4 **Prescribe self-management strategies, non-pharmacologic treatments and non-opioid medications as the preferred treatment for chronic pain.**

Self-management approaches should be recommended to all patients with chronic pain. Self-management refers to management of the pain, its symptoms, and of one's relationship with the symptoms. (Evidence shows self-management approaches improve self-efficacy in multiple chronic conditions[19 20 21] and that opioid treatment of chronic pain may undermine self-care.[22])

Many non-pharmacological therapies, including physical therapy, weight loss, psychological therapies (e.g. cognitive behavioral therapy) and multidisciplinary rehabilitation can ameliorate pain and function.[13 23 24 25 26] Spinal manipulation, massage and acupuncture may be helpful in some chronic pain conditions.[27 28 29]

Non-opioid pharmaceuticals (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) may also be helpful for a variety of chronic pain conditions.[30 31 32 33 34 35 36 37 38 39 40 41]

Due to the favorable benefit-to-risk profile, these noninvasive, non-opioid therapies are preferred and should be offered to all patients with chronic pain. There is a lack of evidence showing any sustained functional benefit of long-term opioid therapy for chronic pain, but there is evidence of dose- and duration-dependent harms (See *Guideline #5*).

DO IT Create acute and chronic pain order sets that include non-pharmacologic treatment, non-opioid treatment and common referral sources (such as physical therapy, psychotherapy, substance use treatment, addiction specialists, pain medicine specialists, etc.).

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5 **Do not initiate long-term opioid therapy for most patients with chronic pain.**

While benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are significant and increase with increasing dose and duration of opioid use.[12 42 43] Risks to patients include overdose, overdose death, addiction, depression, opioid induced hypogonadism, opioid-induced hyperalgesia, and worsening function.[18 44 45 46 47 48 49 50 51 52 53] A 2017 Cochrane Review found good-quality evidence that use of opioids for greater than two weeks is associated with a significantly increased risk of experiencing an adverse event when compared to use of a placebo and non-opioid pharmacotherapy, and identified a very high absolute rate (78%) for adverse events.[54] Due to this unfavorable balance of risks compared to benefits, initiating opioid therapy for common causes of chronic pain including low back pain, osteoarthritis pain, fibromyalgia, neuropathy and headache is not recommended. The decision to initiate opioid therapy must be made on a case-by-case basis after carefully weighing the known risks against possible benefits.

DO IT Develop a system for opioid stewardship, i.e. monitoring opioid prescribing practices, outcomes and provider alignment with guidelines and best available evidence.

- See *References, Veterans' Administration 2017 Clinical Practice Guideline for Opioid Therapy*, "Recommendation 1) We recommend against initiation of long-term opioid therapy for chronic pain."

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6 **Coordinate interdisciplinary care for patients with high-impact chronic pain to address pain, substance use disorders and behavioral health conditions.**

There is an increased risk of poor outcomes including opioid overdose, opioid use disorder and death, for patients taking opioids that have substance use disorders or behavioral health conditions.[7 8 55 56 57] These clinical situations can be challenging to manage, and are further complicated by the possibility of providers inadvertently exposing the patient to dangerous drug-drug interactions. Interdisciplinary care for patients is advised, even as more research is needed on efficacy and feasibility of arranging such care.

The key disciplines that benefit patients with higher complexity chronic pain include primary care, substance use specialties, pain medicine, mental health, dietitians, health coaching and movement specialties (e.g. physical therapy). If interdisciplinary care is not available in a single care setting, it should be coordinated virtually between distinct care sites.

DO IT Use available case management resources, which may be offered by facilities, insurance companies, accountable care organizations or other local resources.

7 **For patients on long-term opioid therapy, document informed consent which includes the risks of opioid use, options for alternative therapies and therapeutic boundaries.**

The degree of risk associated with long-term opioid therapy (See *Guideline #5)* warrants completion of informed consent, to ensure and document patient and provider understanding of the risks and benefits of opioid therapy. Informed consent should be obtained prior to initiation and following any changes to the treatment plan.

A risk stratification should be performed as part of a risk/benefit assessment prior to initiating or continuing opioid therapy in patients with chronic pain. Risk assessment can be accomplished either by using existing opioid risk assessment tools such as the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain – Revised (SOAPP-R). There are known limitations of risk tools, including low-sensitivity for the ORT and patient burden for longer tools like the SOAPP-R.

The care of patients with chronic pain should include a comprehensive medical and pain-related evaluation that includes assessing for substance use, psychiatric comorbidities and functional status. Comorbidities of anxiety and depression in particular may influence pain perception and exacerbate pain complaints.

DO IT Incorporate an informed consent document for regular clinic use.

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8 **Do not use long-term opioid therapy in patients with untreated substance use disorders.**

The recommendation against long-term opioid therapy for patients with substance use disorders is supported by at least five large studies and national recommendations.[8 12 43 56 57] Among patients with untreated substance use disorder, opioids carry a significant risk for adverse outcomes including opioid use disorder, opioid overdose and death. The lack of evidence of efficacy of long-term opioid therapy (See *Guideline #5)* and considerable evidence of significant harms of overdose, death and suicide outweighs any potential modest benefit of prescribing long-term opioid therapy in this population. In these patients, treatment of pain should optimize non-pharmacologic and non-opioid pharmacotherapy.

For patients already receiving long-term opioid therapy who are diagnosed with an untreated substance use disorder, clinicians should monitor closely, offer or arrange for substance use disorder treatment, and proceed with an exit strategy from the use of long-term opioid therapy for chronic pain (See *Guideline #17).*

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9 **Avoid concurrent use of opioids and benzodiazepines. If patients are currently prescribed both agents, evaluate tapering or an exit strategy for one or both medications.**

Concurrent use of opioids and benzodiazepines is associated with an increased risk of overdose and death and there is a FDA Black Box Warning, the FDA's strongest warning, against it.[58] Both agents cause central nervous system depression and can decrease respiratory drive, and their combined use is associated with a 4-10 fold increased risk of opioid overdose death.[59 60 61 62] The greatest risk is associated with the use of higher doses of opioids.[63]

Particular caution should be exercised when opioids are used with other sedatives/hypnotics.[56] Data from the Arizona Enhanced Surveillance showed that 17% of reported fatal overdoses had a sedative-hypnotic along with the opioid, versus 8% of reported nonfatal overdoses.

Many patients with chronic pain have other psychological comorbidities.[64] It is important to note that there is a lack of evidence of efficacy for benzodiazepines in the management of PTSD or chronic anxiety. The 2017 *Veterans Administration/ Department of Defense Clinical Practice Guideline for Post-Traumatic Stress Disorder and Acute Stress Disorder* provides a strong recommendation against the use of benzodiazepines for the treatment of PTSD due to lack of evidence of benefit and their association with known adverse events.[65] It is also important to coordinate a patient's care with other providers and check the AZ CSPMP to determine if patients are receiving a benzodiazepine or other drug capable of inducing fatal drug-drug interactions, such as fentanyl with CYP3A4 inhibitors and drugs that can prolong the QT interval.

Patients who are receiving concurrent opioid and benzodiazepine therapy should be assessed for exiting or tapering one or both agents, but abrupt discontinuation is not recommended. Abrupt discontinuation of benzodiazepines may be associated with serious adverse events including seizures and possible death. For high complexity patients, consider consultation with pain medicine specialists, substance use specialists and/or mental health specialists.

- See *Appendix E: How to approach an exit strategy.*
- See *Appendix G: How to connect with local and national resources,* FDA Black Box Warning, which was signed and requested by the health officials at the Arizona Department of Health Services in 2016.
- See *Appendix G: How to connect with local and national resources,* Arizona Data from Enhanced Surveillance, showing that for both fatal and non-fatal overdoses, the most common drug combination was opioids and benzodiazepines.

10 Check the Arizona Controlled Substances Prescription Monitoring Program before initiating an opioid or benzodiazepine, and then at least quarterly.

Checking the Arizona Controlled Substances Prescription Monitoring Program (AZ CSPMP) before prescribing an opioid analgesic or benzodiazepine controlled substance and at least quarterly during treatment is good medical practice and a mandate under Arizona Revised Statutes 36-2606.[66] Use of the AZ CSPMP provides objective data to assist with identification of harmful medication interactions or evidence of multiple providers prescribing controlled substances. There are exceptions to the legal mandate (including for patients receiving hospice and palliative care). Data comparing states with an implemented prescription database compared to states without one showed 1.55 fewer deaths / 100,000 people.[67]

As of the publication of these guidelines, methadone prescriptions do not appear in the AZ CSPMP. Prescribers must recognize this limitation, and methadone-prescribers are in turn encouraged to consult the AZ CSPMP to check for patients who are being prescribed benzodiazepines by their psychiatrists or primary care physicians.

Recognizing that patients may provide inaccurate names and dates of birth, patients should be able to verify their identity when receiving an opioid prescription. This corroboration adds a safeguard against opioid misuse.

DO IT Ensure that clinicians and assigned delegates are registered and able to access the Arizona Controlled Substances Prescription Monitoring Program.

- See *Appendix G: How to connect with local and national resources,* Legislative language on AZ CSPMP.

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11 Discuss reproductive plans and the risk of neonatal abstinence syndrome and other adverse neonatal outcomes prior to prescribing opioids to women of reproductive age.

There are studies that have shown an association of opioid use in pregnancy with birth defects, including neural tube defects, congenital heart defects, gastroschisis, preterm delivery, poor fetal growth, stillbirth and neonatal abstinence syndrome.[13] In 2017, the American College and Obstetrics and Gynecology and the American Society of Addiction Medicine published a Committee Opinion to avoid or minimize the use of opioids for chronic pain management and to highlight alternative pain therapies such as non-pharmacologic and non-opioid pharmacologic treatment.[68]

For women of reproductive age, contraceptive counseling and access to contraceptive services should be a routine part of substance use disorder treatment to minimize the risk of unplanned pregnancy.[68]

For pregnant women with opioid use disorder, opioid agonist pharmacotherapy is the recommended therapy and is preferable to medically supervised withdrawal.

- See *Appendix G: How to connect with local and national resources,* ACOG/ASAM Committee Opinion #711.
- See *Appendix G: How to connect with local and national resources,* Arizona Data from Enhanced Surveillance, showing that 151 infants were born with suspected neonatal abstinence syndrome during the first 60-day period.

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12 If opioids are used to treat chronic pain, prescribe at the lowest possible dose and for the shortest possible time. Reassess the treatment regimen if prescribing doses ≥50 MEDs.

There is no absolutely safe dose of opioids.[69] Risk for opioid use disorder increases with duration and dose.[12 42 43] Risk of prescription opioid overdose and death exists even at low opioid dosage levels, and increases with prescribed dose. Opioid dosages between 50-99 MEDs have been found to increase risks for opioid overdose by factors of 1.9 to 4.6 compared with dosages <20 MEDs, and dosages ≥100 MEDs are associated with increased risks of overdose 2.0 to 8.9 times the risk at <20 MEDs.[7 8 56 70] As such, careful documentation and decision-making must be undertaken to accurately weigh risks against benefits for high-dose opioid prescriptions. The primary goal of care for a patient with chronic pain is maximizing function and minimizing pain-related suffering, rather than elimination of pain.

For higher risk patients, consider consultation with a pain-management specialist, substance-use disorder specialist, mental health specialist or coordination of interdisciplinary care.

Of note, extended-release/long-acting opioids have not been proven to be safer or more effective than short-acting opioids for managing chronic pain. There is an association between long-acting opioid use and significantly increased risk of all-cause mortality.[18]

DO IT Develop a system for opioid stewardship, i.e. monitoring opioid prescribing practices, outcomes and provider alignment with guidelines and best available evidence.

- See *Appendix G: How to connect with local and national resources,* Arizona Data from Enhanced Surveillance, showing that the mean MEDs prescribed to persons with suspected overdoses and deaths was 96 MEDs.

13 Counsel patients who are taking opioids on safety, including safe storage and disposal of medications, not driving if sedated or confused while using opioids and not sharing opioids with others.

Some of the dangers from opioid use can extend from the patient into the public. Household members of persons in possession of opioids are themselves at increased risk of an opioid overdose.[71] Children are in danger of initiating opioids or having opioid poisoning.[72] The public is at risk from a driver that is impaired.[73] Counseling and educating patients and their families about safety is imperative, as is notifying them that sharing of controlled substances is a felony, subject to imprisonment or fines.

- See *Appendix G: How to connect with local and national resources,* DEA on Sharing of Controlled Substances.
- See *Appendix G: How to connect with local and national resources,* Safe Disposal Locations.

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14 Reevaluate patients on long-term opioid therapy at least every 90 days for functional improvements, substance use, high-risk behaviors and psychiatric comorbidities through face-to-face visits, PDMP checks and urine drug tests.

There is a heightened risk for developing opioid use disorder in patients who take opioids for more than 90 days.[74 75] There is also a heightened risk for opioid use disorder in persons with concurrent substance use and psychiatric comorbidities.[76 77 78] Face-to-face visits should focus on function and quality of life (rather than only pain intensity), optimizing treatment for medical and psychiatric comorbidities, assessing progress towards the patient's goals and values, and routine safety monitoring with PDMP checks and urine drug testing. The use of risk mitigation strategies, including face-to-face visit, PDMP checks and urine drug testing protect both patients and providers. Beginning in October 2017, checking the PDMP is a legal mandate in Arizona.[66] While there is no clear evidence that urine drug testing improves outcomes, it can help identify patients with substance use disorders and other high-risk behaviors so that evidence-based therapy and risk mitigation strategies can be implemented. It is recognized that urine-drug screens (e.g. immunoassays) have limitations in sensitivity and specificity, and thus should be confirmed through appropriate tests (e.g. gas chromatography-mass spectrometry or high performance liquid chromatography).

DO IT Create a checklist for refill requests for long-term opioids which includes an evaluation for adverse effects, assessment for substance or opioid-use disorder, check of the CSPMP and urine drug screens and review of the management plan.

DO IT Create a registry for established patients on long-term controlled substances, and apply risk mitigation strategies as detailed in *Guidelines #7-17*.

- See *Appendix A: How to implement these guidelines into clinical flow,* providing an example registry.
- See *Appendix C: How to evaluate patients for opioid use disorder,* including diagnostic criteria and later notes on diversion.
- See *Appendix G: How to connect with local and national resources,* Legislative language on PDMP.

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15 Assess patients on long-term opioid therapy on a regular basis for opioid use disorder and offer or arrange for medication-assisted therapy (e.g. methadone and buprenorphine) to those diagnosed.

All patients using opioids are at-risk for developing an opioid use disorder.[69] There is strong evidence to support the use of opioid agonist therapy (i.e. methadone or buprenorphine) for patients with opioid use disorder.[79] Methadone-maintenance therapy for opioid use disorder is dispensed at federally-licensed opioid treatment programs whereas buprenorphine can be prescribed by DATA-2000 waivered clinicians (See *Appendix G* for Waiver Training). Opioid agonist therapy decreases opioid use, opioid-related overdose deaths, criminal activity and infectious disease transmission.[80 81 82] It increases social functioning and retention in treatment.[80 81] It also improves outcomes for the babies of opioid-dependent pregnant women.[83]

For patients with opioid use disorder, withdrawal management, otherwise known as detoxification, is less effective compared to agonist therapy and is associated with a significantly increased risk of relapse and treatment failure.[80 84 85] Withdrawal management should be used in conjunction with opioid antagonist therapy (e.g. injectable extended-release naltrexone) and/or other behavioral treatment with the understanding that attrition, mortality and return to use is higher compared to opioid agonist therapy.[86]

According to several conservative estimates, every dollar invested in addiction treatment programs provides cost savings by a ratio of 12 to 1.[87]

DO IT Become a buprenorphine-waived prescriber.

DO IT Collect and maintain substance use treatment resources that are relevant to the patient population served by the facility.

- See *Appendix C: How to evaluate and manage patients for opioid use disorder.*
- See *Appendix G: How to connect with local and national resources,* Arizona survey results for accessibility of Medication Assisted Treatment.
- See *Appendix G: How to connect with local and national resources,* Buprenorphine Waiver Training.

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16 Offer naloxone and provide overdose education to all patients and to family/significant others of patients at risk for opioid overdose.

Naloxone administration has been identified as a life-saving measure following opioid overdose. There is moderate evidence that take-home naloxone programs are effective at improving overdose survival and decreasing mortality and it is plausible that effectiveness would be observed in the clinical setting as well.[13] Distribution of naloxone for reversal is supported by Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration, Veterans Administration, Department of Defense, American Medical Association and other associations.

Patients at risk for opioid overdose include those with opioid use disorder or substance use disorder, those with a higher prescribed opioid dosage, those with mental health conditions, those who use opioids in combination with other sedating substances, those who have other conditions such as HIV, liver or lung disease or suffer from depression, or household members of people in possession of opioids.[71] Still, consider offering naloxone and overdose education to all patients, regardless of recognized risk factors, on long-term opioid therapy.

DO IT Create or use standing orders for naloxone.

- See *Appendix G: How to connect with local and national resources,* Arizona Naloxone Standing Orders, making naloxone available to patients and family members at pharmacies without a prescription.
- See *Appendix G: How to connect with local and national resources,* Arizona Data from Enhanced Surveillance, showing that over 1,000 doses of naloxone were administered to suspected opioid overdoses during the first 60-day surveillance period.

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17 Individualize a careful exit strategy from the use of long-term opioid therapy for chronic pain, when indicated by a risk assessment.

Long-term opioid therapy is associated with known risks and unproven benefits (See *Guideline #5*). Patients with chronic pain who are prescribed long-term opioid therapy should receive an individualized treatment plan to minimize opioid-related adverse events. Treatment plans are guided in part by evaluating the risk of continuing the current treatment plan and the risk of changing it. When indicated by risk assessment, treatment plans should include the development of an opioid exit strategy, which transitions patients from long-term opioid therapy to a different treatment strategy, and should be tailored to each patient. Treatment planning is a process and not a static event, and is guided by continual re-evaluation (See *Guideline #14* and *#15*).

The primary exit strategies include a) tapering the opioid dose b) rotating to buprenorphine and then gradually tapering the buprenorphine dose and c) offering or arranging medication-assisted treatment for patients with opioid use disorder. The choice of exit strategy cannot be done casually or with a “one-size-fits-all” approach; it should be guided by a biopsychosocial assessment of the patient, including evaluation of co-occurring medical and psychiatric conditions, substance use disorders, and the patient’s social support system. While there is clear evidence for the effectiveness of treating opioid use disorder with medication-assisted treatment (See *Guideline #15*), there is no established evidence to otherwise guide the best opioid exit strategy approach for an individual.

While opioid tapering seems a logical intervention for patients on long-term opioid therapy at risk for adverse events, tapering {Strategy (a)} may not be optimal for all patients. Generally, patients with lower MED prescriptions, lower pain-related dysfunction and lower psychiatric comorbidities can be candidates for a gradual taper (See Appendix E for tapering guidance).

In contrast, consider Strategy (b) (rotation to buprenorphine and subsequent buprenorphine tapering) for patients with higher MEDs, and higher pain-related dysfunction and comorbidities. After initiating an exit strategy, ongoing biopsychosocial assessment may guide the clinician to switch to a different strategy.

Abrupt opioid discontinuation is not recommended as an exit strategy, unless required for immediate safety concerns (e.g. evidence for diversion, threatening behavior, serious disruptive behavior, suicidal ideation or behaviors).

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