Opioids for Pain Management
Clinical Practice Guideline
MedStar Health

These guidelines are provided to assist physicians and other clinicians in making decisions regarding the care of their patients. They are not a substitute for individual judgment brought to each clinical situation by the patient's primary care provider-in collaboration with the patient. As with all clinical reference resources, they reflect the best understanding of the science of medicine at the time of publication, but should be used with the clear understanding that continued research may result in new knowledge and recommendations.

RATIONALE
While opioids remain an essential medication class for the management of acute and chronic pain, there is increasing awareness of and attention to their risks. Opioids are the most common prescription medications that are misused or diverted. According to the 2015 National Survey on Drug use and Health, at least 12.5 million Americans age 12 and older misused opioid pain relievers in the prior year, with hydrocodone containing products representing the opioids most likely to be misused. Further, even when taken as prescribed, any person who takes opioids for more than 30 days is at increased risk of opioid addiction. The purpose of this guideline is to improve awareness, both to providers and patients, of opioids risks and benefits, and will help to preserve the ability of providers to safely prescribe chronic opioid therapy where such therapy is appropriate.

DEFINITIONS

Acute Vs. Chronic Pain
(WHO definition http://www.who.int/medicines/areas/quality_safety/Scoping_WHOGuide_non-malignant_pain_adults.pdf?ua=1)

A commonly used definition of acute pain is pain lasting less than 30 days, and a commonly used definition of chronic pain is pain lasting more than three months. However, these definitions are arbitrary and not essential for deciding on treatment strategies. Symptoms and causes of the two types of pain may overlap and pathophysiological factors can be independent of duration. Therefore, this division between acute and chronic pain based on duration may be problematic.

Acute pain is of sudden onset, is felt immediately following injury, is severe in intensity, but is usually short-lasting. It arises as a result of tissue injury stimulating nociceptors and generally disappears when the injury heals.
Chronic pain is continuous or recurrent pain that persists beyond the expected normal time of healing. Chronic pain may begin as acute pain and persist for long periods or may recur due to persistence of noxious stimuli or repeated exacerbation of an injury. Chronic pain may also arise and persist in the absence of identifiable pathophysiology or medical illness. Chronic pain can negatively affect all aspects of daily life, including physical activities, school attendance, sleep patterns, family interactions and social relationships and can lead to distress, anxiety, depression, insomnia, fatigue or mood changes, such as irritability and negative coping behavior. As pain is an outcome of an interaction of many factors, the patient as a whole must be considered when evaluating the clinical features of pain. Therefore, a holistic approach may be required to relieve pain.

Pain Medication (analgesics) – medication whose primary function is to relieve pain and is divided into two groups: 1) opioids (narcotics) and 2) non-opioids. Opioids are used in treatment of acute and chronic pain and are indicated for severe pain or when moderate pain is disabling, when non-opioid therapy has failed, or the need for more aggressive intervention is needed.

Indications for chronic opioid use: While there is a risk of harm from any medication, the risk of harm is increased with opioids. This risk exists for the patient who is prescribed opioids, and for family members who intentionally or unintentionally have access to these medications. While it is important to identify and treat pain, it is important to balance potential benefit against risk. Because the potential for risk increases with chronic use, prescribers should exercise additional caution when prescribing opioids for chronic use. Opioids are indicated for chronic pain when: (a) pain is moderate to severe, and/or disabling; (b) aggressive intervention is warranted, or; (c) non-opioid therapy has been tried, and has failed to adequately control pain.

Physical dependence – using opioid daily for a few weeks may result in a physical dependence that manifests itself with withdrawal symptoms when stopped.

Opioid tolerance – tolerance means that the same dose of opioid gives less pain relief. Nicotine (in any form) increases opioid tolerance and craving to increase use.

Addiction – addiction is the use and/or craving of a drug despite harm to one’s quality of life, health, or social relations. A personal history of addiction or family history of addiction disorder may increase the risk. Nicotine (in any form) use increases this risk.

Withdrawal symptoms – withdrawal symptoms may include runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, body aches and/or flu like feeling. These symptoms may last 7-10 days or longer but is rarely life threatening. Certain medical conditions will also increase this risk and will need to be monitored more carefully.

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Side effects of opioids – common side effects may begin after 24-48 hours of use. Common side effects include constipation, nausea, itching, hives, drowsiness, loss of appetite, upset stomach, sweating, and dizziness. Less common side effects include difficulty urinating, feeling slowed down, sexual dysfunction, irregular menses, confusion, increased sensitivity to pain, increased pain with increased opioid dose, muscle twitching, sadness, depression, irregular heartbeat, and sleep apnea. Patients on long term opioid therapy should be prescribed an appropriate bowel regimen.

OPTIMAL OPIOID PRESCRIBING

MedStar Health endorses the CDC recommendations for prescribing opioids for chronic pain.

CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50
morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

9. Clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

* All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); see full guideline for evidence ratings.

<table>
<thead>
<tr>
<th>Opioid (oral or transdermal)</th>
<th>MME conversion Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>0.15</td>
</tr>
<tr>
<td>Fentanyl transdermal (in mcg/hr)</td>
<td>2.4</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>1</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>4</td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
</tr>
<tr>
<td>1-20 mg/day</td>
<td>4</td>
</tr>
<tr>
<td>21-40 mg/day</td>
<td>8</td>
</tr>
<tr>
<td>41-60 mg/day</td>
<td>10</td>
</tr>
<tr>
<td>61-80 mg/day or more</td>
<td>12</td>
</tr>
<tr>
<td>Morphine</td>
<td>1</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>1.5</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>3</td>
</tr>
</tbody>
</table>

**Special Populations:**

1. The elderly—elderly patients have increased sensitivity to both the therapeutic and the adverse effects (constipation, urinary retention, dry mouth and sedation) of opioid pain medications. They also are more likely to have impaired kidney function. Consequently, starting doses should be lower and escalation should be slower than for younger patients.

2. Patients with chronic kidney disease or chronic liver disease—opioids should be used cautiously, with attention to dose and route of excretion.

3. Pregnant patients—according to the 2012 ACOG Committee Opinion on Opioid Abuse, Dependence, and Addiction, 1% of pregnant women reported nonmedical use of opioid containing pain medication. Opioid dependent pregnant women should be co-managed by the obstetrician and addiction medicine specialist. General principles of care include avoidance of abrupt discontinuation of opioids, use of methadone or buprenorphine for opioid assisted treatment, and vigilance for the neonatal abstinence syndrome in the neonate.
The patient’s medical record should include the diagnosis causing chronic pain as well as a discussion of risks, benefits, alternatives and goals of therapy. It is important for the patient to realize that this medication is not designed to completely eliminate his/her pain but rather to reduce the pain so that the patient is able to perform activities of daily living as well as engage in social activities to improve quality of life.

Consideration should be given to assessing risk of opioid misuse using one of the available screening tools (SOAPP, Opioid Risk Tool).

Note that chronic pain management is optimally achieved through the relationship of the patient with a single provider who knows him/her well. Episodic care with providers who do not have a true relationship with the patient (such as in the ED) is not an effective means of achieving true management of chronic pain.

All patients who are prescribed chronic opioid therapy and/or are at increased risk of opioid addiction as determined by the provider (even if prescribed short term opioid therapy) must sign a Controlled Substances Agreement. MedStar Health considers the Controlled Substances Agreement mandatory for all patients who are prescribed 90 days or more of continuous opioid therapy.

All Controlled Substance Agreements should be reviewed and renewed annually if opioid therapy is ongoing.

A violation the Controlled Substance Agreement may result in discontinuation of narcotic medication (abrupt or rapid taper as clinically appropriate) and/or termination of the patient from the provider’s practice.

Unannounced random urine or serum toxicology screens may be requested to determine compliance with this agreement and the narcotic treatment regimen. This may include screens for illegal substances. Refusal of this testing may lead to a rapid weaning schedule to discontinue the opioid medication and/or prompt termination from this practice.

The patient must receive a copy of the Opioid prescribing guideline as well as a copy of the signed Controlled Substance Agreement.

The patient, nor share their medication with anyone, and further agrees to keep their opioid prescription closely safeguarded from others, and especially from children – who are at increased risk of harm and death from ingestion. The patient must also understand that they may not share, sell, trade, exchange their opioid medication for money, goods, services, etc., or permit others to have access to their opioid medications, and these opioid medications must be secured at all times from wrongful access.
Opioid Risk Tool

<table>
<thead>
<tr>
<th>Mark each box that applies</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Family history of substance abuse</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Illegal drugs</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Rx drugs</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>Personal history of substance abuse</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Illegal drugs</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Rx drugs</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>Age between 16-45 yrs</strong></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>History of preadolescent sexual abuse</strong></td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td><strong>Psychological disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADD, OCD, bipolar, schizophrenia</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Depression</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Screening totals**

Interpretation: Low risk for future opioid abuse: ≤3  
Moderate risk for opioid abuse: 4-7  
High risk for opioid abuse: ≥ 8

**Clinician Resources:**

Prescription Drug Monitoring Programs:
http://www.namsdl.org/prescription-monitoring-programs.cfm
http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm
https://crisphealth.org/CRISP-HIE-SERVICES/Prescription-Drug-Monitoring-Program-PDMP

Milligram Morphine Dose Calculator:
http://www.agencymeddirectories.wa.gov/Calculator/DoseCalculator.htm

**Patient Resources:**
Opioid Treatment Programs

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http://dpt2.samhsa.gov/treatment/directory.aspx

Buprenorphine Physician Locator

References
1. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

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Controlled Substance Agreement

The purpose of this contract is to protect your ability to obtain controlled substances and to protect our ability to provide them to you while maintaining a safe, controlled treatment plan.

I am requesting and being prescribed the following medicine to treat ________________________________________________________________________ because other treatments and medications have not adequately managed my condition. I understand it is unlikely that any medication will completely control my problem, but it is meant to help improve my quality of life.

1. I understand that the possible complications of this particular medicine may include:

<table>
<thead>
<tr>
<th>□ Narcotic pain meds</th>
<th>□ Anti-anxiety meds</th>
<th>□ Sedatives/Hypnotics</th>
<th>□ ADHD meds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addiction</td>
<td>Addiction</td>
<td>Addiction</td>
<td>Addiction</td>
</tr>
<tr>
<td>Sleepiness</td>
<td>Sleepiness</td>
<td>Sleepiness</td>
<td>Trouble sleeping</td>
</tr>
<tr>
<td>Slowed breathing</td>
<td>Slowed breathing</td>
<td>Slowed breathing</td>
<td>Weight loss</td>
</tr>
<tr>
<td>Death from overdose particularly if used with benzodiazepines</td>
<td>Death from overdose particularly if used with alcohol</td>
<td>Death from overdose particularly if used with alcohol</td>
<td>Death from overdose</td>
</tr>
<tr>
<td>Trouble urinating</td>
<td>Falls, particularly in the elderly</td>
<td>Falls, particularly in the elderly</td>
<td>Headache</td>
</tr>
<tr>
<td>Nausea</td>
<td>Cognitive difficulties, particularly in the elderly</td>
<td>Nightmares</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td>Itching or hives</td>
<td>Impaired functioning</td>
<td>Hallucinations</td>
<td>Hallucinations</td>
</tr>
<tr>
<td>Constipation which may be severe enough to require medical attention</td>
<td>Sleep disturbance, particularly in the elderly</td>
<td>Agitation</td>
<td>Cardiac symptoms including elevated blood pressure, rapid heart rate and sudden cardiac death</td>
</tr>
<tr>
<td>Sexual problems</td>
<td></td>
<td></td>
<td>Headache</td>
</tr>
</tbody>
</table>

2. I understand that if I am not taking the medication as prescribed that this could result in a dangerous situation such as coma, organ damage, or even death. I understand and agree to take the medication only as prescribed by my provider.

3. I also understand that if I run out of my medication or if my medication is stopped suddenly, I could have withdrawal symptoms which can be very uncomfortable, dangerous or even life-threatening.

4. I understand that all of my refills will be obtained at this office during regular office hours, and that no refills will be available during evenings or on weekends. There will be no “emergency” refills.

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5. I understand that I must keep my medication in a safe and secure place at all times so that the medication is not lost or stolen, and understand that I am responsible for making sure that the medicine lasts the appropriate amount of time. I understand that I will not receive additional pain medicine ahead of time. I understand and agree that I will keep my medication away from children and others who might take it by mistake and be harmed.

6. I agree not to share, sell, trade, give medication for money, goods, or services, etc. or allow others to have the ability to get to these medications and they must be out of reach at all times from improper access but most important it must be kept safe from children. I agree not to alter my medication in any way (crushing, chewing, injecting, insufflation). I also agree that I will not use illegal controlled substances including but not limited to cocaine, heroin, marijuana, crystal meth, ecstasy, ketamine or other mood changing drugs and/or alcohol. I understand that the use of these medications by someone other than me is illegal and can result in overdose and/or death, especially by children.

7. I agree that while I am in the United States of America, I will get my prescriptions from this office only and agree that I will not attempt to get medications from another healthcare provider without notifying my provider within three business days.

8. I agree, upon request, to bring all unused pills to my follow up appointments for pill counts and understand that I may be tested unannounced (blood and/or urine) to make sure that I am taking my medications as prescribed. I also understand that if I do not go for blood or urine testing or fail to submit to a blood or urine test upon request by my provider, it is also considered a failed drug test.

9. I understand that I have been advised and understand that I should not drive a motor vehicle or operate machinery that could put my life or someone else’s life at risk until I get used to the way the medication may affect me. While taking this medication, I will follow this same care when and if my dose of controlled substance (narcotic pain medication) is increased.

10. Women – If I become pregnant, there are known and unknown risks to the unborn child which can include addition and/or withdrawal at birth and could be life threatening to an infant. I must inform my doctor right away if I am pregnant or think I am pregnant.

11. I know that my provider and drug store must follow any state or federal laws about misuse, sale, and other diversion of my pain medication.

12. I permit my provider to share this agreement with my chosen drug store, emergency room, hospital, and other providers who are treating me to better organize my care, and I agree to give up my right of privacy or confidentiality with this agreement.
13. I understand and permit my provider and drug store to cooperate fully with any city, state, or federal law enforcement agency in the investigation of any possible misuse, sale, or other diversion of my pain medication.

14. I also give my permission for other providers, emergency departments, or drug stores to report violations (breaking) of this agreement to my prescribing provider.

15. I understand that any violation of this agreement will result in one or more of the following:

   a. Rapid tapering off of medications and no further prescriptions after they are tapered off
   b. A referral to the appropriate specialist (pain specialist, psychiatrist, etc) with enough medication coverage to last only until the first appointment takes place
   c. A referral for substance abuse treatment
   d. Notification of violation of this Controlled Substance Agreement to my pharmacy and the State database for the Prescription Drug Monitoring Program
   e. Notification of violation of this Controlled Substance Agreement to my insurance company
   f. Termination from my doctor’s practice along with a notification of this termination to all MedStar facilities and practices in accordance with applicable laws and regulations.

16. I agree to fill and refill ALL of my prescriptions only at the pharmacy that I have chosen below. A change of pharmacy must be made in person with the prescribing provider or by phone discussion with the prescribing provider, and a note will be sent of this controlled substance agreement to the new drug store as well as notice of ending of service notice to the old drug store.

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AGREEMENT

I understand I have the right to complete management of my symptoms, to have my questions answered regarding treatment, to participate in a discussion of different treatment options, and to receive compassionate and timely care. I understand that my provider will act in my best interest and provide full, accurate, and complete information so that I may make an educated decision regarding my care. I also understand that any exceptions to this document must be documented by my provider in this agreement.

I have had the opportunity to read this contract or have it read to me. The contract has been fully explained to me, and I understand all its terms. I agree to follow the rules in this contract and understand that any violation of this contract will result in ending of therapy with a controlled substance and possibly an ending of the provider-patient relationship in accordance with applicable laws and regulations. All of my questions and concerns regarding treatment have been answered to my satisfaction, and copies of these documents have been given to me. I understand I have the right and power to sign this agreement and accept all of its terms.

I agree to use (pharmacy)________________________________________________________________________(phone)

located at____________________________________________________________________________________(address)

to fill prescriptions for all of my controlled substance medications. If my drug store location must be changed, I will notify my provider at my regular office visit or through a phone conversation with my provider.

Patient Name ___________________________ Date of Birth ___________________________

Patient Signature ________________________ Date __________________________

Prescribing Provider Signature _____________________________________________________________

<table>
<thead>
<tr>
<th>Drug prescribed</th>
<th>Amount</th>
<th>Frequency</th>
<th>Refills</th>
</tr>
</thead>
</table>

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