



Prescribing Guidelines for Pennsylvania

A grayscale photograph of a person's back and shoulder, with their hand resting on their lower back. A red glow highlights the area of the lower back, indicating pain.

TREATING CHRONIC NON-CANCER PAIN

Chronic pain is a major health problem in Pennsylvania and throughout the United States, with nearly one-third of the U.S. population suffering from pain at any given time. Research shows, chronic pain is more common in women than men and the incidence of chronic pain increases with age. Chronic pain results in significant health care expenditures and lost productivity, and the harm caused to the individual, their family and society is significant.

Pennsylvania has experienced an alarming rise in drug overdose deaths in recent years. In 2016,

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4,642 individuals were reported to have died from an opioid overdose. This equates to approximately 13 individuals a day across the Commonwealth and represents a 37 percent increase over 2015 deaths. Pennsylvania's overdose death rate is more than twice the national average, with rural counties experiencing greater increases over urban counties. Ninety percent of the 20 Pennsylvania counties with the highest drug overdose death rates are rural, and recent data indicate that the drug overdose rate in Pennsylvania continues to rise.



The original guideline on the use of opioids to treat chronic noncancer pain was published in 2014. This update is intended to reflect changes in best practices that have been developed since the publication of the original guidelines. These guidelines do not address the use of opioids for acute pain, nor do they address the use of opioids for the treatment of pain at the end-of-life. Proper treatment of chronic pain includes an interdisciplinary and multi-model approach that is tailored to help the patient control pain and relieve suffering. Treatments for chronic pain may include physical therapy, acupuncture, osteopathic or chiropractic manipulative treatment, cognitive-behavioral therapy, proper use of medications from several drug classes and other focused interventions. Selection of treatment options should be based on completion of a careful history and physical examination, use of medically-indicated tests, followed by the establishment of a diagnosis and treatment plan that includes goals of care. Specific treatment options should be based on best evidence whenever possible.

Non-Opioid Treatment Options

A detailed review of non-opioid treatment options goes beyond the scope of this document. Non-opioid medication options include careful use of acetaminophen, non-steroidal anti-inflammatory medications, anti-seizure medications (such as gabapentin, pregabalin, oxcarbazepine, topiramate and others), tricyclic antidepressants, serotonin-norepinephrine reuptake inhibitors and transdermal local anesthetics. In addition, there is growing interest in the use of cannabinoids for the treatment of a variety of chronic pain conditions. It is important to note that non-opioid analgesics confer sustained pain relief that is as good or better than that associated with chronic opioid administration.

Cognitive-behavioral therapy and mindfulness-based therapy can be very effective as these therapies can provide improved symptom control, physical functioning, adaptive coping and self-

efficacy. It is important to note that patients with chronic pain commonly experience depression and anxiety. Appropriate treatment of comorbid depression and anxiety can improve biopsychosocial functioning. Attempts to treat pain without treating these psychosocial comorbidities of pain are not likely to lead to improved pain control.

Activating physical therapy, including aquatic therapy, is a critical component in improving pain control and physical functioning in most patients. Massage therapy may be effective in some patients. Supportive modalities such as yoga and Tai Chi may be very effective in improving pain and physical functioning in some patients.

Interventional therapy, such as epidural steroid injections, radiofrequency procedures and spinal cord stimulation, can provide effective pain relief in patients experiencing specific pain disorders. Interventional therapy may allow for improved pain relief that can facilitate participation in activating physical therapy, aquatic therapy and life style changes that may lead to sustained improvement in pain control and physical functioning.

Palliative care involves the management of symptoms in the setting of any serious illness. The focus of palliative care is on improving the quality of the person's life. Palliative care is appropriate for anyone facing a serious medical condition, regardless of his or her prognosis, care goals or function. Hospice is one subtype of palliative care. Interdisciplinary teams of experts use a holistic approach, providing care services to patients whose goals are exclusively focused on comfort when their expected prognoses are shorter than six months. Within the context of palliative care, it is important to note that serious illness and substance use disorders can co-exist, and care of patients with advanced disease and addiction can be challenging and goes beyond the scope of this guideline.

The included guidelines address the use of opioid pain medication for chronic noncancer pain. They are intended to help healthcare providers improve



patient outcomes and to supplement, but not replace, the individual provider's clinical judgment.

It is recommended that providers review other evidence-based guidelines and the Pennsylvania State Guidelines on various medical subspecialties and patient populations, pharmacy guidelines, and dental guidelines, which may provide insight into treatment options for these populations. **In addition, given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease.**

Practice Recommendations

Clinicians should incorporate the following key practices into their care of the patient receiving opioids for the treatment of chronic noncancer pain:

Initial Evaluation:

1. Before initiating chronic opioid therapy, clinicians should conduct and document a history that includes a detailed review of the patient's pain experience, with a well-documented physical examination.
 - a. Patient evaluation should include careful assessment for co-existing psychiatric and other disorders, including depression, anxiety disorders and sleep disorders.
 - b. Patient evaluation should include careful assessment for past and current substance use disorder, as well as risk assessment for development of aberrant drug-related behavior following chronic opioid administration. The use of validated screening tools (such as the NIDA Drug Use Screening Tool: Quick Screen or the Brief Screener for Alcohol, Tobacco and other Drugs (BSTAD)) may facilitate patient assessment for substance use disorder and risk for aberrant drug-related behavior.
 - c. Patient evaluation should include careful assessment for conditions that increase the risk of harm from chronic opioid administration, including sleep-disordered breathing (obstructive sleep apnea and central sleep apnea), co-existing pulmonary disease, and concurrent use of centrally-acting sedating medications, such as benzodiazepines.
 - d. Patient evaluation should include documentation of current medications, allergies, and past medical history.
2. Appropriate testing to confirm the underlying diagnosis should be completed before starting chronic opioid therapy. Selection of necessary tests should be based on best evidence regarding the use of specific tests (including radiological studies) that are indicated for evaluation of the individual patient's signs and symptoms.
3. A urine drug screen should be obtained and reviewed before initiating chronic opioid therapy. In addition, Pennsylvania state law requires clinicians to obtain and review a report from the Prescription Drug Monitoring Program (PDMP) before prescribing all controlled substances. Care should be taken to obtain PDMP data from all relevant states, which usually can be accomplished through the Pennsylvania PDMP program.
4. Medical records from past health care, including the results of relevant laboratory and radiological studies, should be obtained and reviewed, as they often are a valuable source of information



regarding past care, including response to medications, specifically opioids.

5. The initial patient evaluation should include documentation of a diagnosis, treatment plan and goals of therapy. Goals of therapy should be specific and measurable, and should be integrated into ongoing patient monitoring throughout treatment.

Initiation of Therapy:

1. Initial treatment with opioids should be considered by clinicians and patients as a therapeutic trial to determine whether chronic opioid therapy is appropriate. Both clinicians and patients should understand that chronic opioid therapy is not effective for all patients, either due to lack of efficacy or the development of unacceptable adverse events, including aberrant drug-related behavior.
2. When starting chronic opioid therapy, the clinician should discuss the risks and potential benefits associated with treatment, so that the patient can make an informed decision regarding treatment. Reasonable goals and expectations for treatment should be agreed upon, and the patient should understand the process for how the care will be provided. Patients should be instructed on proper storage and disposal of controlled substances. Clinicians should advise patients on the necessity of periodic compliance checks that will include urine or saliva drug testing and pill counts. Clinicians should document this discussion and the patient's agreement with the treatment plan with a signed opioid treatment agreement.
3. Opioid selection, initial dosing and dose adjustments should be individualized according to the patient's health status, previous exposure to opioids, response to treatment (including attainment of established treatment goals) and predicted or observed adverse events.
 - a. Clinicians should clearly document the prescribed daily opioid dose, and calculate and document the oral morphine equivalent daily dose (commonly referred to as MME or MEDD). Risk of serious adverse events, including death, increase with higher doses of MEDD and MEDD above 90 mg/ day have not been demonstrated to confer improvements in pain control, while doses above 90 mg/ day MEDD are associated with significantly increased risk of harm.
 - b. Opioids should not be administered concurrently with benzodiazepines except in rare cases where the risk of harm is outweighed by the benefits of administering both medications. Concurrent use is associated with a significant increased risk of serious adverse events, including death. When used in combination, justification for this use should be clearly documented.
 - c. Caution should be used in patients at high risk for harm with chronic opioid therapy, including those with sleep-disordered breathing and co-existing significant respiratory disease. Clinicians should consider starting at a lower dose, titrating slowly, using a longer dosing interval and monitoring more frequently.
 - d. Caution should be used with the administration of methadone, as the administration of methadone for the treatment of chronic pain is associated with increased risk of harm. Clinicians and patients should be aware that methadone has prolonged pharmacokinetics, such that steady-state



levels are not achieved until 7 - 10 days of consistent dosing. Therefore, rapid dose changes are associated with increased risk of overdose and death. Clinicians should strongly consider obtaining a baseline QTc interval measure via electrocardiogram (ECG) before starting methadone therapy, then monitoring QTc interval following any methadone dose adjustment, or following the addition of or dose adjustment of any other medication that is known to prolong the QTc interval.

- e. When chronic opioid therapy is used for an elderly patient, clinicians should consider starting at a lower dose, titrating slowly, using a longer dosing interval and monitoring more frequently.
4. Caution should be used with the administration of chronic opioids in women of childbearing age, as chronic opioid therapy during pregnancy increases risk of harm to the newborn. Opioids should also be administered with caution in breastfeeding women, as most opioids are transferred to the baby in breast milk. Clinicians should consider routinely obtaining urine or blood pregnancy tests to allow for coordination of care with the patient and the patient's obstetrician early in pregnancy, should pregnancy during chronic opioid therapy occur. Continuation of opioids during pregnancy confers increased risk of harm to the developing fetus and newborn.
5. Naloxone should be prescribed to patients who are at increased risk for compromise of ventilation with chronic opioid therapy. This includes patients receiving daily opioid doses above 50 mg / day MEDD, patients also taking benzodiazepines or other centrally-acting sedating medications, patients at risk for or who have been diagnosed with sleep disordered

breathing, and those patients with moderate or severe concurrent respiratory disease. In addition, consideration should be given to prescribing naloxone to patients with coexisting psychiatric conditions as well as those patients with a history of any substance use disorder, including tobacco use disorder.

Care During Chronic Opioid Therapy:

1. Ongoing monitoring during chronic therapy is guided by periodic clinician-patient interactions. During these interactions, a careful assessment of the patient's response to therapy should be completed and documented. This assessment should include careful assessment for adverse events associated with therapy, including the presence of aberrant drug-related behavior. Clinician-patient interactions should occur at a frequency that is medically indicated for the individual patient, but should be completed at least every three months.
 - a. Monitoring should include documentation of response to therapy (pain intensity; physical and mental functioning, including activities of daily living; and assessment of progress toward achieving therapeutic goals), presence of adverse events, and adherence to prescribed therapies.
 - b. Clinicians should consider increasing the frequency of ongoing monitoring, as well as referral for specialty care, including pain medicine, sleep medicine, psychology, psychiatry and addiction medicine for patients who may require these services. Initiation and continuation of chronic opioid therapy may need to be contingent upon participation in specialty care in patients identified to be at high risk for treatment failure and/or harm absent such care.



- c. It is not appropriate to refer patients receiving chronic opioid therapy to the emergency department to obtain prescriptions for opioids.
2. Total daily opioid doses above 90 mg / day MEDD is not associated with improved pain control, but is associated with a significant increase in risk of harm. Therefore, clinicians should carefully consider if doses above 90 mg / day MEDD are indicated. Consultation for specialty care may be appropriate for patients receiving high daily doses of opioids. Rare exceptions can be made for patients already on high dose opioid therapy chronically who have proven to benefit from the dose, tolerate it, and show no aberrant drug-related behaviors. A discussion about decreasing to 90 mg / day MEDD should occur, however, to limit the possibility of opioid-induced hyperalgesia and other adverse events, especially in those who are not clearly benefitting.
3. Clinicians should carefully monitor patients for aberrant drug-related behaviors through completing a query of the PDMP before prescribing any controlled substance. The clinician should carefully document any abnormal findings, and document what changes, if any, these abnormal results will have on the patient's treatment plan. The literature supports the use of multiple tools[^], including:
 - a. Periodic urine drug screens, which should be completed at least annually. Clinicians should strongly consider use of an assessment method, such as mass spectrometer analysis, over less precise measures, such as immune assays, to ensure sufficient accurate data are available to guide clinical decision-making.
 - b. Periodic pill counts.
 - c. Query of the PDMP, which must be completed each time a controlled substance is prescribed.
4. When a dose of chronic opioid therapy is initiated or increased, the clinician should provide counseling to the patient on the risk of cognitive impairment that can adversely affect the patient's ability to drive or safely do other activities. The risk of cognitive impairment is increased when opioids are taken with other centrally acting sedatives, including alcohol and benzodiazepines.

Discontinuation of Chronic Opioid Therapy:

1. In patients who have engaged in aberrant drug-related behaviors, clinicians should carefully determine if the risks associated with chronic opioid therapy outweigh documented benefit. Clinicians should consider restructuring therapy (frequency or intensity of monitoring), referral for assistance in management, or discontinuation of chronic opioid therapy. Appropriate referral for addiction evaluation and treatment should be provided. A clinician may refer the patient to their insurance carrier or the Department of Drug and Alcohol Programs Get Help Line at 1-800-662-4357 (HELP) or www.DDAP.PA.GOV
2. Clinicians should discontinue chronic opioid therapy in patients who engage in opioid-related behavior that poses a serious safety risk, repeated aberrant drug-related behaviors, behaviors consistent with substance use disorder, behaviors consistent with non-medical use or diversion, or who demonstrate no progress toward meeting therapeutic goals, or experience intolerable adverse effects. Clinicians should use careful clinical judgment to determine if opioids should be rapidly discontinued, or if opioids should be slowly tapered. If the decision is made between



provider and patient to taper, tapering plans should be individualized and should minimize symptoms of withdrawal. Providers should refer to the CDC's Pocket Guide for Tapering Opioids for Chronic Pain. Rapid discontinuation of opioids should be reserved only for those patients engaged in addiction, diversion, or when continuation of opioids poses risk of harm.

- a. Patients with symptoms of substance use disorder, including opioid use disorder, should have a facilitated referral for addiction specialty evaluation and treatment. These patients should not be discharged from the practice absent proper referral. A clinician can refer the patient to their insurance carrier or local county drug and alcohol program if the patient is uninsured or underinsured. Contact information for making a referral to the local county drug and alcohol program can be found [here](#).
3. Clinicians should be aware of and understand current federal and state laws, regulatory guidelines and policy statements that govern the use of chronic opioid therapy for chronic non-cancer pain.

Resources

Centers for Disease Control and Prevention. Pocket Guide: Tapering Opioids for Chronic Pain.

Centers for Disease Control and Prevention. Guideline Resources: Videos. [Information on Prescriber and Patient Conversations](#)

+ Chou, R, Weimer, MB, Dana, T. Methadone overdose and cardiac arrhythmia potential: Findings from a review of the evidence for an American Pain Society and College on Problems of Drug Dependence clinical practice Guideline. *J Pain*. 2014; 15:338-365.

Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain*. 2009;10(2):113-130.

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. *JAMA*. 2016;315(15):1624-1645.

Johannes CB, Le TK, Zhou X, Johnston JA, Dworkin RH. The prevalence of chronic pain in United States adults: results of an Internet-based survey. *J Pain*. 2010;11(11):1230-1239.

National Heart Lung and Blood Institute. Evidence-based management of sickle cell disease. Expert Panel report. Washington, DC: National Institutes of Health; 2014.

Pennsylvania Medical Society, Opioid Crisis CME: <https://www.pamedsoc.org/learn-and-lead/online-cme/medications-pain-management-opioids>

Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. *Mil Med*. 2016;181(5):397-399.

Reid MC, Eccleston C, Pillemer K. Management of chronic pain in older adults. *BMJ*. 2015;350:h532.

Tuggle G. Analysis of overdose deaths in Pennsylvania, 2016. In: Agency USDE, ed. Philadelphia, PA: United States Drug Enforcement Agency; 2017.

* Vickers, Andrew J. Et al. Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis. *J Pain*. 2017.

Wisniewski AM, Purdy CH, Blondell RD. The epidemiologic association between opioid prescribing, non-medical use, and emergency department visits. *J Addict Dis*. 2008;27(1):1-11.



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