Medications for substance use disorders

National Association of Insurance Commissioners

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CENTER FOR EVIDENCE-BASED POLICY

Center for Evidence-based Policy

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- We support states around the country with evidence to guide decision making and improve health outcomes
- We are public university-based, not-for-profit, nonpartisan, do not engage in lobbying, and our staff have no financial conflicts of interest

Disclosures

- No conflicts of interest

Outline

- What are substance use disorders?
- What medications are used for substance use disorders?
  - Opioid use disorder, opioid reversal agents, and opioid withdrawal
  - Alcohol use disorder
  - Tobacco use disorder
- Common issues in clinical practice
- Resources

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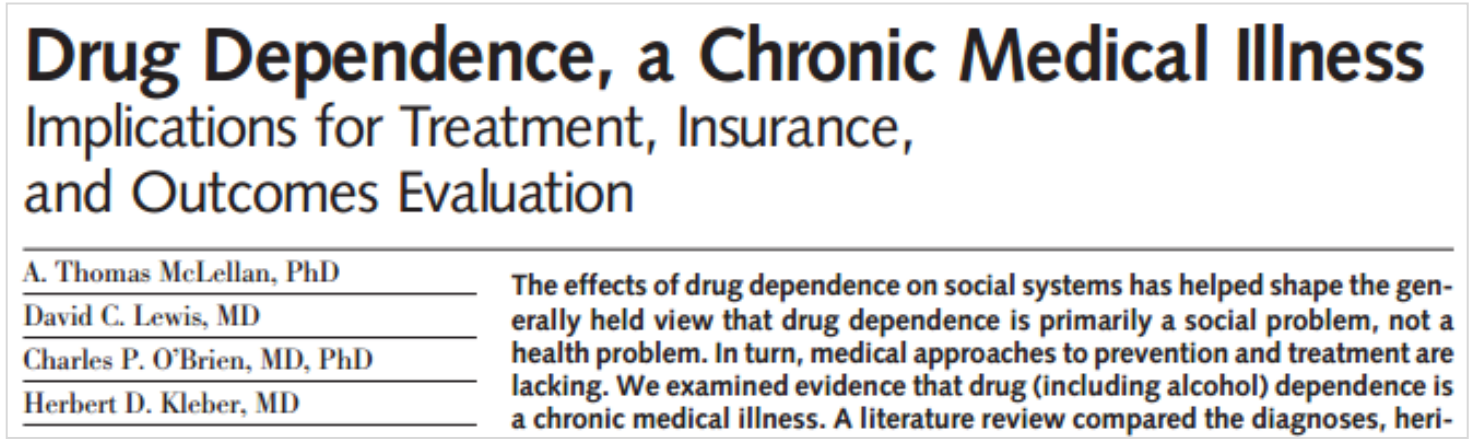
Background: Substance Use Disorders (1 of 2)

- Substance use disorder refers to a problematic pattern of use leading to clinically significant impairment or distress
- Characterized by:
  - Continued use despite consequences
  - Persistent desire to cut down
  - Tolerance
  - Withdrawal
- Name has changed, previously “abuse” and “dependence”
- “Addiction” is commonly understood but not medically precise

Source: Diagnostic and Statistical Manual of Mental Disorders (DSM-5)

Background: Substance Use Disorders (2 of 2)



Drug Dependence, a Chronic Medical Illness
Implications for Treatment, Insurance, and Outcomes Evaluation

A. Thomas McLellan, PhD
David C. Lewis, MD
Charles P. O'Brien, MD, PhD
Herbert D. Kleber, MD

The effects of drug dependence on social systems has helped shape the generally held view that drug dependence is primarily a social problem, not a health problem. In turn, medical approaches to prevention and treatment are lacking. We examined evidence that drug (including alcohol) dependence is a chronic medical illness. A literature review compared the diagnoses, heri-

- Substance use disorders share many key features with other chronic medical illnesses:
  - Genetic heritability
  - Periods of remission and relapse
  - Objective diagnostic criteria and response to guideline-based treatment
- Development and increased uptake of medication treatments

Source: McLellan, et al. (2002)

Background: Substance Use Disorder Medication

- Terminology of medication treatments for substance use disorders has changed
- MAT: Medication-Assisted Treatment → Medication for Addiction Treatment
  - Recognizing the central role of medications, especially for opioid use disorder
- MOUD: Medication for Opioid Use Disorder
- Medications can have an FDA-approved indication or can be widely accepted for “off-label” use
- Patient values, preferences, and prior experiences really drive medication selection

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Medication Treatments: Opioid Use Disorder (1 of 3)

- Early recognition that opioid use disorder is different than other drug and alcohol use disorders
- Psychosocial treatments alone are generally ineffective, resulting in frequent relapse
- By the early 1900's:
  - Short-term treatment with opioids to ease withdrawal was well established
  - Long-term treatment with opioids was believed to be effective, but was controversial

Source: Institute of Medicine Committee on Federal Regulation of Methadone Treatment (1995)

Medication Treatments: Opioid Use Disorder (2 of 3)

- Three FDA-approved treatments:
  - **Methadone** (oral)
  - **Buprenorphine** (sublingual alone and in combination with naloxone, or long-acting injectable)
  - **Naltrexone** (oral or long-acting injectable)
- **Methadone** for opioid use disorder can only be dispensed in federally-regulated Opioid Treatment Programs (medical benefit)
- One additional FDA-approved medication for opioid withdrawal symptoms: **Lucemyra** (lofexidine)

Source: SAMHSA (2021)

Medication Treatments: Opioid Use Disorder (3 of 3)

- Broadly, medications for opioid use disorder:
  - Reduce drug use, overdose, and death
  - Reduce HIV and hepatitis C infection
  - Reduce crime
- Treatment is effective and lifesaving*
  - Only methadone and buprenorphine have evidence of reduced mortality
- Any medication is superior to treatment without medication
- The three medications are delivered in different settings, patients often self-select, and there is not one "best" option

Sources: Center for Evidence-based Policy (2019); SAMHSA (2021)

Medication and Form	Opioid Use Disorder	Pain	Brand Name (Notes)
Sublingual buprenorphine tablet	X		Subutex
Sublingual buprenorphine/naloxone tablet	X		Zubsolv
Sublingual buprenorphine/naloxone film	X		Suboxone
Buprenorphine buccal film		X	Belbuca (Bunavail for OUD was discontinued in 2020)
Buprenorphine transdermal		X	Butrans
Long-acting injectable buprenorphine	X		Sublocade, Brixadi

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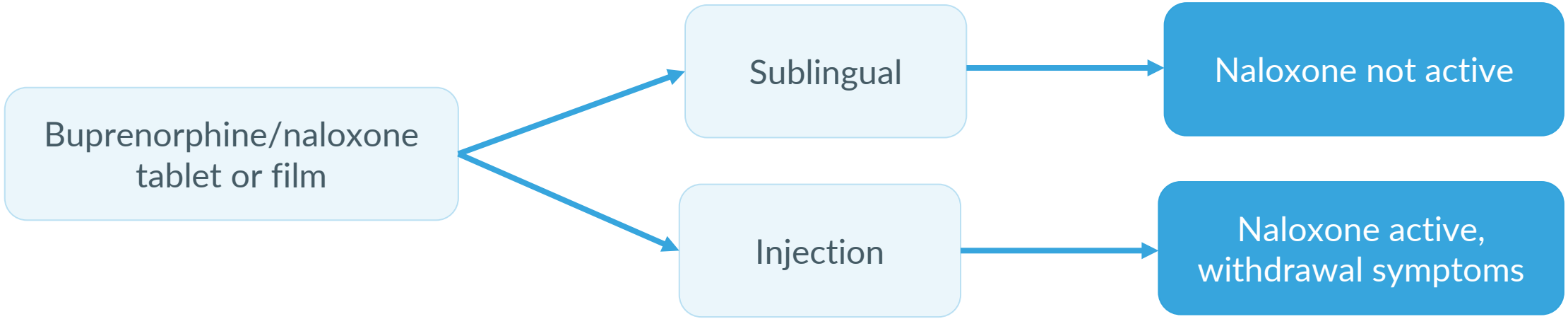

Medication Treatments: Opioid Reversal Agents

- Naloxone is effective for reversing opioid overdose, can be administered intranasally by laypeople, and is available OTC:
  - **Narcan**: the original 4 mg nasal spray
  - **Rextovy**: also 4 mg
  - **RiVive**: 3 mg, but similar levels reach bloodstream
  - Generic **naloxone** intranasal
- **Kloxxado**: higher dose of naloxone (8 mg), prescription only
- **Opvee** (nalmefene) was also approved as an alternative, promoted due to longer duration of action, prescription only
- Provider organizations advocate that nalmefene should not replace naloxone due to higher cost and lack of clear evidence of superiority

Sources: FDA (2026) and ACMT/AACT Joint Statement (2023)

Medication Treatments: Opioid Withdrawal

- **Lucemyra** (lofexidine) is the only medication FDA-approved for withdrawal symptoms, up to 14 days
- Generic medications are also commonly used off label for this purpose:
  - **Clonidine** (same mechanism of action as lofexidine)
  - Generic anti-nausea medications
  - Generic OTC antidiarrheals
  - Acetaminophen and NSAIDs like ibuprofen

Source: American Society of Addiction Medicine (2020)

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Medication Treatments: Alcohol Use Disorder

- Alcohol withdrawal is life-threatening and typically managed with older generic drugs in the outpatient or inpatient setting
- Three FDA-approved medications for ongoing treatment:
  - **Disulfiram** (generic)
  - **Acamprosate** (generic)
  - **Naltrexone**
    - Generic or brand oral
    - Brand long-acting injectable (Vivitrol)
- Other generic drugs are used off-label, including:
  - **Gabapentin**
  - **Topiramate**

Source: American Psychiatric Association (2018)

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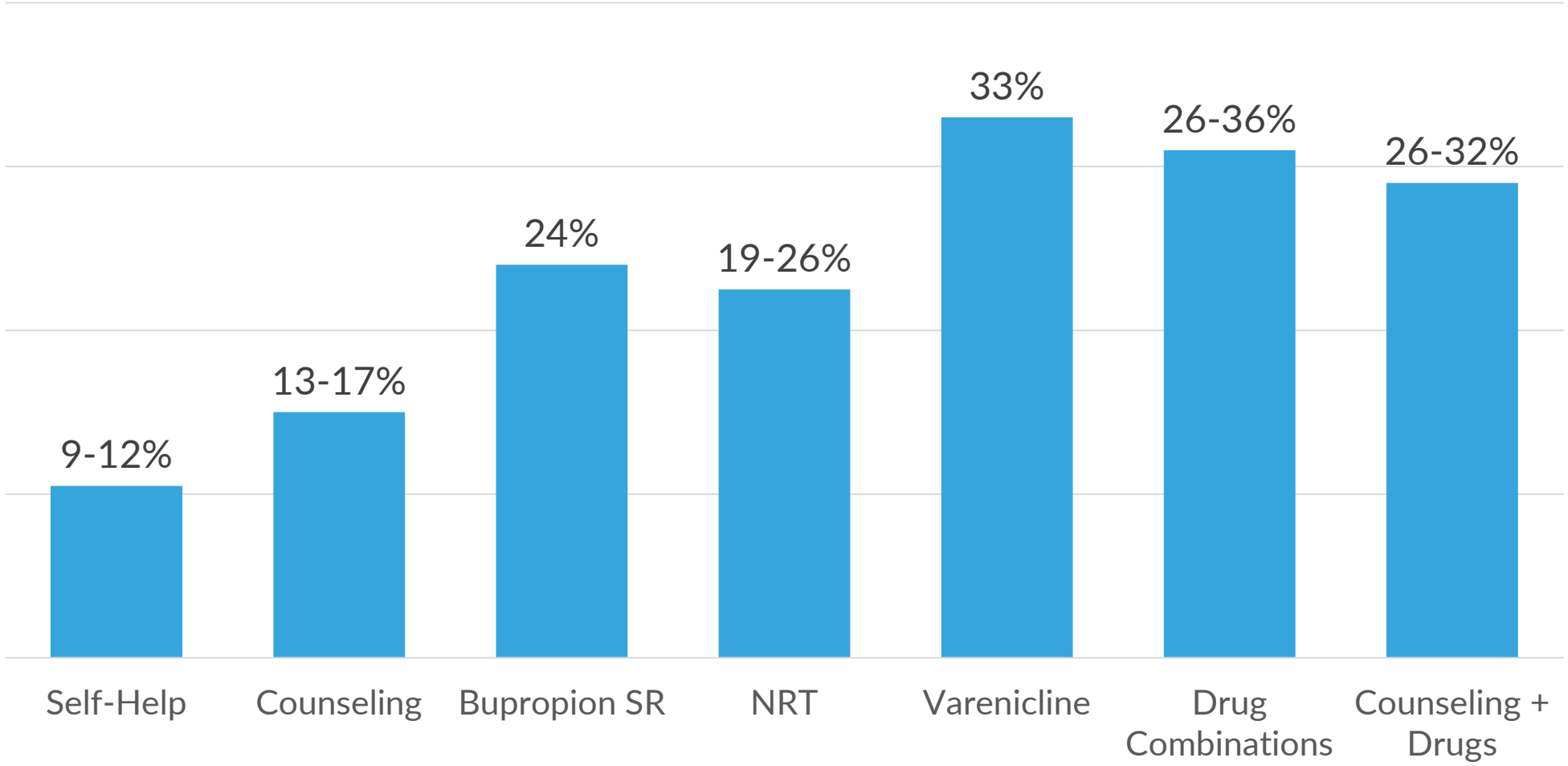
Medication Treatments: Tobacco Use Disorder

- Pharmacotherapy is divided into nicotine products and other drugs
- **Nicotine replacement therapy** (NRT), all OTC:
  - Patch
  - Gum
  - Lozenge
  - Intranasal
  - Inhaler
- **Chantix** (available as generic varenicline, prescription only)
- **Zyban** (available as generic bupropion SR, prescription only)

Source: United States Preventive Services Taskforce (2021)

Medication Treatments: Tobacco Cessation Success Rates



Source: Fiore, et al. (2008)

Medication Treatments: Summary

- Substance use disorders are chronic, relapsing and remitting, medical illnesses
- Medication treatments for substance use disorders are effective and lifesaving
- They are a core part of treatment and not considered “optional,” “extra,” or “ancillary”
- While there are a wide variety of medications, several are currently brand-only products

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Common Formulary Issues in Clinical Practice

- Overall:
  - High tiering of medication treatments for substance use disorders
- Opioid use disorder and opioid reversal agents:
  - Lack of coverage of methadone for opioid use disorder (medical benefit) and long-acting injectable buprenorphine (brand only)
  - Medical versus pharmacy benefit coverage of injectable buprenorphine (some settings will not buy and bill, requiring coordination with pharmacies; not always clear to patient and prescriber)
  - Different prior authorization criteria for buprenorphine and methadone for opioid use disorder versus pain
- Alcohol use disorder: lack of coverage of injectable naltrexone
- Tobacco use disorder: lack of coverage of some forms of NRT

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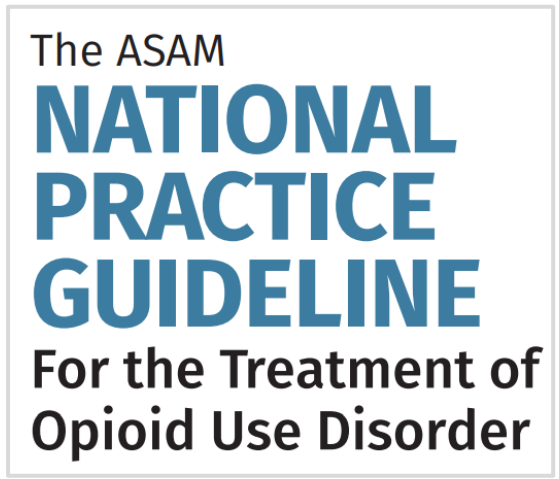
Resources: Care Standards for Opioid Use Disorder

- Substance Abuse and Mental Health Services Administration (2021)

https://store.samhsa.gov/product/tip-63-medications-opioid-use-disorder/pep21-02-01-002

- American Society of Addiction Medicine (2020)

https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline



Resources: Care Standards for Alcohol Use Disorder

- American Psychiatric Association (2018)

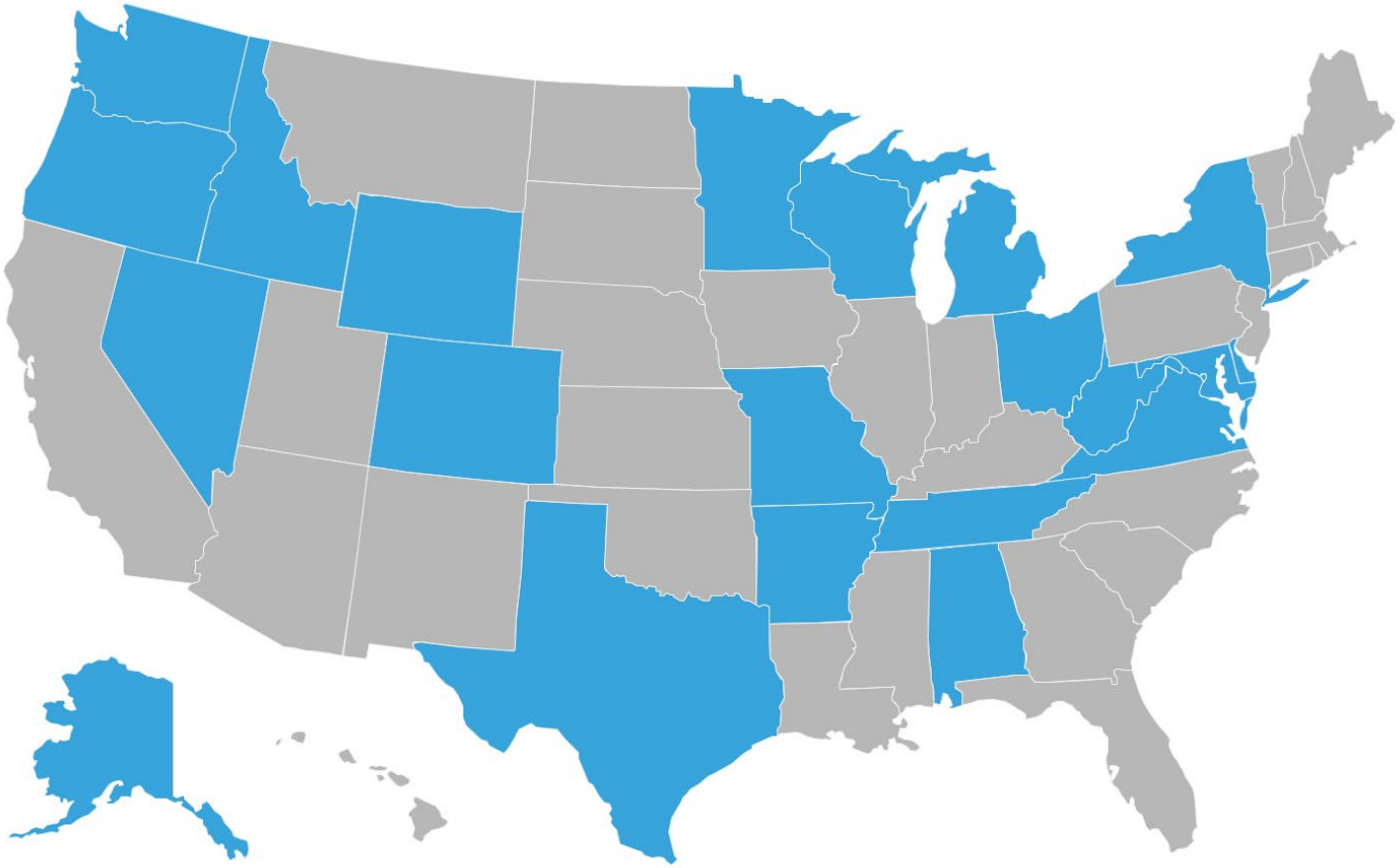
https://psychiatryonline.org/doi/book/10.1176/appi.books.9781615371969

Resources: Care Standards for Tobacco Use Disorder

- United States Preventive Services Task Force (2021)

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions

Resources: Center for Evidence-based Policy

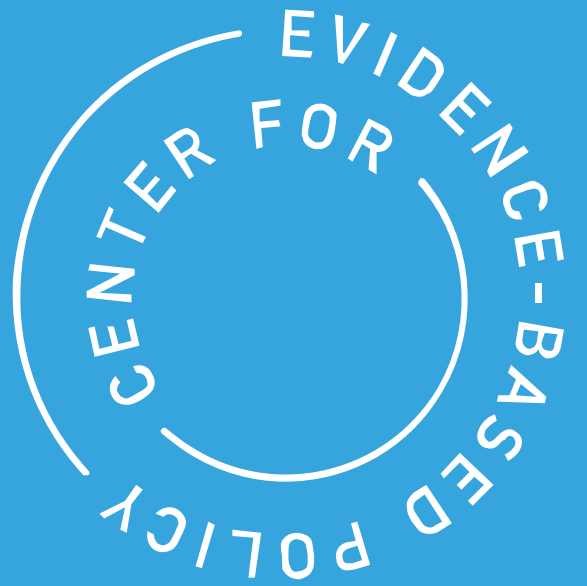


If you are one of the states in blue, you may already have access to some or all Center research and reports (most likely through the state Medicaid program)

Resources: Center for Evidence-based Policy

- Buprenorphine formulation coverage and criteria for treatment of opioid use disorder
- Efficacy and safety of extended-release injectable and implantable buprenorphine for opioid use disorder
- Comparative effectiveness and harms of buprenorphine and methadone for opioid use disorder
- Tapering or discontinuing opioid maintenance therapy in pregnancy: clinical evidence
- High-dose buprenorphine for opioid use disorder
- Effectiveness and harms of naloxone for opioid overdose
- And more!

Questions?
Email: bachhmar@ohsu.edu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