

# Pennsylvania Guidelines

on the Use of

## Opioids to Treat Chronic Noncancer Pain





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Chronic pain is a major health problem in the United States, occurring with a point-prevalence of about one-third of the US population.<sup>1</sup> More women than men experience chronic pain, and the prevalence of chronic pain increases with age. The impact of pain on individuals and society is substantial. In a recent survey, individuals reporting frequent or persistent pain within the last 3 months reported that their pain often caused problems with sleep and mood, and 32% reported not being able to work.<sup>2</sup> The economic impact of chronic pain in the United States is staggering. A recent Institute of Medicine report estimated the annual cost in the United States was \$560 to over \$600 billion, including healthcare costs (\$261-300 billion) and lost productivity (\$297-336 billion).<sup>3</sup>

Chronic pain is best treated using an interdisciplinary, multi-modal approach. The treatment team often includes the patient and his or her family, the primary care provider, a physical therapist, a behavioral health provider and one or more specialists. Patient outcomes are optimized when several treatments are used in a coordinated manner. These treatments may include activating physical therapy, cognitive-behavioral therapy, proper use of medications, and interventions when indicated. Reliance on only one medication or treatment modality can lead to inadequate pain control and increased risk of harm.

Chronic opioid therapy is a common treatment option for chronic pain, and its use has increased substantially over the last 15 years, in spite of limited evidence of safety and long-term efficacy in the general patient population. Prescription drug abuse has increased significantly over the last 15 years, and this increase has been attributed in part to the increased use of opioids to treat chronic noncancer pain.<sup>4</sup> About 6.1 million Americans abused or misused prescription drugs in 2011. Drug poisoning deaths, the vast majority of which involve prescription drugs, surpassed traffic-related accidents as the leading cause of injury-related deaths in the United States in 2009.<sup>5</sup>

Prescription opioids are now responsible for over 16,000 deaths and 475,000 Emergency Department visits a year in the United States.

These guidelines address the use of opioids for the treatment of chronic noncancer pain. 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. These guidelines are intended to help health care providers improve patient outcomes when providing this treatment, including avoiding potential adverse outcomes associated with the use of opioids to treat pain. These guidelines are intended to supplement and not replace the individual prescriber's clinical judgment. Additional detailed information may be obtained from recently published evidence based guidelines.<sup>6-8</sup>

Opioid analgesics may be necessary for the relief of pain, but improper use of opioids poses a threat to the individual and to society. Providers have a responsibility to diagnose and treat pain using sound clinical judgment, and such treatment may include the prescribing of opioids. Providers also have a responsibility to minimize the potential for the abuse and diversion of opioids. Therefore, providers should use proper safeguards to minimize the potential for abuse and diversion of opioids.

These guidelines suggest that health care providers incorporate the following key practices into their care of the patient receiving opioids for the treatment of chronic noncancer pain:

- Before initiating chronic opioid therapy, clinicians should conduct and document a history, including documentation and verification of current medications, and a physical examination. Appropriate testing should be completed before starting chronic opioid therapy. The initial evaluation should include documentation of the patient's psychiatric status and substance use history. Clinicians should consider using a valid



screening tool to determine the patient's risk for aberrant drug-related behavior.

- Opioids should rarely be used as a sole treatment modality. Rather, opioids should be considered as a treatment option within the context of multimodality therapy. Providers should recognize that high risk patients, including those with significant psychiatric co-morbidities, may require specialty care, and that chronic opioid therapy may not be possible absent needed specialty care.
- Patients at risk for obstructive sleep apnea (OSA) are at increased risk for harm with the use of chronic opioid therapy. Providers should consider the use of a screening tool for OSA, refer patients for proper evaluation and treatment when indicated, and seek to ensure patients with OSA are compliant with treatment.
- When starting chronic opioid therapy, the provider 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, including proper storage and disposal of controlled substances. Providers should proactively review the necessity of periodic compliance checks that may include urine or saliva drug testing and pill counts. Providers may wish to document this discussion through the use of an opioid treatment agreement.
- 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 will not be effective for all patients, either due to lack of efficacy or the development of unacceptable adverse events, including aberrant drug-related behavior.
- Patient's 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.
- Caution should be used in patients also taking benzodiazepines, as the use of benzodiazepines in addition to chronic opioid therapy increases the risk of serious adverse events.
- 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. Providers should be aware of the special pharmacokinetics of methadone and the need for careful dosing and monitoring.
- 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 be administered with caution in breastfeeding women, as some opioids may be transferred to the baby in breast milk.
- 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.
- Patients with co-existing psychiatric disorder(s) may be at increased risk of harm related to chronic opioid therapy. Therefore, clinicians should carefully weight the risk of harm against the potential for benefit when considering chronic opioid therapy, and if chronic opioids are used, consider careful dose selection, frequent monitoring and consultation where feasible.
- It is not appropriate to refer patients receiving chronic opioid therapy to the emergency department to obtain prescriptions for opioids.
- When a dose of chronic opioid therapy is increased, the clinician is advised to provide counseling 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.
- Total daily opioid doses above 100 mg / day of oral morphine or its equivalent 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 100 mg / day of oral morphine or its equivalent are indicated. Consultation for specialty care may be appropriate for patients receiving high daily doses of opioids.

- Clinicians should reassess patients on chronic opioid therapy periodically and as warranted by changing circumstances. 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.
- Clinicians should carefully monitor patients for aberrant drug-related behaviors. Monitoring may include periodic review of available information regarding the prescribing of opioids and other controlled substances to the patient through available databases, urine or saliva drug screening or pill counts. Consideration should be given to routine periodic urine drug screening as a monitoring tool.
- Clinicians should consider increasing the frequency of ongoing monitoring, as well as referral for specialty care, including psychological, psychiatric and addiction experts for patients identified to be at high risk for aberrant drug-related behavior.
- 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.

- Clinicians should discontinue chronic opioid therapy in patients who engage in repeated aberrant drug-related behaviors or drug abuse-diversion, experience no progress toward meeting therapeutic goals, or experience intolerable adverse effects.
- 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.

### References

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