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Treatments, Technologies, and Models for Management of Acute and Chronic Pain in People With a History of Substance Use Disorder

Purpose

The purpose of this topic development brief is to explore and scope the evidence on treatments, technologies, and models for management of acute and chronic pain in persons with a history of substance use disorder, in order to help determine whether this topic is suitable for further action such as commissioning a systematic review or technical brief to inform clinical or policy decision making (including potential coverage determinations), or to inform future research priorities. This topic development brief is part of the Dr. Todd Graham Pain Management Study, to inform a report to Congress on acute and chronic pain management for individuals entitled to Medicare benefits.[1]

Issue

Pain and substance use disorders (related to prescription or illicit opioids, or other medications or substances with addiction potential) are common conditions that frequently co-occur.[2,3] Pain and substance use disorders share common features such as dysregulated dopamine and reward pathways that can be mutually reinforcing; therefore, effective treatment of both is critical. A number of factors complicate management of pain in patients with substance use disorders, including lower pain tolerance, higher analgesic requirements, the addiction potential of some medications used to treat pain, concurrent use of other substances (e.g. alcohol, cannabis), and the presence of other psychiatric conditions.[4-9] In addition, the use of partial or full opioid antagonists to treat opioid use disorder may complicate acute pain management.[9,10] These challenges of managing coexisting pain and substance use disorder may be greater in Medicare populations due to higher medical complexity, presence of disability, or older age.

Key Findings

- Evidence on treatment of acute pain in patients with opioid use disorder is insufficient to guide a policy or clinical action at this time; however, a scoping review suggests that strategies that involve continuation of medications for opioid use disorder (including partial or full agonists) while managing the acute pain episode warrant additional research. A randomized trial of reduced versus full-dose buprenorphine/naloxone is currently in progress (expected completion 2023).[11]
- For patients with chronic pain and opioid use disorder, limited evidence from randomized trials suggests that methadone and buprenorphine/naloxone may have similar pain and

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drug use outcomes and that psychosocial interventions utilizing cognitive-behavioral therapy principles may improve pain-related outcomes for some individuals.
- No study evaluated the effectiveness of technologies or models of care for treatment of pain in patients with substance use disorders, or the management of pain and co-occurring nonopioid substance use disorders.
- Studies on treatment of patients with acute or chronic pain and substance use disorders did not specifically evaluate populations potentially eligible for Medicare (e.g., based on younger age of the patients evaluated in the studies).

Background

Pain and substance use disorders are common conditions that frequently co-occur. Acute pain, usually defined as pain lasting for less than 30 days, is ubiquitous following surgery. Acute pain is also the most common reason for emergency department visits, and is commonly encountered in primary care, other outpatient settings, and inpatient settings.[12-14] Chronic pain, often defined as pain lasting longer than 3 to 6 months, or past the time of normal tissue healing, has an estimated prevalence of 20.4 percent in U.S. adults, with 8.0 percent reporting high impact (resulting in limitations in major life domains) chronic pain.[15] Substance use disorders are also common. In 2019, there were an estimated 20.4 million Americans 12 years or older with past-year substance use disorder.[16] Of these, approximately 18.1 million had an alcohol use disorder, 1.4 million had a prescription pain reliever use disorder, and about 8.3 million had an illicit drug use disorder. Much of the literature on pain and co-occurring pain and substance use disorder has focused on opioid use disorder because a significant proportion of opioid use disorders originate from opioids prescribed for pain;[17] in addition, there were over 46,000 overdoses related to opioids in 2018.[18] An estimated one-third to two-thirds of patients with opioid use disorder also suffer from chronic pain,[2,19,20] and a systematic review found that the rate of opioid use disorder in patients with chronic pain ranged from 8 percent to 12 percent.[21]

Coexisting pain and substance use disorders impact persons entitled to Medicare. The prevalence of pain increases with age. Approximately 27.6 percent of U.S. people 65 to 84 years old reported chronic pain in 2016, and 10.7 percent had high-impact chronic pain (defined as chronic pain limiting life or work activities on most days or every day in the past 6 months).[15] In people 85 years of age and older, the prevalence of chronic pain was 33.6 percent and the prevalence of high impact chronic pain was 15.8 percent. In 2018, nearly 1 million adults aged 65 and older had a substance use disorder,[16] and the prevalence of opioid use disorder in this age group appears to be increasing; data indicates that first time OUD admissions for adults 55 years or older increased 41 percent from 2004 to 2013 and 54 percent from 2013 to 2015.[22]

Management of pain in people with substance use disorders can be a challenge. Pain and substance use disorders share similar features, including dysregulated dopamine and reward pathways that can result in mutual negative reinforcement. In addition, pain can be a feature of substance use disorder, be associated with withdrawal or craving, and be a powerful trigger for substance use disorder. Therefore, effective treatment of pain might also improve substance use disorder outcomes, and vice versa.[23,24] A number of additional factors complicate management of pain in patients with substance use disorders. These include lower pain tolerance, higher analgesic requirements, the addiction potential of some medications or substances used in the management of pain (e.g., opioids, benzodiazepines gabapentinoids, and others), the high frequency of polysubstance use, and the frequent presence of other concomitant psychiatric conditions (e.g., depression, anxiety, post-traumatic stress disorder, and others).[4-9] The 2016 Centers for Disease Control and Prevention guideline on long-term opioid therapy for chronic pain recommends that primary care clinicians in outpatient settings assess patients for opioid use

disorder and offer or arrange evidence-based treatment if opioid use disorder is present.[25] Evidence-based treatments approved by the U.S. Food and Drug Administration for treatment of opioid use disorder include maintenance therapy with the long-acting opioid agonist methadone, the partial opioid agonist buprenorphine, or the opioid antagonist naltrexone. Use of these medications are considered the standard of care for treatment of opioid use disorder but may complicate management of pain, particularly when buprenorphine or naltrexone are used, due to blocking effects on other opioids.[4] The degree to which blocking effects may be overcome with use of full opioid agonists, and the doses required to overcome blocking effects, has been an area of uncertainty.[26,27]

A number of treatments and models have been utilized for management of acute and chronic pain in patients with a history of substance use disorder. In patients with pain and co-occurring opioid use disorder, treatment with medications for opioid use disorder with full or partial opioid agonist effects (methadone or buprenorphine) or opioid antagonist effects (naltrexone) are considered first-line treatment.[25] In addition to treating the underlying substance use disorder, methadone and buprenorphine have full or partial opioid agonist analgesic effects, while naltrexone blocks both the euphoric effect and the analgesic properties of all opioids. However, in patients with acute pain, use of such medications can be a challenge due to long-half (methadone) and partial or full opioid blockade (buprenorphine and naltrexone). In such patients, traditional approaches include discontinuation of buprenorphine or naltrexone and transition to an opioid agonist prior to elective procedures; discontinuation of methadone and transition to an alternative opioid agonist prior to elective procedures; or continuation of the medications for treatment of opioid use disorder with use of divided or increased doses or the addition of other opioids.[10,28,29] With all of these strategies, use of nonopioid therapies (pharmacological or nonpharmacological) is recommended. Recently, some experts have suggested routinely continuing buprenorphine in patients undergoing elective procedures, given the risk of withdrawal, relapse, or more difficult-to-control pain with discontinuation and the potential to effectively overcome partial opioid blockade with opioid analgesics.[30] In patients on higher doses of buprenorphine, continuing the buprenorphine but decreasing to a lower dose may reduce mu-receptor blockade and enable analgesic effects of other opioid agonists.[31] Methadone generally can be continued during acute pain episodes because it is a full agonist, but naltrexone is discontinued when possible due to near-complete opioid blockade. Guidelines on management of acute pain in patients taking medications for opioid use disorder have been based on very limited evidence or expert consensus.[30,32]

Other treatment options include psychological therapies (e.g., cognitive behavioral therapy, contingency management, relapse prevention, motivational interventions, brief interventions), other nonpharmacological therapies (e.g., exercise, mind-body interventions, physical modalities, and complementary and integrative therapies), nonopioid medications, and interdisciplinary approaches. These therapies aim to address behavioral aspects of the underlying substance use disorder, improve pain or function, or both.

Models of care that have been used for treatment of opioid use disorder that could be applied to management of pain in patients with opioid or other substance use disorders include practice-based (office-based opioid treatment and various models that are integrated with care for other conditions [e.g., HIV or mental health]) and systems-based models (medical home, hub and spoke and similar models, telehealth models, and various models that coordinate treatment initiation with long-term management among different settings [e.g., emergency department or inpatient initiation of treatment]).[33] Technologies such as mobile applications to monitor patient symptoms enable patients to more easily communicate with clinicians, facilitate psychological or other nonpharmacological therapies, provide decision support for clinicians, or function as

wearable sensors could also be useful to support management of patients with pain and co-occurring substance use disorders.[34]

Management of pain specifically in Medicare populations with substance use disorders may be more challenging that other populations with these conditions due to higher medical complexity, presence of disability, or older age. Therefore, understanding the evidence on effective or promising treatments, technologies, and models for managing such patients in this population could improve symptoms, quality of life, and function while improving substance use disorder-related outcomes.

Scope

1. In patients with acute or chronic pain and a history of substance use disorder, what are the effects of treatments, technologies, and models of care on pain, function, quality of life, mental health outcomes, opioid utilization, drug use outcomes, and adverse events (including overdose and mortality)?

The research questions explored in this Topic Brief are listed below and are analyzed according to the PICOTS framework in Table 1.

Table 1. Questions and PICOTS (population, intervention, comparator, outcome, timing, and setting)

Questions	1. Effects of treatments, technologies, and models of care
Population	Patients with acute or chronic pain and current or past substance use disorder (including, but not limited to, opioid use disorder)
Interventions	Treatments • Medications for opioid use disorder (methadone, buprenorphine, naltrexone; including management strategies in patients with acute pain on these medications) or other substance use disorders • Psychological treatments • Other non-pharmacological treatments (e.g., exercise, mind-body interventions, physical modalities, and complementary and integrative approaches) • Non-opioid medications • Interdisciplinary approaches • Technologies (e.g., mobile applications or wearable sensors) Models of care • Practice-based (office-based opioid treatment and various models that are integrated with care for other conditions) • Systems-based (medical home, Hub and Spoke and similar models, telehealth models, and various models that coordinate treatment initiation and long-term management among different settings)
Comparators	Placebo, usual care, or no treatment; other treatment, technology, or model of care
Outcomes	Pain, function, quality of life, mental health outcomes, opioid utilization, drug use outcomes, and adverse events (including overdose and mortality)
Timing	Any
Setting	Any

Assessment Methods

We conducted a literature search (Appendix A) and assessed the topic of treatments, technologies, and models for acute and chronic pain in persons with a history of substance use disorder for priority using a hierarchical process using adapted assessment criteria (Appendix B). Assessment of each criterion, based on consultation with local experts and a scan of the literature, determined the need to evaluate the next one.

1. Appropriateness
2. Importance
3. Current state of the evidence
4. Value and potential impact

For this Topic Brief, we defined value and potential impact as the potential for informing a policy/evidence action, suitability for commissioning a systematic review or technical brief, and implications for future research.

Current State of the Evidence

Based on a literature scan and consultation with local experts, this is a topic of clinical importance and appropriate for further assessment.

- Pain and substance use disorders are common conditions that frequently co-occur. The prevalence of chronic pain increases with age and the incidence of hospital admissions for substance use disorders in older adults is increasing.[16,22,35] Although substance use history complicates treatment of chronic pain, management of pain is critical for improving symptoms and function and may improve substance use disorder outcomes. However, treatment of patients with co-occurring pain and substance use disorders is a challenge and optimal approaches are uncertain. Management of persons entitled to Medicare may be particularly challenging due to greater medical complexity, presence of disability, or older age.[36-38]

Evidence on treatments, technologies, and models for treatment of acute and chronic pain in persons with a history of substance use disorder is available and has identified approaches that might be effective (medications for opioid use disorder and psychological therapies for chronic pain) or are promising (continuation of medications for opioid use disorder for acute pain), but the quality of the evidence was very low and the studies did not specifically evaluate Medicare-relevant populations. The current evidence is summarized in Table 2.

Acute pain and co-occurring opioid use disorder

- A well-conducted rapid review conducted by the U.S. Department of Veterans Affairs on the management of acute pain in patients taking medication for opioid use disorder identified 12 observational studies, based on searches conducted through April 2020.[29] However, the quality of evidence was assessed as very low. Only three studies in the rapid review used a control group; all were retrospective cohort studies and assessed as being at high risk of bias. Methodological limitations included baseline differences between groups and failure to control for confounding. All studies were conducted in patients undergoing surgery. The most informative study (n=51, mean age 39 years) found that in patients with opioid use disorder treated with methadone or buprenorphine prior to surgery, those who received their opioid use disorder medication the day after surgery used lower doses of patient control analgesia versus those who did not receive their medication the day after surgery, though pain and adverse events were similar.[39] Effects on substance-use disorder-related outcomes were not assessed. The two other controlled studies were not informative because they compared outcomes in patients treated with medications for opioid use disorder versus patients without opioid use

disorder. Of nine uncontrolled studies, seven were single subject case reports and the other two had two and five patients; in addition, the review noted that the quality of reporting was suboptimal. Two uncontrolled studies[40,41] in the review reported that patients taking buprenorphine were effectively treated for pain with opioid analgesics while continuing buprenorphine.

- An analysis not included in the rapid review of a randomized trial of pregnant women with opioid use disorder (n=18) who were randomized to take methadone versus buprenorphine found that postpartum pain following vaginal delivery improved markedly from day 1 to 5 in both groups; acetaminophen/oxycodone and ibuprofen were used for pain relief.[42]

Chronic pain and co-occurring opioid use disorder

- A systematic review[43] funded by the AHRQ on opioid therapy for chronic pain (search date August 2019) included three randomized trials of treatment of patients with prescription opioid use disorder. However, one trial[44] excluded patients with pain and another small trial[45] was terminated early because all patients randomized to a buprenorphine taper switched to maintenance therapy or had a relapse. The third, fair-quality trial (n=54) compared methadone versus buprenorphine/naloxone in patients with chronic non-cancer pain and prescription opioid dependence.[46] Approximately 40 percent of patients were receiving opioid medications at baseline. There was no difference between methadone versus buprenorphine/naloxone in pain, function, side effects, or use of unprescribed opioids, cocaine, or other drugs based on urine drug testing.
- Four additional randomized trials evaluated non-pharmacological therapies in patients with chronic pain and substance use disorders.
    - Two trials compared a psychosocial pain management intervention (Improving Pain during Addiction Treatment, ImPAT) versus psycho-education in patients with pain with various substance use disorders.[47,48] The psychosocial pain management intervention combined cognitive-behavioral therapy principles and acceptance based approaches to pain management with content related to avoiding the use of substances to cope with pain, delivered as 10 sessions over 10 weeks or eight sessions over 4 weeks. Outcomes were assessed at 12 months. One trial (n=129, mean age 52 years) found the psychosocial pain education was associated with decreased pain intensity and improved pain-related functioning versus psycho-education.[47] The other trial (n=510, mean age 34 years) found the psychosocial pain intervention associated with decreased pain intensity in women, but not men; there was no difference in pain related function.[48] Effects on pain intensity ranged from 0.6 to 0.7 point on a 10 point pain scale. There were no differences between interventions in alcohol or drug use in either trial.
    - One small trial (n=30, mean age 50 years) found no difference in pain intensity between mindfulness-oriented recovery enhancement versus treatment as usual in patients with chronic pain on methadone maintenance therapy, though the mindfulness interventions reduced cravings and improved measures of affect.[49]
    - A small pilot trial (n=22, mean age 50 years) of veterans with chronic pain and opioid misuse (defined as a score ≥9 on the Current Opioid Misuse Measure or DSM-5 opioid use disorder) found no differences between acceptance and commitment therapy for chronic pain plus mindfulness based relapse prevention for opioid misuse versus usual care in pain interference, pain intensity, prescribed opioid dose, or current opioid misuse, but was underpowered and had imprecise estimates.[50]

- A retrospective before-after study (n=53) of patients on methadone maintenance therapy referred for treatment of uncontrolled pain found that over 12 months, the dose of methadone was increased to 200 percent of the dose used in methadone maintenance, with a marked reduction in pain scores and no serious adverse events or side effects.[51] This study was conducted prior to the current understanding of dose-dependent risks associated with methadone.[52]

Evidence on technologies or models of care for acute or chronic pain and co-occurring substance use disorder is not available

- No systematic review or primary study evaluated technologies or models of care for management of patients with acute or chronic pain and substance use disorders. A scoping review funded by AHRQ on models of care for treatment of opioid use disorder in primary care did not address management of co-occurring pain.[53] A systematic review identified and described mobile applications for opioid use disorder (presence of pain not specified) but found no studies evaluating effects of applications on outcomes.[34] A systematic review of mobile applications for chronic pain did not identify any studies focusing on patients with co-occurring substance use disorders and the review identified shortcomings in the development and assessment of currently available applications, including failure to include health care providers in the development of the applications and incorporation of features that were not evidence-based or fully described.[54]

Evidence on treatment of acute or chronic pain and co-occurring nonopioid substance use disorders is not available

- No systematic review or primary study evaluated management of patients with acute or chronic pain and co-occurring non-opioid substance use disorders.

Ongoing trials may provide additional evidence to inform this topic

- A search of ClinicalTrials.gov identified three ongoing trials of psychological interventions in patients with chronic pain and co-occurring opioid use disorder (expected completion 2021, 2023, and 2025)[55-57] and one ongoing trial of full dose versus reduced dose buprenorphine/naloxone for acute (perioperative) pain (expected completion 2023).[11]

Table 2. Studies of treatments for acute and chronic pain in patients with a history of substance use disorder

Type of Pain	Description of Interventions	Number of Studies (N)	Main Findings	Quality Ratings, Where Available*
Acute	Medication for opioid use disorder (provision of medication taken for opioid use disorder on the day after surgery)	SR: 1 SR with 1 observational study (51) and small (1 to 5 patients) case reports and series Additional studies: 1 observational study (18) In-progress studies: 1 (76)†	Receipt of medication for opioid use disorder on day after surgery associated with decreased patient control analgesia utilization; cases and treatment series of patients effectively treated for pain while taking buprenorphine for opioid use disorder	High risk of bias: 1 controlled observational study in SR
Chronic	Methadone vs. buprenorphine/naloxone (1 study); methadone for analgesia	SR: 1 SR with 1 RCT (54) Additional studies: 1 observational study (53) In-progress studies: 0	No difference between methadone versus buprenorphine/naloxone in pain, function, side effects, or drug/substance use; methadone for analgesia reduced pain intensity without serious adverse events or side effects	Fair: 1 RCT in SR
Chronic	Psychosocial pain medication interventions vs. psycho-education (2 studies); mindfulness-oriented recovery enhancement vs. treatment as usual (1 study); acceptance and commitment therapy plus mindfulness-based relapse prevention (1 study)	SR: 0 Additional studies: 4 RCTs (691) In-progress studies: 3 (410)†	Psychosocial pain management intervention may be associated with decreased pain intensity versus psycho-education; effects on pain-related function mixed; no difference in drug use outcomes Other psychosocial interventions evaluated in small trials with imprecise estimates.	Not included in systematic reviews

Abbreviations: N = number of subjects; RCT = randomized controlled trial; SR = systematic review

*For studies included in systematic reviews, based on the ratings assigned in the reviews
†Planned enrollment

See Appendix B for detailed description of all EPC assessment criteria.

Summary of Assessment Criteria

Value and Impact

- For acute pain and opioid use disorder, evidence is extremely limited and insufficient to guide a policy or coverage action. However, treatment strategies that involve continuation of medications for opioid use disorder (including partial or full agonists) while treating acute pain appear promising and publication of an in-progress trial of full versus reduced dose buprenorphine/naloxone for acute (perioperative) pain could further inform this topic.

- For chronic pain and opioid use disorder, limited evidence could inform a policy or coverage action regarding provision of methadone or buprenorphine/naloxone, or a psychosocial pain intervention.
- Given recent systematic reviews and limited new evidence, a new systematic review is not currently warranted.
- The publication of ongoing trials on psychosocial interventions in patients with chronic pain and co-occurring opioid use disorder could warrant reconsideration of the suitability for a new systematic review.
- Research gaps include optimal approaches to use of medication for opioid use disorder in persons with acute pain; benefits and harms of non-pharmacologic therapies and non-opioid medications for acute pain and opioid use disorder; comparative studies of FDA-approved treatments for opioid use disorder, non-pharmacologic therapies, and non-opioid medications for chronic pain and opioid use disorder; technologies and models of care for treatment of acute or chronic pain and co-occurring substance use disorder; and treatments and approaches for pain and co-occurring non-opioid substance use disorders. Ideally, studies would enroll patients enrolled in Medicare or potentially eligible for Medicare based on age, disability, or other factors.

Related Resources

We identified additional information in the course of our assessment that might be useful.

- Substance Abuse and Mental Health Services Administration Tip 54: Managing Chronic Pain in Adults With or in Recovery from Substance Use Disorders[9]
- CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016[25]
- American Society of Addiction Medicine National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use[32]
- Perioperative Pain and Addiction Interdisciplinary Network (PAIN) Clinical Practice Advisory for Perioperative Management of Buprenorphine[30]

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Afterword

Medicare beneficiaries and other people with acute and chronic pain often receive treatment that does not successfully address pain, resulting in profound physical, emotional, and societal costs to them and their families, friends, and caregivers. Centers for Disease Control and Prevention data indicate 50 million adults in the United States have chronic daily pain, with nearly 20 million experiencing high-impact pain that interferes with daily life or work.[1] At the same time, the country is also coping with an opioid and substance use disorders crisis that involves shifting "waves" of overdose deaths associated with heroin, synthetic opioids, and prescription drugs, and intensifying polysubstance use. The country is also experiencing the COVID-19 public health emergency, which poses its own challenges for individuals, and the healthcare system.

Opioid analgesics play an essential role in treating pain, and pain management in the context of the nation's substance use crisis has rapidly evolved beyond an opioid-centric approach. Clinicians and healthcare systems need more information about multimodal pain care options in outpatient and inpatient settings to effectively treat Medicare and other patients with pain, and people with both pain and either active or historic substance use disorders, including knowledge about complementary care, analgesic medications, and medical devices that are potentially effective.

To address this challenge, AHRQ has undertaken three topic briefs and two systematic reviews to inform Medicare coverage and payment for treatment of acute and chronic pain in support of the Dr. Todd Graham Pain Management Study, section 6086 of the SUPPORT Act.

The topic briefs are:

- Care Coordination and Care Plans for Transitions Across Care Settings
- Treatments and Technologies Supporting Appropriate Opioid Tapers
- Treatments, Technologies, and Models for Management of Acute and Chronic Pain in People With a History of Substance Use Disorder

The systematic reviews are:

- Interventional Treatments for Acute and Chronic Pain
- Integrated Pain Management Programs

If you have comments on this report, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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[1] Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001–1006. DOI: http://dx.doi.org/10.15585/mmwr.mm6736a2external icon.

Appendix A. Methods

We assessed the topic for suitability for further action such as commissioning a systematic review or technical brief to inform clinical or policy decision making, or to inform future research priorities with a hierarchical process using assessment criteria adapted from the **AHRQ Effective Health Care Topic Development process**. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance, based on a preliminary literature scan and telephone interviews or email correspondence with six local experts with expertise in pain management and substance use disorder.

Current State of the Evidence

We searched for high-quality, completed or in-process evidence reviews published in the last 3 years on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
    - AHRQ Evidence Reports https://www.ahrq.gov/research/findings/evidence-based-reports/index.html
    - EHC Program https://effectivehealthcare.ahrq.gov/
    - US Preventive Services Task Force https://www.uspreventiveservicestaskforce.org/
    - AHRQ Technology Assessment Program https://www.ahrq.gov/research/findings/ta/index.html
- US Department of Veterans Affairs Products publications
    - Evidence Synthesis Program https://www.hsrd.research.va.gov/publications/esp/
    - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program https://www.healthquality.va.gov/
- Cochrane Database of Systematic Reviews https://www.cochranelibrary.com/
- PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/
- Ovid MEDLINE https://www.ovid.com/product-details.901.html
- ClinicalTrials.gov https://www.clinicaltrials.gov/

We conducted a search on December 4, 2020, on Ovid® MEDLINE® and The Cochrane Library. The search strategy included terms for pain and substance use disorder. We reviewed all of the citations identified in the search for potentially relevant citations, and classified identified studies by study design to estimate the size and scope of a potential evidence review. We also searched ClinicalTrials.gov for in-progress studies.

Database: Ovid MEDLINE(R) ALL 1946 to December 4, 2020

1 Chronic Pain/
2 exp arthralgia/ or exp back pain/ or exp headache/ or exp musculoskeletal pain/ or neck pain/ or exp neuralgia/ or exp nociceptive pain/ or pain, intractable/ or fibromyalgia/ or myalgia/
3 Pain/
4 chronic.ti,ab,kw.
5 3 and 4
6 ((acute or chronic or persistent or intractable or refractory) adj3 pain).ti,ab,kw.

7 (((back or spine or spinal or leg or musculoskeletal or neuropathic or nociceptive or radicular) adj1 pain) or headache or arthritis or fibromyalgia or osteoarthritis).ti,ab,kw.
8 1 or 2 or 5 or 6 or 7
9 substance-related disorders/ or opioid-related disorders/
10 (opioid* adj2 (abuse or disorder)).ti,ab,kf.
11 "substance use disorder*".ti,ab,kf.
12 or/9-11
13 8 and 12
14 limit 13 to "all aged (65 and over)"
15 Medicare/
16 (medicare or disabled or disabilit* or kidney or renal or "lou gehrig*" or "amyotrophic lateral sclerosis" or "als").ti,ab.
17 15 or 16
18 13 and 17
19 14 or 18

Value and Potential Impact

Based on the literature scan, we assessed the nomination for value and potential impact, based on the quality and extent of available evidence. We evaluated the potential for the evidence to (1) inform a policy or coverage action; (2) suitability for commissioning a new systematic review or technical brief; and (3) implications of current evidence on future research needs.

Appendix B. Assessment Criteria

Domain	Criteria	Assessment
1. Appropriateness	1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the United States?	Yes (treatments, technologies, and models of care)
	1b. Is the nomination a request for an evidence report?	No
	1c. Is the focus on effectiveness or comparative effectiveness?	Yes
	1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes (pain and substance use disorders commonly co-occur and may reinforce one another)
2. Importance	2a. Represents a significant disease burden; large proportion of the population	Yes, pain and substance use disorders commonly co-occur and both conditions represent a significant disease burden in the Medicare population
	2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the U.S. population or for a vulnerable population	Yes, management of pain in patients with substance use disorders is a challenge for clinicians and patients and could improve quality of life, function, and substance use disorder outcomes.
	2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes
	2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes, management of pain and substance use disorders can require high-cost interventions and care and these conditions can result in complications associated with high costs.

Domain	Criteria	Assessment
3. Current State of Evidence	3a. A recent high-quality systematic review or other evidence review is not available on this topic 3b. Adequacy (type and volume) of research for a new systematic review or technical brief	Yes. A high-quality recent scoping review is available on management of acute pain in patients treated for opioid use disorder with medications. A high-quality recent review is also available on management of chronic pain in patients with prescription opioid use disorder. The quality of evidence is very low for acute pain but suggests that provision of medications for opioid use disorder on the day after surgery (in patients taking them prior to surgery) may reduce analgesic requirements and that pain may be effectively treated in patients who continue taking buprenorphine or methadone. The evidence is limited for chronic pain but suggests that methadone and buprenorphine may be associated with similar outcomes and that a psychosocial pain intervention combining cognitive-behavioral therapy concepts, acceptance-based approaches, and education about not using substances to cope with pain may be associated with improved pain intensity.
4. Value and Potential Impact	4. Effectively utilizes existing research and knowledge by considering: - Newly available evidence - Research needs	Low quality evidence could inform a policy or coverage action for treatment of chronic pain and substance use disorder using either methadone or buprenorphine/naloxone, or a psychosocial intervention. Given recent systematic reviews and limited new evidence, a new systematic review is not currently warranted. Research is needed to clarify optimal approaches to pain and co-occurring substance use disorders, in Medicare-relevant populations; a key research gap is benefits and harms of strategies to manage acute pain and opioid use disorder in patients taking medications for opioid use disorder that involve continuation of the medication for opioid use disorder (including partial of full agonists) while treating the acute pain episode. Publication of in-progress trials on psychosocial interventions for chronic pain and opioids use disorder and buprenorphine for acute pain and opioid use disorder could impact assessments of value and potential impact.