

### Develop a Treatment Plan

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Treatment plans should be developed in collaboration with the patient, and family or others if appropriate. Determine together whether to stay on opioids, reduce opioid dose at a rate consistent with patient's clinical and social situation, or transition to medication-assisted treatment (MAT). Patients may want to stop chronic opioid therapy due to a variety of reasons, including lack of efficacy, impact on quality of life, and concerns about addiction.<sup>1</sup> In determining a treatment pathway, clinicians and patients may have divergent priorities. While providers may be most concerned about overdose or addiction, many patients may consider that they personally may have low risk of serious adverse outcomes. Patients are more likely to fear pain, suffering, and loss of control more than a serious event. However, patients also are likely to have priorities for effective pain treatment beyond simple pain relief, including wanting better emotional well-being, improved physical activity, better sleep, and greater social participation.

Shared decision-making can be appropriate if the appropriate treatment pathway is unclear. This is not appropriate if there is clear evidence supporting a particular treatment pathway (e.g., opioid use disorder). Shared decision-making does not require the provider to give up prescribing decision authority. However, shared decision-making does involve the patient and provider both sharing information, deliberating about options, and agreeing on a course of action. One method for achieving consensus is the use of motivational interviewing. This approach involves *“expressing empathy and avoiding arguing, developing discrepancy, rolling with resistance, and supporting self-efficacy (client’s beliefs/he can successfully make a change).”*<sup>2</sup> The goal of motivational interviewing is understanding the patient’s motivations and barriers to change in order to change a behavior (e.g., smoking cessation).

The documented treatment plan should be supported by the following:

- **Collaborative care model.** Chronic pain should be managed through a collaborative care model as described in the 2019 Bree [Collaborative Care for Chronic Pain Report and Recommendations](#). These guidelines focus on the use of a care team to achieve goals of improved function, increased quality of life, and greater patient autonomy, rather than a primary focus on pain relief.
- **Behavioral health providers, where possible.**<sup>2</sup> Pain alone does not cause depression, anxiety, or alcohol use disorder, although it can exacerbate these conditions. In addition, patients may experience anxiety or fear associated with changes in treatment approach.
  - Useful language - “These providers are here to help you through these changes”
  - Opioids are effective at suppressing symptoms of anxiety and post-traumatic stress disorder.
  - Sleep dysfunction makes everything worse
  - Anger, shame, grief, questioning whether life has meaning or purpose
- **Non-opioid pharmacological pain management.** This can include acetaminophen, non-steroidal anti-inflammatory drugs, topicals (e.g., capsaicin, lidocaine, diclofenac), anticonvulsants, intermittent steroid injections, serotonin/norepinephrine reuptake inhibitors, and others as indicated.
- **Non-pharmacological pain management.** Identify, support and enhance what patients are already doing to manage chronic pain with life activity impacts. Discuss:
  - Exercise

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- Cognitive-behavioral therapy
- Integrative health practices (e.g., massage, acupuncture, spinal manipulation).
- Reactivation methods (e.g., physical therapy, activity coaching)
- Movement and body awareness strategies (e.g. yoga, tai chi, qigong).
- Multidisciplinary rehabilitation
- Manual therapies

### Pathway #1: Maintain and Monitor

This pathway can be considered if the patient meets the following criteria:

- Clear evidence of clinically meaningful improvement in function on opioids along with satisfactory work/home productivity
- No history of non-fatal overdose or other serious adverse events
- Not on combinations of opioids and sedatives
- Has a destructive disease process such as (but not limited to) systemic lupus erythematosus, sickle cell anemia
- Opioids are not prescribed for a centralized pain condition (e.g., non-specific musculoskeletal disorder, fibromyalgia, headaches)
- No history of alcohol misuse or illicit substance use
- No history of opioid misuse or diversion
- Opioid dose is <90 mg/day MED
- No unexpected controlled substances on PDMP
- No unexpected results from UDT
- No history of requesting early refills
- No history of lost or stolen medication
- Opioid prescribing is consistent with DOH pain management rules

Follow the 2015 AMDG Guideline, 2016 CDC Guideline and DOH pain management rules for prescribing and monitoring chronic opioid therapy.

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### Pathway #2: Taper or Wean

Patients should be tapered or weaned if they meet the following criteria from the 2015 AMDG Guideline (table 8) or the 2016 CDC Guideline\*:

- Patient requests opioid taper
- Patient is maintained on opioids for at least 3 months, and there is no sustained clinically meaningful improvement in function (CMIF), as measured by validated instruments
- Patient's risk from continued treatment outweighs the benefit (e.g. decreased function and increased risk for opioid-related toxicity from concurrent drug therapy or comorbid medical conditions)
- Patient has experienced a severe adverse outcome or overdose event
- Use of opioids is not in compliance with DOH's pain management rules or consistent with the AMDG Guideline
- Patient exhibits aberrant behaviors (Table 9 in 2015 AMDG opioid Guideline)
- \*Is on dosages  $\geq$  50 MME without benefit or opioids are combined with benzodiazepines
- \*Shows signs of substance use disorder (e.g., work or family problems related to opioid or other substance use, difficulty controlling use)
- \*shows early warning signs for overdose risk such as confusion, sedation, or slurred speech

The taper plan could include tapering to a lower dose or weaning completely off opioids. Review the CDC Pocket Guide: Tapering Opioids for Chronic Pain, that follows similar principals to the 2015 AMDG Opioid guideline on whether to reduce or discontinue chronic opioid therapy (COT). Providers should be aware of available resources to help patients.

- **Engage and encourage.** Providers should validate patients' experience and fear about tapering, including concerns about uncontrolled pain, withdrawal, abandonment, and loss of control. Appropriate education regarding the potential benefits of tapering should be part of the effort to engage the patient in a taper. Except in cases of clear opioid use disorder, illicit drug use, diversion of prescribed opioids or imminent overdose risk, it is usually possible to develop a tapering plan jointly with the patient and family over a series of clinical visits. Reassuring patients that they will not be abandoned is crucial before and during the taper process. It is important to set realistic expectations about withdrawal symptoms during the tapering process.
- **Individualize.** The decision to taper a patient's opioid dose and the schedule to use should be individualized to each specific patient and take into account patient preferences and life circumstances, whenever possible. Involve the patient in developing a taper plan
- **Consult with other providers.** Specific consultation may be important for patients at high risk of harm during a taper, such as pregnant women or patients with other substance use disorders.
- **Protocol.** In general, patients should be tapered using their long-term opioid medication. Patients taking only short-acting opioids can often be tapered more quickly. Patients taking intermittent opioids do not need to be tapered.
- **Go slow.** Typical taper rates range from 10% per week to as slow as 10% per month. Use of the updated AMDG taper plan calculator can be extremely useful ([Washington State Opioid Taper](#))

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[Plan Calculator](#)). Some patients with complex medical and psychiatric co-morbidities may require a slower taper. Tapers may be paused to address withdrawal symptoms, but, in general, **should not be reversed**.

- **Watch for intolerable withdrawal symptoms.** Table 10 in the 2015 AMDG Opioid Guideline summarizes the array of available treatments for the main symptoms associated with withdrawal during tapering (opioid abstinence syndrome). The most commonly used treatments include alpha adrenergic agonists such as clonidine for restlessness, sweating and tremors, antiemetics (e.g., ondansetron or prochlorperazine) for nausea, loperamide or anti-spasmodics (eg, dicyclomine) for diarrhea, NSAIDs, gabapentin or muscle relaxants (e.g., cyclobenzaprine, tizanidine or methocarbamol) for muscle pain, neuropathic pain, or myoclonus, or antidepressants such as nortriptyline (25 mg hs), mirtazapine (15 mg hs), or trazodone (50 mg hs). Benzodiazepines and sedative-hypnotics should not be used. If the above drug therapy does not sufficiently address withdrawal symptoms, consider slowing or pausing the opioid taper.
- **Use support and adjunctive therapies.** Every patient should be actively supported. Engage the family/significant other to support the patient's taper plan. Peer support can also be a helpful resource. Provide evidence-based treatments, such as cognitive behavioral therapy and reactivation via psychologically informed physical therapy. Comorbid mental health conditions should be treated. If available, multimodal care through a structured intensive multidisciplinary program (SIMP) can be helpful for complicated clinical scenarios (e.g., high dose, concurrent sedatives, comorbid mental health).
- **Monitor.** Patients being tapered require close follow-up by the principal tapering provider, both during and after the taper. Patients undergoing a taper should be monitored for worsening or unmasked depression and anxiety and for emergence of opioid use disorder. Providers should collaborate with mental health specialists as needed. The Prescription Monitoring Program should be checked regularly throughout this period.
- **Use of buprenorphine to assist with taper.** Temporary use of buprenorphine may facilitate a taper plan by minimizing withdrawal symptoms. Potential benefits include:
  - Increasing patient willingness to attempt dose reduction
  - Facilitating more rapid dose reduction
  - Addressing physiological consequences of high-dose long-term opioid use (craving, withdrawal, prolonged abstinence syndrome)
- **Complex persistent dependence.** For patients who experience prolonged and severe physical withdrawal symptoms and negative emotional symptoms after tapering opioids, the provider should consider the possibility of complex persistent dependence. These patients may benefit from transition to buprenorphine for pain.

(Refs: Oldfield BJ, et al. Pain Medicine 2018;19(S1):S38-S45. Guillod P, Edens EL, Becker WC. JAMA Intern Med. 2017;177(1):17-18. Becker WC, et al. J Subst Abuse Treat. 2015; 48(1):128-31)

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### Pathway #3: Transition to Medication Assisted Treatment (MAT) for OUD

Refer to the 2015 AMDG Interagency Guideline on Prescribing Opioids for Pain, Part VI (Recognition and Treatment of opioid use disorder):

- Use evidence-based therapy including medication-assisted treatment (MAT) if opioid use disorder is present. Follow the 2017 Bree Collaborative [Opioid Use Disorder Treatment Report and Recommendations](#) and the [2015 Agency Medical Directors Guideline on Prescribing Opioids for Pain](#) Part VI Recognition and Treatment of opioid use disorder.
- In many cases, a clear diagnosis of opioid use disorder using DSM-5 criteria may not be apparent. Failed attempts at tapering, or persistent and severe withdrawal symptoms in spite of best medical treatment to address these symptoms, or failed multidisciplinary treatment for chronic pain, may indicate the need for a trial of MAT.
- Patients must abstain from short acting opioid agonists for at least 8 to 12 hours (best accomplished overnight; a longer interval is usually required for long acting opioids or fentanyl) and be in mild-to-moderate withdrawal (a score of  $\geq 8$  on the Clinical Opiate Withdrawal Scale)
- Once a patient is having mild-to-moderate withdrawal, administer 2 to 4 mg of sublingual buprenorphine or buprenorphine plus naloxone. If patient has no unacceptable side effects, administer an additional 4–8 mg sublingually at 1–2 hours, followed by adjustment according to response up to 32 mg daily in divided doses

## **Evidence**

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### **Engagement**

### **Assessment**

The PEG assessment should be done at each visit.<sup>3</sup>

### **Treatment pathways-Maintain and monitor**

#### **Treatment pathway-Tapering**

Substantially more evidence on tapering has been published since the literature review on the 2015 AMDG guideline was completed in December 2014.

Frank et al (2017), using GRADE methodology, conducted a systematic review of 67 studies, including 11 randomized trials.<sup>4</sup> The review concluded that, based on very low quality of evidence, several interventions may be effective at promoting tapering, and pain, function, and quality of life may improve with tapering. The strongest evidence with fair-good studies included interdisciplinary programs with mean opioid discontinuation rates of 87% and behavioral interventions, with mean opioid discontinuation rates of 21%. Very weak studies included buprenorphine dose reduction and ketamine-assisted dose reduction. The authors concluded that 1) education for patients on COAT should include the message that pain severity, function, and quality of life may improve after opioid tapering, 2) there should be consideration of referral to a multidisciplinary, multimodal pain program to support opioid dose reduction, and 3) team-based strategies with close follow-up to support opioid tapering when multidisciplinary programs are not available.

Berna et al (2015) conducted a comprehensive review of 117 articles and offered recommendations for everyday practice targeted at primary care physicians.<sup>5</sup> An overarching conclusion was that discontinuing COAT is most often hindered by patients' psychiatric co-morbidities and poor coping skills, as well as a lack of formal guidelines for prescribers to successfully taper. Several issues pointed out by Berna et al (2015) provide additional potential guidance: 1) Immediately following a successful taper of COAT, or after discontinuing post-op opioids, sensory hyperalgesia may occur, 2) the potential utility of use of objective and subjective opiate withdrawal scales (Clinical Opiate Withdrawal Scale [COWS]; Subjective Opiate Withdrawal Scale [SOWS]), 3) Overall, aggregating patients across numerous studies, patients report improvements in function without associated worsening in pain (N=1007) or even decreased pain levels (N=513), 4) Patients who take opioids only intermittently (<once daily) do not need a formal taper, 5) Empirical protocols since the 1990s favor tapers using the patient's long term opioid treatment medication, vs switching to another medication for the taper, 6) psychological support may be needed to address possible anxiety related to the taper, underlying depression, and deficient pain- and stress-coping strategies, 7) A taper agreement, including a collaboratively formulated plan, may help foster an effective therapeutic relationship and minimize the risk of breaking trust, 8) in patients with opioid dependence, buprenorphine may reverse opioid-induced hyperalgesia and reduce

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opioid tolerance. Convincing evidence from 8 studies (aggregated N=14,224), including 3 randomized clinical trials and a large open-label observational study, supports the benefits of this practice.

Several recent randomized trials of tapering have been reported since 2015; they have in common difficulty in recruitment or high drop-out rates, emphasizing the importance of patient and provider engagement in any tapering program. Sullivan et al reported a 22 week RCT with opioid taper support vs usual care (N=35).<sup>6</sup> Although this study did not achieve significant differences in opioid dose reduction or pain severity ratings between the supported group vs the usual care group, self-reported pain interference and pain self-efficacy were improved in the intervention group. This was essentially a feasibility study to launch a larger funded study now underway.

In an observational study at a single pain clinic at Stanford University, Darnall et al (2018) reported that 75% of eligible patients on COAT (82/110) volunteered to enter a tapering protocol.<sup>7</sup> Patients were followed for 4 months (completers) on a slow taper, with only education (a self-help book) and physician support, but no behavioral intervention; 38% (31/82) of enrolled patients did not complete the four month end-date survey and were considered drop outs. Among completers, baseline opioid dose (median dose =288 MED/day) was reduced to a median of 150 mg MED. Dose reduction was not associated with worse pain intensity or pain interference. Duration of opioid use did not predict taper success. Thus, even patients on very high doses followed closely in a pain clinic may be willing to at least initiate a taper protocol.

Frank et al conducted key informant interviews among 24 Colorado patients who were currently on COAT and had not tried tapering (6/24, 25%), were currently tapering (12/24, 50%), or who had discontinued COAT (6/24, 25%).<sup>8</sup> Patients perceived a low risk of overdose and a higher and more immediate risk of increased pain with tapering. Fear of withdrawal and a perceived lack of effectiveness of non-opioid options were identified as barriers. Social support and a trusted health care provider to facilitate tapering were identified as helpful among those with tapering experience. Improved quality of life was reported following successful tapering. Another qualitative study on a small number of patients emphasized the individualized nature of communications regarding possible tapering and emphasized assuring patients they would not be abandoned. (Matthias et al, 2017)<sup>9</sup>

Evidence on taper speed is almost entirely based on studies of patients with opioid use disorder related to heroin use (not chronic pain). Consensus opinions on taper speed range from 5-10% every 2-4 weeks to 2-10% every 4-8 weeks, with pauses as needed.<sup>10</sup> Veterans Administration recommendations are for 5-20% every 4 weeks. Detailed example tapers are also offered.<sup>11</sup> Sudden discontinuation is strongly NOT recommended. A cohort study from Vermont Medicaid, in whom discontinuation occurred in a median of 1 day, indicated that most patients either had no taper or rapid taper. Forty-nine percent of these patients had an opioid related hospitalization or emergency department visit subsequent to the sudden or rapid discontinuation. A majority (60%) of these Medicaid recipients had a diagnosed substance use disorder prior to tapering, and <1% had been transitioned onto an OUD medication.<sup>12</sup> On April 9, 2019 the FDA published a Drug Safety Communication strongly advising against abrupt discontinuation among patients on long-term opioid therapy.<sup>13</sup>

Studies published to date have not been designed to evaluate effects of tapering on overdose risk, use of illicit opioids, or suicidality/suicide events. Research is needed on effectiveness of adjunctive treatments; buprenorphine taper in the context of chronic pain with or without prescription opioid taper; speed of taper; and the effects of patient and clinical factors on taper outcomes. More research is

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also needed evaluating tapering in primary care and the health systems support necessary for effective tapering in primary care. Multiple randomized trials of interventions to promote opioid taper are underway.

### Treatment pathway-Treat for Opioid Use Disorder or Complex Dependence

Medication assisted treatment (MAT) combines the use of medications with behavioral therapy (e.g., counseling) for a whole-person approach, augmenting behavioral therapy alone and has been shown to be more effective than behavioral therapies, medically-supervised withdrawal, or abstinence alone.<sup>14,15,16</sup>

### Health Systems Interventions

Use of the **Six Building Blocks**, as originally devised for chronic disease management at Group Health Cooperative of WA, and expanded by work at the MacColl Institute, has been recently applied to assist primary care practitioners in safety net clinics, such as Federally Qualified Health Centers, to improve management of patients on COT. The Bree Collaborative Care model for Chronic Pain (<http://www.breecollaborative.org/wp-content/uploads/Recommendations-Chronic-Pain-Final-2018.pdf>) follows the principals of the Six Building Blocks. Use of telecare to deliver collaborative management is an emerging area (Kroenke K et al, Contemp Clin Trials 2013;34:270-281; Kroenke K et al, JAMA 2014;312(3):240-248). In this model, lower intensity intervention can be delivered by a pharmacist care manager.

Delivery of **multimodal pain care** in the community has the most evidence in randomized controlled trials for the effective treatment for chronic musculoskeletal pain, one of the most important contributors to years lived with disability in the US (Murray et al)<sup>17</sup>

A **peer support specialist** has been used in the Southern Oregon Pain Guidance effort to assist the patient on COT throughout, including as a teacher/mentor, as a tapering and withdrawal coach, as an advocate, and as a resource purveyor, for example, with available community resources. The peer support specialist has also worked with providers on difficult conversation training.

**Institutional multidisciplinary panel support** for primary care practitioners to assist with the care and assessment of patients on COT has been employed at Veterans Administration health Centers in Portland and New Haven. The Department of Labor and Industries is now exploring similar types of support mechanisms through its Centers for Occupational Health and Education.<sup>18,19,20</sup>

The **Vermont Hub and spoke model**, also being explored in Washington's Accountable Communities of Health, has been applied to the care of patients with opioid use disorder, but it could also be deployed to assist in the more complex phases of care for the patient on COT, particularly those with more severe dependence or OUD.

**Multidisciplinary pain clinics** have been used at the University of California-San Francisco, Cleveland Clinic, the Mayo Clinic, and by the WA Department of Labor and Industries, to assist with prescription opioid tapering.

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### References

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## Appendices

DSM-5 Criteria for Diagnosis of Opioid Use Disorder	
<b>Diagnostic Criteria*</b> <small>These criteria not considered to be met for those individuals taking opioids solely under appropriate medical supervision.</small>	
Check all that apply	
<input type="checkbox"/>	Opioids are often taken in larger amounts or over a longer period of time than intended.
<input type="checkbox"/>	There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
<input type="checkbox"/>	A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
<input type="checkbox"/>	Craving, or a strong desire to use opioids.
<input type="checkbox"/>	Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.
<input type="checkbox"/>	Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
<input type="checkbox"/>	Important social, occupational or recreational activities are given up or reduced because of opioid use.
<input type="checkbox"/>	Recurrent opioid use in situations in which it is physically hazardous
<input type="checkbox"/>	Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.
<input type="checkbox"/>	*Tolerance, as defined by either of the following: (a) 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 an opioid
<input type="checkbox"/>	*Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms

Total Number Boxes Checked: \_\_\_\_\_

Severity: **Mild:** 2-3 symptoms. **Moderate:** 4-5 symptoms. **Severe:** 6 or more symptoms

### Appendix C: [2015 Agency Medical Directors Guideline](#)

#### Reasons to Discontinue COAT and Considerations Prior to Taper

- Consider tapering patients in an outpatient setting if they are not on high dose opioids or do not have comorbid substance use disorder or an active mental health disorder, as this can be done safely and they are at low risk for failing to complete the taper.
- 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. If SIMP is not available, engage patients in activities that emulate the biopsychosocial approach of such a program. Rarely, inpatient management of withdrawal may be necessary.
- Refer patients with aberrant behaviors (Table 9) for evaluation and treatment.

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- Consider sequential tapers for patients who are on chronic benzodiazepines and opioids. Coordinate care with other prescribers (e.g. psychiatrist) as necessary. In general, taper off opioids first, then the benzodiazepines.
- Do not use ultra-rapid detoxification or antagonist-induced withdrawal under heavy sedation or anesthesia (e.g. naloxone or naltrexone with propofol, methohexital, ketamine or midazolam).
- 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.
- Adjust the rate, intensity, and duration of the taper according to the patient's response (e.g. emergence of opioid withdrawal symptoms (Table 10)).
- Watch for signs of unmasked mental health disorders (e.g. depression, PTSD, panic disorder) during taper, especially in patients on prolonged or high dose opioids. Consult with specialists to facilitate a safe and effective taper. Use validated tools to assess conditions (Appendix B: Validated Tools for Screening and Assessment).
- Consider the following factors when making a decision to continue, pause or discontinue the taper plan: a. Assess the patient behaviors that may be suggestive of a substance use disorder b. Address increased pain with use of non-opioid options. c. Evaluate patient for mental health disorders. d. If the dose was tapered due to safety risk, once the dose has been lowered to an acceptable level of risk with no addiction behavior(s) present, consider maintaining at the established lower dose if there is CMIF, reduced pain and no serious adverse outcomes.
- Do not reverse the taper; it must be unidirectional. The rate may be slowed or paused while monitoring for and managing withdrawal symptoms.
- Increase the taper rate when opioid doses reach a low level (e.g.  $< 15$  mg/day MED), since formulations of opioids may not be available to allow smaller decreases.
- Use non-benzodiazepine adjunctive agents to treat opioid abstinence syndrome (withdrawal) if needed. Unlike benzodiazepine withdrawal, opioid withdrawal symptoms are rarely medically serious, although they may be extremely unpleasant. Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued (Table 10).
- Refer to a crisis intervention system if a patient expresses serious suicidal ideation with plan or intent, or transfer to an emergency room where the patient can be closely monitored.
- Do not start or resume opioids or benzodiazepines once they have been discontinued, as they may trigger drug cravings and a return to use.
- Consider inpatient withdrawal management if the taper is poorly tolerated.