5-day Initial Supply Limitation**

**NOTE: This section applies to members who are opioid-naïve. If a member is new to plan but the physician has attested that the patient is NOT opioid-naïve than the initial 5-day supply limit would NOT apply.**

1. The **initial** prescription 5-day supply limitation for short-acting opioid medications *does not* apply to prescriptions for the following conditions and care instances:

- a. Active oncology diagnosis
- b. Hospice care
- c. End-of-life care (other than hospice)
- d. Palliative care
- e. Skilled nursing facility care
- f. Traumatic injury, excluding post-surgical procedures
- g. Chronic conditions for which the provider has received PA approval
- h. Post-surgical procedures

NOTE: If the short-acting opioid is being requested for post-surgical procedures, the initial prescription is limited to no more than a 14-day supply.

**-AND-**

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

**Authorization will be issued for:**

- **12 months: Active Oncology Diagnosis, Skilled nursing facility care**
- **6 months: Hospice care, End-of-Life Care (other than hospice), Palliative care, Chronic conditions for which the provider has already received PA approval**
- **3 months: Traumatic injury, excluding post-surgical procedures**
- **Post-surgical procedures: Initial prescription is limited to no more than a 14-day supply and refills are limited to no more than a 7-day supply**

**(iii) Short-Acting Opioids: Criteria for Quantity Limit Reviews**

**A. Quantity Limit Requests (MDD)**

**ALL** of the following:

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

**-AND-**

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

**-AND-**

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

**-AND-**

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

**-AND-**

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

**-AND-**

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

**Authorization will be issued for 12 months.**

## **APPENDIX**



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310-V-3 ICD-10-CM E

### **(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.

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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](http://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/](http://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](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](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](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.
- 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: 10.1185/03007995.2013.79161736. 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-Arizona
<b>Change Control</b>	
Date	Change
3/2017	New policy for Long-Acting Opioids for Arizona.
4/2017	Updated language throughout to clarify which diagnoses are applicable to each section. Updated quantity limit review criteria.
5/2017	Added Arymo to the policy. Removed the statement regarding use for an FDA approved age range for members under the age of 18 years. Defined a look-back period for the short-acting opioid trial



	in the long-acting opioid section. Updated authorization duration language. Updated excluded diagnoses to cancer, hospice care and end-of-life care (non hospice).
6/2017	Updated prescriber requirement language in the Non-cancer pain/Non-hospice care or end-of-life care (other than hospice)-related pain quantity limit section.
9/2017	Added Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), and Vantrela ER (hydrocodone bitartrate extended-release), opium and butorphanol nasal spray to the policy. Combined SAO and LAO into one policy. Updated methadone daily max MED.
10/2017	Updated the SAO edit to a 5-days supply instead of a 7-days supply.
10/2017	Updated methadone daily max MED in background. Removed tramadol ER from long acting quantity limit review section. Removed note regarding tramadol ER listed under the medications section. Updated preferred products.
1/2018	Separated short-and long-acting opioids into individual policies. Added maximum dosage for tapentadol. Updated background.
2/2018	Updated background. No changes to clinical intent.