
NORTHSTAR HEALTHCARE CONSULTING

CLINICAL COMPASS

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CHRONIC OPIOID THERAPY GUIDELINES FOR USE IN CHRONIC NONCANCER PAIN

INTRODUCTION

One of the controversies involving chronic opioid therapy (COT) involves its use in the treatment of chronic pain unrelated to active cancer. Examples of chronic noncancer pain (CNCP) conditions that warrant COT include fibromyalgia, osteoarthritis, and back pain. Proper patient assessment is required in order to provide safe and efficacious therapy that avoids opioid misuse, addiction, diversion, and mortality. The following are the most recent clinical practice guidelines provided by

the American Pain Society and the American Academy of Pain Medicine used to guide chronic opioid therapy in adults with CNCP. Included in parenthesis are separate grades for the strength of the recommendation (strong is based on the benefits of following the recommendation clearly outweighing possible harms and burdens, weak is based on weaker evidence or more closely balanced benefits to harms or burdens) and the quality of evidence (see Appendix).



PATIENT SELECTION AND ESTABLISHMENT OF RISK

Physicians must first conduct a proper patient assessment before starting COT. Included should be a history and physical, and testing for substance abuse, misuse, or addiction risk. If

CNCP is determined to be moderate or severe and has a detrimental impact on quality of life, a trial of COT may be considered by clinicians. Clinicians should conduct and document a benefit to harm assessment prior to and during COT (*recommendation: strong, evidence: low-quality*).

OPIOID MANAGEMENT PLANS

Informed consent should be obtained from patients before initiating COT. Goals, expectations, potential risks, and alternatives to opioids should be included in an ongoing discussion with the patient regarding COT (*recommendation: strong, evidence: low-quality*). A written COT management plan may be considered by clinicians in order to document patient and clinician responsibilities and expectations, and would also be helpful in educating patients (*recommendation: weak, evidence: low-quality*).

PREFERRED DRUG LIST (PDL) OPIOIDS

Listed below is the preferred drug list for opioids used in chronic therapy.

Drug	Preferred	Non-Preferred	PA	QLL
Avinza		NP	PA	QLL
Duragesic	P			QLL
Fentanyl patch generic		NP	PA	QLL
Fentora		NP	PA	QLL
Kadian	P			QLL
Morphine SA generic	P			QLL
MS Contin		NP		QLL
Opana/ER		NP	PA	QLL
Oramorph SR		NP	PA	QLL
Oxycodone ER generic		NP	PA	QLL
Oxycontin		NP	PA	QLL

P=preferred, NP=non-preferred, PA=prior authorization, QLL=quantity level limits

INITIATION AND MODIFICATION OF COT

Both clinicians and patients should consider initial opioid therapy to be on a trial basis lasting several weeks to months, during which the dosage should be adjusted to the individual patient. Should outcomes during the trial be deemed to be beneficial, a decision may be made to proceed with COT. Assessment of the patient's health, prior opioid exposure, therapeutic goals, and possibility of detriment to the patient should be the basis upon which opioid selection, dosing, and modifications are made (*recommendation: strong, evidence: low-quality*). There are currently no recommendations regarding selection of short vs. long acting opioids or dosing on an as needed vs. around the clock schedule due to lack of quality evidence. However, it has been proposed that short acting opioids may be a safer selection during opioid initiation, and transition to long acting opioids dosed around the clock may improve adherence, pain control, and lower abuse potential.

PROPER METHADONE ADMINISTRATION

Initiation and dose modifications of methadone should be made by experienced clinicians who are aware of its risks and proper use (*recommendation: strong, evidence: moderate-quality*). Characterized by a long and variable half-life, variable pharmacokinetic profile, and possibility of adverse cardiac events, methadone requires careful initiation, titration, and conversion from other opioids.

MONITORING COT

Proper COT monitoring should be characterized by recording:

- pain intensity
- level of functioning
- analysis of therapeutic goal progression
- adverse events
- proper adherence to therapy

Patient assessment should be periodically performed during COT, and also if alterations occur in the basis upon which COT is made. To ensure adherence to the plan of care, urine drug screens or other information should be gathered periodically from patients who have demonstrated or have an elevated risk of abnormal drug-related behaviors (*recommendation: strong, evidence: low-quality*). Patients on chronic opioid therapy without an elevated risk and no history of display of abnormal drug-related behaviors may be considered for periodic urine drug screens or gathering of necessary information to ensure that the plan of care is being adhered to (*recommendation: weak, evidence: low-quality*).

CONSIDERATION OF COT IN HIGH-RISK PATIENTS

If COT is being considered for patients diagnosed with CNCP who have a prior history of drug abuse, psychiatric complications, or adverse drug-related conduct then it is necessary for stricter monitoring guidelines to be administered more frequently. Conferment with a mental health or addiction specialist is strongly advised in such situations. COT in patients who display abnormal drug-related behaviors should be assessed for whether it is appropriate, requires reconfiguration, should be terminated, and whether referral for guidance in COT administration is necessary (*recommendation: strong, evidence: low-quality*). Should serious abnormal drug-related behavior or diversion be discovered by the clinician, COT should be discontinued while detoxification and withdrawal assistance are considered.

DOSE ESCALATION, HIGH-DOSE THERAPY, OPIOID ROTATION, & CONSIDERATION OF DISCONTINUATION

Clinicians should examine possible causes of frequent dose escalations and whether the benefits justify the increased risk in such situations. Clinicians should also consider reducing the dose or weaning patients off of COT by checking the patient on follow up visits, and being aware of the possible presence of the following:

- adverse effects related to opioids
- alterations in the condition of health
- altered treatment plan obedience
- no advancement towards attaining the goals of therapy
- unusual drug-related behaviors

(*recommendation: strong, evidence: low-quality*). For patients who experience unacceptable adverse effects or insufficient benefit despite dose increases, clinicians should consider opioid rotation as a potential strategy (*recommendation: weak, evidence: low-quality*).

ADVERSE EFFECTS RELATED TO OPIOIDS

Clinicians should be prepared to identify and treat adverse effects that are commonly associated with opioids such as:

- constipation
- nausea
- sedation
- pruritis
- mycolonus

(recommendation: strong, evidence: moderate-quality). Proper anticipation and treatment reduces the odds that patient will cease therapy due to intolerable adverse effects. Initiation of a bowel regimen including increased fluid and fiber intake, stool softeners, and laxatives before constipation development is recommended in the elderly and patients with additional constipation risks. There are no recommended pharmacologic therapies for opioid related sedation and exposure to other drugs and substances with sedating effects should be avoided. There is an increased possibility of respiratory depression in patients using opioids who have sleep apnea or other respiratory disorders, and therefore opioids should be initiated and titrated carefully.

USE OF PSYCHOTHERAPEUTIC CO-INTERVENTIONS

Non-opioid therapies should be used in conjunction with COT to address the possible presence of comorbidities, psychological disturbances, and altered function that may accompany CNCPP. Focus should be upon integration of psychotherapeutic interventions, functional restoration, interdisciplinary therapy, and other complementary non-opioid therapies in order to address the complexity of CNCPP as a biopsychosocial condition *(recommendation: strong, evidence: moderate-quality)*.

DRIVING AND WORK SAFETY

Clinicians should advise patients of the cognitive side effects of opioid therapy including somnolence, altered mental status, incoordination, altered concentration, and slowed reflexes that may affect driving and work safety. Patients should be instructed not to drive or participate in activities that may be dangerous if they are impaired or show signs of impairment *(recommendation: strong, evidence: moderate-quality)*.

IDENTIFYING A MEDICAL HOME & WHEN TO OBTAIN CONSULTATION

Communication and consultation among all doctors involved in the patient's care should be organized by a primary physician chosen by the patient on COT, who is responsible for the patients overall care regardless of whether or not this physician prescribes COT *(recommendation: strong, evidence: low-quality)*. This model, called a patient-centered primary care medical home, requires consultation with other professionals by the primary physician for the benefit of the patient due to the access to skills and resources that the primary physician cannot deliver *(recommendation: strong, evidence: moderate-quality)*.

BREAKTHROUGH PAIN

Following an initial and continuous scrutiny of therapeutic risk vs. benefit, clinicians may contemplate opioid use on an as-needed basis for breakthrough pain in patients on around the clock COT (*recommendation: weak, evidence: low-quality*). Assessment of breakthrough pain should be separate from baseline pain, and it may be due to advancement of the underlying condition or a separate pain condition. Due to limited evidence, there are no practice guidelines regarding treatment strategies for patients with CNCP who experience breakthrough pain.

OPIOID USE DURING PREGNANCY

Women of childbearing potential should be advised by their physician about the dangers and benefits of COT use during pregnancy and postpartum. Unless possible benefits outweigh the risks, as in severe disabling pain only controlled with opioids, COT should be used minimally or not at all during pregnancy. Should COT be used during pregnancy, clinicians should be prepared to address the additional risks posed to the mother and newborn (*recommendation: strong, evidence: low-quality*).

Neonatal risks include:

- opioid withdrawal
- low birth weight
- prolonged QT syndrome
- hypoxic ischemic brain injury
- premature birth
- neonatal death

POLICIES FOR OPIOID THERAPY

Clinicians should use available resources to take steps towards awareness of the federal and state laws, regulatory guidelines, and policies that direct the medical use of COT for CNCP (*recommendation: strong, evidence: low-quality*). While clinicians often have limited knowledge of recent laws, guidelines, and policies governing COT, they are more vulnerable to investigation or disciplinary action if they do not comply with enforced practice standards or regulations.

CONCLUSIONS

The authors believe to safely and effectively use COP for CNCP, it is essential that guidelines be created by multidisciplinary panels of experts that base the guidelines upon the best evidence available. In order balance the benefits vs. risks of COT for CNCP, opioid therapy must include patient evaluation, alignment with recognized risks, appropriate initiation and titration, monitoring at regular intervals, and expectation and management of adverse effects. While these concepts are necessary, the authors admit to the barriers of affordability and availability. However, time barriers facing clinicians in a real world setting are not mentioned. Clinicians may only be able to spend 15-20 minutes with a patient. In order for clinicians to embrace these recommendations, they must be convinced that these guidelines can be realistically implemented. Although this concept is not addressed, the guidelines do have useful, recurring themes: council patients adequately, perform regular follow ups and evaluations of efficacy and proper use, carefully initiate and titrate COT after exhausting other therapeutic alternatives, and continuously document the management plan.

APPENDIX

Listed below are the quality and criteria for the body of evidence utilized to form recommendations of strong or weak for each of the guidelines for COT. Methods used to rate the recommendations were created based upon Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group.

<u>Quality of evidence</u>	<u>Body of evidence that supports a recommendation</u>
High	<ul style="list-style-type: none">• Consistent results from well designed and conducted studies that directly assess the effects on health outcomes.• Includes at least 2 consistent, high quality, randomized controlled trials, OR• Includes multiple, consistent observational studies with no major design flaws, which shows major effects.
Moderate	<ul style="list-style-type: none">• Sufficient evidence to determine effects on health outcomes.• Strength of evidence is limited by: number, quality, size, or consistency of studies; OR indirect nature of evidence on health outcomes; OR generalizability to routine practice.
Low	<ul style="list-style-type: none">• Insufficient evidence to determine the effects on health outcomes.• Due to: limited number or quality of studies, inconsistencies among higher quality studies, study design flaws, gaps in the chain of evidence, or absence of information on important health outcomes.

REFERENCE

Chou R, Fanciullo GJ, Fine PG, et al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *J Pain*. 2009 Feb;10(2):113-130.