Opioid Stewardship and Chronic Pain

A GUIDE FOR PRIMARY CARE PROVIDERS

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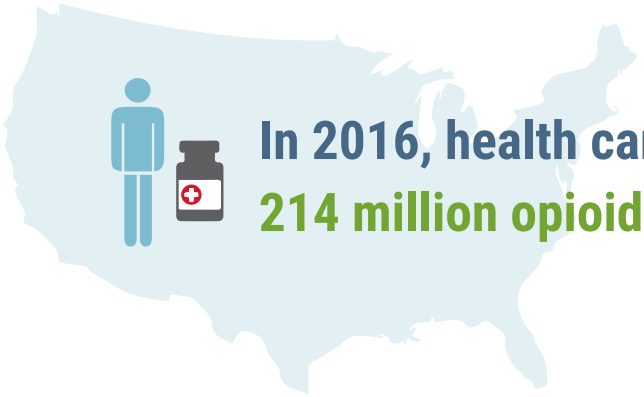
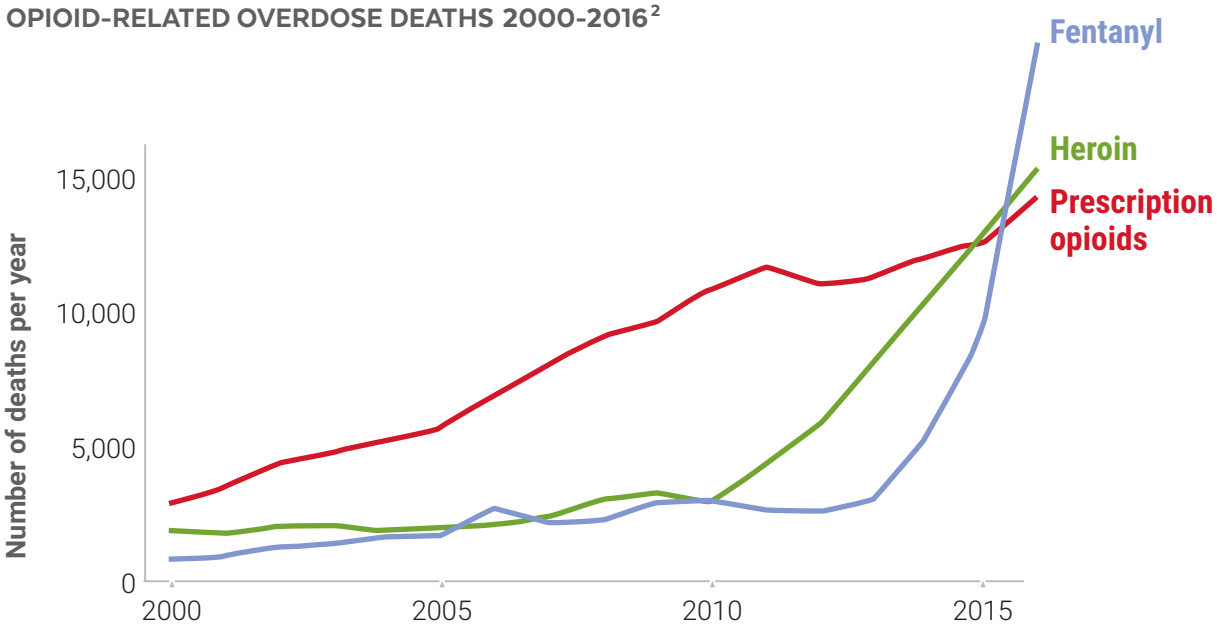
More than 1 in 10 American adults experience chronic pain.



In 2016, health care providers wrote 214 million opioid prescriptions.[1]

Increasing opioid prescribing correlated to increasing overdose deaths and presaged a national crisis now also involving illicit opioids.

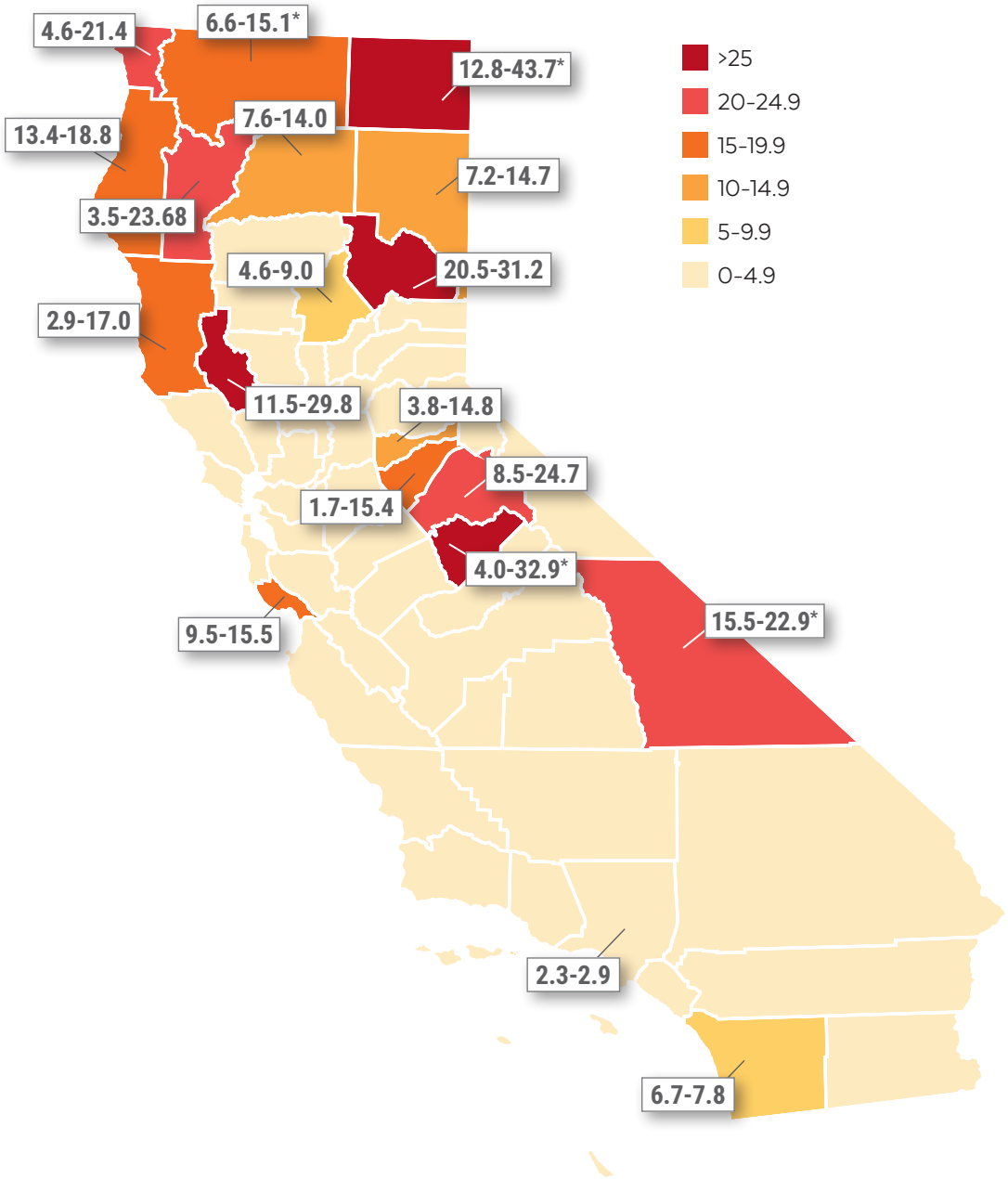
OPIOID-RELATED OVERDOSE DEATHS 2000-2016[2]



Data for 2016 is provisional. Fentanyl includes fentanyl analogues. Prescription opioids excludes synthetic opioids.

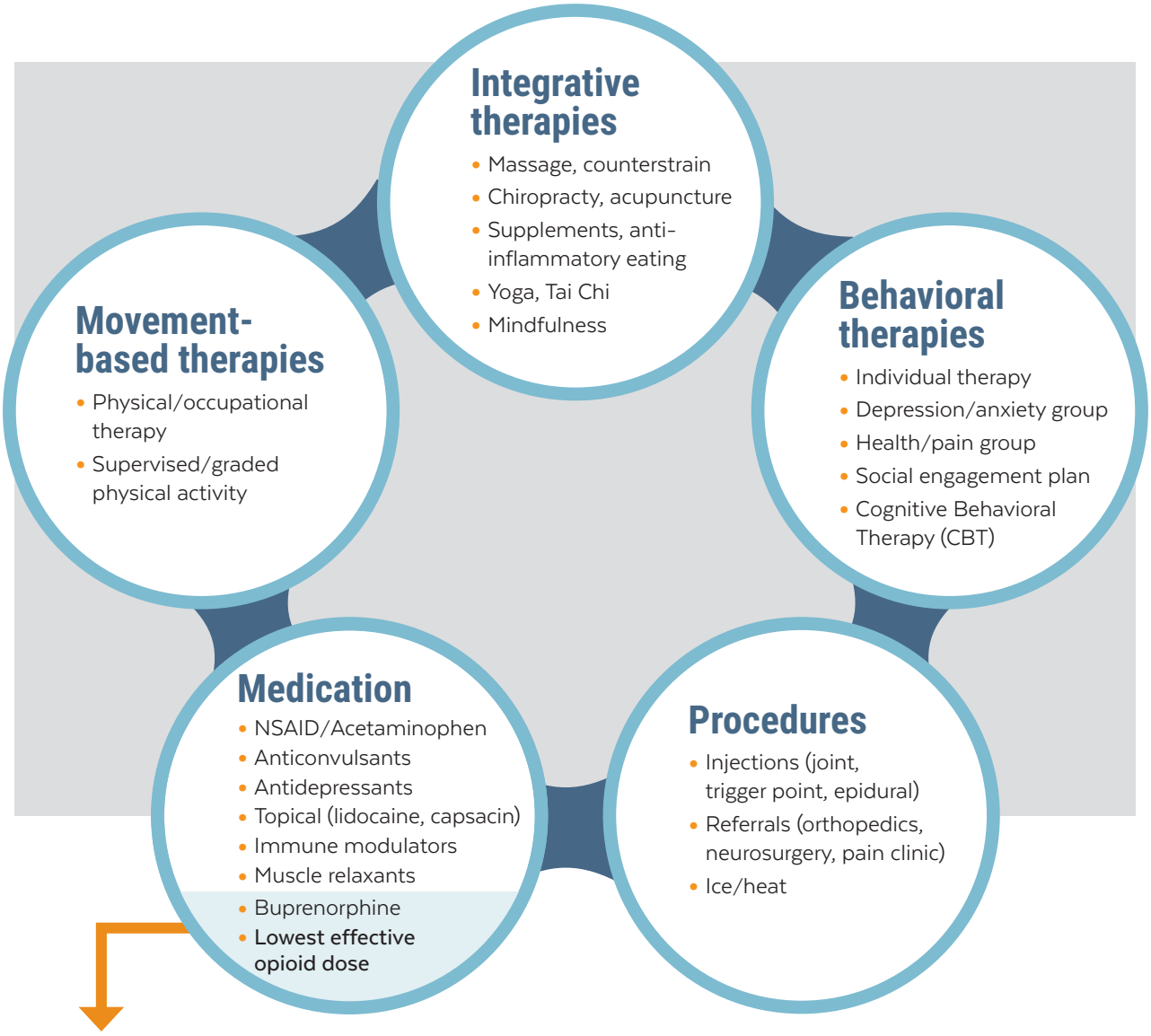
Opioid overdose deaths in California

AGE-ADJUSTED RATE PER 100,000 RESIDENTS BY COUNTY, 2012-2016[3]



*The following counties had zero deaths in noted years. **Inyo**: 2012, 2014, 2015. **Mariposa:** 2016. **Modoc**: 2015, 2016. **Plumas**: 2016. **Siskiyou**: 2013.

Managing chronic non-cancer pain



If opioid medication is part of the treatment plan, take the following steps:

- >> **ASSESSMENTS OF RISK, ADHERENCE, FUNCTION AND PAIN:** at least annually
- >> **INFORMED CONSENT OR CONTROLLED SUBSTANCE AGREEMENT:** at least annually
- >> **PRESCRIPTION DRUG MONITORING PROGRAM:** check CURES every 4 months
- >> **PRESCRIBE NALOXONE:** every two years

If managing opioid use disorder, options include:

- >> Prescribe buprenorphine
- >> Arrange for methadone maintenance or extended-release naltrexone
- >> Arrange for residential or outpatient treatment

Pain and function assessments

Assessments should focus on both pain and function.

- **Assessments are essential when initiating opioid treatment or seeing a new patient** already on long-term opioid therapy.
- **Reassessments should take place at regular intervals** to ensure benefit and evaluate adverse events.

CDC recommends

Assessments should take place within three months of starting treatment and at least annually thereafter.

TOOLS

- There are several tools for assessing pain and function, such as the Brief Pain Inventory or Initial Pain Assessment Tool.

ONE SIMPLE TOOL IS THE PEG—A 3 QUESTION SCALE

1. What number best describes your pain on average in the past week:

0 1 2 3 4 5 6 7 8 9 10

No pain — Pain as bad as you can imagine

2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?

0 1 2 3 4 5 6 7 8 9 10

Does not interfere — Completely interferes

3. What number best describes how, during the past week, pain has interfered with your general activity?

0 1 2 3 4 5 6 7 8 9 10

Does not interfere — Completely interferes

The PEG is as valid and reliable as the longer Brief Pain Inventory and is sensitive to changes in pain.[4] PEG can be found online at: **tinyurl.com/hfdvzm3**

Risk factor assessment

Once you have determined that opioids are indicated for a patient, assessing for risk factors may help guide therapeutic decisions.

Assessing for risk of an opioid use disorder can be done with simple questions like:

"How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?"[5]

in a primary care setting (with an answer of one or more considered positive) this question was 100% sensitive and 73.5% specific in detecting a substance use disorder compared with a standardized diagnostic screening.

When assessing for safety with opioid therapy, consider:

- Concomitant medications (particularly benzodiazepines)
- Comorbidities that can affect respiration (e.g. sleep apnea, tobacco or alcohol use disorder)
- History of prior overdose or similar adverse reaction to opioids
- Total daily dose of opioids

The presence of risk factors does not necessarily contraindicate opioid therapy, but can be used to emphasize alternatives, limit dose and intensify monitoring.

Urine drug screening

Urine drug screening can be used to check for substances that are expected and not expected to be present. This can help guide an informed discussion with patients about their medications.

- **Urine drug screening should NOT be used as a punitive tool,** rather it should be used like hemoglobin a1c, as a guide to ensure optimal care.

CDC recommends

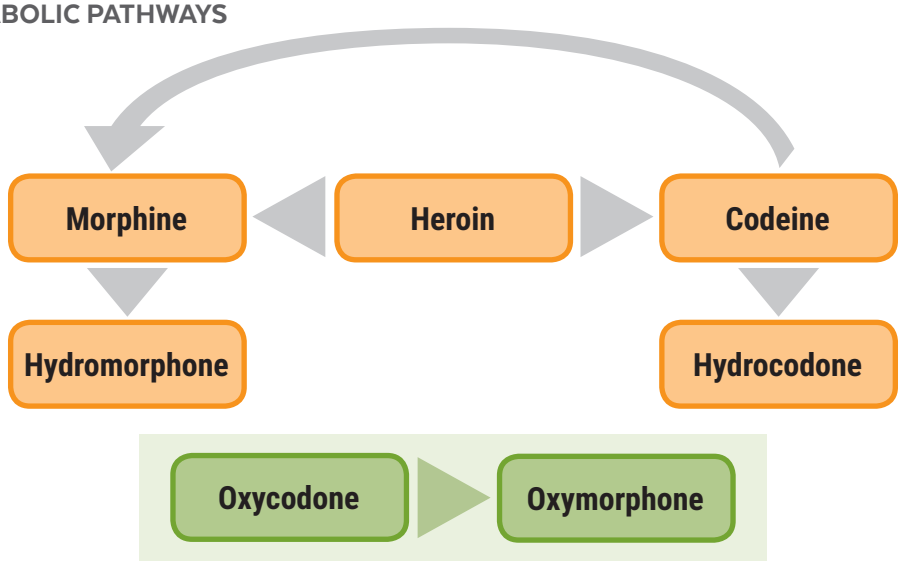
Conduct urine drug screening at first opioid prescription and at least annually thereafter.

CONTACT YOUR LAB FOR ASSISTANCE INTERPRETING URINE DRUG SCREENING RESULTS

Tests and interpretations can vary by lab. Reach out to your local lab when you need help interpreting results.

- **Not all assays test for all substances.** Opioids like methadone, fentanyl and buprenorphine may not appear on all tests.
- **Some opioids may be metabolites of opioids a patient is prescribed.** For example, the presence of hydromorphone in the urine of a patient prescribed morphine may be due to metabolism rather than use of non-prescribed opioids.

OPIOID METABOLIC PATHWAYS



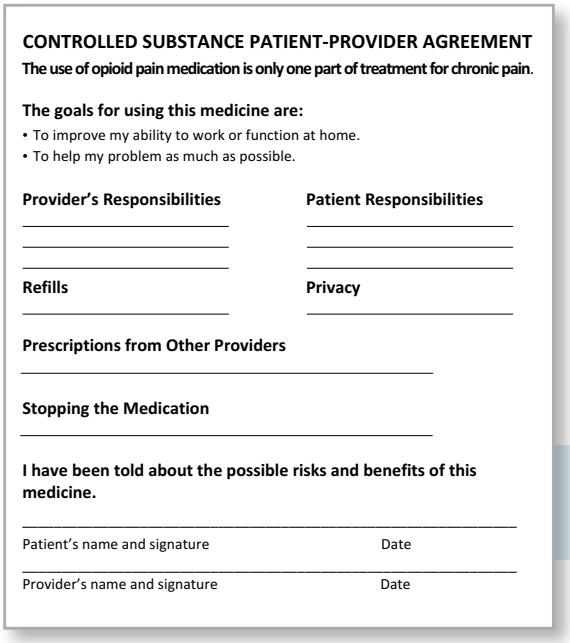
Informed consent

Informed consent and treatment agreements

- **Informed consent** is a joint, documented discussion between provider and patient, addressing risks associated with opioids and clarifying expectations.
- **Controlled substance agreements** are written documents, similar to and possibly replacing informed consent, that include expectations of both the patient and provider. They are generally signed by the patient and renewed annually.

CDC recommends

Review informed consent or controlled substance agreements at least annually.



CONTROLLED SUBSTANCE PATIENT-PROVIDER AGREEMENT

The use of opioid pain medication is only one part of treatment for chronic pain.

The goals for using this medicine are:

- To improve my ability to work or function at home.
- To help my problem as much as possible.

Provider's Responsibilities _____

Patient Responsibilities _____

Refills _____

Privacy _____

Prescriptions from Other Providers _____

Stopping the Medication _____

I have been told about the possible risks and benefits of this medicine.

_____
Patient's name and signature Date

_____
Provider's name and signature Date

At a minimum, providers should offer written information to patients about the benefits and risks of opioid therapy and document patients' understanding and agreement.

Controlled substance agreement templates are available online.

Additional considerations

- Remind patients to keep opioids in a locked and safe place.
- Encourage safe disposal of drugs, like take-back programs.

Starting opioid therapy

CDC recommends

Consider using episodic short-acting opioids and keeping at lowest effective dose.

Exercise caution:

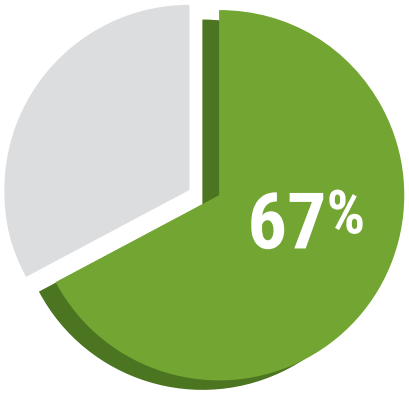
- Doses ≥ **50 MME**
- Concurrent use of benzodiazepine, alcohol or methadone for pain

Avoid if possible:

- Dose ≥ **90 MME**

Inheriting patients already on opioid therapy can be complex

- Discuss with former provider
- Complete baseline assessments
- Establish expectations
- Engage in opioid use disorder treatment if appropriate



67% of those prescribed opioids for 90 days are still using opioids at 2 years.[6]

Tapering or discontinuing opioids

WHEN TO TAPER:

- When risks outweigh benefits

Consider tapering when opioid dose ≥90 MME or patient also takes benzodiazepines.

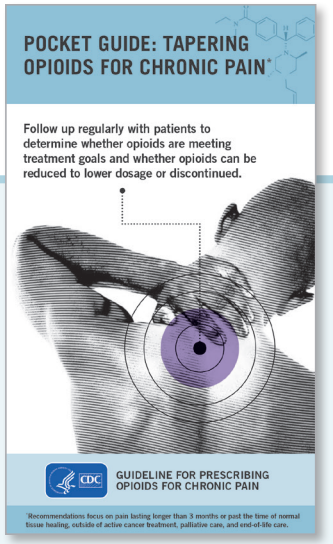
HOW TO TAPER:

- 1 medication at a time
- Tapers often involve a monthly reduction of 10% of original dose, although it may be much slower
- Tapers may be as rapid as 50% in situations such as a low original dose or life-threatening adverse events

Consider a partial taper or transition to buprenorphine for some patients, particularly those on years of opioid therapy.

Patient engagement

- Individualize the plan and be prepared to adjust
- Work with patient to set realistic goals
- Remind patient that reducing opioid use may reduce sensitivity to pain
- Encourage patient to engage support networks
- Use motivational interviewing techniques
- Discuss with patient life stressors that may affect opioid use



Go to this link for a CDC patient toolkit on tapering: **tinyurl.com/hfr7drd**

Prescription Drug Monitoring Program (CURES)

California's Prescription Drug Monitoring Program **(CURES**: **Controlled Substances Utilization Review and Evaluation System)** is an online system used by prescribers to review prescriptions for controlled substances.

- **As of January 2016, CURES registration is mandatory** for all California licensed prescribers and pharmacists who are authorized to prescribe scheduled drugs.
- **As of 2018, California law (SB482) requires checking CURES** when starting opioid prescribing and re-checking **every 4 months.**

High quality prescription drug monitoring programs with mandated use may be associated with reduced opioid prescribing[7] and modest reductions in opioid analgesic deaths.[8]

CURES is updated weekly, although some prescriptions may not appear for weeks to months.

How to use CURES

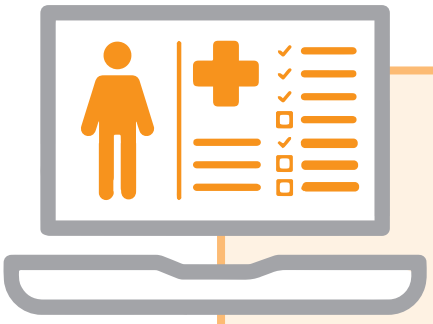
HOW TO APPLY

- Use this link: **oag.ca.gov/cures**
- Click on the registration link on right panel.
- Follow instructions.

Record your password and security questions to simplify password reset.

FEATURES OF CURES

- **Save search list**: Save patient searches so they are easily available next time you log in.
- **Peer-to-peer communication**: Send notes, emails and alerts to providers/pharmacists about mutual patients.
- **Alerts/messaging**: Receive daily alerts with information on patients who reach prescribing thresholds.

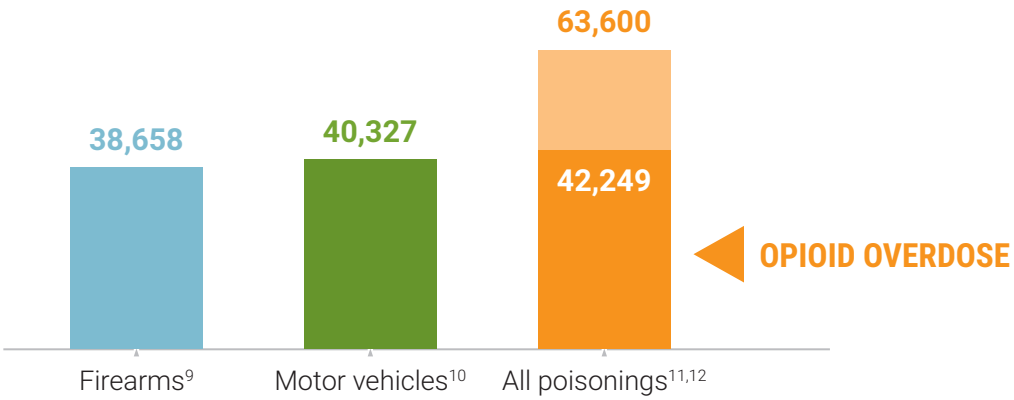


CURES alerts prescribers to patients with multiple prescribers, high-dose opioid prescriptions, concomitant opioids and benzodiazapines and daily opioids over 90 days.

Naloxone

Opioid overdose leads injury-related deaths in the US, but is preventable

INJURY-RELATED MORTALITY, 2016



Prior opioid overdose is a major risk for overdose.

A patient who has previously overdosed is **6 times more likely** to overdose in the subsequent year.[13]

OTHER FACTORS THAT INCREASE RISK OF OVERDOSE:

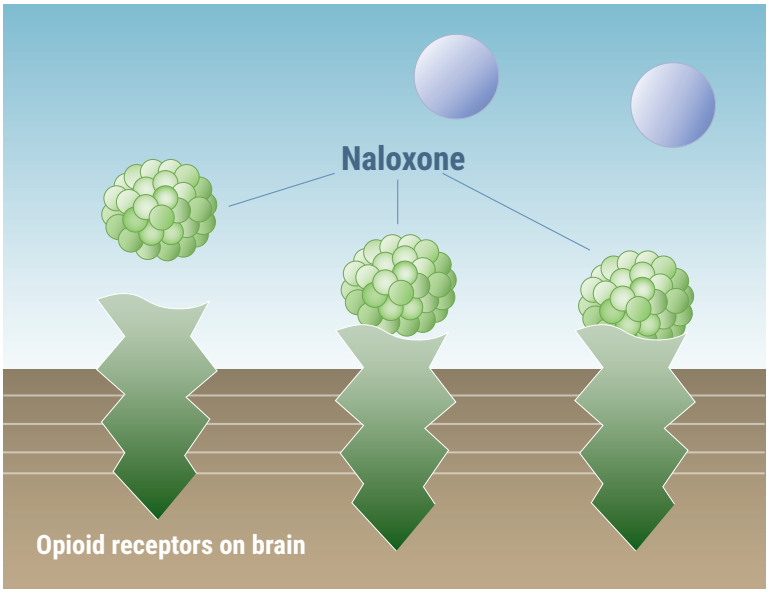
Reduced tolerance: period of abstinence, change in dose, release from incarceration

Genetic predisposition

Concomitant use of substances: benzodiazepines, alcohol

Naloxone

NALOXONE MECHANISM OF ACTION



- Highly specific, high-affinity opioid antagonist used to reverse the effects of opioids
- Lasts 30-90 minutes
- Can be administered by laypeople
- Virtually no side effects or effects in the absence of opioids

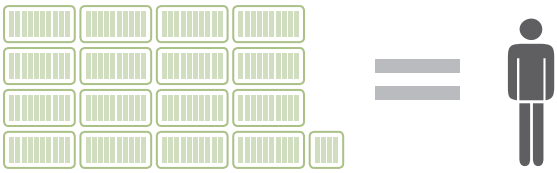
PROVIDING NALOXONE TO PEOPLE WHO USE DRUGS IS COST-EFFECTIVE[14]

Cost:

$421 per quality-adjusted life-year gained

Benefit:

164 naloxone scripts = 1 prevented death

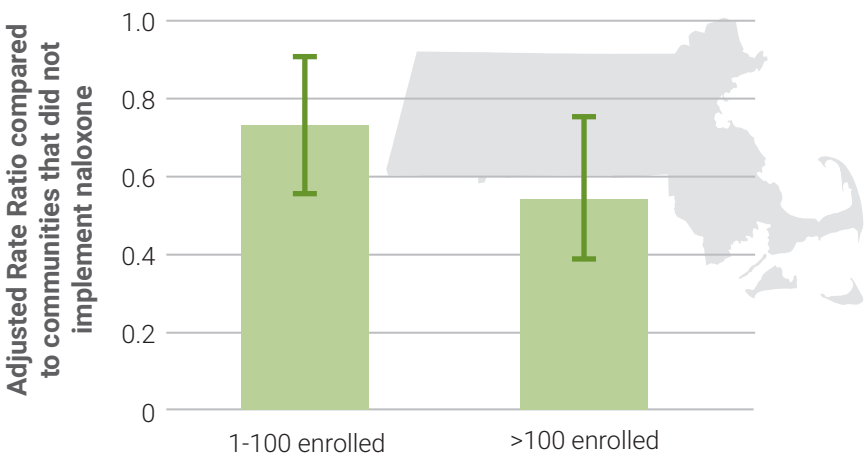


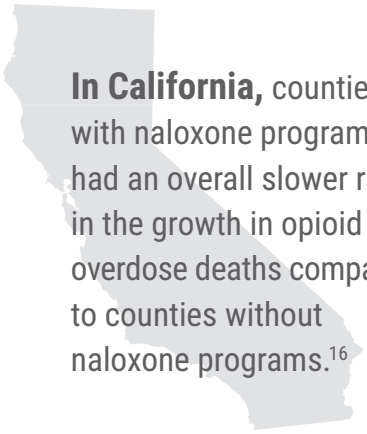
Emerging data suggests that providing naloxone may encourage patients to be safer with their opioid use. If this is the case, the intervention would be cost-saving and **36 prescriptions** would prevent one death.

Naloxone is effective

NALOXONE IS ASSOCIATED WITH REDUCED OVERDOSE MORTALITY

FATAL OPIOID OVERDOSE RATES BY NALOXONE IMPLEMENTATION IN MASSACHUSETTS[15]



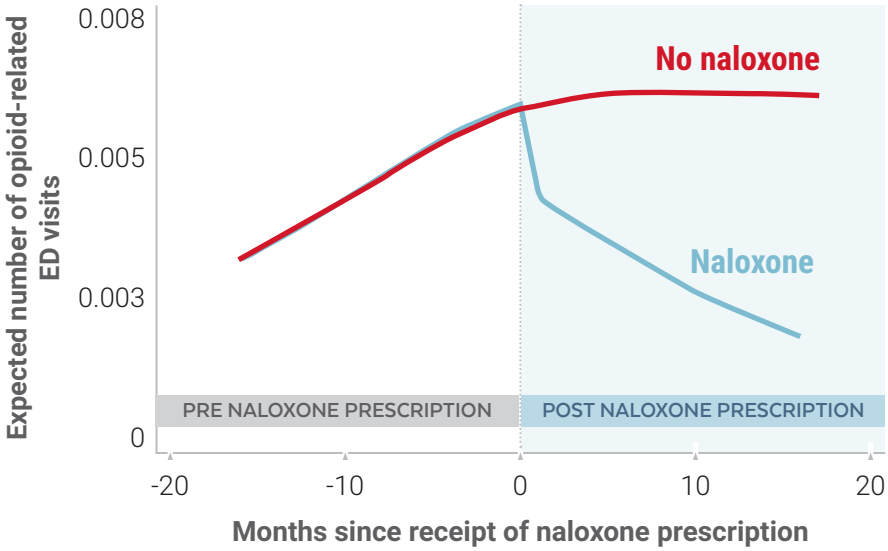


In California, counties with naloxone programs had an overall slower rate in the growth in opioid overdose deaths compared to counties without naloxone programs.[16]

Ratios with 95% confidence intervals, adjusted for population age <18, male, race/ethnicity, below poverty level, medically supervised inpatient withdrawal, methadone and buprenorphine treatment, prescriptions to doctor shoppers, year

NALOXONE MAY REDUCE OPIOID RELATED ADVERSE EVENTS[17]

OPIOID RELATED EMERGENCY DEPARTMENT VISITS BY RECIPIENT OF NALOXONE PRESCRIPTION AMONG PRIMARY CARE PATIENTS ON OPIOID THERAPY FOR CHRONIC PAIN*



Prescribing naloxone to 29 patients averted 1 opioid-related emergency department visit in the following year.

*In a population with a rate of opioid-related emergency department visits of 7/1000 person years.

Indications for naloxone prescribing

"By being able to offer something concrete [naloxone] to protect patients from the danger of overdose, I am given an opening to discuss the potential harms of opioids in a non-judgmental way."

—Primary care provider

CDC recommends

- On prescribed opioids with:
  - Opioid use ≥50 MMEs/day
  - Benzodiazepine use
  - History of substance use disorder
  - History of opioid overdose
  - Other factors that increase overdose risk, including comorbidities or concomitant medications

CONSIDER NALOXONE FOR PATIENTS:

- With past or current illicit opioid use
- At risk of witnessing an opioid overdose

"I have never really thought about [overdose] before…[naloxone] was more so an eye opener for me to just look at my medications and actually start reading [about] the side effects, you know, and how long should I take them…I look at different options, especially at my age."

—Patient on opioids for pain

Opioid safety language

COMMUNICATING WITH PATIENTS ABOUT NALOXONE

The word "overdose" may have negative connotations and prescription opioid users may not relate to it.

Some patients have overdosed and don't realize it.

Out of 60 patients on opioid therapy for pain, 22 (37%) had stopped breathing or required help to be woken up due to opioids.[18]

45% **of these patients denied overdosing, calling it a bad reaction**

Instead of using the word "overdose," consider language like "accidental overdose," "bad reaction" or "opioid safety." **You may want to say**:

"Opioids can sometimes slow or even stop your breathing."

"Naloxone is the antidote to opioids—it can be used if there is a bad reaction where you can't be woken up."

"Naloxone is for opioid medication like an epinephrine pen is for someone with an allergy."

"Naloxone is important to have in the home in case someone is accidentally exposed to opioid painkillers."

State law encourages naloxone prescribing

Naloxone is NOT a controlled substance. **Any licensed healthcare prescriber can prescribe naloxone.** California law provides additional protections to encourage naloxone prescribing and distribution.

PROVIDER AND PATIENT PROTECTIONS (CA AB635)

- **Providers are encouraged to prescribe naloxone** to patients receiving a long-term opioid prescription.
- **Naloxone prescriptions also can be written directly to third party individuals** (caregivers, family members, friends, etc.) who are in a position to witness and assist a person at risk of an opioid overdose.
- **A licensed healthcare prescriber can issue a standing order** for the dispensing of naloxone by healthcare or community workers to individuals at risk of experiencing or witnessing an overdose.
- **Laypeople can possess and administer naloxone** to others during an overdose situation.

GOOD SAMARITAN PROTECTIONS (CA AB472)

- **Witnesses of an overdose who seek medical help are provided legal protection** from arrest and prosecution for minor drug and alcohol violations.

PHARMACIST PROVISION OF NALOXONE (CA AB1535)

- **Pharmacists are allowed to directly prescribe and dispense naloxone** to patients at risk of experiencing or witnessing an opioid overdose.

Prescribing naloxone

Formulations

INTRANASAL

- Naloxone 4mg #1 two pack,
  use PRN for suspected opioid overdose

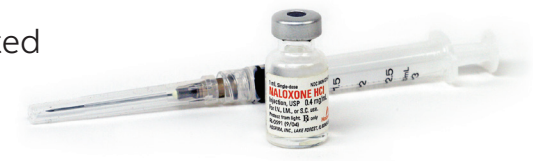
AUTO-INJECTOR

- Naloxone auto-injector 2mg #1 two pack,
  use PRN for suspected opioid overdose

If the above devices are not optimal or accessible, a prescription can be written for a naloxone vial and syringe. In this situation, education should be provided directly to the patient.

INJECTABLE

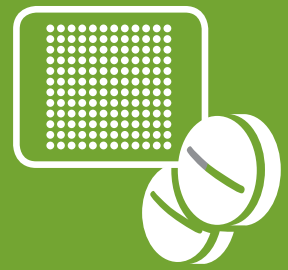
- Naloxone 0.4mg IM #2, use PRN for suspected overdose, IM syringe (3ml 25g 1" syringe) #2



SBIRT CODES COVER TRAINING

(per 15 min intervals)

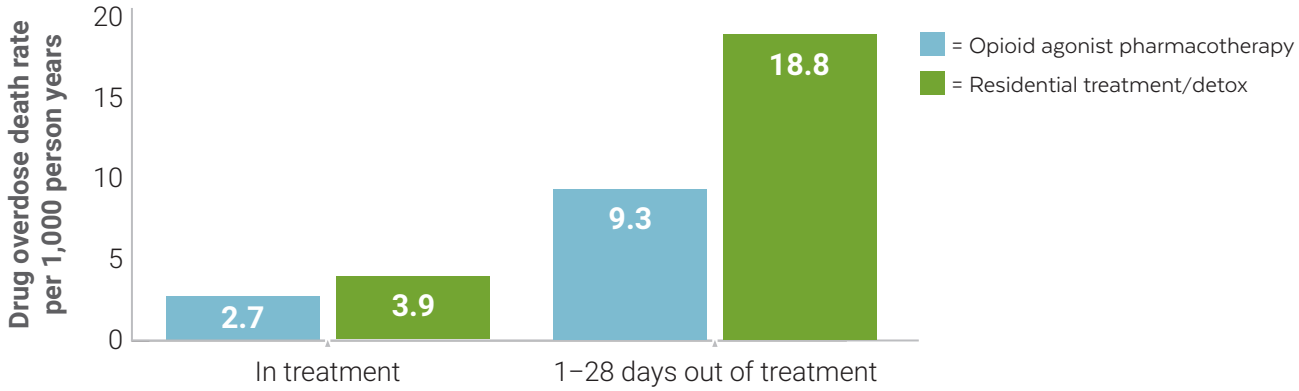
MediCare:	MediCal:	Commercial:
G0396	H0050	CPT99408



Managing opioid use disorder

- If your patient has an opioid use disorder, it is essential to arrange for treatment.
- **Treatment with medications has the best evidence for managing opioid use disorder** and should be considered for all patients with significant disease.
- When therapy for opioid use disorder is stopped, the risk of death increases.

DRUG OVERDOSE DEATH RATE PER 1,000 PERSON YEARS AMONG 151,983 PEOPLE WITH OPIOID USE DISORDER SEEKING TREATMENT IN THE UNITED KINGDOM[19]



FDA-APPROVED MEDICATION TREATMENT OPTIONS

- Buprenorphine (with or without naloxone)
- Methadone
- Extended-release naltrexone

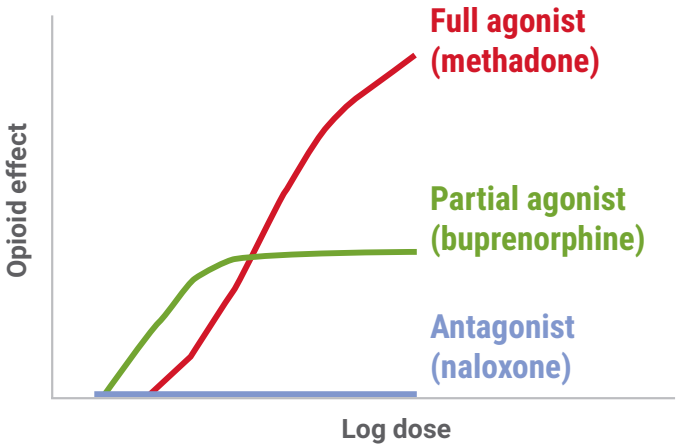
Like treatment for other chronic diseases such as diabetes, these medications should be considered long-term therapy.

BEHAVIORAL/PSYCHOLOGICAL TREATMENT OPTIONS

- Support groups such as Narcotics Anonymous
- Outpatient or inpatient rehabilitation and counseling

If not personally providing the treatment, a warm handoff to other providers is critical.

Buprenorphine



BUPRENORPHINE

- A partial opioid agonist
- Lasts 36 hours
- Has very high affinity, blocking effects of heroin or other opioids

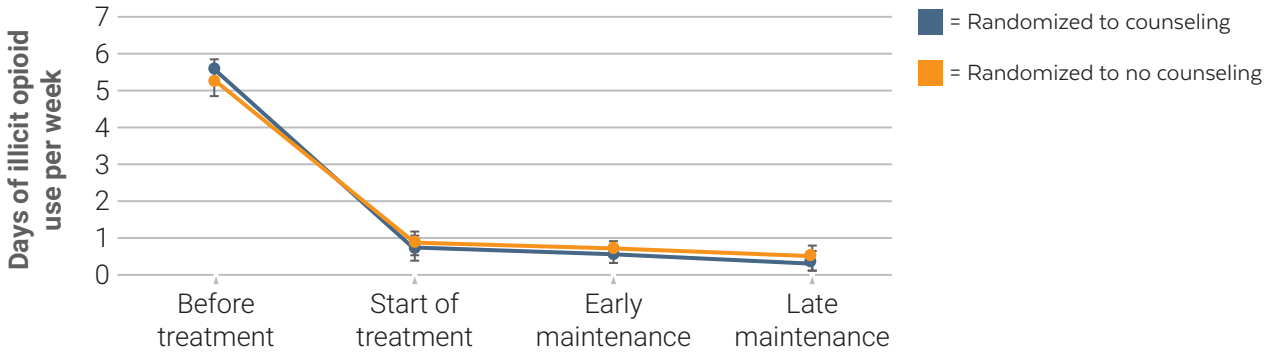
SAFETY PROFILE

- Due to the "ceiling effect" of a partial agonist, buprenorphine has:
  - Low potential for misuse and diversion
  - Low risk of respiratory depression or overdose
- Maintenance is critical: opioid use disorder requires long-term care.
- Buprenorphine treatment is safe and effective during pregnancy.
- Most buprenorphine for opioid use disorder treatment is co-formulated with naloxone to discourage diversion or injection of the product.

Buprenorphine is an effective medication to treat opioid use disorder in primary care

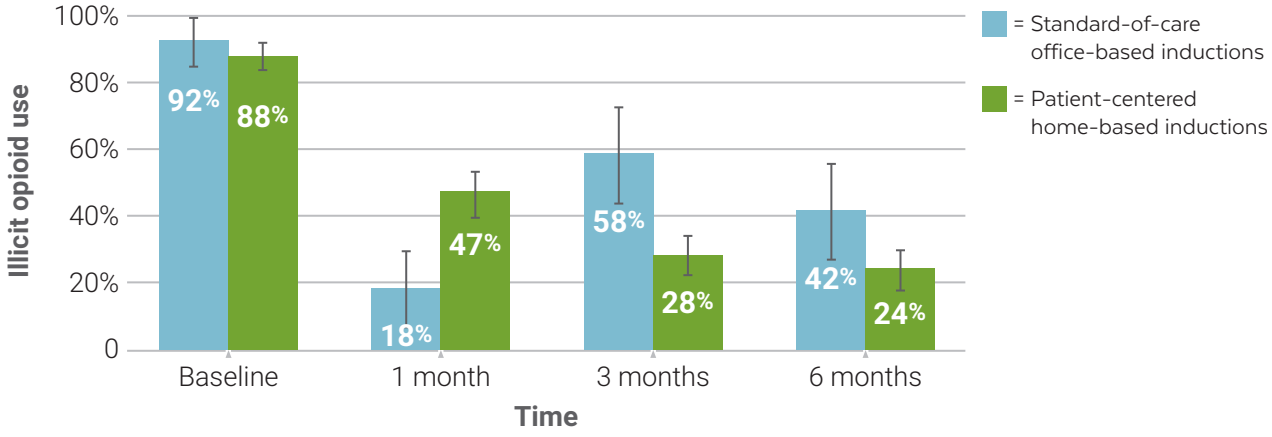
ROUTINE MEDICATION MANAGEMENT CAN BE AS EFFECTIVE AS COMBINING BUPRENORPHINE WITH COUNSELING

While counseling should be sought if available, lack of access should not be a barrier to treatment.[20]



PATIENTS CAN BE STARTED ON BUPRENORPHINE IN THE OFFICE *OR* AT HOME

Opioid use patterns are similar if patients start therapy themselves at home.[21]



In a randomized controlled trial of buprenorphine, patients who used only prescription opioids responded even better than those who used heroin (P<0.001).[22]

Buprenorphine reduces mortality...

BUPRENORPHINE REDUCES MORTALITY, POSSIBLY EVEN MORE THAN METHADONE[23]

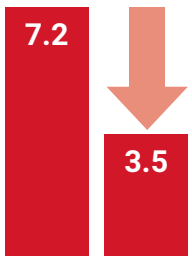
	METHADONE CMR (95%CI)	BUPRENORPHINE CMR (95%CI)
FIRST 4 WEEKS		
All-cause mortality	9.6 (6.5–13.5)	4.3 (2.0–8.2)
Drug related mortality	5.4 (3.2–8.5)	1.0 (0.1–3.4)
REMAINDER OF TREATMENT		
All-cause mortality	6.8 (6.3–7.4)	3.9 (3.1–4.9)
Drug related mortality	1.7 (1.4–2.0)	1.5 (1.0–2.1)

CMR = Crude Mortality Rate per 1,000 person years

...and pain

STUDIES SUPPORT USE OF BUPRENORPHINE FOR CHRONIC PAIN[24]

In a study of 35 patients on 200-1,370 morphine equivalent milligrams of opioids for chronic pain, after two months of sublingual buprenorphine:



Pain scores reduced
from 7.2 to 3.5 (p<0.001)

Quality of life scores increased
from 6.1 to 7.1 (p=0.005)

Prescribing buprenorphine as maintenance treatment for opioid use disorder requires an "X" number

- **An "X" number is a separate DEA registration number** that must be used when buprenorphine is prescribed for opioid use disorder.
- After getting an "X" number, you can prescribe ≤30 patients in year 1 and ≤100 patients in subsequent years.
- MDs and DOs can apply to treat ≤275 patients after treating 100 patients for a year.

To obtain an "X" number:

IF YOU ARE A LICENSED MD OR DO:

- Complete a free, 8-hour training (or have substance use disorder treatment experience). For more information: **samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver**.
- Complete and submit a physician waiver.

IF YOU ARE A LICENSED NP OR PA:

- Complete a free, 24-hour training. For more information: **samhsa.gov/medication-assisted-treatment/qualify-nps-pas-waivers**.
- Complete and submit a waiver.

YOU WILL RECEIVE A SECOND DEA REGISTRATION CARD WITH YOUR "X" NUMBER.

Prescribing buprenorphine **ONLY** for pain does **NOT** require an "X" number, but may require prior authorization.

How to prescribe buprenorphine

FOR OPIOID USE DISORDER:

- No prior authorization necessary for MediCal
- Most patients stabilize between 8-24mg (initial dose is generally 4-8mg)
- Medication is generally administered sublingually and daily

FOR PAIN:

- Any formulation can be used, including the transdermal patch
- No prior authorization necessary for MediCal
- No "X" number required
- Medication is generally administered 2-3 times daily

Formulations

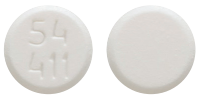
STANDARD FOR OPIOID USE DISORDER:

- Coformulated buprenorphine/naloxone SL tab or film

- Subcutaneous injection

IF PATIENT DOES NOT TOLERATE/CANNOT ACCESS STANDARD PRODUCTS:

- Monoformulated buprenorphine SL tablets



IF TREATING PAIN, MAY ALSO CONSIDER:

- Monoformulated buprenorphine transdermal patch

Additional medical care for patients with opioid use disorder

Due to increased risk for various complications, patients with an opioid use disorder should also be considered for:

- **Screening for infections** such as HIV, hepatitis B, hepatitis C, sexually-transmitted infections and tuberculosis (at least annually for most patients)
- **Vaccinations** such as hepatitis A, hepatitis B, tetanus-diphtheria-pertussis, influenza and pneumococcus
- **Aggressive management of cardiac risk factors**, particularly for people who also use stimulants or tobacco, including blood pressure and lipid control, as well as smoking cessation
- **Treatment of other comorbid substance use disorders**, including tobacco and alcohol use disorders
- **Treatment of comorbid psychiatric disorders**
- **Education** about safer injection practices and provision of clean injection equipment

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The recommendations contained in this brochure are general and informational only; specific clinical decisions should be made by providers on an individual case basis.

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