

**Oregon Health Authority**  
**Oregon Opioid Taper Guidelines Task Force**  
**AGENDA**



**Oregon Opioid Taper Guidelines Task Force**

May 23, 2019

1:30 p.m. - 4:00 p.m.

Portland State Office Building

800 NE Oregon, Room 1A

Conference Line: 1-888-278-0296

Public Meeting ID: 843163

**Goals**

- Review and finalize principles for guidelines
- Review and continue discussion of guidelines

**Agenda**

- **Welcome, goals, agenda review, introductions** - Dana Hargunani, Chief Medical Officer, Oregon Health Authority; Diana Bianco, Principal, Artemis Consulting
- **Updates**
  - HERC
  - Noteworthy new publications
- **Principles for guidelines**
  - Review and finalize
- **Guideline content**
  - Review work thus far
    - Next steps on Patient Assessment/Evaluation
  - Continue topic review and discussion
    - When to consider tapering
    - Approach to tapering
- **Public comment** (approx. 3:45)
- **Next steps and summary**
  - Next meeting: June 14<sup>th</sup>, 9:00-11:30
  - July and August meetings

Everyone is welcome to the meetings. For questions about accessibility or to request an accommodation, please call 971-304-6236 or write [Ootg.info@dhs.oh.a.gov](mailto:Ootg.info@dhs.oh.a.gov). Requests should be made at least 48 hours prior to the event. Documents can be provided upon request in an alternate format for individuals with disabilities or in a language other than English for people with limited English skills. To request a document in another format or language, please call 971-304-6236 or write [Ootg.info@dhs.oh.a.gov](mailto:Ootg.info@dhs.oh.a.gov).

**IN THIS SECTION****FDA STATEMENT**

# **Statement by Douglas Throckmorton, M.D., Deputy Center Director for Regulatory Programs in FDA's Center for Drug Evaluation and Research, on new opioid analgesic labeling changes to give providers better information for how to properly taper patients who are physically dependent on opioids**

**For Immediate Release:**

April 09, 2019

**Statement From:**

Deputy Director for Regulatory Programs - About the Center for Drug Evaluation and Research  
Douglas Throckmorton MD

As the Department of Health and Human Services (HHS) continues to make progress against the opioid crisis, the FDA remains focused on striking the right balance between reducing the rate of new addiction by decreasing excessive exposure to opioids through rational prescribing, while still enabling appropriate access to treatment for patients living with serious pain. We are also committed to making sure that patients who use opioids take them correctly, and if opioid treatment is no longer needed, that patients and their healthcare providers know how to discontinue the medication safely. Proper discontinuation of opioids is important because everyone who is treated with opioids for any length of time develops a physical dependence—meaning there are withdrawal symptoms if the treatment suddenly stops. However, being physically dependent is very different than being addicted. In contrast to physical dependence, addiction also involves behaviors, thoughts and feelings such as: a strong desire to take the drug; difficulties in controlling drug use; persisting in drug use despite harmful consequences; and a higher priority given to drug use than to other activities and obligations.

Recently, the FDA has received reports of serious harm, including serious withdrawal symptoms, uncontrolled pain and suicide, in patients who are physically dependent on opioid pain medicines when these medicines are suddenly discontinued or when the dose is reduced too quickly, often without adequate patient communication, follow-up or support. These practices have also been associated with patients attempting to find other sources of opioids in

order to minimize their withdrawal symptoms or self-medicate for pain. Patients may also attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin and other substances. These may be signs of addiction (or opioid use disorder), but they may also be signs that a patient is physically dependent and has stopped opioid treatment too suddenly. There is an appropriate, evidence-based, safe way to taper opioids that can avoid severe side effects and minimize risks. Critically important, any taper must be tailored to the individual patient's clinical and personal situation because of the many factors involved.

Currently, FDA-approved labeling for opioid pain medications, as well as guidelines ([https://www.cdc.gov/drugoverdose/pdf/Clinical\\_Pocket\\_Guide\\_Tapering-a.pdf](https://www.cdc.gov/drugoverdose/pdf/Clinical_Pocket_Guide_Tapering-a.pdf)) from the Centers for Disease Control and Prevention (CDC), describes the need to gradually reduce the dosage of an opioid medication over time, while monitoring carefully for signs of withdrawal. Yet, we know this is not always the way it's handled in clinical practice. We need to do more to ensure that providers and patients have adequate guidance for safe opioid tapering.

That's why today we're requiring changes to the prescribing information for all opioid analgesic medicines used in the outpatient setting and issuing a Drug Safety Communication (FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering) for health care providers and patients on this important issue. We'll also engage with physician groups to walk through these updates, so they can provide the information to their members.

These changes will provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. This information is intended to be used when the health care provider and the patient have determined together that a decrease in dose or discontinuation of the opioid is appropriate.

When a health care provider and patient agree to taper the opioid, a variety of factors should be considered including: the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. These labeling changes also emphasize the importance of having informed discussions between patient and clinician and ensuring follow-up and support for patients managing pain and changes to their medication regimens.

There is no standard opioid tapering schedule suitable for all patients. Together, the health care provider and patient should agree on how to gradually reduce the dose of the opioid to avoid serious withdrawal symptoms, worsening of pain and psychological distress. Patients should be closely monitored during the opioid taper, and particularly for those who have been treated for a long duration and/or with higher doses for chronic pain, they should be offered a multimodal treatment approach including mental health support, as needed. If a substance use disorder is suspected, the patient should be assessed and treated using evidence-based strategies, such as medication-assisted treatment.

We're constantly monitoring the safety of opioid pain medicines, and we're also updating the prescribing information to include new information on other side effects of opioid use including central sleep apnea and drug interaction; we've also updated information on proper storage and disposal of these medicines consistent with the information available on our Disposal of Unused Medicines (</drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know>) webpage.

At the FDA, we are continuing to aggressively confront the opioid crisis, while advancing policies to help make sure that patients with pain have access to appropriate, evidence-based care.

We're working with the National Academies of Sciences, Engineering, and Medicine to help advance the development of evidence-based guidelines (</news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-development-evidence-based-indication>) for appropriate opioid analgesic prescribing for acute pain resulting from specific conditions or procedures. The primary scope of this work is to understand what evidence is needed to ensure that clinical practice guidelines for opioid analgesic prescribing are sufficient and to identify what research is needed to generate that evidence in a practical and feasible manner.

Soon, we'll also advance policies to require that immediate-release formulations of opioids be made available in fixed-quantity packaging – such as blister packs – that contain doses (e.g., tablets) more typical of what patients may need for common acute pain conditions and procedures. Our data shows that many acute pain indications for which opioids are prescribed, such as post-surgical indications, require just one or two days of analgesic medicines. By having opioids packaged in fixed-quantity units (e.g., one or two days of pills), we believe providers will be more likely to write prescriptions for these short durations, and it will discourage the dispensing of 30 pill supplies, a prescribing practice that is still too common.

The FDA remains committed to addressing the opioid crisis on all fronts, with a significant focus on decreasing unnecessary exposure to opioids and preventing new addiction; supporting the treatment of those with opioid use disorder; fostering the development of novel pain treatment therapies and opioids more resistant to abuse and misuse; and taking action against those involved in the illegal importation and sale of opioids. The agency will also continue to evaluate how opioids currently on the market are used, in both medical and illicit settings, and take regulatory action where needed.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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## Inquiries

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**Oregon Health Authority**  
**Oregon Opioid Taper Guidelines Task Force**  
**MEETING NOTES**



**Oregon Opioid Taper Guidelines Task Force**

April 12, 2019

2:00 p.m. - 4:30 p.m.

Portland State Office Building

800 NE Oregon, Room 1A

Conference Line: 1-888-278-0296

Public Meeting ID: 843163

**Welcome, goals, agenda review, introductions**

Diana Bianco, Principal of Artemis Consulting, welcomed the Task Force and asked Task Force members and public to introduce themselves. She reviewed the agenda.

Dana Hargunani, Chief Medical Officer of the Oregon Health Authority, provided an update on the Health Evidence Review Commission's (HERC) consideration of five chronic pain conditions on the Prioritized List. The HERC has paused its deliberation to allow for a third-party review of the evidence informing the proposal. Dana also shared that OHA is having its Conflict of Interest policies reviewed (including that of the HERC).

The Task Force finalized its ground rules for working together.

**Principles for guidelines**

The Task Force reviewed the list of principles developed at our first meeting. The Task Force adopted the list of principles with two changes:

- Changed "practical" and replaced it with "applicable to different practice sites" to better represent the intent.
- Removed "medically realistic" from the list and added evidence-based.

**Key components for inclusion in the guidelines**

The Task Force reviewed the working draft outline, with a focus on headings, organization, and potential missing items. We will continue to revise the outline based on Task Force discussions and input, particularly regarding subheadings. The Task Force made the following revisions:

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- Consider adding the following terms to the list of definitions:
  - Abandonment
  - Weaning, with emphasis on the difference between weaning (or discontinuation of opioids) and tapering; it was noted that this would be further explored later in the meeting
- Add two additional:
  - When to refer
  - Considerations for special populations (oncology, hospice, palliative care, end of life, maternity, pediatric)

#### Guideline content

Diana provided an overview of the planned approach for building the guideline content, which includes review of a discussion guide prepared by staff that contains language from existing resources. The Task Force will use this content as a starting point for creating the guideline, noting when they want to adopt existing language and concepts, revise language, or create new content. The purpose of our initial walk through the discussion guide is to focus on broad concepts. We will revisit each section to ensure Task Force input is reflected.

#### Guideline Section: Definitions

- **Tapering:** The Task Force agreed to accept the CDC definition with notation of source.
- **Opioid tolerance definition:** Use the DSM-5 criteria as basis for definition with revised language and notation of source.
  - Revise “to achieve intoxication” and replace with “to achieve desired effect whether therapeutic or recreational”.
  - Look at ASAM definition for reference.
  - Possibly include content in the guidelines to address illicit user population. Could fall into “when to refer” or “special population” sections.
- **Opioid withdrawal definition-** Use the DSM-5 criteria as definition with notation of source.
- **Opioid withdrawal syndrome definition -** Use the DSM-5 criteria as definition with notation of source
  - The group recommended reversing the sequence of the “opioid withdrawal” and “opioid withdrawal syndrome” definitions

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- **Opioid use disorder/addiction definition** - Use the DSM-5 criteria as basis for definition with revised language and notation of source.
  - Use the word “criteria” instead of “symptoms” with regards to severity scoring
- **Opioid dependence definition**- Do not include a definition for this term
  - Make a note that “opioid dependence” is no longer used by the DSM-V with explanation that it is essentially now part of the opioid use disorder definition within DSM-V
  - Do not include a definition of the term CPOD here since there is not an evidence-basis for this term. Instead, expand on CPOD and OUD in special populations (or other) section.
- **Patient Abandonment language**- Use legal definition of abandonment
  - Include legal definition of “abandonment” to clarify and differentiate from other uses of term i.e., representing the patient perception of being abandoned
  - Expand abandonment out to a separate section to address the nuance of abandonment from multiple perspectives. Suggested to be under new heading titled “patient-centered care”.

During the discussion regarding content for the definitions section of the guideline, the Task Force discussed whether -- and how -- the guidelines should address the approach to tapering for individuals with opioid use disorder, other substance use disorder (SUD), and dual diagnoses of mental illness and SUD. Multiple Task Force members felt that the guidelines did need to address approaches to care for these more complex patients, and others considered these topics to be outside the scope of the prescribing guidelines. Overall, the Task Force agreed that the guidelines would need to give some sort of indication as to how to support patients with more complex presentations.

#### Guideline Section: Patient Assessment/Evaluation

The Task Force began discussion of the proposed guideline section on patient assessment and evaluation. The group discussed the purpose of this section and potential content. We need clarification and additional information about what constitutes a “high dose.” Katrina Hedberg will provide PDMP data to aid in the development of this definition.

The Task Force discussed how an algorithm could be useful for the assessment and evaluation (ideally one that already exists, if possible). Elements could include the following:

- Why does the patient have pain?

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- Does the patient have a clinical diagnosis that warrants opioids?
- What other comorbidities does the patient have?
- What is the patient's pain level?
- What dose of opioids is the patient taking?
- What functional improvements does the patient have while taking opioids?
- What other treatments has the patient been using for pain?
- Does the patient meet any OUD criteria?

Another member suggested including the CDC recommendations #1 and 2 as included in the guidance document, as that is the language utilized for teaching purposes. It was suggested that standardized screening tools be utilized as appropriate (i.e., GED-7, PHQ-0, PC-PTSD).

Dr. Dogra shared information about a tool used by the Veteran's Association called the "VA Storm", which includes sections on pain assessment/evaluation; psychosocial environment; and co-occurring conditions. While Dr. Dogra cannot share the tool itself, she can provide additional information about content.

The Task Force provided the following input:

- **Pain assessment/evaluation** – We should have a sort of algorithm/visual tool using existing content.
- **Psychosocial environment** – This section should address determinants of health, including both protective and risk factors (i.e., homelessness, family support, social supports)
- **Co-occurring conditions** – This section should address behavioral risks and both physical and mental health

Parking Lot:

Task Force members discussed the goal of tapering: to taper to a lower dose or to taper off completely. Some members don't think the focus should be on individuals on low doses of opioids; other members stated that even a low dose of opioids -- when it is not an appropriate treatment for the underlying condition -- is problematic.

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**Resources**

Task Force members were reminded that if they have additional resources (i.e., sources of content for the guidelines), they should be sent to Lisa Bui. A Task Force member suggested that the new FDA statement on rapid discontinuation be included in the resources list.

**Meeting evaluation**

Diana asked for feedback regarding what worked and what didn't work in terms of the structure of the meeting and meeting materials. Task Force members provided the following comments:

- Staff did a great job with draft language, references, providing a starting point; it was good to have content to work with
- Facilitation was excellent and kept us moving forward
- The meeting felt productive
- The outline and preparation worked well
- Much more engaging
- Should have a stronger executive presence at the meetings (i.e., hospital leadership)

**Public comment** (approximately 4:15)

None.

**Next steps and summary**

The next meeting will include the following items:

- Review summary of Meeting #2
- Continue discussion on Patient Assessment/Evaluation section
- Begin discussion of When to consider tapering section

Next meeting: May 23, 2019 from 1:30 p.m.– 4:00 p.m.

**Oregon Opioid Taper Guidelines Task Force  
Oregon Opioid Taper Prescribing Guidelines  
Draft Outline  
as of 5/14/19**

- I. Acknowledgements
  - a. Task Force membership
- II. Background
- III. Principles
- IV. Definitions
  - a. Tapering
  - b. Opioid tolerance
  - c. Opioid withdrawal
  - d. Opioid Withdrawal Syndrome
  - e. Opioid Use Disorder
  - f. Opioid dependence
  - g. Abandonment

V. Patient-centered approach

- ~~VI.~~ Patient assessment/evaluation
  - a. Pain
  - b. Opioid use, Substance Use Disorder
  - c. Psychosocial environment
  - d. Co-occurring conditions

~~VI.~~VII. When to consider tapering

~~VII.~~VIII. Approach to tapering

- a. Patient education
- b. Setting goals and defining success
- c. Taper plans
  - i. General Approach
  - ii. Taper Plan Examples
  - iii. Role of medication-assisted therapy (MAT)

d. Special patient populations (oncology, hospice, palliative care, end of life, maternity, pediatric); consider adding reference to "COPD" disposition

~~d.~~e. Multidisciplinary supports

Commented [LTB1]: Added per review of resources 5/7

e.f. Social and cultural supports

f.g. Monitoring and reassessment

g.h. Managing Withdrawal

Commented [LTB2]: Added per review of resources 5/7

IX. Long-term support and follow-up

~~VIII.X.~~ When to refer

~~IX.XI.~~ Provider education

~~X.XII.~~ Organizational supports

~~XI.XIII.~~ Resources

a. References

b. Sample scripts

# Oregon Opioid Taper Prescribing Guidelines

## WORKING DOCUMENT

### Acknowledgements

### Task Force membership

### Background

### Principles

The Oregon Opioid Taper Prescribing Guideline Task Force adopted the following principles that should underlie these guidelines for opioid tapering, including:

- Compassionate
- Patient-centered
- Flexible
- Trauma-informed
- Promote patient engagement and shared decision-making
- Support informed consent
- Focus on harm reduction
- ~~Medically-realistic~~Data driven
- Evidence-based
- Focus on pain science
- Promote an integrated approach
- ~~Practical~~Applicable to different practice settings
- Accessible/clear

### Definitions

The following are definitions adopted by the Oregon Opioid Taper Prescribing Guidelines Task Force to inform their work:

**Tapering:** Collaborating with a patient to achieve a a reduced opioid dosage or reducing dosage and discontinuing opioid therapy. (CDC)

**Opioid Tolerance:** Defined by either of the following: a) need for markedly increased amounts of opioids to achieve desired effect whether therapeutic or recreational~~achieve intoxication or desired effect~~, b) markedly diminished effect with continued use of the same amount of opioid. (DSM-5)

**Opioid Withdrawal syndrome:** Defined by Criteria A and B, including:

A) Either of the following: 1) cessation of (or reduction in) opioid use that has been heavy and prolonged (several weeks or longer), or 2) administration of an opioid antagonist after a period of opioid use;

B) Three (or more) of the following, developing within minutes to several days after Criterion A: dysphoric mood; nausea or vomiting; muscle aches; lacrimation or rhinorrhea; pupillary dilation, piloerection, or sweating; diarrhea; yawning; fever; or insomnia. (DSM-5)

**Opioid Use Disorder:** A problematic pattern of opioid use leading to clinically significant impairment or distress. To confirm a diagnosis of OUD, at least two of the following should be observed within a 12-month period (the last two diagnostic criteria, related to tolerance and withdrawal, are not considered to meet OUD for individuals taking opioids solely under appropriate medical supervision):

- a. Opioids are often taken in larger amounts or over a longer period than was intended.
- b. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
- c. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
- d. Craving, or a strong desire or urge to use opioids.
- e. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
- f. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
- g. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- h. Recurrent opioid use in situations in which it is physically hazardous.
- i. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- j. Exhibits tolerance (discussed in the next section).
- k. Exhibits withdrawal (discussed in the next section).

Severity of OUD is specified as: Mild (2-3 criteria), Moderate (4-5 criteria), or Severe (6 or more criteria). (DSM-5)

**Medical Abandonment:** a medical professional's discontinuation of an established doctor-patient relationship before the patient's necessary treatment has ended and without arranging for continuing treatment or care. It is a form of medical malpractice. (Black's Law Dictionary 10th Edition, 2015).

## Oregon Opioid Taper Guidelines Task Force DISCUSSION GUIDE

### Reference documents

- **Centers for Disease Control & Prevention (CDC):** Pocket Guide: Tapering; Training Module 5: Assessing and Addressing Opioid Use Disorder; Guideline for Prescribing Opioids for Chronic Pain
- **Oregon Pain Guidance (OPG):** Tapering Guidance & Tools; Pain Treatment Guidelines
- **Veteran's Health Administration/Dept. of Defense (VA/DoD):** Opioid Taper Decision Tool; Transforming the Treatment of Chronic Pain: Moving Beyond Opioids
- **Washington Agency Medical Director's Group (WA):** AMDG 2015 Interagency Guideline on Prescribing Opioids for Pain
- **Diagnostic and Statistical Manual of Mental Disorders (DSM-5)**
- **FDA statement** - new opioid analgesic labeling changes: <https://www.fda.gov/news-events/press-announcements/statement-douglas-throckmorton-md-deputy-center-director-regulatory-programs-fdas-center-drug-0>
- **No Shortcuts to Safer Opioid Prescribing** by Dowell, Haegerich, Chou (New England Journal of Medicine, 2019): <https://www.nejm.org/doi/full/10.1056/NEJMp1904190>

### Definitions

#### Tapering definition

1. **CDC:** Tapering to a reduced opioid dosage or tapering and discontinuing opioid therapy
2. **OPG:** Opioid dose reduction
3. **VA/DoD:** Determine if the initial goal is a dose reduction or complete discontinuation. If initial goal is determined to be a dose reduction, subsequent regular reassessment may indicate that complete discontinuation is more suitable.
4. **WA:** Reducing or discontinuing chronic opioid analgesic therapy

#### Opioid tolerance definition

1. **DSM-5:** Defined by either of the following:
  - a. Need for markedly increased amounts of opioids to achieve intoxication or desired effect
  - b. Markedly diminished effect with continued use of the same amount of opioid

#### Opioid withdrawal definition

1. **DSM-5:** Defined by either of the following:

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- a. Characteristic opioid withdrawal syndrome
- b. Same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms

**Opioid withdrawal syndrome definition**

- 1. **DSM-5:** Defined by Criteria A and B:
  - a. Either of the following: 1) Cessation of (or reduction in) opioid use that has been heavy and prolonged (several weeks or longer), or 2) administration of an opioid antagonist after a period of opioid use.
  - b. Three (or more) of the following, developing within minutes to several days after Criterion A: dysphoric mood; nausea or vomiting; muscle aches; lacrimation or rhinorrhea; pupillary dilation, piloerection, or sweating; diarrhea; yawning; fever; or insomnia.

**Opioid Use Disorder/Addiction definition**

- 1. **DSM-5:** Opioid Use Disorder (OUD) is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress. To confirm a diagnosis of OUD, at least two of the following should be observed within a 12-month period (the last two diagnostic criteria, related to tolerance and withdrawal, are not considered to meet OUD for individuals taking opioids solely under appropriate medical supervision):
  - a. Opioids are often taken in larger amounts or over a longer period than was intended.
  - b. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
  - c. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
  - d. Craving, or a strong desire or urge to use opioids.
  - e. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
  - f. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
  - g. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
  - h. Recurrent opioid use in situations in which it is physically hazardous.
  - i. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
  - j. Exhibits tolerance (discussed in the next section).
  - k. Exhibits withdrawal (discussed in the next section).

Severity of OUD is specified as: Mild (2-3 symptoms), Moderate (4-5 symptoms), or Severe (6 or more symptoms).

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### Opioid dependence definition

1. **DSM-5:** term no longer utilized
2. **OPG:** Complex Persistent Opioid Dependence (CPOD)
  - o **Complex:** Dependence is complicated by desire to continue taking opioid for the treatment of pain. Withdrawal is complicated by anhedonia and hyperalgesia which, unlike classic 'physical' symptoms, may not reverse within days.
  - o **Persistent:** Tapering is poorly tolerated. Tapering, therefore, may fail, or is highly protracted (takes months or years).
    - **What distinguishes CPOD from OUD:**
      - No craving
      - No compulsive use
      - No harmful use that is not medically directed (patient takes opioid exactly as prescribed)
      - Social disruption is attributed to pain and not to OUD
3. **WA:** The term "opioid dependence," while often acceptable to patients, is best avoided due to possible confusion with its outdated formal definition in DSM-IV.

### Patient Abandonment language (use to develop definition?)

1. **CDC:** Let patients know that most people have improved function without worse pain after tapering opioids. Some patients even have improved pain after a taper. Tell patients "I know you can do this" or "I'll stick by you through this"
2. **OPG:** The prescriber's job is to remain empathic, yet resolute, and communicate to patients that a careful risk-benefit assessment informed by experience and compassion has led to this treatment plan and that to continue opioids under these circumstances would be to cause the patient further harm. Tapering down the opioid dose or not prescribing opioids doesn't mean you aren't taking care of the patient. Reassure each patient that supportive adjunctive treatment of withdrawal will be provided as needed, and may be quite helpful, but set expectations that this will not include dangerous replacement medications.
3. **VA/DoD:** When a decision is made to taper, special attention must be given to ensure that the Veteran does not feel abandoned. Prior to any changes being made in opioid prescribing, a discussion should occur between the Veteran, family members/caregivers, and the provider either during a face-to-face appointment or on the telephone. Listen to the Veteran's story; let the Veteran know that you believe their pain is real; include family members or other supporters in the discussion; acknowledge the Veteran's fears about tapering.

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4. **WA:** Patients on COAT can be reluctant to change, and many who agree to try will have difficulty as the dose is reduced. Such reluctance and difficulty in tapering often reflect anxiety. There may be apprehension about worsening of pain and withdrawal symptoms or, if there is opioid use disorder, about reduced access to the drug. Exploring each of these possibilities in a non-judgmental manner helps the provider understand the patient's perspective and helps the patient have realistic expectations. This, in turn, strengthens the therapeutic relationship and supports future strategies.

**Patient assessment/evaluation to determine whether to taper**

(example components to include but not limited to):

▪ **Pain assessment/evaluation**

1. **CDC:** Focus on functional goals and improvement, engaging patients actively in their pain management. Assess pain using validated instruments such as the 3-item (PEG) Assessment Scale.  
***Determining When to Initiate or Continue Opioids for Chronic Pain***  
(CDC Guideline)  
***Recommendation 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.  
***Recommendation 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.
2. **OPG:** Specific review of symptoms related to Central Sensitization spectrum, physical exam, past medical and psychiatric history, pain and, most important, functional assessment to evaluate progress with treatment over time: Oswestry, Low Back Pain Intensity, Visual Analog Scale, PEG 3-item scale for pain tracking.
3. **VA/DoD:** Assess pain and functional treatment goals and adherence to treatment plan (no specific assessment)
4. **WA:** Perform a thorough history and physical examination at initial visit for pain management. Do not pursue diagnostic tests unless risk factors or "red flags" indicate the need for further evaluation. Assess and document function and pain using validated tools at each visit where opioids are prescribed (3-item PEG, 2-item Graded Chronic Pain Scale to assess pain intensity and pain interference, STarT Back to assess risk of transitioning to chronic pain)

Commented [DB1]: Relying on existing content, we should consider developing an algorithm/visual.

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▪ **Assessing and addressing opioid/other substance use and opioid use disorder/substance use disorder**

1. **CDC: *Assessing Risk and Addressing Harms of Opioid Use (CDC Guideline)***

Recommendation 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 ( $\geq 50$  MME/day), or concurrent benzodiazepine use, are present.

Recommendation 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.

Recommendation 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.

2. **OPG:** Query the PDMP, UDS POC in-office will provide results at the time of the visit, substance-abuse risk screening. If patient has OUD, transition to MAT; if patient has Complex Persistent Opioid Dependence, transition to Buprenorphine off-label for pain, or slow down taper and re-assess quarterly.

3. **VA/DoD:** If patient has OUD, use a shared decision-making approach to discuss options for OUD treatment. First-line is MAT, preferred buprenorphine/naloxone; alternative is injectable naltrexone. Ensure screening and treatment is offered for conditions that can complicate pain management before initiating opioid taper. The lifetime prevalence for OUD among patients receiving long-term opioid therapy is estimated to be about 41%: approximately 28% for mild symptoms, 10% for moderate symptoms and 3.5% for severe symptoms of OUD.

l. Patients with chronic pain who develop OUD from opioid analgesic therapy need to have BOTH pain and OUD addressed. Either tapering the opioid analgesic or continuing to prescribe the opioid without providing OUD treatment may increase the risk of overdose and other adverse events. Refer to DSM 5 criteria for OUD.3

m. Use a shared decision-making approach to discuss options for OUD treatment: First-line: Medication Assisted Therapy (MAT)

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- i. **PREFERRED:** Opioid Agonist Therapy (OAT)—  
buprenorphine/naloxone (Suboxone®) or methadone  
maintenance\*
      - ii. **ALTERNATIVE:** Extended Release (ER) Injectable Naltrexone  
(Vivitrol®)
    - n. MAT can be provided in a variety of treatment settings including:  
residential SUD treatment, intensive outpatient SUD treatment, regular  
SUD specialty care clinic, primary care or general mental health clinic,  
or federally regulated opioid treatment program.
  - 4. **WA:** Assess the patient behaviors that may be suggestive of SUD;  
address increased pain with use of non-opioid options; evaluate patient for  
mental health disorders. Opioid Risk Tool (ORT), CAGE Adapted to  
Include Drugs (CAGE-AID), Screener and Opioid Assessment for Patients  
with Pain – Revised (SOAPP-R), Current Opioid Misuse Measure  
(COMM), DIRE, Alcohol Use Disorders Identification Test (AUDIT).
- **Psychosocial environment**
  - 1. **CDC:** Because psychological distress frequently interferes with  
improvement of pain and function in patients with chronic pain, use  
validated instruments such as the Generalized Anxiety Disorder (GAD)-7  
and the Patient Health Questionnaire (PHQ)-9 or the PHQ-4 to assess for  
anxiety, post-traumatic stress disorder, and/or depression.
  - 2. **OPG:** Mental health screening, for co-occurring mental health disorders  
related to trauma, depression, anxiety, depression, ACES, and PTSD.
  - 3. **VA/DoD:** Ensure screening and treatment is offered for conditions that can  
complicate pain management before initiating opioid taper:
    - a. Mental health disorders (PTSD, anxiety disorders, depressive  
disorders)
      - i. If suicidal, then activate suicide prevention plan
      - ii. If high suicide risk or actively suicidal, consult with mental  
health provider before beginning taper
  - 4. **WA:** Use validated instruments to assess predictors of suboptimal  
recovery such as depression, fear avoidance, and catastrophizing, which  
can lead to persistent pain and functional limitation (PHQ-9, GAD-7, PC-  
PTSD).
- **Co-occurring conditions**
  - 1. **CDC:** Certain risk factors are likely to increase susceptibility to opioid-  
associated harms and warrant incorporation of additional strategies into  
the management plan to mitigate risk, such as sleep-disordered breathing,  
pregnant women, renal or hepatic insufficiency, patients aged 65 and  
older, mental health conditions, substance use disorder, and prior nonfatal  
overdose.

**Commented [DB2]:** This section should be divided into two sections: Protective and risk factors (social determinants of health such as homelessness, family support, social supports and environmental factors) and Co-occurring conditions (including mental health and physical health).

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2. **OPG:** Co-morbid conditions can increase the risks from opioids: respiratory disease (COPD, sleep apnea, etc.), abnormalities in the endocrine system (depressed testosterone, hypoxemia), cardiac arrhythmias, obesity, dementia, fibromyalgia, depression, anxiety, substance use disorder, history of drug overdoses.
3. **VA/DoD:** Screening for conditions that complicate pain management before initiating opioid taper. Mental health disorders, OUD, SUD, “Moral Injury”, Central sensitization, Medical Complications (lung disease, heart disease, renal disease, fall risk), Sleep Disorders. Assess for medical comorbidities that increase risk (for opioid use): lung disease, sleep apnea, liver disease, renal disease, fall risk, advanced age;
4. **WA:** Screen for medical conditions that could increase sensitivity to opioid-related side effects such as comorbid mental health disorders (especially PTSD and major depressive disorder), and COPD, CHF, sleep apnea, advanced age, or renal or hepatic dysfunction.

### When to Consider Tapering

*Various elements can be included (none specifically identified by the TF yet)*

Example with broad set of elements to consider:

- **VA/DoD:** Consider tapering opioids when:
  - No pain reduction, no improvement in function or patient requests to discontinue therapy
  - Severe unmanageable adverse effects (e.g., drowsiness, constipation, cognitive impairment)
  - Dosage indicates high risk of adverse events (e.g., doses of 90 MEDD and higher)
  - Non-adherence to the treatment plan or unsafe behaviors (e.g., early refills, lost/stolen prescription, buying or borrowing opioids, failure to obtain or aberrant UDT)
  - Concerns related to an increased risk of SUD (e.g., behaviors, age <30, family history, personal history of SUD)
  - Overdose event involving opioids
  - Medical comorbidities that can increase risk (e.g., lung disease, sleep apnea, liver disease, renal disease, fall risk, advanced age)
  - Concomitant use of medication can increase risk (e.g., benzodiazepines)
  - Mental health comorbidities that can worsen with opioid therapy (e.g., PTSD, depression, anxiety)

By various components:

- **Patient request**

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1. **CDC:** Patient requests dose reduction
2. **OPG:** *none*
3. **VA/DoD:** Patient requests to discontinue therapy
4. **WA:** Patient requests opioid taper

▪ **Treatment progress**

1. **CDC:** Patient does not have clinically meaningful improvement in pain and function
2. **OPG:** Thorough and systematic risk benefit assessment reveals that benefits outweigh risks, e.g., continued pain and dysfunction
3. **VA/DoD:** No pain reduction, no improvement in function. Consider tapering opioids in Veterans where the risk of continuing the opioid outweighs the benefit of continuing the opioid.
4. **WA:** Patient is maintained on opioids for at least 3 months, and there is no sustained clinically meaningful improvement in function, as measured by validated instruments

**2. High dose/ co-prescribing**

1. **CDC:** Patient is on dosages  $\geq 50$  MME/day without benefit or opioids are combined with benzodiazepines
2. **OPG:** Dose over 90 MED; co-prescribed sedative hypnotics
3. **VA/DoD:** Dosage indicates high risk of adverse events (e.g., doses of 90 MEDD\* and higher); Concomitant use of medications that increase risk (e.g., benzodiazepines)
4. **WA:** At increased risk for opioid-related toxicity from concurrent drug therapy or comorbid medical conditions

**3. Substance use disorder**

1. **CDC:** Patient shows signs of SUD
2. **OPG:** Patient meets criteria for Opioid Use Disorder or Complex Persistent Opioid Dependence
3. **VA/DoD:** Concerns related to an increased risk of SUD\*\*\*\* (e.g., behaviors, age < 30, family history, personal history of SUD†)
4. **WA:** Patient has a SUD (except tobacco) or exhibits aberrant behaviors

**4. Adverse events or warning signs**

1. **CDC:** Patient experiences overdose or other serious adverse event; or patient shows early warning signs for overdose risk such as confusion, sedation, or slurred speech
2. **OPG:** Risk assessment reveals mental health disorder, co-morbid conditions, opioid adverse effects, diversion, or other aberrant behavior
3. **VA/DoD:** Severe unmanageable adverse effects (e.g., drowsiness, constipation, cognitive impairment); Non-adherence to the treatment plan or unsafe behaviors\*\* (e.g., early refills, lost/stolen prescription, buying or

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borrowing opioids, failure to obtain or aberrant UDT\*\*\*); Overdose event involving opioids

4. **WA:** Patient's risk from continued treatment outweighs the benefit; patient has experienced a severe adverse outcome or overdose event

### Approach to Tapering

#### ▪ Patient education

1. **CDC:** Make sure patients receive appropriate psychosocial support. Let patients know that most people have improved function without worse pain after tapering opioids. Some patients even have improved pain after a taper, even though pain might briefly get worse at first.
2. **OPG:** none
3. **VA/DoD:** Use Bio-Psycho-Social Model. Offer Veterans pain education groups. [especially Cognitive Behavioral Therapy (CBT) or Acceptance and Commitment Therapy (ACT) for Pain, if available]. Offer physical therapy and Complementary and Integrative Health (CIH) interventions such as: acupuncture, meditation, yoga. Slowly tapering opioids to reduce opioid risks while not "cutting off" the Veteran. Commit to working with the Veteran on other options for improved function and some decrease in pain.
4. **WA:** Promote patient efforts aimed at increased functional capabilities. Prescribing in acute and subacute phase: Provide patient education on safekeeping of opioids, benzodiazepines, and other controlled substances. Additionally, several resources provided areas: Chronic Pain, Fibromyalgia, Headaches, Medications, Stress and Mental Health, Sleep, Setting Patient Health Goals, Opioid Safety

#### ▪ Setting goals and defining success

1. **CDC:** 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. Experts thought that goals should include improvement in both pain relief and function (and therefore in quality of life). Experts noted that function can include emotional and social as well as physical dimensions.
2. **OPG:** For tapering to be successful, clinicians must approach the taper as an alliance with the patient with the goal of improving their safety and quality of life.
3. **VA/DoD:** Draw out their goals for life (not just being pain-free). Determine if the initial goal is a dose reduction or complete discontinuation. If initial goal is determined to be a dose reduction, subsequent regular

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reassessment may indicate that complete discontinuation is more suitable. The goal of opioid tapering is to improve the balance of risks and clinically meaningful benefits for patients on LOT. (main goals of these focus group participants included returning to work, minimizing pain, maintaining a functional life, avoiding invasive medical procedures, and getting off opioids). Maintain focus on patient goals throughout treatment, including any changes in those goals over time. Uses SMART goals method for patient goal setting. The goals of the Stepped Care Model for Pain Management include functional rehabilitation, improvement in quality of life, and prevention of the pain becoming chronic and associated deterioration in function

- 4. WA:** Clinically meaningful improvement is defined as an improvement in pain AND function of at least 30% as compared to the start of treatment or in response to a dose change. A decrease in pain intensity in the absence of improved function is not considered meaningful improvement except in very limited circumstances such as catastrophic injuries (e.g. multiple trauma, spinal cord injury, etc.). perioperative pain plan: Set expectations with them about realistic pain management goals, including functional recovery activities, need for multimodal treatment, limits of therapy, timely return to preoperative baseline opioid dose (if any) or lower, and the analgesic tapering timeline. Resource: Swedish STOMP Brochure is designed to help patient set health goals to alleviate pain and improve quality of life. It includes general information about pain, goal-setting ideas and steps to take to achieve those goals.

- **Taper plans**

- General Approach

- 1. CDC:** 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. Tapering plans should be individualized and should minimize symptoms of opioid withdrawal while maximizing pain treatment with nonpharmacologic therapies and nonopioid medications.
- 2. OPG:** All legacy patients have a systematic assessment of the risk and benefits of continued opioid therapy. In some cases, where the risks are minimal, and the patient appears to be doing well, continued opioid therapy may be justified. In many cases though a thorough and systematic risk benefit assessment (RBA) will reveal continued pain and dysfunction that indicate that a taper should be initiated, in conjunction with increased use of non-opioid therapies and possible referral to behavioral health or other specialists.
- 3. VA/DoD:** Prior to any changes in therapy, discuss the risks of continued use, along with possible benefits, with the Veteran. Establish a plan to

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consider dose reduction, consultation with specialists, or consider alternative pain management strategies.

4. **WA:** Help the patient understand that chronic pain is a complex disease, and opioids alone cannot adequately address all of the patient's pain-related needs. Exploring the patient's resistance to discontinuing opioids will guide taper strategy. Refer patients with aberrant behaviors for evaluation and treatment. Establish the rate of taper based on safety considerations:

- a. Immediate discontinuation if there is diversion or non-medical use,
- b. Rapid taper (over a 2 to 3 week period) if the patient has had a severe adverse outcome such as overdose or substance use disorder, or
- c. Slow taper for patients with no acute safety concerns. Start with a taper of  $\leq 10\%$  of the original dose per week and assess the patient's functional and pain status at each visit.

- o Taper Examples: See examples document

▪ **Role of medication-assisted therapy (MAT)**

1. **CDC:** For patients meeting criteria for opioid use disorder, clinicians should offer or arrange for patients to receive evidence-based treatment, usually medication-assisted treatment with buprenorphine or methadone maintenance therapy in combination with behavioral therapies.
2. **OPG:** strongly recommended that all providers prescribing opioids for chronic pain obtain an X-Waiver. Many providers have found that buprenorphine is an effective tool to assist with tapering high dose COT patient and for some patients
3. **VA/DoD:** MAT can be provided in a variety of treatment settings including: residential SUD treatment, intensive outpatient SUD treatment, regular SUD specialty care clinic, primary care or general mental health clinic, or federally regulated opioid treatment program. Use a shared decision-making approach to discuss options for OUD treatment: First-line: Medication Assisted Therapy (MAT) PREFERRED: Opioid Agonist Therapy (OAT)—buprenorphine/naloxone (Suboxone®) or methadone maintenance\* ALTERNATIVE: Extended Release (ER) Injectable Naltrexone (Vivitrol®)
4. **WA:** Patients diagnosed with opioid use disorder should receive a combination of medication-assisted treatment and behavioral therapies. Do not prescribe methadone for chronic pain unless you are knowledgeable of methadone's non-linear pharmacokinetics, unpredictable clearance, multiple drug-to-drug interactions and additional monitoring requirements. Consider prescribing naloxone as a preventive rescue medication for patients with opioid use disorder, especially if heroin use is suspected.

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▪ **Multidisciplinary supports**

1. **CDC:** Some studies suggest that using behavioral therapies in combination with these treatments can reduce opioid misuse and increase retention during maintenance therapy and improve compliance after detoxification.
2. **OPG:** none
3. **VA/DoD:** Complementary and Integrative Health (CIH) interventions such as: acupuncture, meditation, yoga.
4. **WA:** In addition to medication, therapies should include physical activation and behavioral health interventions (such as cognitive behavioral therapy, mindfulness, coaching, patient education, and self-management). Consider spinal manipulation in patients with low back pain. Encourage and facilitate those who have work-related injuries to participate in programs that coordinate efforts to help them get back to work. Do this early in their recovery. Refer patient to a multidisciplinary rehabilitation program if s/he has significant, persistent functional impairment due to complex chronic pain. Seek consultation from a pain management specialist or Structured Intensive Multidisciplinary Pain Program (SIMP; described in Non-opioid Options) for patients who have failed taper in an outpatient setting or who are at greater risk for failure due to high dose opioids, concurrent benzodiazepine use, comorbid substance use disorder or any active mental health disorder.

**Table 1. Cognitive Behavioral and Non-pharmacological Therapies for Chronic Pain**

<b>Cognitive</b>	Address distressing negative cognitions and beliefs, catastrophizing (pain coping characterized by excessively negative thoughts and statements about the future)
<b>Behavioral approaches</b>	Mindfulness, meditation, yoga, relaxation, biofeedback
<b>Physical</b>	Activity coaching, graded exercise
<b>Spiritual</b>	Identify existential distress, seek meaning and purpose in life
<b>Education (patient and caregivers):</b>	Promote patient efforts aimed at increased functional capabilities

Adapted from Argoff, 2009 & Tauben, 2015

▪ **Social and cultural supports**

1. **CDC:** Although findings are mixed, some studies suggest that effectiveness is enhanced when psychosocial treatments (e.g., contingency management, community reinforcement, psychotherapeutic counseling, and family therapy) are used in conjunction with medication-assisted therapy
2. **OPG:** none

**Commented [LTB3]:** Limited to no details on cultural supports for the patient on tapering. Family supports listed.

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- 3. **VA/DoD:** Include family members or other supporters in the discussion. Acknowledge the Veteran’s fears about tapering; use motivational interviewing (MI) techniques,
  - 4. **WA:** Group support activities: These evidence based programs teach strategies for understanding chronic pain and provide a support network with both clinician and lay led (by fellow chronic pain sufferers) workshops, 2.5 hours once a week for 6 weeks. These offer a free or low-cost community based model that has demonstrated short term improvements in pain and multiple quality of life variables.
- **Monitoring and reassessment**
    - 1. **CDC:** Adjust the rate and duration of the taper according to the patient’s response. Don’t reverse the taper; however, the rate may be slowed or paused while monitoring and managing withdrawal symptoms. Once the smallest available dose is reached, the interval between doses can be extended and opioids may be stopped when taken less than once a day. 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.
    - 2. **OPG:** On a quarterly basis, we recommend that you review the patient’s case and confirm that they continue to benefit from opioid treatment.
    - 3. **VA/DoD:** Review PDMP\* data at least every 3 months and perform UDT\*\* at least annually\*\*\*

**Follow up with the Veteran during the taper:**

Follow Up	Slowest Taper (over years)	Slower Taper (over months)	Faster Taper (over weeks)	Rapid Taper (over days)
<b>When</b>	1 to 4 weeks after starting taper then monthly before each reduction	1 to 4 weeks after starting taper then monthly before each reduction	Weekly before each dose reduction	Daily before each dose reduction or if available offer inpatient admission
<b>Who</b>	PACT Team*			
<b>How</b>	Clinic and/or telephone**	Clinic and/or telephone**	Clinic and/or telephone**	Hospital, clinic or telephone**
<b>What</b>	Patient function,*** pain intensity, sleep, physical activity, personal goals, and stress level			

- 4. **WA:** Evaluate function and pain using brief validated instruments at these critical decision-making phases: a. At the end of the acute phase (6 weeks

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following an episode of pain or surgery), to determine whether continued opioid therapy is warranted. b. At the end of the subacute or perioperative phase (12 weeks following an episode of pain or surgery), to determine whether non-opioid treatment will help or if prescribing COAT is warranted. c. During chronic use with regular assessment and documentation of function and pain.

**Table 6. How Often to Monitor Patients on COAT**

Level of Risk	Recommended Frequency
Low risk (no risk factors)	Every 6 months
Moderate risk	Every 3 months
High risk or opioid doses >120 mg/day MED	Every month

- **Managing Withdrawal**
  1. **CDC:** none
  2. **OPG:** none
  3. **VA/DoD:** Manage withdrawal symptoms. Autonomic symptoms, anxiety, dysphoria, myalgias, sleep disturbance, nausea, abdominal cramping, diarrhea. Short-term oral medications can be utilized to assist with managing the withdrawal symptoms, especially during fast tapers. not treat withdrawal symptoms with an opioid or benzodiazepine.
  4. **WA:** Treat withdrawal symptoms: restlessness, sweating or tremors, nausea, diarrhea, muscle pain, neuropathic pain or myoclonus, insomnia