QUALIFYING STATEMENTS

The Department of Veterans Affairs and the Department of Defense guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

This Clinical Practice Guideline is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

These guidelines are not intended to represent TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at www.tricare.mil or by contacting your regional TRICARE Managed Care Support Contractor.

Version 3.0 – 2017
I. Summary of Recommendations

Recommendations were made using a systematic approach considering multiple domains: the confidence in the quality of the evidence, balance of desirable and undesirable outcomes, patient or provider values and preferences, and other implications, as appropriate (e.g., resource use, equity, acceptability).

For the treatment of chronic pain

We recommend:
• Alternatives to opioid therapy (OT) such as self-management strategies, other non-pharmacological treatments, and, when pharmacologic therapies are used, non-opioids over opioids

We recommend against:
• Initiating long-term opioid therapy (LOT) for chronic pain
• LOT, particularly in the following patient populations due to increased risk of adverse events with OT: untreated substance use disorder (SUD), concurrent benzodiazepine use, less than 30 years of age

If initiating OT for chronic pain

We recommend:
• A short duration (consideration of OT ≥90 days requires re-evaluation and discussion with patient)
• The lowest dose indicated, as there is no safe dose and risk increases with dose
• Informed consent discussion of risks and benefits of OT and alternative therapies upon initiation
• Ongoing risk mitigation, including random urine drug testing (and appropriate confirmatory testing), checking state prescription drug monitoring programs, monitoring for overdose potential and suicidality, providing overdose education, prescribing of naloxone rescue and accompanying education, and suicide risk assessment (and intervening if necessary)
• Evaluation of risks and benefits at least every three months and more frequently as dose increases
• Tapering OT to reduced dose or to discontinuation when risks of LOT outweigh benefits (avoid abrupt discontinuation unless required for immediate safety concerns; individualize tapering)
• Interdisciplinary care (addressing pain, SUD, and/or mental health problems) for patients presenting with high risk and/or aberrant behavior

We recommend against:
• Doses >90 mg morphine equivalent daily dose (MEDD) for treating chronic pain
• Prescribing long-acting opioids for acute pain, as an as-needed medication, or on initiation of LOT

If continuing OT for chronic pain

We recommend:
• Ongoing risk mitigation, assessment for opioid use disorder (OUD) and suicide, and consideration for tapering
• For patients with evidence of untreated SUD, close monitoring, SUD treatment, and tapering
• For patients with concurrent use of OT and benzodiazepines, tapering one or both medications
• For patients taking >90 mg MEDD, evaluation for tapering to reduced dose or to discontinuation
• For patients with chronic pain and OUD, medication assisted treatment of OUD

For acute pain

We recommend:
• Alternatives to opioids for mild-to-moderate acute pain
• If opioids are prescribed, immediate-release opioids at lowest effective dose with reassessment no later than 3-5 days to determine if adjustments or continuation of OT is indicated

We suggest:
• Use of multimodal pain care when opioids are used (should also offer patient education about opioid risks and alternatives to OT)
II. Module A: Determination of Appropriateness for Opioid Therapy

Note: Non-pharmacologic and non-opioid pharmacologic therapies are preferred for chronic pain.

1. Patient with chronic pain
2. Has the patient been on daily OT for pain for more than 3 months?
   Yes → Proceed to Module D
   No → Obtain biopsychosocial assessment (see Sidebar A)
3. Educate/re-educate on:
   - Non-opioid management
   - Self-management to improve function and quality of life
   - Realistic expectations and limitations of medical treatment
4. Implement and optimize non-opioid treatments for chronic pain (e.g., physical, psychological, and complementary and integrative treatments)
5. Are these treatments effective in managing pain and optimizing function?
   Yes → Sidebar B
   No → Sidebar C

Sidebar A: Components of Biopsychosocial Assessment
- Pain assessment including history, physical exam, comorbidities, previous treatment and medications, duration of symptoms, onset and triggers, location/adaption, previous episodes, intensity and impact, patient perception of symptoms
- Patient functional goals
- Impact of pain on family, work, life
- Review of previous diagnostic studies
- Additional consultations and referrals
- Coexisting illness and treatments and effect on pain
- Significant psychological, social, or behavioral factors that may affect treatment
- Family history of chronic pain
- Collateral of family involvement
- Patient beliefs/knowledge of:
  - The cause of their pain
  - Their treatment preferences
  - The perceived efficacy of various treatment options

For patients already on OT, include assessment of psychological factors (e.g., beliefs, expectations, fears) related to continuing vs. tapering OT.

Sidebar B: Examples of Absolute Contraindications to Initiating Opioid Therapy for Chronic Pain
- True life-threatening allergy to opioids
- Active SUD
- Elevated suicide risk (see VA/DoD Suicide CPG)
- Concomitant use of benzodiazepines

Sidebar C: Consideration Checklist for LOT for Chronic Pain
- Risks do not outweigh potential modest benefits
- Patient is experiencing severe chronic pain that interferes with function and has failed to adequately respond to indicated non-opioid and non-drug therapeutic interventions
- Patient is willing to continue to engage in comprehensive treatment plan including non-opioid treatments and implementation of learned active strategies that meets his or her needs to be successful with plan of care
- Clear and measurable treatment goals are established
- Patient is able to access adequate follow-up for OT (see Recommendations 7-9)
- PDMP and UDT are concordant with expectations
- Review of recent medical records is concordant with diagnosis and risk assessment
- Patient is fully informed and consents to the therapy

Abbreviations: LOT: long-term opioid therapy; OT: opioid therapy; PDMP: Prescription Drug Monitoring Program; SUD: substance use disorders; UDT: urine drug test; VA/DoD Suicide CPG: VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide

February 2017
III. Module B: Treatment with Opioid Therapy

1. Candidate for trial of OT with consent (in conjunction with comprehensive pain care plan)

2. Initiate OT using the following approach:
   • Short duration (e.g., 1 week initial prescription; no more than 3 months total)
   • Use lowest effective dose, recognizing that no dose is completely safe
     • A strategy of escalating dose to achieve benefit increases risk and has not been shown to improve function
     • Dose escalation above 20-50 mg MEQ/DD has not been shown to improve function and increases risk
   • Long-acting opioids should not be prescribed for opioid-naive individuals (see Recommendation 13 and Appendix D)
   • Consider alternatives to methadone and transdermal fentanyl (see Recommendation 13 and Appendix D)
   • Assessment of improvement in pain and functional status and adverse effects
   • Offer OEND

3. Is patient medically or psychiatrically unstable?
   - Yes: Admit/provide medical and psychiatric treatment to stabilize as indicated
   - No

4. Is there a clinically meaningful improvement in function in the absence of significant risk factors?
   - Yes
   - No

5. Review and optimize comprehensive pain care plan (e.g., non-opioid treatments, self-management strategies)

6. Follow-up frequently based on patient risk factors (e.g., 1-4 weeks with any dose change; up to every 3 months without dose change if clinically and functionally stable):
   • Assess:
     • Function, risks, and benefits of OT
     • Progress toward functional treatment goals
     • Adverse effects
     • Adherence to treatment plan
     • Complications or co-occurring conditions (e.g., medical, mental health, and/or SUD)
   • Complete risk mitigation strategies (see Sidebar A)
   • Review and optimize comprehensive pain care plan

7. Are factors that increase risks of OT present (e.g., non-adherence, co-occurring conditions, behaviors suggesting OUD, indications for referral)?
   - Yes
   - No

8. Consider one or more of the following:
   • Shortening prescribing interval
   • Intensifying risk mitigation strategies
   • Increasing intensity of monitoring
   • Referring to interdisciplinary care
   • Consulting with or referring to specialty care

9. Are there indications to discontinue or taper? (see Sidebar B)

10. Reassess in 1-3 months or more frequently as determined by patient risk factors (see Sidebar C)

Sidebar A: Necessary Risk Mitigation Strategies
   • OEND
   • UDT
   • PDMP
   • Face-to-face follow-up with frequency determined by risk

Sidebar B: Indications for Tapering and Discontinuation
   • Risks of OT outweigh benefits
   • Lack of clinically meaningful improvement in function
   • Concomitant use of medications that increase risk of overdose
   • Co-occurring medical or mental health conditions that increase risk
   • Concerns about OUD or other SUD
   • Patient non-compliance with opioid safety measures and opioid risk mitigation strategies
   • Patient non-participation in a comprehensive pain care plan
   • Prescribed dose higher than the maximal recommended dose (which increases risk of adverse events)
   • Pain condition not effectively treated with opioids (e.g., back pain with normal MRI; fibromyalgia)
   • Medical or mental health comorbidities that increase risk
   • Improvement in the underlying pain condition being treated
   • Unmanageable side effects
   • Patient preference
   • Diversion

Sidebar C: Factors That May Indicate Need for More Frequent Follow-up
   • Non-adherence to comprehensive pain care plan (e.g., attendance at appointments)
   • Unexpected UDT and PDMP results
   • Non-adherence to opioid prescription (e.g., using more than prescribed and/or running out early)
   • Higher risk medication characteristics (e.g., high-dose opioids, combination of opioids and benzodiazepines)
   • Patients with mental health, medical, or SUD comorbidities that increase risk for adverse outcomes

Abbreviations: MEQ/DD: morphine equivalent daily dose; mg: milligram(s); MRI: magnetic resonance imaging; OEND: Overdose Education and Naloxone Distribution; OT: opioid therapy; OUD: opioid use disorder; PDMP: Prescription Drug Monitoring Program; SUD: substance use disorders; UDT: urine drug test
IV. Module C: Tapering or Discontinuation of Opioid Therapy

1. Indication to taper to reduced dose or taper to discontinuation

2. Repeat comprehensive biopsychosocial assessment (see Module A, Sidebar A)
   - Does the patient demonstrate signs or symptoms of SUD? (see VA/DoD SUD CPG)
   - Immediate discontinuation of opioid therapy
   - Yes
   - No

3. Is there evidence of diversion? Yes
   - Is patient willing to engage in SUD therapy?
   - Yes
   - No
   - Address safety and misuse
   - Assess for withdrawal symptoms and offer expedited taper, immediate discontinuation, or detox as indicated
   - Continue to monitor for SUD and mental health comorbidities and offer treatment as indicated. (see VA/DoD SUD CPG and Academic Detailing Tapering Document)
   - Exit algorithm
   - Manage with non-opioid modalities

4. Is there high risk or dangerous behavior (e.g., overdose event, accidents, threatening provider)? Yes
   - Develop individualized tapering treatment plan (including pace of tapering, setting of care) based on patient and treatment characteristics (see Sidebar A and Recommendations 14 and 15)

5. Follow-up 1 week to 1 month after each change in dosage and after discontinuation considering patient and treatment characteristics
   - Consider the following at each interaction with patient:
     - Educate on self-management and risks of OT
     - Optimize whole person approach to pain care
     - Optimize treatment of co-occurring mental health conditions
     - Optimize non-opioid pain treatment modalities
     - Reassess for OUD and readiness for OUD treatment as indicated

6. Are one of the following present? Yes
   - Patient resistance to taper
   - High risk or dangerous behaviors
   - Increase in patient distress

7. Repeat comprehensive biopsychosocial assessment (see Module A, Sidebar A)

8. Is an SUD identified? Yes
   - Proceed to Module C, Box 4

9. Are either of the following identified? No
   - Use of opioids to modulate emotions (i.e., “chemical coping”)
   - Untreated or undertreated psychiatric disorder
   - Provide additional education about whole person pain care and LOT and reassurance that the patient will not be abandoned
   - Consider more frequent follow-up using the expanded care team (registered nurse, clinical pharmacist, health coach, mental health provider)
   - Consider reduced rate of taper or pause in taper for patients actively engaged in skills training
   - Reassess for OUD throughout the taper

10. Is patient fearful and/or anxious about taper and ability to function on lower dose or without opioids?
    - Yes
    - No

11. Is there concern for diversion? Yes
    - Proceed to Module C, Box 11

12. Yes

13. No

14. Yes

15. No

16. Yes

17. No

18. Yes

19. No

20. Yes

21. No

22. Proceed to Module C, Box 7

Sidebar A: Tapering Treatment

- When safety allows, a gradual taper rate (5-20% reduction every 4 weeks) allows time for neurobiological, psychological, and behavioral adaptations.
- When there are concerns regarding risks of tapering (e.g., unmasked OUD, exacerbation of underlying mental health conditions) consider interdisciplinary services that may include mental health, SUD, primary care, and specialty pain care.
- Address concerns that may negatively impact taper (e.g., inability for adequate follow-up, inability to provide adequate treatment for co-occurring medical and mental health conditions and SUD)

Patient and Treatment Characteristics to Consider when Determining Tapering Strategy

- Opioid dose
- Duration of therapy
- Type of opioid formulation
- Psychiatric, medical, and SUD comorbidities
- Other patient risk factors (e.g., non-adherence, high-risk medication-related behavior, strength of social support, coping)

Abbreviations: LOT: long-term opioid therapy; MAT: medication assisted treatment; OT: opioid therapy; OUD: opioid use disorder; SUD: substance use disorders; VA/DoD SUD CPG: VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders
V. Module D: Patients Currently on Opioid Therapy

1. Patient currently on OT

2. Are there factors that would require immediate attention and possible discontinuation of OT due to unacceptable risk? (see Sidebar A)
   - Yes
   - No

3. Admit/provide treatment to stabilize, including opioid tapering or SUD treatment as indicated

4. Obtain biopsychosocial assessment (see Module A, Sidebar A)

5. Are the following available for review? Prior medical records including current prescriber, prior and current UDT, POMP
   - Yes
   - No

6. Address factors related to incomplete data prior to prescribing

7. Review data and re-assess risks and benefits of continuing OT
   - Yes
   - No

8. Consider strength and number of risk factors (see Sidebar B)

9. Do risks outweigh benefits of continuing OT?
   - Yes
   - No

10. Educate/re-educate on the following (see Sidebar C for talking points):
    - Non-opioid management
    - Self-management to improve function and quality of life
    - Realistic expectations and limitations of medical treatment options
    - Preferred treatment methods are non-pharmacotherapy and non-opioid pharmacotherapy
    - New information on risks and lack of benefits of long-term OT

11. Are any of the following present?
    - Prescribed opioid dose > 90 mg MEDD
    - Combined sedating medication that increases risk of adverse events (e.g., benzodiazepine)
    - Patient non-participation in a comprehensive pain care plan
    - Other indications for tapering (see Module B, Sidebar B)

12. Re-assess and optimize preferred non-opioid treatments for chronic pain (e.g., physical and psychological treatments) recognizing that patient is willing to continue to engage in comprehensive treatment plan including non-opioid treatments

13. Is the patient experiencing clear functional improvement with minimal risk?
   - Yes
   - No

14. Continue OT using the following approach:
    - Shortest duration
    - Use lowest effective dose (recognizing that no dose is completely safe and overdose risk increases at doses > 20-50 mg MEDD)
    - Continual assessment of improvement in pain and functional status and adverse effects

Abbreviations: MEDD: morphine equivalent daily dose; mg: milligram(s); OT: opioid therapy; SUD: opioid use disorder; POMP: Prescription Drug Monitoring Program; SUD: substance use disorders; UDT: urine drug test; VA/DoD Suicide CPG: VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide
VI. Informed Consent Discussion

Given the recognized risks of OT, an optimal approach to care should include a robust signature informed consent process that is patient-centered and provides patients with information about known benefits and harms of OT and treatment alternatives. In 2014, VA established a requirement for signature informed consent, consistent with VA policy for other treatments or procedures with a significant risk of complications or morbidity.

The informed consent discussion starts by focusing on the characteristics of the patient, including the reason the patient is on LOT, the location of his or her pain, and the goals of his or her treatment with opioids. The next part of the discussion focuses on OT itself, including the known risks and side effects of OT as well as the potential benefits. Alternatives to OT must also be discussed with the patient prior to obtaining informed consent. Both the practitioner and patient (or his or her surrogate) acknowledge that the items detailed on the informed consent form were discussed and understood. The patient at this point also acknowledges that he or she understands the importance of a variety of risk mitigation strategies aimed at minimizing the adverse outcomes of OT for the patient and others.

For the most current information on informed consent, see:

- The VA National Center for Ethics in Health Care website: http://www.ethics.va.gov/
- The Opioid Safety Initiative Toolkit: https://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_Toolkit.asp

VII. Additional Resources

- Veterans Administration Pain Management website: https://www.va.gov/painmanagement/
- Defense and Veterans Center for Integrative Pain Management website: http://www.dvcipm.org/
- Chronic Pain Information Page from the National Institute of Neurological Disorders and Stroke: https://www.ninds.nih.gov/Disorders/All-Disorders/Chronic-Pain-Information-Page