

California Health Benefits Review Program

Analysis of California Senate Bill 11 Mental Health Parity and Substance Use Medications

A Report to the 2019-2020 California State Legislature

February 13, 2019



Key Findings:

Analysis of California Senate Bill 11 Mental Health Parity and Substance Use Medications

Summary to the 2019–2020 California State Legislature, February 13, 2019



BILL SUMMARY

AT A GLANCE

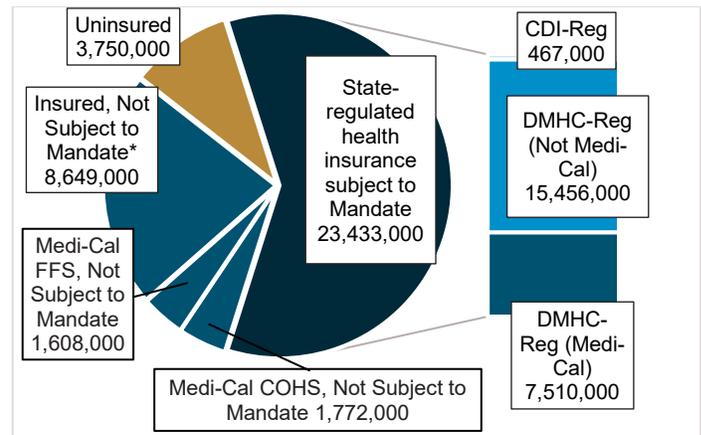
The version of California SB 11 analyzed by CHBRP would, for many enrollees in state-regulated plans and policies, require on-formulary, lowest tier coverage of prescription medications approved by the FDA for treatment of substance use disorders (SUDs). CHBRP estimates that, in 2019, of the 23.4 million Californians enrolled in state-regulated health insurance, 100% will have insurance that required to comply with SB 11.

- Benefit coverage.** Approximately 93% of commercial and CalPERS enrollees and all Medi-Cal enrollees (beneficiaries enrolled in DMHC-regulated plans) would see some change to their benefit coverage.
- Utilization.** Among commercial and CalPERS enrollees, utilization would increase for many of the 13 medications approved by the FDA for SUD treatment. Among all enrollees, a shift to use of the more costly auto-injector formulation of naloxone (the opioid anti-overdose medication) would be expected. Increases in some related services (counseling) and decrease in others (inpatient days) would also occur.
- Expenditures.** Premium increases (less than 0.1%) and a decrease (less than 0.1%) in total enrollee out-of-pocket expenses for covered benefits (cost sharing) would occur.
- Medical effectiveness.** When successfully used as prescribed and directed, clear and convincing evidence indicates that most prescription-only medications approved by the FDA for treatment of SUD are effective.
- Public health.** Barriers to treatment, limited patient willingness, and relapses will limit impacts, but positive health outcomes are expected for patients who engage in treatment.
- Long-term impacts.** Increased rates of OUD may increase related impacts - but barriers to treatment, limited patient willingness, and relapse will continue to be limiting factors for impacts related to all three SUDs.

SB 11 has other aspects but also includes a benefit mandate, which CHBRP was asked to analyze. The benefit mandate would require plans and policies regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) that include a pharmacy benefit that covers outpatient prescription medications related to treatment of substance use disorders (SUDs) to place all medications approved by the federal Food and Drug Administration (FDA) and indicated for treatment of SUDs on formulary and on the formulary's lowest tier and, for those medications, prohibit prior authorization and step therapy (or "fail first") protocols. In addition, SB 11 would prohibit coverage denials for these medications, for counseling, and for "other wrap-around services" if the denial was related to a court order for treatment.

Figure A notes how many Californians have health insurance that would be subject to SB 11.

Figure A. Health Insurance in CA and SB 11



Source: California Health Benefits Review Program, 2019.

Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

In order to analyze the impacts of SB 11, CHBRP has made several analytic assumptions, including that benefit coverage requirements (1) would be applicable to prescription-only medications generally covered through a pharmacy benefit — so not applicable to over-the-counter medications or to medications requiring a clinician for administration and so generally covered through a medical

benefit; (2) would be applicable to covered brand name as well as generic medications; (3) would be applicable to all covered formulations of the medications.

CONTEXT¹

The FDA has approved and indicated 10 prescription-only outpatient medications for treatment of three SUDs: opioid use disorder (OUD), alcohol use disorder (AUD), and/or tobacco use disorder (TUD).

Treatments for SUD, however, are not limited to medications, and frequently also include residential, inpatient, and outpatient care using behavioral therapy, counseling and/or medication, as well as mutual help groups (e.g., Alcoholics Anonymous).

Structural and attitudinal barriers to accessing any treatment for OUD, AUD, and TUD affect use. Structural barriers include being uninsured, utilization management protocols when insurance is present, limited provider supply, and geographic access difficulties. Attitudinal barriers include limited patient receptiveness to treatment. For many with OUD, AUD, and TUD, attitudinal barriers are the most significant barrier to treatment initiation and persistence. The stigma of addiction and the ability to acknowledge an addiction affects patient desire to seek care. Many people with OUD and/or AUD believe they can solve the problem themselves. Similarly, limited patient readiness for treatment is also a barrier for those with TUD: 33% of California smokers are not interested in quitting.

Prior to SB 11, CHBRP estimates that only 20% (one-fifth) of enrollees in plans and policies regulated by DMHC or CDI with OUD use FDA approved and indicated medications for OUD. This underuse is not necessarily related to insurance coverage for treatment and is more likely due to other factors, including other structural barriers (such as limited numbers of providers) and limited willingness to enter treatment. Prior to SB 11, less than 1% of enrollees with AUD or TUD use these medications. This underuse is linked to provider practice (limited prescribing), limited willingness to enter treatment, and other treatment options that do not rely on prescription medications (e.g., over-the-counter nicotine replacement therapy, Alcoholics Anonymous).

¹ Refer to CHBRP's full report for full citations and references.

It should be noted, as well, that even when a patient is willing, treatment adherence is difficult. Relapse rates for patients in treatment for AUD and OUD are significant, and multiple quit attempts before successful cessation is common for TUD.

IMPACTS

Medical Effectiveness

As noted, there are multiple treatments for SUD, but this analysis focuses on the effectiveness of the treatment addressed by SB 11: use of prescription-only outpatient medications approved by the FDA and indicated as treatments for OUD, AUD, and/or TUD that are generally covered through a pharmacy benefit.

Effectiveness is considered through studies of outcomes and studied outcomes vary depending on the SUD. OUD outcomes include opioid use, participation in treatment, and mortality. AUD outcomes include alcohol use and participation in treatment. TUD outcomes include reduced cigarette cravings and abstinence.

The evidence is related to use of the medications when prescribed and used as directed. As already noted, many persons with OUD, AUD, or TUD have difficulty "using as directed" for the recommended period due to structural and attitudinal barriers to treatment. In addition, many people relapse and need to receive treatment repeatedly to abstain from using opioids, alcohol, or tobacco. However, for prescription-only medications approved by the FDA for OUD used as directed for the recommended period:

- There is *clear and convincing* evidence that methadone, buprenorphine, and buprenorphine-naloxone are effective
- There is a *preponderance* of evidence that orally administered naltrexone is not effective.
- Evidence comparing medications is *inconclusive*.

For prescription-only medications approved by the FDA for AUD:

- There is *clear and convincing* evidence that acamprosate and naltrexone are effective.
- There is limited evidence that disulfiram is not effective.
- Evidence comparing medications is *inconclusive*.

For prescription-only medications approved by the FDA for TUD:

- There is clear and convincing evidence that prescription medications are effective.
- There is a preponderance of evidence favoring varenicline over nicotine replacement therapy (NRT).
- There is a preponderance of evidence that there is no difference between NRT and bupropion.

Benefit Coverage, Utilization, and Cost

For this analysis, CHBRP has estimated the impacts of requiring on-formulary coverage for the 13 prescription-only outpatient medications approved by the FDA and indicated as treat one or more of three SUDs, prohibiting the application of prior authorization or step therapy (“fail first”) protocols, and requiring tier 1 or lower cost sharing.

As CHBRP is unaware of coverage denials related to court orders, no measurable impact related to the SB 11 prohibition is expected.

Benefit Coverage

Approximately 95.6% of enrollees in plans and policies regulated by DMHC or CDI have a pharmacy benefit that would need to be altered to be compliant with SB 11.

Most commercial and CalPERS enrollees have on-formulary coverage for most of these medications; all would postmandate. Few of these enrollees have tier 1 (or no) cost sharing for most brand-name medications; all would postmandate. Few of these enrollees have prior

² Federal law restricts methadone treatment to federally certified opioid treatment programs (OTP), known as methadone clinics,

authorization or step therapy protocols applicable to their coverage for these medications; none would postmandate.

All Medi-Cal beneficiaries enrolled in DMHC-regulated plans have coverage for these medications — though for OUD and AUD medications it is through a “carve-out” to the Medi-Cal fee-for-service (FFS) program. Excepting only coverage for the more costly auto-injector formulation of naloxone for OUD (the anti-overdose drug), the FFS program coverage is compliant with SB 11. Postmandate, these enrollees would have coverage from their DMHC-regulated plans as well, including SB 11–compliant naloxone coverage.

Utilization

Table 1 provides medication specific impacts on expected use and on the expected number of users, as well as the broad indirect impacts SB 11 would have on counseling, inpatient days, and emergency room use.

Generally, use of the medications would increase among commercial enrollees and enrollees associated with CalPERS – and new users would be expected for some of the medications. The exceptions are:

- No utilization increase is expected for lofexidine for OUD (used to treat short-term withdrawal symptoms), as the medication is newly approved and not likely to be much prescribed by providers during the initial year after implementation of SB 11.
- Within the increased utilization of naloxone for OUD (used to treat overdoses) there would be a shift such that the more costly auto-injector formulation would represent half of all filled prescriptions.
- No utilization increase is expected for methadone for OUD because it may only be prescribed and delivered through federally certified centers,² which do not bill for medication alone (as would be covered by an SB 11–compliant pharmacy benefit).

see Title 42 of the Code of Federal Regulations Part 8 (42 CFR § 8)

- No utilization increase is expected for disulfiram for AUD, as providers have concerns regarding its lack of effectiveness.

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans almost all use would be unchanged, as the new SB 11-compliant coverage would be almost identical to their current coverage through the Medi-Cal FFS carve-out program. However, use of naloxone for OUD would shift towards the more costly auto-injector formulation because patients prefer it to other formulations of naloxone. The shifted utilization would be covered by the beneficiaries' newly SB 11-compliant plan (rather than to the existing FFS carve-out program).

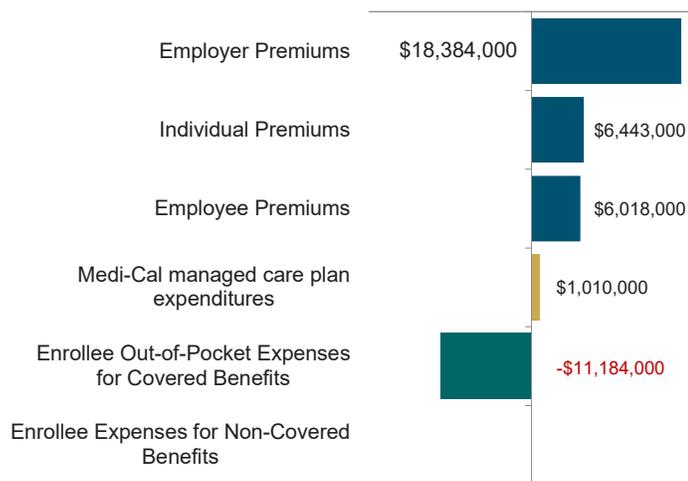
A 12.5% increase in use of related counseling would be expected among all enrollees using OUD and AUD medications.

Decreases in some related treatments and services would occur for some new (but not continuing) users of these medications. For new users of medications for OUD and AUD, reductions in inpatient days, detox days, and emergency department visits would be expected.

Expenditures

As noted in Table 1 and Figure B, SB 11 would result in premium increases of less 0.1% for all market segments less than a 0.1% decrease in total enrollee out-of-pocket expenses (cost-sharing) for covered benefits.

Figure B. Expenditure Impacts of SB 11



Source: California Health Benefits Review Program, 2019.

Cost-sharing impacts among enrollees using the medications would range from no impact (for Medi-Cal beneficiaries, who have no premandate cost sharing) to an average annual decrease of \$418.28 among enrollees in individual market plans and policies.

Medi-Cal

Medi-Cal impacts related to OUD and AUD would be related only to a shift of naloxone for OUD (for overdose treatment) use to the more costly auto-injector formulation. Otherwise, the Medi-Cal FFS program provides SB11-compliant coverage, but SB 11 would make the auto-injector more easily accessible through DMHC-regulated plans. Some impact would be expected due to plans changing benefit coverage for TUD medications (which are not part of the Medi-Cal FFS carve out) to be compliant with SB 11.

CalPERS

CalPERS premiums would be expected to increase less than 0.1%.

Number of Uninsured in California

No measureable impact is expected.

Public Health

In the first postmandate year, CHBRP estimates the following public health impacts. As enrollees may use more than one medication, these enrollee estimates reflect an upper bound.

Approximately 3,100 enrollees with newly compliant benefit coverage would use FDA-approved OUD medications, though 40% to 60% may experience relapse. Health outcomes related to successful use of these medications may include reducing illicit opioid use, opioid overdose and associated mortality, transmission of hepatitis C and HIV, and poor maternal-infant outcomes. Among those new users, SB 11 would also increase maintenance treatment retention and increase overdose reversals (through the use of naloxone).

Approximately 2,200 enrollees with newly compliant benefit coverage would use FDA-approved AUD medications, though 50% or more may experience relapse. Health outcomes of successful treatment would

include decreases in undesirable outcomes such as injuries/accidents and poor pregnancy outcomes.

Approximately 5,500 enrollees with newly compliant benefit coverage would use FDA-approved TUD medications, some of whom will relapse. Health outcomes of successful treatment would include increasing quit rates and sustaining abstinence, as well as decreases in undesirable outcomes, such as poor birth outcomes and smoking-exacerbated conditions (e.g., cancer and heart attacks).

Long-Term Impacts

Long-term utilization of FDA-approved OUD medications could increase as OUD prevalence increases in the state. CHBRP estimates that the level of use per user per year predicted in 2019 (see Table 1) would not change over time, but utilization overall would increase with additional use of opioids. Due to continuing structural and attitudinal barriers, CHBRP expects the portion of persons with OUD in treatment to remain limited, even as the total number of persons with OUD increases. In the case of AUD and TUD treatment, there is very low baseline utilization of the FDA-approved prescription-only medications for the two conditions. Physicians and patients are not frequently using the prescription-only medications. As the lack of use does not appear to be due to restrictions imposed by health plans and insurers, limited use is expected to continue.

A key barrier to abstinence for any SUD is patient interest and readiness to abstain. CHBRP anticipates the demand for treatment of OUD, AUD, and TUD would continue as relapsed patients attempt abstinence again and first-time initiators join the pool of patients seeking care. SB 11 would continue to facilitate prescription medication treatment for some enrollees (whose insurance did not previously offer compliant benefit coverage), but limited patient readiness for SUD treatment and the demand-supply mismatch for OUD and AUD treatment are likely to remain significant barriers to care in future years assuming no other public policies are implemented.

Although the quantitative long-term impact of SB 11 on premature death associated with OUD, AUD, and TUD is unknown, it stands to reason, based on the effectiveness of FDA-approved medications for these SUDs, that there would be a reduction in premature deaths for those enrollees who successfully engage in treatment.

Essential Health Benefits and the Affordable Care Act

SB 11 would alter the terms and conditions of existing benefit coverage, but would not require coverage for a new benefit and so appears not to exceed the definition of EHBs in California.

A Report to the California State Legislature

Analysis of California Senate Bill 11

Mental Health Parity

February 13, 2019

California Health Benefits Review Program

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www.chbrp.org

REVISION HISTORY

Date	Description of Revisions
October 7, 2019	<p>The medical effectiveness section of the analysis has been updated to make clear that:</p> <ul style="list-style-type: none">• oral and extended-release injectable formulations of naltrexone should be considered separately because these treatments have different delivery systems.• discontinuation of any medication approved by the Food and Drug Administration (FDA) for treatment of opioid use disorder is associated greater sensitivity to opioids which may lead a person to overdose if they resume taking the same dose of opioids if they did prior to initiating treatment.• extended-release injectable naltrexone is associated with a higher risk of relapse prior to initiation of treatment because patients must be abstinent from opioids before initiating treatment.



The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications are available at www.chbrp.org.

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Table 1. SB 11 Impacts on Benefit Coverage, Utilization, and Cost, 2019

	Baseline	Postmandate	Increase/ Decrease	Change Postmandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	23,433,000	23,433,000	0	0%
Total enrollees with health insurance subject to SB 11	23,433,000	23,433,000	0	0%
Percentage of enrollees with health insurance subject to SB 11	100%	100%	0%	0%
Total Enrollees with OPD Coverage	22,412,000	22,412,000	0	0%
Number of enrollees with health insurance fully compliant with SB 11 - Commercial Coverage	1,021,111	14,902,000	13,880,889	1359%
Percentage of enrollees with health insurance fully compliant with SB 11 - Commercial Coverage	7%	100%	93%	1359%
Number of enrollees with health insurance fully compliant with SB 11 - Medi-Cal Coverage	0	7,510,000	7,510,000	100%
Percentage of enrollees with health insurance fully compliant with SB 11 - Medi-Cal Coverage	0%	100%	100%	100%
Number of enrollees with health insurance partially compliant with SB 11 - Commercial Coverage	13,880,889	0	-13,880,889	-100%
Percentage of enrollees with health insurance partially compliant with SB 11 - Commercial Coverage	93%	0%	-93%	-100%
Number of enrollees with health insurance partially compliant with SB 11 - Medi-Cal Coverage	7,510,000	0	0	-100%
Percentage of enrollees with health insurance partially compliant with SB 11 - Medi-Cal Coverage	100%	0%	0%	-100%
Number of Enrollees (Commercial, CalPERS, and Medi-Cal) with on-formulary coverage for				
Methadone	12,323,000	23,433,000	11,110,000	90%
Buprenorphine	12,189,000	23,433,000	11,244,000	92%
Combination Buprenorphine/Naloxone	12,189,000	23,433,000	11,244,000	92%
Naloxone	12,323,000	23,433,000	11,110,000	90%
Nicotine - Inhaler	11,370,000	23,433,000	12,063,000	106%
Nicotine - Nasal Spray	11,370,000	23,433,000	12,063,000	106%
Varenicline	19,765,000	23,433,000	3,668,000	19%
Bupropion HCL SR	19,833,000	23,433,000	3,600,000	18%
Acamprosate	12,323,000	23,433,000	11,110,000	90%
Naltrexone - Oral AUD	12,323,000	23,433,000	11,110,000	90%
Naltrexone - Oral OUD	12,323,000	23,433,000	11,110,000	90%
Disulfiram	19,833,000	23,433,000	3,600,000	18%
Percentage of Enrollees (Commercial, CalPERS, and Medi-Cal) with on-formulary coverage for				
Methadone	53%	100%	47%	90%

	Baseline	Postmandate	Increase/ Decrease	Change Postmandate
Buprenorphine	52%	100%	48%	92%
Combination				
Buprenorphine/Naloxone	52%	100%	48%	92%
Naloxone	53%	100%	47%	90%
Nicotine - Inhaler	49%	100%	51%	106%
Nicotine - Nasal Spray	49%	100%	51%	106%
Varenicline	84%	100%	16%	19%
Bupropion HCL SR	85%	100%	15%	18%
Acamprosate	53%	100%	47%	90%
Naltrexone - Oral AUD	53%	100%	47%	90%
Naltrexone - Oral OUD	53%	100%	47%	90%
Disulfiram	85%	100%	15%	18%

Utilization and Cost

Number of Enrollees with SUD using OPD

Substance Use Disorder Medication

Methadone	11,696	11,696	0	0.0%
Buprenorphine	1,181	1,482	301	25.4%
Combination				
Buprenorphine/Naloxone	7,336	9,167	1,831	25.0%
Naloxone	995	1,508	513	51.6%
Nicotine - Inhaler	203	1,554	1,351	666.3%
Nicotine - Nasal Spray	40	220	180	454.0%
Varenicline	10,966	13,121	2,155	19.7%
Bupropion HCL SR	18,489	20,319	1,830	9.9%
Acamprosate	1,637	2,020	382	23.4%
Naltrexone - Oral AUD	4,984	6,145	1,162	23.3%
Naltrexone - Oral OUD	2,124	2,619	495	23.3%
Disulfiram	4,379	5,058	679	15.5%

Percentage of Enrollees with SUD using OPD

Substance Use Disorder Medication

Methadone	0.050%	0.050%	0.000%	0.000%
Buprenorphine	0.005%	0.006%	0.001%	25.444%
Combination				
Buprenorphine/Naloxone	0.031%	0.039%	0.008%	24.965%
Naloxone	0.004%	0.006%	0.002%	51.622%
Nicotine - Inhaler	0.001%	0.007%	0.006%	666.339%
Nicotine - Nasal Spray	0.000%	0.001%	0.001%	453.957%
Varenicline	0.047%	0.056%	0.009%	19.652%
Bupropion HCL SR	0.079%	0.087%	0.008%	9.896%
Acamprosate	0.007%	0.009%	0.002%	23.364%
Naltrexone - Oral AUD	0.021%	0.026%	0.005%	23.305%
Naltrexone - Oral OUD	0.009%	0.011%	0.002%	23.305%
Disulfiram	0.019%	0.022%	0.003%	15.495%

Average Count of Monthly Scripts

Supplied per User per Year

Substance Use Disorder Medication

Methadone	11.59	11.59	-	0.0%
Buprenorphine	4.23	4.60	0.37	8.7%
Combination				
Buprenorphine/Naloxone	6.48	8.31	1.83	28.2%

	Baseline	Postmandate	Increase/ Decrease	Change Postmandate
Naloxone	1.00	1.28	0.28	28.2%
Nicotine - Inhaler	1.55	1.59	0.04	2.6%
Nicotine - Nasal Spray	4.37	6.53	2.15	49.2%
Varenicline	2.07	2.06	(0.01)	-0.5%
Bupropion HCL SR	3.46	3.42	(0.04)	-1.2%
Acamprosate	1.85	2.08	0.23	12.4%
Naltrexone - Oral AUD	2.77	3.23	0.46	16.6%
Naltrexone - Oral OUD	2.30	2.94	0.63	27.6%
Disulfiram	2.56	2.66	0.09	3.7%
Average Cost / Script				
Substance Use Disorder Medication				
Methadone	\$486	\$486	\$0	0.0%
Buprenorphine	\$138	\$138	\$0	0.0%
Combination				
Buprenorphine/Naloxone	\$388	\$388	\$0	0.0%
Naloxone	\$2,378	\$2,378	\$0	0.0%
Nicotine - Inhaler	\$485	\$485	\$0	0.0%
Nicotine - Nasal Spray	\$392	\$392	\$0	0.0%
Varenicline	\$382	\$382	\$0	0.0%
Bupropion HCL SR	\$26	\$26	\$0	0.0%
Acamprosate	\$211	\$211	\$0	0.0%
Naltrexone - Oral AUD	\$219	\$219	\$0	0.0%
Naltrexone - Oral OUD	\$581	\$581	\$0	0.0%
Disulfiram	\$99	\$99	\$0	0.0%
Average Annual Cost / User				
Substance Use Disorder Medication				
Methadone	\$5,637	\$5,637	\$0	0.0%
Buprenorphine	\$582	\$633	\$51	8.7%
Combination				
Buprenorphine/Naloxone	\$2,518	\$3,229	\$710	28.2%
Naloxone	\$2,378	\$3,048	\$671	28.2%
Nicotine - Inhaler	\$753	\$773	\$20	2.6%
Nicotine - Nasal Spray	\$1,714	\$2,557	\$843	49.2%
Varenicline	\$789	\$785	-\$4	-0.5%
Bupropion HCL SR	\$91	\$90	-\$1	-1.2%
Acamprosate	\$390	\$438	\$48	12.4%
Naltrexone - Oral AUD	\$606	\$707	\$100	16.6%
Naltrexone - Oral OUD	\$1,339	\$1,707	\$369	27.6%
Disulfiram	\$252	\$262	\$9	3.7%
Behavioral Health Counseling				
AUD Counseling	\$8,440	\$11,814	\$3,374	40.0%
TUD Counseling	\$93	\$150	\$57	61.5%
OUD Counseling	\$12,256	\$15,263	\$3,007	24.5%
Offset Usage for New Users				
AUD Inpatient Days	NA	-\$12,206	-\$12,206	0.0%
AUD Detox Days	NA	-\$7,155	-\$7,155	0.0%
AUD Emergency Room	NA	-\$3,871	-\$3,871	0.0%
OUD Inpatient Days	NA	-\$4,048	-\$4,048	0.0%
OUD Detox Days	NA	-\$655	-\$655	0.0%

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)³ conduct an evidence-based assessment of the medical, financial, and public health impacts of the benefit mandate included in Senate Bill (SB) 11 Mental Health Parity and Substance Use Medications.

The mandate included in SB 11 would, for many enrollees, affect the coverage of medication used to treat substance use disorders (SUDs). SB 11 would require plans and policies regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) that include a pharmacy benefit that covers outpatient prescription medications related to treatment of SUDs comply with the following:

- Place all medications approved by the federal Food and Drug Administration (FDA) for treatment of SUDs:
 - On formulary and
 - On the formulary's lowest tier.
- For those medications, prohibit:
 - Prior authorization protocols and
 - Step therapy (or “fail first”) protocols.
- Prohibit coverage denials related court orders for treatment.

In addition, SB 11 would prohibit coverage for counseling or “other wrap-around services” related to these medications due to court orders for treatment.

The full text of SB 11 can be found in Appendix A.

Further descriptions of the utilization management protocols SB 11 would prohibit (prior authorization and step therapy) are included in the *Background on Substance Use Disorders* section of this report.

Relevant Populations

Although all health plans and policies regulated by DMHC or CDI would be subject to SB 11, plans and policies without a pharmacy benefit would not have to comply. The bill would require compliance from the health insurance of the 22.4 million enrollees in DMHC-regulated plans or CDI-regulated policies that include a pharmacy benefit (see Appendix D). This represents a little over half of all Californians and represents 95% of the 23.4 million Californians who will have health insurance that may be subject to any state health benefit law — plans and policies regulated by DMHC or CDI. Among this group are a majority of Medi-Cal beneficiaries, as many are enrolled in DMHC-regulated plans.⁴

³ CHBRP's authorizing statute is available at <http://chbrp.org/faqs.php>.

⁴ See *Estimates of Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php#revize_document_center_rz44

Analytic Approach

CHBRP has focused this analysis on medications related to the treatment of three SUDs:

- Alcohol Use Disorder (AUD)
- Opioid Use Disorder (OUD)
- Tobacco Use Disorder (TUD)

As there are no medications approved by the FDA as treatments for the other SUDs (such as disorders related to use of amphetamines or cocaine), those disorders are not included in this analysis.

CHBRP has focused this analysis on SB 11’s potential impacts on the coverage of prescription-only medications that the FDA has approved as treatments for SUD. These medications are listed in Table 2. The list does not include medications that may be used off-label (without approval by the FDA for the treatment of SUDs) and the list does not include medications available over-the-counter (without a prescription).

Table 2. Medications related to SB 11 Coverage Requirements

Substance Use Disorder (SUD)	Prescription-only medication approved to treat SUD
Opioid Use Disorder (OUD)	Buprenorphine
	Methadone
	Naloxone
	Naltrexone (a)
	combination Buprenorphine/Naloxone
	Lofexidine (b)
Tobacco Use Disorder (TUD)	Nicotine Replacement Therapy - inhaler (c)
	Nicotine Replacement Therapy - nasal spray (c)
	Varenicline (b)
	Bupropion HCL SR
Alcohol Use Disorder (AUD)	Acamprosate
	Naltrexone – Oral (a)
	Disulfiram

Source: California Health Benefits Review Program, 2019

Notes: (a) Naltrexone is used to treat both OUD and AUD. (b) Not available as a generic. (c) Nicotine replacement therapy is also available in non-prescription, over-the-counter formulations, including patch, gum, and lozenge.

Key: AUD = alcohol use disorder; OUD = opioid use disorder; SUD = substance use disorder; TUD = tobacco use disorder

Key Assumptions

In order to complete this analysis of SB 11, CHBRP has made a number of analytic assumptions.

As SB 11 specifies that it would apply to plans and policies that cover medications approved by the FDA for treatment of SUDs, CHBRP has assumed the bill would not affect the health insurance of enrollees in plans or policies that do not include a pharmacy benefit. Less than 5% of all enrollees in plans and policies regulated by DMHC or CDI have no pharmacy benefit through their state-regulated health insurance (see Appendix D), though the figure is higher among commercial and CalPERS enrollees, about 7%. For this analysis, those enrollees are considered to have health insurance compliant with SB 11.

As SB 11 specifies “on formulary” and “lowest tier,” terms related to pharmacy benefit coverage, CHBRP has assumed the bill would apply to medications covered through a pharmacy benefit, and would not apply to medications covered only through a medical benefit.⁵

As SB 11 does not exempt from compliance coverage for methadone, CHBRP has assumed SB 11 would require compliant pharmacy benefit coverage for it. Although methadone is commonly on formulary as a treatment for pain, methadone as a treatment for OUD can only be prescribed by and delivered through federally certified centers (“methadone clinics”).⁶ As these centers do not currently bill for medications (as pharmacies do) and are not licensed as outpatient pharmacies, CHBRP has assumed that SB 11–compliant pharmacy benefit coverage for methadone would not alter utilization within the first year of implementation.

As SB 11 specifies “lowest tier,” CHBRP has assumed it would require relevant medications not already on “tier 0” (no cost sharing) or not already on “tier 1” (standard only for generics) regardless of generic/brand-name status to become “tier 1.”

As SB 11 specifies that the requirements are related to “prescription” medications, CHBRP has assumed the bill would apply only to the coverage of medications approved by the FDA as treatments for SUD that are available by prescription only, and would not apply to the coverage of medications available over-the-counter (OTC) without a prescription.⁷

As SB 11 is silent regarding generic status, CHBRP has assumed that if both generic and brand-name versions were covered through a pharmacy benefit, all coverage would have to be as specified by SB 11.

As SB 11 is silent regarding formulation (pill, injectable, patch, etc.), CHBRP has assumed that if multiple prescription-only formulations were covered through a pharmacy benefit, all coverage would have to be as specified by SB 11.

The interaction of laws governing DMHC-related plans (the Health & Safety Code) and the laws governing the Medi-Cal program (Welfare & Institutions Code) are complex. It would require a legal

⁵ Extended-release naltrexone, buprenorphine implants, and extended-release buprenorphine (all FDA-approved, prescription only medications for SUD treatment) require outpatient clinical services for injection or implantation and are generally covered under the medical benefit. Other formulations of these medications (sublingual tablets and buccal film) are generally covered through a pharmacy benefit.

⁶ Federal law restricts methadone treatment to federally certified opioid treatment programs (OTP), known as methadone clinics, see Title 42 of the Code of Federal Regulations Part 8 (42 CFR § 8)

⁷ Some formulations of nicotine replacement therapy (patch, lozenge, gum) are available over-the-counter (without a prescription). Others (nasal spray, inhaler) are prescription-only.

analysis to be certain of the impacts of SB 11 on DMHC-regulated plans enrolling Medi-Cal beneficiaries. For this analysis, and based on lay-person interpretation, CHBRP has assumed these plans would be required to comply with the bill's requirements. In cases where a medication is currently part of a "carve-out" (covered by Medi-Cal through fee-for-service or other program, rather than through the DMHC-regulated plan), CHBRP has assumed SB 11 would create "double coverage," which would allow a beneficiary to access benefit coverage through the plan or through the carve-out route. However, in the absence of reason to believe the benefit coverage would be more desirable to the enrollee, CHBRP has assumed that the enrollee would continue to use the "carve-out" coverage.

As CHBRP has located no evidence of coverage related to treatment of SUDs being denied in connection with a court order, CHBRP has assumed that the related prohibition included in SB 11 would have no measurable impact in the first year after implementation.

Interaction with Existing Requirements

Although a number of federal laws and regulations restrict providers in regards to the medications specified by SB 11 (see the *Background* section of this report), CHBRP is aware of few state or federal benefit coverage laws or regulations that would directly interact with compliance to the outpatient SUD prescription medication coverage requirements addressed in SB 11.

California Policy Landscape

California law and regulations

CHBRP is unaware of California laws or regulations that directly address coverage of outpatient medications for SUD.

CHBRP is aware that the California Department of Health Care Services (DHCS) regularly excludes from pharmacy benefit coverage a number of the medication listed in Table 2 when contracting with DMHC-regulated plans. With such "carve-outs" in effect, the medications to treat OUD and some to treat AUD are covered for Medi-Cal beneficiaries through some other Medi-Cal program — fee-for-service (FFS) other. CHBRP is unaware of medications to treat TUD being included in any carve-outs.

CHBRP is aware that California's governor issued, on January 7, 2019, an executive order (N-01-19) that there be, as of 2021 a single purchaser for prescription medications for all Medi-Cal beneficiaries and potentially for other Californians as well. Though details are as of yet unclear, such a program could lead to DHCS (or another statewide program) separately managing the pharmacy benefit for Medi-Cal beneficiaries and perhaps some other enrollees in DMHC-regulated plans (such as enrollees associated with CalPERS). In such a situation DHCS, and other entities, could contract with DMHC-regulated plans to exclude the pharmacy benefit. This could increase the number of enrollees without a pharmacy benefit through their state-regulated health insurance (see Appendix D) and could decrease the number of enrollees with health insurance that must comply with SB 11's coverage requirements.

CHBRP is aware that a law passed in 2018⁸ requires providers to offer to some patients prescriptions for naloxone (or other anti-overdose medications). In time, this law could increase the annual baseline utilization of naloxone and so increase the related impacts projected by CHBRP for SB 11.

⁸ 2018's AB 2760 altered the Business and Professions Code, Article 10.7.

Similar requirements in other states

A recent Illinois bill, SB 1707, which is very similar to California's SB 11, became law (Illinois Legislature, 2019). Passage of the bill is too recent for its impacts to be apparent.

Federal Policy Landscape

Federal Mental Health Parity and Addiction Equity Act

The federal Mental Health Parity and Addiction Equity Act (MHPAEA) addresses parity for mental health benefits.⁹ The MHPAEA requires that if mental health or substance use disorder services are covered, cost-sharing terms and treatment limits be no more restrictive than the predominant terms or limits applied to medical/surgical benefits. The MHPAEA applies to the large-group market, but the ACA requires small-group and individual market plans and policies purchased through a state health insurance marketplace to comply with the MHPAEA. This federal requirement is similar to the California mental health parity law,¹⁰ although the state law applies to some plans and policies not subject to the MHPAEA.

Although CHBRP has not analyzed the non-mandate portion of SB 11 (sections 1 and 3), which deal directly with MHPAEA requirements, current California coverage of the medications addressed by SB 11's benefit mandate (sections 2 and 4) has been influenced by compliance with the MHPAEA.

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how SB 11 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).¹¹

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

Essential Health Benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. QHPs, and all other non-grandfathered individual and small group market health insurance must cover a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{12,13}

⁹ Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by the ACA.

¹⁰ H&SC Section 1374.72; IC Section 10144.5 and 10123.15.

¹¹ The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other_publications/index.php.

¹² The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: [cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf](https://www.cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf).

¹³ H&SC Section 1367.005; IC Section 10112.27.

CHBRP estimates that approximately 12% of Californians have health insurance that is subject to the EHB requirement.¹⁴

States may require QHPs to offer benefits that exceed EHBs.¹⁵ However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.^{16,17} State rules related to provider types, cost-sharing, or reimbursement methods would *not meet* the definition of state benefit mandates that could exceed EHBs.¹⁸

SB 11 would alter the terms and conditions of existing benefit coverage, but would not require coverage for a new benefit and so appears not to exceed the definition of EHBs in California.

Federally Selected Preventive Services

The ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost-sharing when delivered by in-network providers as soon as 12 months after a recommendation appears in any of the following:¹⁹

- The United States Preventive Services Task Force (USPSTF) A and B recommendations;
- The Health Resources and Services Administration (HRSA)-supported health plan coverage guidelines for women's preventive services;
- The HRSA-supported comprehensive guidelines for infants, children, and adolescents, which include:
 - The Bright Futures Recommendations for Pediatric Preventive Health Care; and
 - The recommendations of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; and
- The Advisory Committee on Immunization Practices (ACIP) recommendations that have been adopted by the Director of the Centers for Disease Control and Prevention (CDC).

As an A recommendation, the USPSTF recommends medications approved by the FDA to treat TUD for all non-pregnant adults who use tobacco (USPSTF, 2009). Through its interaction with the ACA, this

¹⁴ See *Estimates of Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php#revize_document_center_rz44

¹⁵ ACA Section 1311(d) (3).

¹⁶ State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

¹⁷ However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

¹⁸ Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

¹⁹ A resource on this ACA requirement is available on the CHBRP website: www.chbrp.org/other_publications/index.php.

results in a prevention services benefit mandate and prohibits cost-sharing (regardless of formulary tier) for these medications. However, the interaction is silent in regards to:

- Whether brand-name (as well as generic) versions must be covered,
- Whether all formulations (lozenge, patch, nasal spray, etc.) must be covered, and
- Whether all covered versions/formulations must be covered without applicable cost-sharing.

In terms of its interaction with SB 11, it appears that the prevention services mandate is stricter on cost-sharing – it completely prohibits, where SB 11 allows “lowest formulary tier” coverage, which may include some cost-sharing. However, the prevention services mandate may not be as broadly applicable as SB 11 – it may not be relevant to all covered formulations of a medication or to both brand name and generic if both are covered, as CHBRP has assumed that SB 11 would be.

BACKGROUND ON SUBSTANCE USE DISORDERS

Substance Use Disorder (SUD) is the clinical diagnosis for substance use that meets criteria per the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), including impaired control, social impairment, risky use, increased tolerance, and withdrawal symptoms (APA, 2013). The American Society of Addiction Medicine characterizes addiction as “the inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission” (ASAM, 2011).

There are a number of licit and illicit substances that qualify for a SUD diagnosis including: opioids (heroin and misuse of prescription pain medications such as fentanyl and oxycodone), alcohol, cannabis, nicotine, inhalants, hallucinogens, amphetamine, caffeine, cocaine, and sedatives. Treatments for SUD include residential, inpatient, and outpatient care using behavioral therapy, counseling, and/or prescription medication. Mutual help groups (e.g., Alcoholics Anonymous, Narcotics Anonymous) also support those with SUD to quit substance use and maintain sobriety.

SB 11 would require state-regulated plans and policies that include a pharmacy benefit to cover all prescription medications approved and indicated by the FDA for treatment of substance use disorders. SB 11 would also require placement of these medications on the lowest formulary tier and would prohibit prior authorization or step therapy. **Ten medications are approved by the FDA for the treatment of *opioid use disorder (OUD)*, *alcohol use disorder (AUD)*, and *tobacco use disorder (TUD)*; Table 2 shows the only medications and disorders that meet the conditions of SB 11.**

SUD in California: Prevalence, Mortality, Health Services Use, and Disparities

CHBRP reports the most recent data available and cites national data when California data are unavailable. In this report, misuse/abuse/dependence (or heavy drinking) rates are used as proxy measures when use disorder data are unavailable. Data sources and prevalence rates in California vary among the three use disorders:

- OUD prevalence ranges between 0.51% and 1.1% (SAMSHA, 2018; Clemans-Cope et al., 2018)
- AUD prevalence is 5.51% (SAMSHA, 2017)
- TUD prevalence is 16.23% (based on all tobacco products, CDPH, 2018)

Of note, polysubstance use is common among those diagnosed with substance use disorder, and many patients have more than one SUD. For example, in the U.S., among those reporting alcohol use disorder, 23.8% also report nicotine dependence, and 3.9% report a concomitant prescription opioid use disorder. Among those reporting a prescription opioid use disorder, 35.2% also reported alcohol use disorder and 45.4% reported concomitant nicotine dependence (NIDA, 2018). The diagnosis and treatment of multiple use disorders is complex and treatment and recovery rates for each substance use disorder may vary for a single patient. It is possible for a patient to be in recovery from one SUD, but not another.

Opioid Use Disorder (OUD)

The DSM-5 characterizes OUD as a pattern of opioid use (e.g., oxycodone, hydrocodone, and heroin) that results in significant impairment or distress. People meeting at least two of 11 specified criteria within

a 12-month period are diagnosed with mild, moderate, or severe OUD depending on the number of criteria met (APA, 2013).

In 2017, the U.S. Surgeon General declared the opioid crisis a U.S. public health emergency due to the escalating rates of opioid overdose, and related mortality and other harms (HHS, 2018). In addition to a greater risk of mortality, people with OUD are at a higher risk for developing cardiac dysrhythmias; respiratory depression; impairment in daily function; and premature death (Blanco et al., 2013). Additional conditions include HIV, hepatitis A, B, and C, tuberculosis, and endocarditis, which lead to increased use of health care services to treat those conditions (SAMHSA, 2016; Tsui et al., 2014).

OUD prevalence

Estimated prevalence rates for OUD in California range from 0.51% to 1.1%. The 2016-2017 National Survey on Drug Use and Health estimated a 0.51% prevalence rate for self-reported “pain reliever use disorder” (excluding heroin use) (SAMSHA, 2018). However, an analysis by Clemans-Cope et al (2018) estimated county-level OUD and treatment needs in California by adjusting rates from the 2015 NSDUH and CDC population counts. Their estimate is double that of the SAMSHA prevalence rate at 1.1%, or about 350,000 Californians with OUD. Clemans-Cope and colleagues defined OUD as abuse of or dependence on nonmedical use of prescription pain relievers *and/or* heroin by persons aged 12 years and older.

OUD treatment relapse rates

Many providers consider OUD to be a chronic condition. As with most chronic conditions, medication adherence and long-term control of the condition (relapse prevention) are challenging. A literature review by McLellan et al. compared what they called “relapse” rates (i.e., medication adherence) between four chronic conditions: substance use disorders (alcohol and opioid), diabetes, asthma, and hypertension. They found that adherence rates for medications for substance use disorders in the first year of treatment (40%-60%) were similar to or higher than adherence rates for medications used to manage diabetes, asthma, and hypertension (30%-50% for type 1 diabetes; 50%-70% for asthma and hypertension) (McLellan et al., 2000). Health care professionals note that relapse is common during the recovery process for many patients and it is important for patients to work with their provider to resume or modify the treatment plan (NIDA, 2017).

Mortality

The CDC attributes the increase in premature mortality across the U.S. since 2013 to a significant increase in overdose deaths associated with illicitly manufactured synthetic opioids (fentanyl). Those using opioids obtained illegally (on the street) are unaware of variations in strength for every dose purchased; illicitly manufactured fentanyl appears to remain a significant problem in 2018 (Hedegaard, 2017). After 25 years of increasing life expectancy in the U.S., researchers from the National Center for Health Statistics reported that life expectancy fell from 78.9 years in 2014 to 78.6 years in 2016 (Kochanek et al., 2017). At the population level, researchers linked this decrease in life expectancy in part to the opioid epidemic (Dowell et al., 2017). Increase in overall death rates were most significant for age groups 15 to 24 years (7.8% increase), 25 to 34 years (10.5% increase), and 35 to 44 years (6.7% increase) (Kochanek et al., 2017; Rudd et al., 2016).

The California Opioid Overdose Surveillance Dashboard shows an age-adjusted mortality rate for all opioid overdose deaths of 5.23/100,000 Californians in 2017 (2,196 deaths) the highest annual rate yet reported in California (CDPH, 2018).

There are significant mortality rate differences among demographic groups. Native Americans, followed by whites, had the highest opioid overdose mortality rates in California in 2017 (17.56/100,000 and 8.9/100,000) as compared with Asians who had the lowest opioid overdose mortality rate at 0.97/100,000 (CDPH, 2018). California males were twice as likely to die from opioid overdose as females (7.32 deaths/100,000 and 3.08 deaths/100,000, respectively).

OUD-related health services use

The California Opioid Overdose Surveillance Dashboard provides a variety of statistics about California's experience with opioid use. About 10/100,000 Californians were seen in emergency departments (ED) for opioid (excluding heroin) overdose in 2017 (CDPH, 2019). Males and females have about the same rate of emergency department visits for opioid overdoses (10.4/100,000 and 10.0/100,000, respectively). Among various age cohorts, the Dashboard shows that Californians aged 55 to 69 years have the highest crude rates of emergency department visits for opioid overdose (~15/100,000), closely followed by younger patients (aged 20-29 years) (~14/100,000) (CDPH, 2019).

In contrast to the pattern of mortality rates, the California Opioid Overdose Surveillance Dashboard shows that blacks and whites have similar rates of hospitalizations for opioid overdose (11.9/100,000 and 11.6/100,000, respectively), followed by Native Americans (5.9/100,000), Latinos (4.3/100,000), and Asians (1/100,000) (CDPH, 2019). See the *Benefit Coverage, Utilization, and Cost Impacts* section for discussion about estimated cost-offsets attributable to SB 11.

Alcohol Use Disorder (AUD)

The DSM-5 characterizes AUD as a pattern of alcohol use (e.g., wine, beer, and spirits) that results in significant impairment or distress. People meeting at least two of 11 specified criteria within a 12-month period are diagnosed with mild, moderate, or severe AUD depending on the number of criteria met (APA, 2013).

AUD is the third leading cause of preventable mortality in the U.S. Excessive alcohol use increases the risk of developing serious acute and chronic health problems, including but not limited to brain damage (including dementia), liver disease, heart disease, immunosuppression and infections, hypertension, cancers, depression, pancreatitis, fetal alcohol syndrome, and traumatic injuries or deaths from falls, car accidents, physical altercations, suicide and homicide (NIAAA, 2018).

AUD prevalence

The 2016-2017 NSDUH estimates that 5.51% of Californians aged 12 years and older have AUD, with those aged 18-25 years experiencing the highest prevalence rate (9.90%) (SAMSHA, 2017).

The national rate of AUD is estimated to be 6.2% among adults aged 18 and older (NIAAA, 2018). The 2017 Behavioral Risk Factor Surveillance Survey data show that males and females have similar rates of heavy drinking²⁰ (proxy indicator for AUD) (6.6% and 6.0%, respectively). More significant differences were reported by age cohort and race/ethnicity. Heavy drinking was highest among those aged 18-34 years, followed by those aged 55-64 years (7.3% and 6.0% respectively) (CDC, 2015). Differences among racial ethnic groups exist with non-Hispanic whites reporting higher rates of heavy drinking than blacks (non-Hispanic) and Hispanics (8.7%, 4.5%, and 5.2%, respectively) (CDC, 2015).

²⁰ Behavioral Risk Factor Surveillance System Survey defines heavy drinking as males consuming >14 drinks/week and females consuming >7 drinks/week. CHBRP uses this as a proxy indicator of AUD.

Nationally, the National Institute on Alcohol Abuse and Alcoholism reports that Hispanics and Blacks have relatively lower rates of alcohol use disorders than do non-Hispanic whites; however, ethnic and racial disparities still exist for alcohol-related diseases, problems, and deaths in these groups (NIAAA, 2019). For example, Hispanics and Blacks have a higher risk for developing alcohol-related liver disease and subsequent cirrhosis mortality than whites. Self-reported rates of DUI are highest among mixed race and Native Americans and Alaska Natives (NIAAA, 2019).

The National Institute on Drug Abuse reports a series of statistics regarding disparities in alcohol misuse/abuse according to sexual orientation (NIDA, 2017). For example, 2013 survey data from the U.S. Census Bureau showed that a more gay or lesbian adults, and bisexual adults aged 18 to 64 years reported past-year binge drinking (five or more drinks on a single occasion) than heterosexual adults (35.1%, 41.5%, and 26.0%, respectively) (Ward et al., 2014). Another analysis of LGBT people in treatment for SUDs found that they initiated alcohol consumption earlier than their heterosexual counterparts (McCabe et al., 2013).

AUD treatment relapse rates

Of the substance use disorders that have medication treatment options, AUD is the disorder least associated with medication-assisted treatment. An estimated one-third of people with AUD receive treatment (medication and/or counseling), of which fewer than 10% use AUD prescription drug treatment (Jonas et al., 2014; NIAAA, 2018). Generally, AUD is treated in specialty facilities, or patients choose to attempt abstinence through mutual-help organizations such as Alcoholics Anonymous. AUD is treated less commonly through primary care (Jonas et al., 2014).

In addition to previously cited relapse rates from McLellan et al (2000), other studies show AUD relapse rates ranging from 50% to 70% of people in treatment for AUD (medication and/or counseling) relapsing within 3 months of treatment initiation to 60% to 85% relapsing within the first year (Brandon et al., 2007; Moos and Moos, 2006; Seo et al., 2013). Recent evidence demonstrates that some reduction in alcohol consumption can still be beneficial, even if abstinence is not achieved (Jonas et al., 2014; Mann et al., 2017).

AUD-related mortality

The CDC Alcohol-Related Disease Impact database reports the number of alcohol-attributable deaths due to excessive alcohol consumption. In California, of the 10,671 alcohol-attributed deaths in 2013 (most recent data), 5,558 deaths were due to chronic conditions associated with liver disease/cirrhosis (more than 3,500 deaths), followed by stroke (193), hypertension (238), and cancer (325) (CDC, 2013). The remaining 5,113 deaths were from acute causes, including more than 1,000 motor vehicle deaths, 1,000 homicides, 800 suicides, and 600 falls resulting in death (CDC, 2013).

AUD-related health service use.

Among the 119,600 non-fatal emergency room visits and 30,000 non-fatal hospitalizations for alcohol-related injuries and poisonings in 2014, men, whites, and Hispanics experienced disproportionate representation similar to the death rates. Similarly, alcohol-related traffic deaths are many times more frequent among Native Americans or Alaska Natives than among other minorities. Hispanics are overrepresented among drunk drivers and DUI-related fatalities (CDPH, 2018).

Tobacco Use Disorder (TUD)

The DSM-5 characterizes TUD as a pattern of tobacco use (e.g., smoking, chewing) that results in significant impairment or distress. People meeting at least two of 11 specified criteria within a 12-month period are diagnosed with mild, moderate, or severe TUD depending on the number of criteria met (APA, 2013). As there is no known safe level of tobacco consumption, any daily use of tobacco is clinically considered TUD.

Public health campaigns, smoking policy changes (tobacco taxation, tobacco sales restrictions, workplace restrictions, etc.), and the ACA-requirement for coverage of cessation therapies by many plans and policies have contributed to California having the second lowest rate of adult smoking in the U.S. (11.4%). However, California still has the largest number of smokers due to the size of its population (3.2 million adult smokers) (CDPH, 2018). Cigarette use combined with other tobacco product (e.g., cigars, chewing tobacco, electronic cigarettes) use gives an overall tobacco-use prevalence rate of 16.4% of adult Californians. CDPH also reports significant variation in smoking prevalence among subpopulations. For example, there is a three-fold difference between the populations with the highest and the lowest smoking rates: 24.2% of American Indians as compared with 8.6% of Asian/Pacific Islanders. African Americans have the second highest rate of smoking in California (20.7%) followed by whites (13.0%) and Hispanics (11.5%). The smoking rate among Medi-Cal beneficiaries is above the state average at 17.4%, as compared with below average rates among the employment-based insured (9.8%) and privately purchased insureds (9.2%) (CDPH, 2018).

Treatment and cessation rates for TUD

Table 3 shows the prevalence of smoking cessation methods that California smokers reported using (one or more) to quit smoking in the past year, based on the 2016-2017 California Adult Tobacco Survey (CDPH, 2018). Prior research has shown that former smokers recalled an average of 4.7 quit attempts before successfully abstaining (CDPH, 2018).

Table 3. Methods (one or more) Used to Quit Cigarette Smoking in the Past Year among Adults in California Aged 18-64, 2016-2017

Method	2016	2017
Quit Cold Turkey	67.4%	67.0%
Medication (e.g., bupropion, varenicline)	6.7%	5.7%
Nicotine Patches, Gum, or Lozenges	18.5%	19.2%
Counseling	4.1%	5.6%
Self-Help Materials	5.9%	10.6%
California Smokers' Helpline	7.3%	4.6%
Electronic Smoking Devices*	19.5%	14.6%

Source: California Health Benefits Review Program, 2019, adapted from CDPH, 2018.

* Electronic smoking devices are not an FDA-approved method of smoking cessation.

TUD morbidity and mortality

Tobacco use is the leading cause of preventable illness and death in the United States and California. The CDC estimates that smoking and exposure to tobacco smoke account for approximately 40,000 deaths annually in California and that 440,000 youth today will die prematurely due to tobacco exposure. There is a robust body of literature demonstrating poor health outcomes associated with smoking including cardiopulmonary disease, cancer, dental disease, and poor fetal outcomes (e.g., low birthweight, stillbirth, preterm delivery). Furthermore, indirect effects of smoking through second-hand and third-hand smoke places non-smokers at higher risk for cardiovascular disease, cancer, and stroke, and children at higher risk for ear infections, asthma attacks, bronchitis, and sudden infant death syndrome (SIDS) (CDC, ATS, 2013). The California Department of Public Health (CDPH) reported that current smokers have the highest rate of chronic obstructive pulmonary disease (12.7%) followed by never smokers (5.5%) and former smokers (4.8%). Rates of smoking-attributable mortality for lung cancer for men was 85% (5,175) and 64% (3,625 deaths) for women in 2016 (CDPH, 2018). Among the 10 categories of cancer, 9 categories of cardiovascular disease, and 5 categories of respiratory disease, the smoking attributable mortality rate was above 60% accounting for more than 20,000 preventable deaths in California in 2014 (CDPH, 2018).

Unmet Needs for OUD, AUD, and TUD Treatment

OUD: In calculating the OUD treatment gap in California, Clemans-Cope et al (2018) estimated that about 20% with OUD will seek medication assisted treatment based on study findings from Wu et al (2016) that considered opioid-related treatment received by people with OUD in the U.S. See the *Structural and Attitudinal Barriers* section for discussion about contributing factors to unmet need for treatment.

AUD: An estimated one-third of people with AUD receive treatment (medication and/or counseling), of which fewer than 10% use AUD prescription drug treatment (Jonas et al., 2014; NIAAA, 2018). Generally, AUD is treated in specialty facilities or through mutual-help organizations such as Alcoholics Anonymous; it is treated less commonly through primary care (AHRQ, 2014). In 2017, 5.41% of Californians aged 12 years and older reporting a need for but not receiving AUD treatment (and 9.93% among those aged 18-25 years) (SAMSHA, 2017). See the *Structural and Attitudinal Barriers to OUD, AUD and TUD Treatment* section for discussion about contributing factors to unmet need for treatment.

TUD: Based on California Health Interview Survey data, 72% percent of adult smokers in California thought about quitting in the next six months and 58% percent made an attempt in the past year. Table 3 shows California smokers' preferred quitting "cold turkey" (67%) over other methods such as over-the-counter nicotine replacement therapy (nicotine patches, gum, or lozenges) (19%). Prescription medications were used by 5.7% smokers, who may report using more than one cessation method simultaneously (CDPH, 2018).

Structural and Attitudinal Barriers to OUD, AUD and TUD Treatment

Barriers to accessing treatment for OUD, AUD and TUD include drug utilization management techniques (see side bar), provider supply, geographic access, and patient receptiveness to treatment. According to the Pew Foundation, two key barriers to the use of medications for OUD are limited insurance coverage for medications and limited provider supply.

Drug Utilization Management

These tools help insurance carriers manage the cost or safety of use of outpatient prescription drugs. In addition to minimizing the use of more expensive prescription drugs, these techniques are used sometimes for clinical reasons such as promoting adherence to clinical recommendations for specific illnesses or protecting enrollees from outdated or potentially dangerous drugs (PBMI, 2015). As discussed further in the *Benefit Coverage, Utilization, and Cost Impacts* section, formulary coverage for prescription medications approved and indicated by the FDA to treat SUDs is common for enrollees in DMHC-regulated plans and CDI-regulated policies. (See box for definitions of utilization management tools.)

Provider Supply

Although formulary coverage and utilization management may provide some barrier to treatment, provider supply including provider attitudes and geographic access can also pose structural barriers to treatment and are more difficult to address through legislated benefit mandates.

Significant prescribing restrictions limit access to OUD medications. Federal law restricts methadone treatment (for OUD) to federally certified opioid treatment programs (“methadone clinics”). Methadone must be initiated through admission to a certified methadone clinic. Initially, patients must take their daily methadone treatment under direct clinical supervision. Once a patient is stabilized, it is possible for some patients to take methadone at home in between required clinic visits. Federal guidelines recommend a minimum 12-month treatment plan, and many patients continue with methadone for years (SAMHSA, 2015). (*Due to the federal restrictions, CHBRP assumes SB 11 would not change administration, payment, or barriers to methadone treatment. See Benefit Coverage, Utilization, and Cost Impacts section for further discussion.*) Clemans-Cope et al. (2018) reported that there are 152 SAMHSA-certified methadone clinics in California, which can treat 46,430 patients simultaneously.

In order to prescribe buprenorphine for OUD, another FDA-approved treatment for OUD, federal law requires health care providers to receive special training and certification called a DATA 2000 Waiver. Providers (physicians, physician assistants, and nurse practitioners) can treat no more than 30 simultaneous patients during first year of waiver, and must reapply to increase to 100 patients. Addiction medicine physicians may treat up to 275 patients at a time (SAMHSA, 2018). In 2018, there were 5,821 physicians waived to prescribe buprenorphine in California (CHCF, 2018). Several studies suggest that, of certified buprenorphine providers, only 44% to 66% actually prescribe the medication for OUD, and most do not choose to reach their maximum-allowed patient caseload (Hutchinson et al., 2014; Jones et al., 2015; Walley et al., 2008). This leads to wait lists in some areas, which have been shown to decrease uptake of OUD medications by people with OUD (Fisher et al., 2017). A recent treatment capacity

Prescription Drug Benefit Management

The following are used to help health plans and insurers control costs and manage patient safety (PBMI, 2015):

Formulary. The formulary is a list of prescription drugs that the health plan or insurer agrees to pay for in whole or in part.

Tier. Formularies divide the covered drugs into tiers, each tier having a distinct cost-sharing level. Prescription drugs in the lower tiers (0-2), usually generics and preferred brand name drugs, are less costly to both the enrollee and to the health plan or insurer than drugs listed in upper tiers (3-5).

Prior Authorization. This utilization management tool requires providers to submit documentation of medical need to the health plan for approval of coverage for some prescription drugs.

Step Therapy. This utilization management tool requires an enrollee to try and fail one or more formulary-required drugs prior to receiving coverage for the initially preferred drug. Step therapy protocols usually recommend starting with a drug that is less expensive (generics) and/or has more “post-marketing safety experience”.

analysis by Clemans-Cope et al. (2018) estimated that an additional 3,500 to 4,100 providers would need to be trained and certified to treat the OUD population in California.

Provider willingness to treat OUD and AUD can also be limited; not all providers are comfortable prescribing medications to treat these conditions due to a lack of clinical knowledge, lack of office space and support resources, time pressure, or personal beliefs against using medications to treat OUD (McNeely et al., 2018; HHS, 2016). Many providers are reticent to prescribe medication to treat AUD, despite more than 10 years of provider education campaigns from government entities and the American Medical Association (SAMSHA, 2015). Other reasons for provider nonparticipation include prior training to refer to patients with AUD to specialty treatment centers and systemic division between physical and behavioral health care (SAMSHA, 2015). Wessell et al. found that key facilitators to increasing primary care providers' prescribing AUD medication included provider exposure to evidence and case studies, limited referral options to specialty treatment clinics for their patients (provider-of-last resort), receptive patients, early successful patient outcomes, and low-cost (generic oral naltrexone) availability of AUD medication (Wessell et al., 2014).

Medications for treating TUD and AUD do not require special provider training or waivers, thus these disorders do not face the same provider supply barrier described for OUD.

Patient Attitudinal Barriers

For many with OUD, AUD, and TUD, attitudinal barriers are the most significant barrier to treatment initiation and persistence (Blanco et al., 2013). The stigma of addiction and the ability to acknowledge an addiction affects patient desire to seek care; even more so for those who have co-occurring psychiatric conditions (Fisher et al., 2016; Jones et al., 2015; Verissimo and Grella, 2017). Many people with OUD and/or AUD believe they can solve the problem themselves (Rapp et al., 2006). Rapp et al. (2006) tested a Barrier to Treatment Inventory tool to assess barriers to treatment from the substance abusers' perspective. They reported significant correlation among six of the seven barrier factors: absence of a problem; negative social support; fear of treatment; privacy concerns; time conflict; poor treatment availability; and admission difficulty.

As with OUD and AUD, patient readiness for treatment also presents a barrier for those with TUD. CHIS data shows that a quarter of smokers in California are not interested in quitting. For those who attempt to quit, repeated efforts are needed, with an average of 4.7 quit attempts reported by former smokers before successful cessation (CDPH, 2018).

Social Determinants of Health (SDoH) Related to Substance Use Disorder

SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography, etc.). See the *Long-Term Impacts* section for a full discussion.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 11 would require state-regulated health plans and policies that provide prescription drug benefits for the treatment of substance use disorders (SUD) to place all prescription medications approved by the FDA for treatment of SUDs on the lowest tier of the health plan's drug formulary. The bill would also prohibit a health plan that provides outpatient prescription drug benefits for the treatment of SUDs from imposing any prior authorization or any step therapy requirements before authorizing coverage for a prescription medication approved by the FDA for the treatment of SUDs and from refusing to cover court-mandated treatment for a SUD. The medical effectiveness review summarizes findings from evidence²¹ on the effectiveness of medications that the FDA has approved for treatment of SUD and the impact of utilization management techniques on use of these medications and outcomes. Additional information on SUDs for which there are FDA-approved medications is included in the *Background on Substance Use Disorders* section.

As indicated in the *Background on Substance Use Disorders* section, the FDA has approved prescription medications to treat opioid use disorders (OUD), alcohol use disorders (AUD), and tobacco use disorders (TUD). OUD encompasses abuse of short-acting opioids, such as heroin and morphine, and semi-synthetic opioids such as oxycodone and hydrocodone. AUD involves compulsive use of alcohol and inability to control alcohol intake. Tobacco use disorder encompasses use of all forms of tobacco. (See the *Background on Substance Use Disorders* section for more detailed definitions of these SUDs.)

The FDA has approved different medications for each of these disorders. Table 4 lists the medications the FDA has approved, the SUD(s) they are used to treat, their role in treatment, and how the medication is administered.

Research Approach and Methods

Studies of FDA-approved medications for OUD, AUD, and TUD were identified through searches of PubMed, the Cochrane Library, EMBASE, Scopus, and PsycINFO. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Care Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English. For OUD, the search only included articles published since January 2018 because CHBRP previously reviewed older literature on medications for OUD for its report on AB 2384 which was issued in 2018. The literature search for AUD included articles published from 2013 to present because CHBRP relied on a systematic review completed for the Agency for Healthcare Research and Quality (AHRQ) for a synthesis of older literature on medications for AUD (Jonas et al., 2014). The literature search for TUD included articles published from 2014 to present because CHBRP relied on an AHRQ systematic review for a synthesis of older literature on medications for TUD (Patnode et al., 2015). Of the 947 articles found in the literature review, 65 were reviewed for potential inclusion in this report on SB 11, and a total of 56 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not

²¹ The discussion below is focused on reviews of available literature. As noted in the medical effectiveness approach document (http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php; see p.8), in the absence of well-designed randomized controlled trials (RCTs) published in the peer-reviewed literature that are "fully applicable to the analysis", CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

address FDA-approved medications for SUD, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature. Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Table 4. FDA-Approved Prescription Medications for OUD, AUD, and TUD and Approved Uses

Medication	SUD(s)	Role in Treatment	Mode of Administration
Naloxone	Opioid Use Disorder	Reverse overdose	Injection, nasal spray
Lofexidine	Opioid Use Disorder	Manage withdrawal symptoms	Tablet
Buprenorphine (including buprenorphine-naloxone)	Opioid Use Disorder	Manage withdrawal symptoms, maintain abstinence from opioids	Tablet, film, injection, implant(a)
Methadone	Opioid Use Disorder	Manage withdrawal symptoms, maintain abstinence from opioids	Tablet, liquid(b)
Naltrexone	Opioid Use Disorder, Alcohol Use Disorder	Maintain abstinence from opioids or alcohol	Tablet, injection(c)
Acamprosate	Alcohol Use Disorder	Maintain abstinence from alcohol	Tablet
Disulfiram	Alcohol Use Disorder	Maintain abstinence from alcohol	Tablet
Nicotine replacement therapy	Tobacco Use Disorder	Maintain abstinence from tobacco use	Inhaler, nasal spray(d)
Bupropion sustained release (SR)	Tobacco Use Disorder	Maintain abstinence from tobacco use	Tablet
Varenicline	Tobacco Use Disorder	Maintain abstinence from tobacco use	Tablet

Source: California Health Benefits Review Program, 2019.

Notes: (a) SB 11 only affects coverage for tablet and film formulations of buprenorphine or buprenorphine/naloxone combination. (b) SB 11 would affect coverage for methadone but would not affect the dispensing of methadone because federal law restricts methadone treatment (for OUD) to federally certified opioid treatment programs (i.e., “methadone clinics”).

(c) SB 11 only affects coverage for the tablet formulation of naltrexone.

(d) Other forms of nicotine replacement therapy (i.e., patch, gum, and lozenge) are available over the counter.

Although SB 11 would only affect coverage for FDA-approved medications for OUD, AUD, and TUD that are typically covered as part of a pharmacy benefit (i.e., medications that are orally or intra-nasally administered), the medical effectiveness review discusses medications for OUD that are typically covered as part of the medical benefits (i.e., implantable and injectable formulations) because providers may consider prescribing these medications as alternatives to medications for which SB 11 would affect coverage. CHBRP also did not review literature on medications that are prescribed for AUD but not approved for this purpose, such as baclofen, gabapentin, topiramate, and valproic acid. In addition, CHBRP did not review studies of bupropion extended release (XL) because that formulation of bupropion is not approved for treatment of TUD. CHBRP also did not review literature on the effectiveness of transdermal and intravenous formulations of buprenorphine because the FDA has only approved these formulations of buprenorphine for the treatment of chronic pain. CHBRP is unaware of prescribed/not-approved drugs that are used to treat OUD or TUD. Finally, CHBRP did not review literature on forms of treatment for OUD, AUD, and TUD other than medication, such as counseling, because SB 11 only addresses coverage for prescription medications for these conditions.

Key Questions

CHBRP's medical effectiveness review addressed the following questions:

1. What is the effectiveness of FDA-approved medications for treatment of OUD, AUD, and TUD compared to no treatment or a placebo?
2. What is the relative effectiveness of FDA-approved medications used treat OUD, AUD, and TUD?
3. What are the harms associated with FDA-approved medications used treat OUD, AUD, and TUD?
4. How does health plans' use of utilization management techniques (such as prior authorization and step therapy) affect use of FDA-approved medications for OUD, AUD, and TUD?

Methodological Considerations

The systematic reviews CHBRP cited included overlapping groups of studies of FDA-approved medications for OUD, AUD, and TUD. Thus, their conclusions of these systematic reviews regarding the effectiveness of these medications are not independent of one another.

The systematic reviews included randomized controlled trials (RCTs) and observational studies. RCTs maximize ability to discern whether any differences observed between intervention and comparison groups are due to the intervention or to other factors. However, in the case of FDA-approved medications for OUD, AUD, and TUD, many of the RCTs follow subjects for less than one year, which limits ability to assess the long-term impact of receiving these medications. Most studies that have assessed long-term health impacts, such as mortality, liver disease, lung disease, human immunodeficiency virus (HIV), and hepatitis C, are observational studies. Findings from observational studies need to be interpreted with more caution because observational studies are less able to control for other differences between intervention and comparison groups that may affect the outcome of interest.

Outcomes Assessed

The outcomes assessed by studies of the impact of approved uses of FDA-approved prescription medications for SUDs vary depending on the disorder treated.

FDA-Approved Prescription Medications for OUD

Studies of FDA-approved medications for OUD have primarily examined outcomes related to opioid use and participation in treatment. Outcomes assessed include use of opioids during treatment, use of opioids at follow up, and retention in treatment. Some studies have examined effects of OUD medications on morbidity or mortality. Studies of effects on morbidity have addressed birth outcomes for pregnant women treated for OUD and effects on the likelihood of contracting HIV and hepatitis C, two contagious diseases for which persons who inject opioids are at elevated risk.

FDA-Approved Prescription Medications for AUD

Studies of FDA-approved medications for AUD have primarily examined outcomes related to alcohol use and participation in treatment. Outcomes assessed include drinking days, number of drinks consumed, and reducing lapse/relapse in drinking.

FDA-Approved Prescription Medications for TUD

Studies of FDA-approved medications for TUD have primarily examined outcomes related to cessation of tobacco use. Outcomes assessed include reduced cigarette cravings during treatment, abstinence during treatment, and abstinence of tobacco at follow up.

Some studies have examined effects of TUD medications on birth outcomes for pregnant women treated for TUD, including rates of miscarriage, stillbirth, preterm birth (less than 37 weeks), low birthweight, admissions of babies to neonatal intensive care, and infant development.

Study Findings

FDA-Approved Prescription Medications for OUD

Naloxone for overdose reversal

The FDA has approved subcutaneous, intramuscular, and intranasal formulations of naloxone for reversal of an opioid overdose. Paramedics and emergency department clinicians have used intramuscular naloxone for many years and recent studies suggest that lay people can also administer the medication effectively. All forms of naloxone have been found to reverse opioid overdoses (Boyer 2012; Chou et al., 2017; Kim et al., 2009). Two studies that compared intramuscular and intranasal formulations of naloxone found that the efficacy of intramuscular naloxone (2 mg) and intranasal naloxone (2 mg/1 mL) are similar (Chou et al., 2017). There were also no differences in adverse events associated with naloxone, which include agitation, nausea, and vomiting. CHBRP did not identify any studies that compare the auto-injector formulation of naloxone to the intranasal and older intramuscular formulations of naloxone.

Lofexidine for management of withdrawal symptoms vs. placebo

In 2018 the FDA approved lofexidine for management of symptoms of opioid withdrawal. Two RCTs have found that lofexidine is more effective than a placebo for alleviating withdrawal symptoms as indicated by scores on instruments that measure opioid withdrawal symptoms (Fishman et al., 2018; Gorodetsky et al., 2017). People with less severe withdrawal symptoms may be more willing to abstain from using illicit opioids and to take other medications that the FDA has approved for maintenance treatment. Both RCTs found that persons who received lofexidine were more likely to complete the study than persons who received a placebo.

CHBRP did not identify any studies that compared lofexidine to other medications that are used to alleviate opioid withdrawal symptoms.

FDA-approved prescription maintenance medications for OUD versus placebo or no medication

Research has demonstrated the effectiveness of FDA-approved medications to maintain abstinence from OUD relative to a placebo or no treatment. Most studies were conducted in adults. There is far less literature on effects in adolescents (Minozzi et al., 2014).

Buprenorphine or buprenorphine-naloxone combination

Mattick et al.'s (2014) Cochrane review of 11 RCTs (sample sizes: 40-736 people) found that persons who were given buprenorphine or buprenorphine-naloxone combination medication for maintenance treatment of OUD were more likely to be retained in treatment than people who received a placebo. The authors found that only high-dose buprenorphine (≥ 16 mg) was more effective than placebo in suppressing use of illegal opioids as measured by urinalysis in the trials (Mattick et al., 2014) (3 studies; 729 people).

Two other systematic reviews also found that persons who received buprenorphine or buprenorphine-naloxone were more likely to be retained in treatment than people who received a placebo (Thomas et al., 2014; Timko et al., 2016). Thomas et al.'s (2014) systematic review included 17 RCTs, a randomized crossover study, a study using a self-administered survey, a retrospective descriptive study, and seven reviews or meta-analyses (sample sizes: 12-4,497 people). Timko et al.'s (2016) review of buprenorphine or buprenorphine-naloxone combination included 14 randomized control trials, four quasi-experimental design studies, and nine cohort studies (sample sizes: 70-1,269 people). Timko et al. (2016) reported that 65.7% of persons who received buprenorphine were retained in treatment at 6 months versus 30.9% of persons who received a placebo.

In a systematic review of three prospective or retrospective cohort studies (sample sizes: 1,373-11,940 people) in people with OUD, Sordo et al. (2017) found buprenorphine treatment is associated with substantial reductions in the risk for all cause and overdose mortality in people dependent on opioids relative to not receiving treatment.

One systematic review examining 16 RCTs (sample sizes: 12-653 people) found that buprenorphine and buprenorphine-naloxone combination maintenance treatments were associated with less risk of adverse events and improved maternal and fetal outcomes in pregnancy compared with not receiving treatment (Thomas et al., 2014).

Most studies of buprenorphine have examined the effectiveness of sublingual tablets or film that users must take on a daily basis. An important limitation of these forms of buprenorphine are that users may forget to take the medication every day, may misuse it, or sell it to others. Implantable extended-release

injectable formulations of buprenorphine have been developed to provide longer-acting forms of buprenorphine treatment that are administered in a provider's office. SB 11 would not affect coverage for these forms of buprenorphine because they are covered under a health plan or health insurance policy's medical benefit and not its outpatient pharmacy benefit, but providers may consider prescribing them instead of sublingual tablets or film. CHBRP identified one RCT (sample size: 177 people) that compared buprenorphine implants to sublingual buprenorphine tablets found that people who received the implants were more likely to abstain from opioids for six months (85.7% vs. 71.9%) (Rosenthal et al., 2016).

Naltrexone

A Cochrane review of 13 RCTs (1,158 total people; sample sizes: 20-280 people) (Minozzi et al., 2011) found that there was no statistically significant difference between treatment with oral naltrexone and treatment with placebo or no pharmacological agent with respect to retention, abstinence, and side effects.

As with buprenorphine, an extended release intramuscular injectable formulation of naltrexone has been developed to provide a longer acting form of the medication that does not depend on a patient taking a medication on a daily basis. SB 11 would not affect coverage for the injectable formulation of naltrexone. Findings from one systematic review (Jarvis et al., 2018) found limited evidence that extended-release naltrexone decreases opioid use relative to a placebo. In contrast to methadone and buprenorphine, which can be administered while a person tapers off illicit use of opioids, people must complete detoxification before receiving any formulation of naltrexone. Many people with OUD do not successfully initiate treatment with naltrexone because they are unable to completely abstain from using opioids.

CHBRP did not identify any studies that compared oral naltrexone to extended-release naltrexone for treatment of OUD.

Methadone

As discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, SB 11 will affect coverage for methadone but will not change the manner in which methadone is dispensed because federal law requires that methadone be administered only by federally certified opioid treatment programs (i.e., "methadone clinics"). For these reasons, SB 11 is likely to have a limited impact on costs associated with methadone treatment. CHBRP decided to include methadone in its medical effectiveness review despite SB 11's limited impact on its use because it has been used to treat OUD for many years and providers and patients may consider it as an alternative to buprenorphine.

Two systematic reviews of overlapping groups of studies have compared methadone maintenance treatment to a placebo or no treatment for OUD (Fullerton et al., 2014; Mattick et al., 2009). Fullerton (2014) included 7 RCTs, 2 quasi-experimental studies (sample sizes: 81-319 people) and 15 reviews or meta-analyses of multiple studies. Mattick et al. (2009) assessed 11 RCTs (sample sizes: 32-382 people). Both systematic reviews concluded that methadone is more effective than a placebo or no treatment for retaining patients in treatment and reducing use of illegal opioids as measured by self-report and urine/hair analysis. Mattick et al. (2009) also found that methadone was statistically significantly more effective in the suppression of heroin use as measured by self-report and urine/hair analysis.

Fullerton et al.'s systematic review (2014) found two systematic reviews and one RCT that addressed the impact of methadone on HIV risk. The authors concluded that receipt of methadone maintenance treatment was associated with lower risk of injecting opioids and engaging in sexual behaviors that elevate a person's risk of contracting HIV. A systematic review of nine studies (with a sample that

included 819 incident HIV infections over 23,608 person years of follow-up) concluded that receipt of methadone maintenance treatment reduces risk of HIV transmission (MacArthur et al., 2012).

The authors of one systematic review of RCTs found no statistically significant difference in mortality between persons receiving methadone maintenance treatment and persons who received a placebo or no treatment (4 studies) (Mattick et al., 2009). In a subsequent systematic review of 18 prospective or retrospective cohort studies (sample sizes: 56-122,885 people) that had longer follow-up periods than the studies included in Mattick et al.'s (2009) systematic review, Sordo et al. (2017) found methadone maintenance treatment is associated with substantial reductions in the risk for all cause and overdose mortality in people dependent on opioids. In patients using methadone maintenance treatment there are, on average, 25 fewer deaths/1000 person years than in patients who do not receive methadone maintenance treatment.

Methadone or buprenorphine

A systematic review of 38 observational studies (sample sizes: 18-726 people) found that receipt of either methadone or buprenorphine was associated with less injection drug use, less sharing of injection equipment, less exchange of sex for drugs, and lower likelihood of having multiple sex partners among people with OUD (Gowing et al., 2011). Two cohort studies found that receipt of methadone or buprenorphine was associated with lower risk of hepatitis C among persons with OUD (Nolan et al., 2014; Tsui et al., 2014).

Summary of findings regarding the effects of FDA-approved prescription medication versus placebo or no medication for treatment of OUD: There is clear and convincing evidence from ten systematic reviews and five RCTs that buprenorphine (including buprenorphine-nalaxone) and methadone are more effective than a placebo or no treatment with regard to retention in treatment for OUD, reduction in use of illicit opioid drugs, relapse, lower likelihood of engaging in behaviors associated with elevated risk for HIV and hepatitis C, better birth outcomes, and lower mortality rates. Findings from RCTs of oral naltrexone indicate that it does not improve retention in treatment and abstinence from opioids relative to a placebo or no treatment.

Figure 1. FDA-approved OUD Medication Versus Placebo or No Medication – Methadone and Buprenorphine

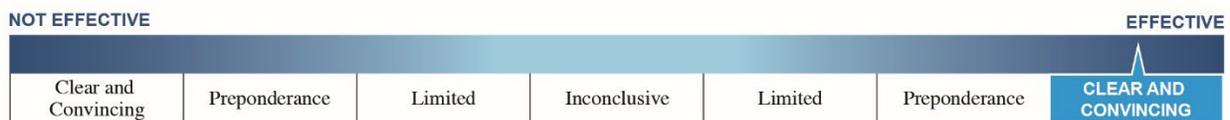
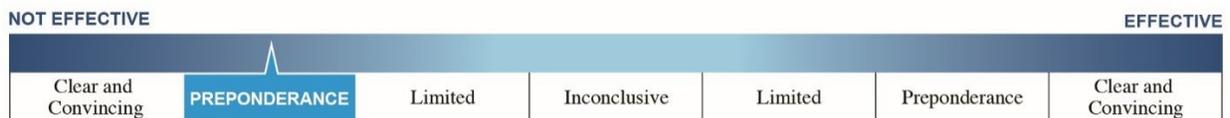


Figure 2. FDA-approved OUD Medication Versus Placebo or No Medication – Oral Naltrexone



Comparison of FDA-Approved Prescription Medications for Maintaining Abstinence from Opioids

Buprenorphine or buprenorphine-naloxone combination vs. Methadone

A large number of studies have compared the effectiveness of methadone to buprenorphine or buprenorphine-naloxone combination for maintenance treatment of OUD. A smaller number of studies have compared naltrexone to buprenorphine or buprenorphine-naloxone combination treatment for maintenance or induction to treatment with extended release naltrexone. Comparative studies of maintenance medications have examined effects on retention in treatment, abstinence from use of opioids, and birth outcomes. CHBRP did not identify any studies that examined the relative effectiveness of maintenance medications used to treat OUD on transmission of hepatitis C or HIV or on engagement in behaviors that increase risk for contracting hepatitis C or HIV. CHBRP also did not identify any studies of the relative impact of maintenance medications used to treat OUD on mortality.

A Cochrane review by Mattick et al. (2014) compared methadone to different formulations of buprenorphine (i.e., sublingual solution, sublingual tablets, combined buprenorphine-naloxone sublingual tablet and an implant). The authors found that compared to methadone, buprenorphine retains fewer people in treatment when doses are flexibly delivered (adjusted to participant need) (5 studies; 788 people; RR=0.83; 95% CI: 0.72 to 0.95) and at low fixed doses (3 studies; 253 subjects; RR=0.67; 95% CI: 0.52 to 0.87). If fixed medium or high doses are used, buprenorphine and methadone are equally effectiveness for retaining people in treatment (7 studies; 780 people; RR=0.87; 95% CI: 0.69 to 1.10) and suppressing illicit opioid use (4 studies; 476 people; SMD 0.25; 95%CI: -0.08 to 0.58).

A systematic review of four studies (three RCTs and one systematic review; sample sizes: 196-1,497 people) concluded that the efficacy of buprenorphine is dose dependent. For comparisons at medium-dose ranges, evidence is mixed. Some studies showed similar effects of methadone and buprenorphine but others suggest that methadone improved treatment retention or reduces illicit opioid use. Only one RCT (sample size: 220 people) reviewed in this study compared high doses of buprenorphine and methadone, and it showed similar outcomes in terms of days in treatment (mean of 96 and 105 days, respectively) or percentage of patients with 12 or more consecutive negative opioid screens (26% versus 28%, respectively) (Thomas et al., 2014).

Timko et al. (2016) identified three RCTs that compared methadone to buprenorphine or buprenorphine-naloxone. The authors found that methadone was associated with better retention in treatment than buprenorphine-naloxone at 4 months (73.9% versus 45.9%) and at 6 months (74.0% versus 46.0%; 57.6%).

An RCT published after the RCTs included in the systematic reviews compared outcomes for persons treated with buprenorphine or buprenorphine-naloxone to persons treated with methadone for an average of 4.5 years following 24 weeks of treatment (Hser et al., 2016). The authors reported that persons treated with buprenorphine or buprenorphine-naloxone were less likely to abstain from using opioids than people treated with methadone (57.2% vs. 68.3%) because they received less ongoing treatment after the 24-week trial ended. The RCT found no statistically significant difference in mortality between people treated with the two medications.

In a systematic review of six RCTs (607 people) that addressed the impact of MAT on people who are addicted to legal opioid prescription drugs (as opposed to heroin and other illegal opioids), Nielsen et al. (2016) found no difference between the effects of methadone and buprenorphine or buprenorphine-naloxone in self-reported opioid use (RR=0.37; 95% CI: 0.08 to 1.63) or opioid positive urine drug tests

(RR=0.81; 95% CI: 0.56 to 1.18), retention in treatment (RR=0.69; 95% CI: 0.39 to 1.22), and adverse events (RR=1.10; 95% CI: 0.64 to 1.91).

Three systematic reviews compared the effectiveness and safety of buprenorphine and methadone for maintenance treatment of pregnant women with OUD. Minozzi et al. (2013) and Thomas et al. (2014) found that when the medication was dosed adequately, methadone and buprenorphine or buprenorphine-naloxone combination treatment showed similar reduction in illicit opioid use among pregnant women but that pregnant women treated with methadone were more likely to remain in treatment. Thomas (2014) also found that rates of neonatal abstinence syndrome were similar for infants born to mothers treated with buprenorphine or methadone but that symptoms were less severe for infants whose mothers were treated with buprenorphine. Zedler (2016) found that buprenorphine and buprenorphine-naloxone were associated with lower risk of preterm birth, greater birth weight, and larger head circumference than methadone and that rates of fetal spontaneous deaths and fetal/congenital abnormalities were similar for the two medications. In a review of 4 RCTs, Minozzi et al. (2013) found three RCTs that compared birth weight. Birth weight was higher in the buprenorphine group in the two trials that could be pooled (mean difference (MD) -365.45 g; 95% CI: -673.84 to -57.07; 2 studies, 150 people). The third double blind RCT reported that there was no statistically significant difference between buprenorphine and methadone groups (sample size: 18). The reported APGAR score (2 studies, 163 people) and number of newborns treated for neonatal abstinence syndrome (3 studies, 166 subjects) did not differ significantly between groups. One RCT (sample size: 131 subjects) comparing methadone with buprenorphine reported side effects. For the mother there was no statistically significant difference; for the newborns in the buprenorphine group there were significantly fewer serious side effects (RR=4.77; 95% CI: 0.59 to 38.49).

Buprenorphine-naloxone combination vs. extended-release naltrexone

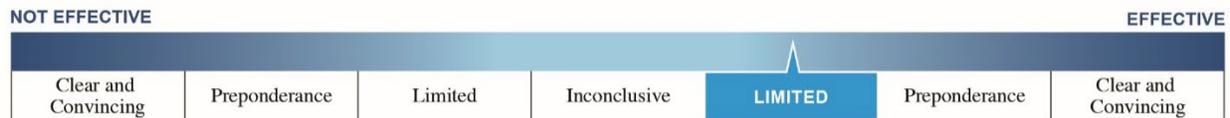
Two RCTs have compared the effectiveness of extended-release naltrexone and buprenorphine-naloxone. Although SB 11 would not affect coverage for extended-release naltrexone, the FDA has approved it for treatment of OUD and providers may present it to patients as an alternative to methadone or to orally administered buprenorphine. One RCT assessed outcomes after 12 weeks of treatment (Tanum et al., 2017) and found no statistically significant difference in the length of time people remained in treatment or their abstinence from use of illicit opioids (as measured by negative urine tests). Persons who received extended-release naltrexone reported less craving for heroin but were more likely to report symptoms of withdrawal. A second RCT examined outcomes after 24 weeks of treatment (Lee et al., 2018). The authors found that participants were less likely to successfully initiate treatment with extended-release naltrexone than with buprenorphine-naloxone which led extended-release naltrexone patients to have a higher relapse rate than patients who received buprenorphine-naloxone. This finding is consistent with findings of studies that have compared extended-release naltrexone to a placebo (Jarvis et al., 2018). Among patients who successfully initiated treatment, there were no statistically significant differences in relapse rates or in abstinence from use of opioids as (measured by negative urine tests and self-report) (Lee et al., 2018).

Summary of findings regarding the comparative effectiveness of different medications used to treat OUD: There is inconclusive evidence from seven systematic reviews and four RCT published after the systematic reviews about the impact of methadone relative to buprenorphine or buprenorphine-naloxone on retention in treatment and abstinence from opioids. There is limited evidence that buprenorphine and buprenorphine-naloxone are associated with better birth outcomes than methadone but women receiving buprenorphine or buprenorphine-naloxone were less likely to remain in treatment than women who receive methadone. One of two RCTs that compare extended-release injectable naltrexone to orally administered buprenorphine-naloxone found that people have more difficulty initiating treatment with extended-release naltrexone and were more likely to relapse.

Figure 3. Comparative Effectiveness of Different FDA-approved Medications Used to Treat Opioid Use Disorder – Methadone vs. Buprenorphine



Figure 4. Comparative Effectiveness of Different FDA-approved Medications Used to Treat Opioid Use Disorder – Buprenorphine vs. Extended-Release Naltrexone (Favors Buprenorphine)



Harms Associated with Use of FDA-Approved Prescription Medications for OUD

Patients who take methadone or buprenorphine to treat OUD may experience side effects that are similar to those of opioids, such as nausea, vomiting, constipation, muscle aches, cramps, constipation, fever, cravings, irritability, and inability to sleep (SAMHSA, 2018). People using methadone may also experience difficulty breathing, lightheadedness, hives, rash, chest pain, rapid heart rate, and hallucinations (SAMHSA, 2018). They also have an increased risk of overdose during the first few weeks of treatment (Sordo et al., 2017).

There is also a risk that people will misuse methadone or buprenorphine due to their opioid effects (SAMHSA, 2018). This risk is higher with buprenorphine than methadone because people are often prescribed a supply of buprenorphine to take on their own, whereas people receiving methadone are usually required to take their medication at a methadone clinic. There is less risk of misuse of extended-release injectable formulations of buprenorphine and naltrexone, coverage for which would not be affected by SB 11, because they are administered in physicians' offices.

Initiation of treatment with extended-release injectable naltrexone carries added risk of harm. Unlike methadone and buprenorphine, which can be used safely while a patient continues to use opioids, patients must withdraw from all opioids before beginning treatment with any formulation of naltrexone. Some patients are unable to do this and may overdose on opioids during the withdrawal period. Lee et al. (2018) found a higher risk of overdose during initiation of treatment among persons slated to receive extended-release injectable naltrexone than among people receiving orally administered buprenorphine.

In addition, patients treated with any FDA-approved medication for OUD who discontinue treatment and resume use of opioids may be sensitive to lower doses of opioids, which could increase their risk of overdose (SAMHSA, 2015). Because relapse is common among people who receive all forms of treatment for OUD, risk of overdose when a person resumes consumption of opioids should be considered when treatment decisions are made (Saucier et al. 2018).

SAMHSA has concluded that the benefits of these medications with regard to mortality, HIV transmission, hepatitis C infection, and birth outcomes outweigh the harms associated with them (SAMHSA, 2015).

Summary of findings regarding harms associated with FDA-approved prescription medications for OUD: People treated with methadone and buprenorphine may experience side effects similar to those of opioids. People who receive methadone have a greater risk of overdose during the first few weeks of treatment. extended-release injectable naltrexone is associated with a higher risk of relapse during induction to treatment because people must abstain from opioids before initiating treatment. Persons treated for OUD with any FDA-approved medications may be sensitive to lower doses of opioids if they relapse following treatment, which could increase their risk of overdose. SAMHSA has concluded that the benefits of these medications outweigh the harms.

Effects of Utilization Management on Use of FDA-Approved Prescription Medications for OUD and Outcomes

CHBRP found two studies that addressed the impact of utilization management on use of medications to treat OUD or patient outcomes. Clark et al. (2014) examined the effects of a change in the Massachusetts Medicaid program's prior authorization requirements for coverage of buprenorphine-naloxone (n=2,049 people). Under the policy, prior authorization was required for doses greater than 16 mg per day. After the prior authorization policy was implemented the number of people prescribed doses of buprenorphine-naloxone greater than 24 mg per day decreased while the number prescribed lower doses per day increased. The relapse rate increased temporarily and the increase was most pronounced among people who received doses greater than 16 mg/day. The relapse rate returned to previous levels within 3 months. The authors did not report any other outcomes. A major limitation of this study is that it assessed the effects of instituting a prior authorization requirement. It does not address the impact of prohibiting prior authorization. This study also does not provide any information about the effects of other utilization management techniques.

Accurso et al. (2018) conducted a retrospective study (n=297 people) on the effect of a change in insurer policy, in which the insurer of a subset of patients in an office-based practice imposed a prior authorization requirement for sublingual buprenorphine dose of 16mg/day, which led physicians in the practice to increase the daily dose for patients on higher daily doses. These patients were compared to other patients in the practice whose insurers did not require prior authorization for higher doses of buprenorphine. The rate of positive urine drug tests among patients who experienced a dose decrease rose from 27.5% to 34.2% (p=0.043). Persons in comparison groups who did not experience a change in buprenorphine dose showed no significant change in positive drug test rates. Moreover, all persons who were prescribed buprenorphine doses greater than 16 mg/day displayed lower rates of positive urine drug tests than groups prescribed lower doses. Retention in treatment was also highest among those prescribed greater than 16 mg/day (Accurso et al., 2018).

Summary of findings regarding the effects of utilization management for FDA-approved medications for OUD: There is *insufficient* evidence to assess the impact of utilization management on use of FDA-approved medications to treat OUD and patient outcomes. Buprenorphine is the only medication that has been assessed and studies have only examined the effects of prior authorization for high doses.

Figure 5. Impact of Utilization Management on Use of FDA-approved Prescription Medications for OUD

NOT EFFECTIVE		INSUFFICIENT EVIDENCE				EFFECTIVE	
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing	

FDA-Approved Prescription Medications for AUD

FDA-approved prescription medications for AUD versus placebo or no medication

Acamprosate

A systematic review (122 RCTs, 1 cohort study; 22,803 people) comparing acamprosate to placebo found that significantly fewer subjects treated with acamprosate returned to any drinking (19 trials) and had significantly fewer drinking days (13 trials) than those treated with placebo. There was no significant difference for return to heavy drinking (7 trials), drinking days (1 trial), or drinks per drinking day (1 trial) between acamprosate and placebo (Jonas et al., 2014).

A meta-analysis (Donoghue et al., 2015) (22 RCTs; 5,236 people) of the efficacy of acamprosate found the risk of returning to any drinking at 6 months was significantly lower for people receiving acamprosate than for people receiving a placebo. There was little difference in the risk of participants discontinuing treatment for any reason.

Naltrexone

A systematic review (122 RCTs, 1 cohort study; 22,803 people) comparing naltrexone to placebo found significantly fewer subjects treated with naltrexone returned to any drinking (21 trials), returned to heavy drinking (23 trials), had significantly fewer drinking days than those treated with placebo (19 trials), had fewer heavy drinking days than those treated with placebo (11 trials), and had fewer drinks per drinking day than those treated with placebo (11 trials) (Jonas et al., 2014). Forty of the 44 studies of naltrexone included in this systematic review assessed the effectiveness of the orally administered for which SB 11 would affect coverage.

One meta-analysis (Donoghue et al., 2015) (27 RCTs; 4,199 people) that examined the efficacy of orally administered naltrexone found the risk of individuals returning to any drinking at approximately 3 months was reduced significantly for the naltrexone group, as was the risk of individuals relapsing to heavy drinking at 3 months. There was no statistically significant difference in the risk of discontinuing treatment for any reason.

A systematic review (4 studies; 798 people; 273 diagnosed with a psychotic disorder) (Sawicka and Tracy; 2017) of orally administered naltrexone in individuals with both psychosis and AUD, found most studies, including those that were more robust methodologically, concluded that people who received naltrexone had fewer drinking days and fewer heavy drinking days than people who received a placebo.

Disulfiram

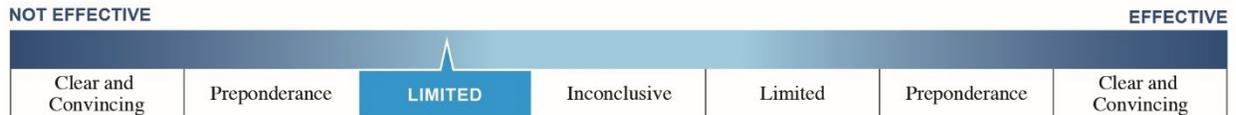
A systematic review (122 RCTs, 1 cohort study; 22,803 people) with 3 RCTs (729 people) comparing disulfiram to placebo found there was no significant difference in return to any drinking and no statistically significant difference in percentage of drinking days between disulfiram and placebo (Jonas et al., 2014).

Summary of findings regarding the effects of FDA-approved prescription medications versus placebo or no medication for treatment of AUD: There is clear and convincing evidence from three systematic reviews that acamprosate and naltrexone are more effective than a placebo or no treatment with regard to return to drinking, return to heavy drinking, percentage of drinking days, and percentage of heavy drinking days. There is limited evidence that disulfiram does not reduce the risk that a person will return to drinking or have a lower percentage of drinking days.

Figure 6. FDA-approved AUD Medication Versus Placebo or No Medication – Acamprosate and Naltrexone



Figure 7. FDA-approved AUD Medication Versus Placebo or No Medication – Disulfiram



Comparison of FDA-approved prescription medications for maintaining abstinence from alcohol

Acamprosate vs. naltrexone

A systematic review (122 RCTs, 1 cohort study; 22,803 people) found that both acamprosate and oral naltrexone were both associated with reduction in return to drinking but found no statistically significant difference between the two medications for return to any drinking (3 studies; 800 participants), return to heavy drinking (4 studies; 1141 people), and percentage of drinking days (2 studies; 720 people) (Jonas et al., 2014).

Naltrexone vs. disulfiram

A systematic review (Jonas et al., 2014) (122 RCTs, 1 cohort study; 22,803 people) included 1 RCT (254 participants) that directly compared naltrexone to disulfiram. The trial reported no statistically significant difference between disulfiram and naltrexone for number of subjects achieving total abstinence, the percentage of days abstinent, or the percentage of heavy drinking days.

A systematic review (4 studies; 561 people; 128 diagnosed with a psychotic disorder) (Sawicka and Tracy, 2017) synthesized findings from two studies that compared orally administered naltrexone to disulfiram for treatment of AUD and two studies that compared a combination of naltrexone and disulfiram to either naltrexone or disulfiram alone. None of the four studies found a statistically significant difference in the number of drinking days and the number of heavy drinking days.

Summary of findings regarding the relative effectiveness of different medications used to treat AUD: There is inconclusive evidence from three systematic reviews about the relative effectiveness of acamprosate, naltrexone, and disulfiram for treatment of AUD. Findings from two studies suggest that acamprosate and naltrexone are equally effective. Studies that compared naltrexone and disulfiram did not find any differences in effects on abstinence from alcohol or heavy drinking days. No studies were identified that compared acamprosate to disulfiram.

Figure 8. Comparative Effectiveness of Different FDA-approved Medications Used to Treat Alcohol Use Disorder



Harms associated with use of FDA-approved prescription medications for AUD

Acamprosate

A systematic review (Jonas et al., 2014) (122 RCTs, 1 cohort study; 22,803 people) of 10 RCTs (sample sizes: 100 to 612 people) examining acamprosate found, compared with placebo, patients treated with acamprosate had a statistically significant higher risk of anxiety, diarrhea, and vomiting. No clinically significant differences were found for quality of life for acamprosate compared with placebo.

Naltrexone

Jonas et al. (2014) reported results from 10 trials (31 to 618 people) on health outcomes for naltrexone compared to placebo. Those treated with naltrexone had a statistically significant higher risk of dizziness, nausea, vomiting, aftertaste, blurred vision, confusion, constipation, drowsiness, dry mouth, loss of appetite, and tremors relative to persons who received a placebo. Six RCTs of naltrexone reported mortality rates; no study found more than one death in each treatment group.

One systematic review (Donoghue et al., 2015) (27 RCTs; 4,199 people) found there was a significantly greater risk of participants in the naltrexone group discontinuing treatment due to adverse events compared to placebo.

Disulfiram

Jonas et al. (2014) reported results from one study (254 people) comparing disulfiram combined with naltrexone, disulfiram combined with placebo, naltrexone alone, and placebo alone showed that patients who received disulfiram had side effects including aftertaste, blurred vision, confusion, constipation, drowsiness, dry mouth, loss of appetite, nausea, and tremors more often than patients in the placebo group. There were no statistically significant between-group differences for other adverse events.

Summary of findings regarding harms associated with FDA-approved prescription medications for

AUD: Use of FDA-approved prescription medications for AUD is associated with mild to moderate side effects, including aftertaste, anxiety, blurred vision, confusion, constipation, diarrhea, dizziness, drowsiness, dry mouth, loss of appetite, nausea, tremors, and vomiting.

Effects of utilization management on use of FDA-approved prescription medications for AUD and outcomes

No studies were identified that assessed the impact of utilization management on use of FDA-approved prescription medications for AUD or treatment outcomes.

FDA-Approved Prescription Medications for TUD

FDA-approved prescription medications for TUD versus placebo or no medication

Nicotine replacement therapy

Two systematic reviews (Hartmann-Boyce et al., 2018; Patnode et al., 2015 ;) found that nicotine replacement therapy is associated with greater likelihood of smoking cessation than placebo or psychotherapy alone. These systematic reviews included RCTs of nicotine inhalers and nicotine nasal spray, the two forms of nicotine replacement therapy for which a prescription is required, as well nicotine patches, gum, and lozenges, which are available without a prescription.

A systematic review (Hartmann-Boyce et al., 2018) (136 studies) comparing any type of nicotine replacement therapy) and a placebo or non-nicotine replacement therapy control group concluded that there is high-quality evidence that nicotine replacement therapy increases quit rates at six months or longer in adults. The systematic review (131 trials, 133 comparisons; 64,600 people) found that each of the six forms of nicotine replacement therapy studied (gum, patch, inhalator, tablets/lozenges, intranasal spray, oral spray) significantly increased the rate of cessation compared to placebo or no nicotine replacement therapy. Pooled estimates from four RCTs of nicotine inhalers indicate that people who were treated with nicotine inhalers were 1.9 times as likely to abstain from smoking as people who received a placebo. Pooled estimates from four RCTs of nicotine nasal spray indicate that people treated with nicotine nasal spray were twice as likely to abstain from smoking as people who received a placebo.

A systematic review of reviews (54 systematic reviews) (Patnode et al., 2015) comparing any type of nicotine replacement therapy with placebo or no nicotine replacement therapy (9 reviews; 51,265 people) included Four of the RCTs included in these systematic reviews examined nicotine inhalers and four examined nicotine nasal spray. The authors concluded that all forms of nicotine replacement therapy, including inhalers and nasal spray, significantly increased the rate of smoking cessation compared with placebo or no nicotine replacement therapy. Participants who received some type of nicotine replacement therapy were 1.6 times more likely to achieve abstinence at 6 months or longer compared with participants in a control group. Seventeen percent of persons who received any form of nicotine replacement therapy abstained from smoking for six months or more versus 10% of people who received a placebo or no nicotine replacement treatment.

Six of the RCTs included in these systematic reviews included in Patnode et al. (2015) review of reviews directly compared different types of nicotine replacement therapy (e.g., patch versus nasal spray). None of these RCTs found statistically significant differences in rates of abstinence from smoking, which

suggests that the benefits of forms of nicotine replacement therapy for which a prescription is required are similar to those of forms of nicotine replacement therapy that are available without a prescription. Nine trials (n=4,664) that compared people who received two types of nicotine replacement therapy to people who received a single type of nicotine replacement therapy were 1.4 times more likely to abstain from smoking.

Bupropion SR

In a systematic review of reviews (54 systematic reviews) (Patnode et al., 2015) (3 reviews; 13,728 people) found a statistically significant benefit to taking bupropion SR versus taking a placebo or no pharmacotherapy on smoking abstinence at 6 months.

A meta-analysis (6 trials; sample size: 5-61) comparing bupropion SR to placebo in people with tobacco use disorder who also have a serious mental illness, found bupropion SR more effective (defined as self-reported sustained smoking cessation, verified biochemically at the longest reported time-point) than placebo (Roberts et al., 2016).

One small RCT of 65 pregnant women (Nanovskaya et al., 2017) found individual smoking cessation counseling along with bupropion SR sustained release increased smoking cessation rates and reduced cravings and total nicotine withdrawal symptoms during the treatment period. However, there was no significant difference in abstinence rates between groups at the end of bupropion treatment and at the end of pregnancy, perhaps because of the small sample size.

Varenicline

A systematic review (Cahill et al., 2016) found high-quality evidence that participants who received varenicline at standard dose (1.0 mg twice a day) had between a two-and a three-fold chance of successful long-term smoking cessation compared to participants who received a placebo (27 trials, 12,625 people). Varenicline at lower or variable doses was also shown to be effective (4 trials, 1,266 people) and lower dose regimens reduced the incidence of adverse events (4 trials).

These findings were consistent with those of a previous systematic review of reviews (Patnode et al., 2015). The authors conducted a meta-analysis and concluded that participants who received varenicline were twice as likely to abstain from smoking six months or more after treatment ended than participants who received a placebo (14 trials, 6,166 people).

A systematic review (3 RCTs; 744 people) on the effectiveness of varenicline in smokeless tobacco cessation found significantly higher 7-day point prevalence of smokeless tobacco abstinence at 12 weeks (48% vs. 33%) but not at 26 weeks (49% vs. 39%) among participants who received varenicline than among participants who received a placebo (Schwartz et al., 2016).

One small RCT (60 participants) of clinically stable adult patients with bipolar disorder found significantly more subjects quit smoking with varenicline than with placebo (48.4% v 10.3%) at 3-months. At the end of non-treatment follow up at 6-months, a higher percentage of varenicline-treated subjects remained abstinent compared to placebo (19.4% v 6.9%), while psychopathology scores remained stable (Chengappa et al., 2015).

One small RCT (33 participants) found varenicline to be effective for increasing smoking abstinence rates in smokers with alcohol abuse or dependence. This study showed varenicline may also decrease alcohol consumption in this population of smokers (Hurt et al., 2018).

Three meta-analyses found varenicline appears to be significantly more effective than placebo in assisting with smoking cessation and reduction in people with severe mental illness (Ahmed et al., 2018; Roberts et al., 2016; Wu et al., 2016). A meta-analysis (8 studies; 398 people) comparing varenicline to placebo in people found that persons with severe mental illness who received varenicline were more likely to abstain from smoking and smoked fewer cigarettes per day than persons with severe mental illness who received a placebo (mean reduced daily cigarettes was 6.39) (Wu et al., 2016). Another meta-analysis (5 RCTs; sample size: 5-128) comparing varenicline to placebo in people with TUD who also have a mental illness, found varenicline more effective (defined as self-reported sustained smoking cessation, verified biochemically at the longest reported time-point) than placebo (Roberts et al., 2016).

A meta-analysis (4 RCTs; 239 people) of patients with schizophrenia, found varenicline treatment significantly reduced the number of cigarettes consumed per day and expired carbon monoxide levels relative to placebo (Ahmed et al., 2018). One systematic review found varenicline is not superior to placebo for smoking cessation in people with schizophrenia (Kishi et al., 2015). Moreover, there was no significant difference in the discontinuation rate due to all causes, clinical deterioration, or side effects between varenicline and placebo (Kishi et al., 2015). The difference between Kishi et al (2015) conclusion and those of the other three meta-analyses reflect differences in the RCTs included in the meta-analysis. Kishi et al. only included RCTs that enrolled persons with schizophrenia whereas Wu et al (2016) and Roberts et al (2016) also included RCTs that enrolled people with bipolar disorder. Kishi et al (2015) also did not include an RCT that Ahmed et al (2018) included in their meta-analysis because the RCT had not been published at the time Kishi et al. completed their analysis.

Summary of findings regarding the effects of FDA-approved prescription medications versus placebo or no medication for treatment of TUD: There is clear and convincing evidence from one systematic review of reviews, nine systematic reviews, and three RCTs that people who use nicotine replacement therapy, bupropion SR, or varenicline have higher rates of smoking cessation than people who receive a placebo or no **medication** for smoking cessation.

Figure 9. FDA-approved TUD Medication Versus Placebo or No Medication



Comparison of FDA-approved prescription medications for maintaining abstinence from tobacco

Nicotine replacement therapy vs. bupropion SR

A systematic review of reviews (Patnode et al., 2015) identified two systematic reviews of studies that compared nicotine replacement therapy to bupropion SR. Neither review found a statistically significant difference in the rates of smoking cessation six months or more after treatment ended, suggesting that the effectiveness of nicotine replacement therapy and bupropion SR do not differ (8 RCTs; 4,086 people).

Nicotine replacement therapy vs. varenicline

There is evidence that varenicline is more effective than nicotine replacement therapy (Baker et al., 2016; Cahill et al., 2016; Chang et al., 2016; Rohsenow et al., 2017).

A systematic review (Cahill et al., 2016) found moderate evidence of that varenicline is more effective than nicotine replacement therapy as measured by point prevalence abstinence at 24 weeks (8 RCTs; 6,264 people). Participants who received varenicline were 1.25 times (95% CI: 1.14-1.37) more likely to abstain from smoking at 24 weeks than participants who received nicotine replacement therapy.

Three studies not included in the systematic reviews found varenicline more effective than nicotine patch for tobacco cessation (Chang et al., 2016; Gray et al., 2015; Rohsenow et al., 2017). One comparative effectiveness study (Chang et al., 2016) (11,968 participants), found varenicline was associated with greater odds of abstinence compared with nicotine replacement patch, at 1 week, 1 month and 6 months after initiation of treatment. Varenicline was also associated with higher odds of abstinence in 6 months, in both smokers with severe dependence on tobacco and smokers with light/moderate dependence. A 4-week RCT (140 females) showed that relative to the nicotine patch varenicline, more than doubled the odds of abstinence upon completion of treatment, although this difference diminished at post-treatment follow-up and was no longer statistically significant (Baker et al., 2015). Another RCT (Rohsenow et al., 2017; 137 people) found varenicline improved the odds of achieving at least 3 months of smoking abstinence in smokers with substance use disorders who were trying to stop, compared with transdermal nicotine patches and that the effect was independent of whether a person had a history of major depressive disorder.

Two studies found no difference in smoking abstinence or quit rates between nicotine replacement therapy and varenicline. One RCT (1,086 people) found that treatment, including 12 weeks of open label treatment with nicotine patch, varenicline, or combination nicotine replacement therapy (nicotine patch + nicotine lozenges) produced no significant differences in biochemically confirmed rates of smoking abstinence at 26 or 52 weeks (Baker et al., 2016). One RCT (737 people, including those with medical and psychiatric comorbidities) found that participants who received varenicline were more likely to be continuously abstinent from smoking at 22 weeks after initiation of treatment than participants who received nicotine replacement monotherapy or combination nicotine replacement therapy but that the difference was no longer statistically significant at 52 weeks following initiation of treatment (Tulloch et al., 2016).

Bupropion SR vs. varenicline

A systematic review (Cahill et al., 2016) found high-quality evidence (5 RCTs; 5877 people) that varenicline is superior to bupropion for sustained abstinence at six months post treatment.

Another systematic review (Roberts et al., 2016) found both varenicline and bupropion had superior treatment efficacy to placebo and were not different from each other. In the review, one trial found when comparing varenicline with bupropion, in terms of treatment efficacy, there was no significant advantage for one treatment over the other.

Nicotine replacement therapy vs. nicotine replacement therapy plus bupropion SR

Thurgood et al.'s (2016) systematic review of RCTs of smoking cessation treatment for persons who have both TUD and another SUD, identified two RCTs (253 participants) that compared receipt of nicotine replacement therapy alone to receipt of nicotine replacement therapy plus bupropion SR. The RCTs found no statistically significant difference in point prevalence and continuous abstinence from smoking between the two groups.

Varenicline vs. nicotine replacement therapy plus varenicline

One meta-analysis (3 RCTs; 904 participants) examined both early outcomes (rate of abstinence from tobacco assessed before or at the end of treatment) and late outcomes (assessed after the end of the treatment). The authors identified one RCT that found that nicotine replacement therapy plus varenicline is more effective than varenicline alone, if nicotine patch treatment is administered prior to a participant’s target date for tobacco cessation (Chang et al., 2015). Two RCTs in which nicotine patch treatment was not administered prior to a participant’s target quit date found no statistically significant difference in abstinence rates before, at, or after the end of treatment.

Varenicline vs. bupropion SR plus varenicline

One systematic review (Vogeler et al., 2016) of three prospective clinical trials and one retrospective outcome research study (N=1,193 people) found combination bupropion SR and varenicline displayed greater efficacy in smoking cessation than varenicline monotherapy as measured by 4-week smoking abstinence and prolonged abstinence (continuous abstinence from week 2 to weeks 12 and 26 of the study). One retrospective study included in the systematic review found that combination bupropion SR and varenicline was associated with a higher rate of continuous abstinence at 52 weeks than varenicline monotherapy (55% vs. 32%) but this finding was not replicated in the prospective trials.

Summary of findings regarding the comparative effectiveness of different medications used to treat TUD: The preponderance of evidence from studies that have compared nicotine replacement therapy to varenicline suggests that varenicline is more effective than nicotine replacement therapy. RCTs that have compared nicotine replacement therapy to bupropion SR have found no statistically significant differences in tobacco cessation outcomes. There is limited evidence that combining varenicline with bupropion SR may improve abstinence from smoking relative to varenicline alone.

Figure 10. Comparative Effectiveness of Varenicline and Nicotine Replacement Therapy for TUD

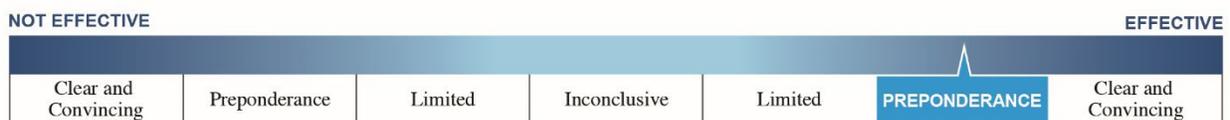


Figure 11. Comparative Effectiveness of Nicotine Replacement Therapy and Bupropion SR for TUD



Harms associated with use of FDA-approved prescription medications for TUD

Nicotine replacement therapy

One Cochrane review (Hartmann-Boyce et al., 2018) found adverse events from using NRT were related to the type of product, and include skin irritation from patches and irritation to the inside of the mouth from gum and lozenges. Persons who received nicotine replacement therapy had higher odds of chest pains or

palpitations relative to control. However, the authors found that chest pains and palpitations were rare in both groups and serious adverse events were extremely rare.

One systematic review (Coleman et al., 2015) (8 studies; 2,199 participants) found no statistically significant differences in birth outcomes, including rates of miscarriage, stillbirth, preterm birth (less than 37 weeks), low birthweight, mean birthweight, admissions of babies to neonatal intensive care or neonatal deaths. One RCT (1,050 participants) of women whose infants were followed to two years of age, found those born to women who had been randomized to NRT were more likely to have healthy development. (Coleman et al., 2015).

In a systematic review of possible serious adverse health effects of nicotine replacement therapy, Lee and Farris (2017) evaluated 34 epidemiological studies and clinical trials regarding the effect of exposure to nicotine replacement therapy on risk of cancer, reproductive/developmental effects, cardiovascular disease, stroke and/or other SAHEs. The authors found many limitations in the evidence, most significantly short-term exposure (≤ 12 weeks) and follow-up to NRT product use in most of the studies, failure to control for changes in smoking behavior following NRT use, and limited information on SAHEs by type of NRT product used. The only SAHE associated with NRT exposure was an increase in respiratory congenital abnormalities reported in one study. Limited evidence indicated a *lack* of effect between NRT exposure and SAHEs for CVD and various reproduction/developmental endpoints. For cancer, stroke and other SAHEs, the evidence was insufficient.

Bupropion SR

In a systematic review of reviews (54 systematic reviews) (Patnode et al., 2015), 2 reviews examined the harms associated with bupropion SR. One review (Mills et al., 2014; n=10,402) suggested no significant increased risk of any cardiovascular event for bupropion SR versus placebo. Another study (Hughes et al., 2014; n=9,631) found no statistically significant increase risk in the rate of serious adverse events, serious psychiatric events, or serious cardiovascular events among participants who received bupropion sustained SR versus placebo. There were 10 cases of seizures within seven trials that comprised between 100 and 502 individuals receiving bupropion SR (over 13,000 total participants).

Varenicline

A Cochrane review (Cahill et al., 2016) found high-quality evidence that the main adverse effect of varenicline was nausea (32 studies; 14,963 participants), which was generally mild to moderate and diminished over time. The authors also found that people who used varenicline were not at greater risk of neuropsychiatric adverse events, such as depressed mood, agitation, suicidal ideation, and suicidal behavior than persons who did not use varenicline.

One meta-analysis comparing nicotine replacement therapy plus varenicline to varenicline alone (3 RCTs; 904 participants) found the most common adverse events were nausea, insomnia, abnormal dreams, and headache but there were no significant differences in odds of these adverse events between nicotine replacement therapy plus varenicline and varenicline alone (Chang et al., 2015).

Another meta-analysis (Schwartz et al., 2016) comparing varenicline to placebo for smokeless tobacco cessation found no statistically significant differences in adverse events reported, including nausea, sleep disturbance, and mood disorders but interpretation is limited by high heterogeneity across studies included in the meta-analysis.

One systematic review of RCTs found there was no statistically significant difference in risk of neuropsychiatric adverse events, including risk of suicide or attempted suicide, suicidal ideation,

depression, irritability, aggression, or death, between participants who received varenicline and participants who received a placebo (39 RTCs; 10,761 participants). Varenicline was associated with an increased risk of sleep disorders, insomnia, abnormal dreams, and fatigue but a reduced risk of anxiety (Thomas et al., 2015).

Summary of findings regarding harms associated with FDA-approved prescription medications for TUD: Use of FDA-approved prescription medications for TUD is not associated with increased risk of serious adverse events, including poor birth outcomes, cancer, cardiovascular disease, stroke, and neuropsychiatric events. Varenicline is associated with mild to moderate side effects, including abnormal dreams, fatigue, headache, insomnia, nausea, and sleep disorders.

Effects of utilization management on use of FDA-approved prescription medications for TUD and outcomes

Findings from one retrospective cohort analysis study (N=15,597) found that prior authorization and step-therapy requirements for varenicline reduced the likelihood that people would fill a prescription for any pharmacotherapy for TUD. Among persons enrolled in health plans included in the study, 63.9% of persons who had a claim for varenicline rejected due to a requirement for prior authorization filled a prescription for any pharmacotherapy for TUD. Among those who faced a step therapy requirement, 46% filled a prescription for any pharmacotherapy for TUD. This study also found that people who had higher out-of-pocket costs for pharmacotherapy for TUD had lower odds of filling a prescription. There was a statistically significant reduction in the odds of filling a prescription for all levels of out-of-pocket costs above \$0 to \$5 (Zeng et al., 2011).

One retrospective cohort study (15,452 participants) found that among Medicare beneficiaries newly initiated on varenicline, greater out of pocket cost was associated with lower adherence, as measured by the proportion of days for which a person had medication available, and lower odds of refilling a prescription for varenicline (Suehs et al., 2014).

Summary of findings regarding the effects of utilization management for FDA-approved medications for TUD: There is *limited* evidence that higher cost sharing is associated with lower rates of adherence to varenicline. This finding suggests that requiring health plans to place varenicline in the lowest tier on its formulary, which SB 11 would require, may improve adherence to varenicline. CHBRP did not identify any studies of effects of utilization management or cost sharing on use of nicotine replacement therapy or bupropion SR.

Figure 12. Impact of Utilization Management on Use of FDA-approve Prescription Medications for TUD



BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 11 would require DMHC-regulated health plans, including non-County Organized Health Systems (COHS) Medi-Cal managed care plans, and CDI-regulated policies that include a pharmacy benefit to (1) cover outpatient prescription medications approved by the FDA for treatment of substance use disorders (SUD), (2) move those medications to tier 1 (i.e., the lowest tier) of the formulary, (3) not require step therapy (or “fail first” protocols) or prior authorization for the medications, and (4) not deny coverage due to related court orders for treatment.

Approximately 95.6% of enrollees in all (commercial and Medi-Cal managed care) DMHC-regulated plans and CDI-regulated policies have pharmacy benefit coverage and would be subject to SB 11. Of the remaining enrollees, 1.4% have no pharmacy benefit and 3.0% have pharmacy benefit coverage that is not regulated by DMHC or CDI. SB 11 does not address these forms of health insurance and so no mandate-related change in benefit coverage or utilization would be expected for these enrollees. CHBRP treats commercial DMHC- and CDI-regulated plans that have no pharmacy benefit, which represent 7% of enrollees in commercial DMHC or CDI-regulated plans, as compliant with SB 11 because they do not have to make any changes in response to SB 11. The remaining 93% of commercial enrollees in plans with a pharmacy benefit are partially compliant because they already comply with at least one component of SB 11, but not all. See Appendix D for a further discussion of pharmacy benefit coverage.

This section reports the potential incremental impacts of SB 11 on estimated baseline benefit coverage, utilization, and overall cost. The benefit coverage, utilization and cost impacts discussed here are based upon published evidence (see the *Medical Effectiveness* section and several key assumptions in addition to those described in the *Policy Context* section about the scope of SB 11.

The estimates are based upon the following core assumptions informed by existing claims data on practice patterns, use of SUD treatments. The *Medical Effectiveness* section, and consultation with a context expert:

- CHBRP anticipates that enrollees who gain coverage for opioid use disorder (OUD) drugs due to SB 11 (i.e., new users) would experience care commensurate with the typical pattern of care seen in patients already getting OUD treatment through their insurance plans in terms of dosing, frequency of refills, and patient needs. The impact of changes to prior authorization, step therapy, and cost sharing are in addition to this coverage-related increase and discussed below.
- There will be no additional use of methadone or injectable buprenorphine for treatment of OUD because SB 11 does not address prescription medications that are administered by clinicians and reimbursed through the medical benefit.
- Use of prescriptions for FDA-approved drug treatment for OUD, except in the case of oral naltrexone (due to preponderance of evidence that it is not effective, see *Medical Effectiveness* section), will increase by 10% for both new and existing commercial enrollees due to the removal of prior authorization and step therapy (i.e., fail first) requirements resulting in an overall increase in use of OUD treatment services including behavioral therapy and medication when associated with use of those medications.
- The proportion of Medi-Cal managed care OUD enrollees receiving most FDA-approved drug treatment for their OUD will not increase because of existing coverage with limited treatment authorization request requirements for each drug. The one exception is the auto-injector version of naloxone, which is expected to increase in use due to the removal of current barriers to use. CHBRP anticipates that the removal of prior authorization and step therapy requirements will increase auto-injector naloxone use such that it represents 50% of the prescriptions for naloxone,

with the nasal spray representing the remaining prescriptions for OUD enrollees. OUD enrollees would be able to fill these prescriptions via their Medi-Cal managed care plan without restriction, when compared to the fee-for-service Medi-Cal program, which requires a prior authorization.

- Use of FDA-approved drug treatment for alcohol use disorder (AUD), except in the case of disulfiram (due to limited evidence of ineffectiveness, see *Medical Effectiveness* section), will increase by 10% for both new and existing commercial enrollees due to the removal of prior authorization and step therapy (i.e., fail first) requirements resulting in an overall increase in use of most AUD treatment services including behavioral therapy and medication when associated with use of those medications.
- The proportion of Medi-Cal managed care AUD enrollees receiving most FDA-approved drug treatment for their AUD will not increase because of existing coverage with limited treatment authorization request requirements for each drug.
- Use of FDA-approved drug treatment for TUD, except in the case of nicotine nasal spray, will increase by 10% for both new and existing commercial and Medi-Cal managed care enrollees due to the removal of prior authorization and step therapy (i.e., fail first) requirements resulting in an overall increase in use of most TUD treatment services including behavioral therapy and medication when associated with use of those medications.
- Reductions in cost sharing due to movement of a drug onto tier 1 of the formulary could shift use for both existing users and new users of OUD (commercial enrollees only), AUD (commercial enrollees only), and tobacco use disorder (TUD) (commercial and Medi-Cal managed care enrollees) to more effective or expensive services that are now required to be covered without prior authorization or step therapy requirements and via tier 1 of the formulary.
- In the postmandate absence of prior authorization or step therapy requirements for medications, CHBRP assumes utilization of supportive counseling services by persons with OUD and AUD will increase by 12.5% from the baseline utilization level among enrollees with commercial health insurance subject to SB 11. While SB 11 does not explicitly remove utilization management requirements for use of counseling, the increase in enrollees seeking and obtaining medication treatment is likely to result in a marginal increase in counseling services related to OUD and AUD treatment.

Other considerations:

- Prior to SB 11, only 20% of enrollees with OUD (which has a 0.51% to 1.1% prevalence rate in the overall population) receive FDA-approved medications. This underuse of OUD treatment is not necessarily related to insurance coverage for treatment and is more likely due to other factors, such as willingness to enter treatment.
- Prior to SB 11, less than 1% of enrollees with AUD and TUD received FDA-approved medications despite a 5.51% prevalence rate for AUD and 16.23% prevalence rate for TUD. Underuse of drugs to treat both conditions is linked to provider practice patterns, willingness to enter treatment, and other options available that do not rely on prescription drugs (e.g., over-the-counter nicotine replacement therapy, Alcoholics Anonymous).
- CHBRP consulted the literature and a content expert regarding physician practice patterns around AUD and TUD treatment. It appears that the low use of AUD and TUD drugs is not necessarily driven by insurance benefits coverage, utilization management, or cost sharing. It is partially related to physician practices around prescribing and treatment of these two conditions,

which results in relatively low utilization of FDA-approved medications, which is unlikely to change due to SB 11.

CHBRP anticipates cost and utilization offsets for OUD and AUD enrollees who become new users of FDA-approved medications. These offsets are described in the *Potential Cost Offsets or Savings in the First 12 Months After Enactment* section.

For further details on the underlying data sources and methods, please see Appendix C.

Baseline and Postmandate Benefit Coverage

Current coverage of medication for OUD, AUD, and TUD was determined by surveying the largest (by enrollment) providers of health insurance in California, including DMHC-regulated Medi-Cal managed care plans. Responses to the survey related to SUD medication coverage represent 89% of enrollees with commercial market health insurance and 57% of enrollees in the DMHC-regulated Medi-Cal managed care market that can be subject to state mandates. Due to the fee-for-service Medi-Cal carve-out for specific pharmacy services for treatment of OUD and AUD, prior to SB 11 there was no coverage in the regulated Medi-Cal managed care plans, though 100% of Medi-Cal enrollees had coverage for the AUD and OUD drugs via the fee-for-service Medi-Cal carve-out. TUD is already included in the benefits required of Medi-Cal managed care plans. As noted in Table 1, 93% of commercial enrollees have health insurance that is partially compliant with SB 11 because they have a pharmacy benefit, cover some or all of the FDA-approved medications for SUD treatment, and have prior authorization or step therapy restrictions attached to their coverage one or more medications. No plans reported restricting access to SUD services for court ordered treatment.

Opioid Use Disorder (OUD) Outpatient Medication Coverage

Table 5 demonstrates that the vast majority of commercial enrollees have on-formulary coverage for the FDA-approved medications for treatment of OUD. 80% or more of enrollees have coverage for OUD medications (buprenorphine, methadone, naloxone, naltrexone, and combination buprenorphine/naltrexone), except for lofexidine which is only covered for 11% of enrollees. Table 5 demonstrates that most commercial enrollees are not subject to prior authorization for OUD-related medications (ranges from 0% for naloxone and naltrexone to 16% for lofexidine). Most enrollees are not subject to step therapy for OUD-related medications (ranging from 0% for naltrexone, lofexidine, and combination buprenorphine/naloxone to 4% for buprenorphine, methadone, and naloxone).

Currently, 0% of Medi-Cal beneficiaries enrolled in managed care plans have health insurance fully compliant with the proposed mandate due to the existing Medi-Cal carve-out. It is important to note that SB 11 would leave the existing carve-out in place for fee-for-service Medi-Cal with existing utilization management requirements (like treatment authorization requests) and formulary limitations, and set up parallel coverage by Medi-Cal managed care plans without those same barriers to utilization for enrollees (Table 6). However, based on content expert input, CHBRP determined that a shift from Medi-Cal fee-for-service to Medi-Cal managed care plans for treatment and payment would be unlikely due to the comprehensive coverage of the FDA-approved drugs for OUD with limited utilization review, prior authorization, step therapy requirements, and no cost sharing. The only drug subject to significant prior authorization via Medi-Cal fee-for-service is auto-injector naloxone, which CHBRP estimated would increase in use via the Medi-Cal managed care plans new parallel coverage and lack of prior authorization or step therapy requirements.

Alcohol Use Disorder (AUD) Outpatient Medication Coverage

Table 5 demonstrates that the vast majority of commercial enrollees have on-formulary coverage for the FDA-approved medications for treatment of AUD mentioned in SB 11. 82% of enrollees have coverage for AUD medication (acamprosate, naltrexone, and disulfiram). Table 5 demonstrates that most enrollees already have access to AUD medications on tier 1 of the formulary (ranging from 63% for acamprosate to 82% for disulfiram and naltrexone). In addition, no enrollees with coverage are subject to prior authorization for naltrexone and disulfiram. Only 1% need prior authorization for acamprosate). No enrollees are subject to step therapy for AUD-related medications. Despite fairly comprehensive coverage for the AUD drugs and virtually no prior authorization or step therapy requirements, use of these FDA-approved drugs to treat AUD remains very low.

Currently, 0% of Medi-Cal beneficiaries enrolled in managed care plans have health insurance fully compliant with the proposed mandate due to the existing Medi-Cal carve-out. It is important to note that SB 11 would leave the existing carve-out in place for fee-for-service Medi-Cal with existing utilization management requirements (like treatment authorization requests) and formulary limitations, and set up parallel coverage by Medi-Cal managed care plans without those same barriers to utilization for enrollees. However, based on content expert input, CHBRP determined that a shift from Medi-Cal fee-for-service to Medi-Cal managed care plans for treatment and payment would be unlikely due to the comprehensive coverage of the FDA-approved drugs for AUD with limited utilization review, prior authorization, step therapy requirements, and no cost sharing.

Tobacco Use Disorder (TUD) Outpatient Medication Coverage

Table 5 demonstrates that fewer commercial enrollees have on-formulary coverage for the FDA-approved medications for treatment of TUD mentioned in SB 11. While 81% of enrollees have coverage for varenicline and 82% have coverage for bupropion HCL SR, 27% have coverage for Nicotine inhalers or nasal spray. Bupropion HCL SR is on tier 1 of the formulary for 76% of enrollees, while varenicline is on tier 1 of the formulary for 60% of enrollees with coverage for the medication. Only 6% of those with coverage for the nicotine inhaler and nasal spray have access to the two medications on tier 1 of the formulary. However, no plans reported restricting utilization of any TUD medications that were covered via step therapy or prior authorization requirements.

TUD medications are not subject to the Medi-Cal carve-out in place for OUD and AUD medications. Table 7 demonstrates that 100% of enrollees have coverage for all TUD medications. However, prior authorization and step therapy requirements vary. 8% of enrollees have prior authorization requirements to access Bupropion HCL SR, although no enrollees are subject to step therapy requirements. For varenicline, nicotine inhaler and nasal spray, 21% of enrollees are subject to prior authorization and 8% are subject to step therapy requirements (Table 6).

Table 5. SB 11 Treatment-Specific Baseline Benefit Coverage for Commercial Enrollees and CalPERS

Medication	% of enrollees with on-formulary medication coverage	% of enrollees with on-formulary medication coverage that is...		
		...on tier 1 of the formulary (commonly the tier for generics)	...Subject to prior authorization requirements	... Subject to step therapy, fail-first, protocols
Buprenorphine	80%	0%	5%	4%
Methadone	82%	0%	1%	4%
Naloxone	82%	0%	0%	4%
Naltrexone	80%	0%	0%	0%
Combination Buprenorphine/Naloxone	80%	0%	1%	0%
Lofexidine	11%	0%	16%	0%
Nicotine - Inhaler	27%	6%	0%	0%
Nicotine - Nasal Spray	27%	6%	0%	0%
Varenicline	81%	60%	0%	0%
Bupropion HCL SR	82%	76%	0%	0%
Acamprosate	82%	63%	1%	0%
Naltrexone - Oral	82%	82%	0%	0%
Disulfiram	82%	82%	0%	0%

Source: California Health Benefits Review Program, 2019.

Table 6. SB 11 Treatment-Specific Baseline Benefit Coverage for Medi-Cal Managed Care Plans

Medication	% of enrollees with on-formulary medication coverage	% of enrollees with on-formulary medication coverage that is...	
		...Subject to prior authorization requirements	... Subject to step therapy, or fail-first protocols
Buprenorphine	Carved Out*	Carved Out*	Carved Out*
Methadone	Carved Out*	Carved Out*	Carved Out*
Naloxone	Carved Out*	Carved Out*	Carved Out*
Naltrexone	Carved Out*	Carved Out*	Carved Out*
Combination Buprenorphine/Naloxone	Carved Out*	Carved Out*	Carved Out*
Lofexidine	Carved Out*	Carved Out*	Carved Out*
Nicotine - Inhaler	100%	21%	8%
Nicotine - Nasal Spray	100%	21%	8%
Varenicline	100%	21%	8%
Bupropion HCL SR	100%	8%	0%
Acamprosate	Carved Out	Carved Out	Carved Out
Naltrexone - Oral	Carved Out	Carved Out	Carved Out
Disulfiram	100%	8%	0%

Source: California Health Benefits Review Program, 2019.

Notes: (*) Carved Out* refers to the fact that Opioid use disorder and alcohol use disorder medication–related coverage for Medi-Cal beneficiaries is generally carved out from their DMHC-regulated plan coverage but available through fee-for-service Medi-Cal.

Baseline and Postmandate Utilization

Commercial (large group, small group, and individual market) and CalPERS enrollees, as well as a majority of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans which would be subject to SB 11. Additional commercial enrollees are enrolled in CDI-regulated policies, which would also be subject to SB 11. Baseline FDA-approved medication and counseling costs and associated utilization for the private insurance market were based on 2016 Milliman commercial claims and enrollment data for the state of California with few exceptions. The Medi-Cal medication and counseling costs and associated utilization were based upon Medi-Cal claims and encounter data for a subset of counties in the state, collected by Milliman.

Opioid Use Disorder Utilization

Enrollees with OUD with coverage for medications in commercial plans use approximately 11.59 methadone, 4.23 buprenorphine, 6.48 combination buprenorphine-naloxone, 2.3 naltrexone, and 1.0

naloxone prescriptions per year (see Table 1). Enrollees with OUD could be receiving treatment through multiple modalities within a 1-year period of time, but are typically receiving one to two distinct treatments at any given time. For example, someone who is receiving buprenorphine treatment may also have obtained naloxone preventively for overdose reversal in emergency situations.

Except in the case of methadone, postmandate utilization of OUD-related FDA-approved maintenance medications would be expected to increase due to the removal of prior authorization and step therapy requirements and movement of FDA-approved treatments to tier 1 of the formulary in 93% of plans. This would result in existing users experiencing a slight increase in use, while new users of services would experience an equivalent level of use. Overall, due to the mix of plans use of drug coverage restrictions, prior authorization, step therapy, and formulary tiers, would result in varying increases in the use of specific drugs: 8.7% increase in Buprenorphine, compared with 28.2% increase in combination buprenorphine/naloxone. In addition, Behavioral therapy is anticipated to increase by 12.5% in overall visit per year based upon new users of OUD medication seeking out behavioral therapy services related to their new receipt of FDA-approved OUD treatment (see Table 1).

Alcohol Use Disorder Utilization

Enrollees with AUD with coverage for medications in commercial plans use approximately 1.85 Acamprostate, 2.77 Naltrexone, and 2.56 Disulfiram prescriptions per year (see Table 1). Enrollees with AUD could be receiving treatment through multiple modalities within a 1-year period of time, but are typically receiving one distinct treatment at any given time.

Postmandate utilization of AUD medications would be expected to increase due to the removal of prior authorization and step therapy requirements in 93% of plans resulting in new users of services, along with the movement of all drugs to tier 1 of the formulary. Due to the variation in coverage for the AUD drugs, along with prior authorization, step therapy and formulary differences CHBRP estimates the use of Acamprostate would increase by 12.4% to 2.08 prescriptions per user per year while that of Naltrexone would increase by 16.6% to 3.23. Disulfiram would only increase by 3.7%, partially due to the already high levels of coverage for the drug and issues with physician prescribing, patient compliance and adherence.

Tobacco Use Disorder Utilization

Based on current Milliman commercial and Medi-Cal claims analysis, enrollees with TUD with coverage for medications use approximately 3.46 bupropion HCL SR, 1.55 nicotine inhaler, 4.37 nicotine nasal spray, and 2.07 varenicline prescriptions per year (see Table 1).

Postmandate utilization of TUD medications are estimated to increase by 2.6% for nicotine inhalers and 49.2% for nicotine nasal spray due to the new coverage of the drugs (only 27% of enrollees had coverage prior to the mandate) and movement to tier 1 on the formulary resulting in new users of services. However, these same changes are estimated to result in slight reductions in use of varenicline (-0.5%) and bupropion HCL SR (-1.2%) due to medication changes and cost-sharing differences.

Baseline and Postmandate Per-Unit Cost

Table 1 provides an estimate of 30-day costs of each type of FDA-approved SUD medication based upon Milliman analysis of current use by commercial enrollees with OUD and Medi-Cal claims for those on TUD medications. The actual unit cost of services would not be anticipated to change postmandate, though the frequency of services would increase due to new users and removal of prior authorization, step therapy,

and limited formulary coverage. Due to the removal of utilization management related to brand-name medication use, CHBRP assumes that emergency doses of naloxone provided to OUD patients being treated with FDA-approved medication for “rescue” overdose reversal purposes would shift to easier to use methods (i.e., nasal spray and auto-injectors) due to lack of prior authorization, step therapy, and formulary limitations. The postmandate increase in naloxone prescribed to OUD medication patients would be split 50/50 between nasal spray and auto-injectors in both the commercial and Medi-Cal managed care enrollees due to the prior authorization requirements being removed and the substantial reduction in cost sharing due to being moved to tier 1 on the formulary.

Baseline and Postmandate Expenditures

Table 8 and Table 9 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

SB 11 would increase total net annual expenditures by \$20,671,000 or 0.0133% for enrollees with DMHC-regulated plans and CDI-regulated policies. This increase is primarily driven by an increase of \$17,820,000 (0.0257%) in spending by private employers for group insurance and \$6,018,000 (0.0283%) in spending by enrollees with group insurance, CalPERS HMOs, and small group Covered California policies.

Premiums

Changes in premiums as a result of SB 11 would vary by market segment (Table 9). In the commercial market, premium increases will occur in all commercial DMHC- and CDI-regulated plans, ranging from a high of 0.1354% in the individual CDI-regulated market to a low of 0.0110% in the CDI-regulated small group market. Among publicly funded plans, CalPERS HMO premiums would increase by 0.0105% while Medi-Cal managed care premiums would increase by 0.0041% for the under 65 population.

Overall, there is a net 0.0227% increase in total health insurance premiums paid by employers, enrollees, and Medi-Cal for newly covered benefits. These differences in premium increases are driven by the underlying variation in coverage of specific drugs, use of prior authorization and step therapy, and formulary restrictions at baseline. In some market segments, plans were already in compliance and would therefore experience very limited changes in utilization, expenditures, and premiums, while in other market segments with limited compliance, the relative cost would be higher.

Enrollee Expenses

SB 11-related changes in enrollee expenses for covered benefits (copays and coinsurance) vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 8, and Table 9) with health insurance that would be subject to SB 11 expected to use the prescription medications during the year after enactment.

CHBRP projects a reduction in copayments or coinsurance rates for users and an increase in prescription medications. However, because cost sharing requirements are limited by the SB 11 requirement to move drugs to tier 1 of the formulary, there is a decrease in total enrollee cost sharing. Enrollee out-of-pocket expenses are expected to decrease by \$11,184,000 (-0.0751%) overall. Due to limitations on Medi-Cal managed care plans use of cost sharing, the enrollee cost sharing changes are concentrated on the

commercial market and relate to the overall increase in service use and associated cost sharing for new services used by OUD, AUD, and TUD users.

Decreases in commercial enrollee per member per month expenses for covered benefits are estimated from a low of -\$0.0167 in CalPERS HMOs to a high of -\$0.2939 in CDI-regulated individual commercial plans (Table 10).

Out-of-Pocket Spending for Covered and Noncovered Expenses

When possible, CHBRP estimates the marginal impact of the bill on out-of-pocket spending for covered and noncovered expenses, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and coinsurance). CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

As noted in Table 1, SB 11's would decrease total enrollee out-of-pocket spending for covered benefits (cost-sharing) by less than 0.1%. For enrollees using medications approved by the FDA for SUDs, SB 11's coverage requirements (on formulary and subject to tier 1 or no cost sharing) would create varied impacts. As noted in Table 7, cost-sharing impacts among enrollees using the medications would range from no impact (for Medi-Cal beneficiaries, who have no premandate cost sharing) to an average annual decrease of \$418.28 among enrollees in individual market plans and policies.

Table 7. Cost Sharing Impact of SB 11

	Large Group	Small Group	Individual	CalPERS HMO	MediCal HMO
% of Enrollees with Cost Sharing Impact from the Mandate (a)	0.4%	0.4%	0.4%	0.3%	0.0%
Avg Annual Cost Sharing Impact Enrollees using FDA approved medications for SUDs (b)	\$ (85.82)	\$ (306.66)	\$ (418.28)	\$ (74.79)	\$ -

Source: California Health Benefits Review Program, 2019

Notes: (a) Not including impacts on premiums; (b) Benefit coverage for Medi-Cal beneficiaries does not generally include any cost-sharing, which would not be changed by SB 11.

It is possible that some enrollees incurred expenses related to treatment and prescription medications for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact. In the case of SB 11, enrollees for TUD may be using over-the-counter nicotine replacement therapy products that could be replaced by prescription drugs to treat TUD. However, due to patient and physician attitudes, compliance and adherence CHBRP does not estimate a shift in use of those treatment options.

Potential Cost Offsets or Savings in the First 12 Months After Enactment

Results indicate that almost all commercial enrollees have on-formulary coverage for the listed drugs and counseling services – but no enrollees had benefit coverage entirely free of the utilization management tools SB 11 would prohibit or with all SUD drugs on tier 1 as required by SB 11 (see Tables 6 and 7). The removal of utilization management and reduction of cost-sharing is expected to increase the number of users of SUD drugs and associated counseling services by approximately 10% for commercial OUD and

AUD members, and by approximately 10% for commercial and Medi-Cal managed care TUD members. CHBRP assumed no change in utilization for disulfiram, oral naltrexone for OUD, injectable buprenorphine and methadone.

Postmandate Offset Services – Inpatient, Outpatient, and Professional

There are likely to be changes in the utilization of non-SUD-related services as a result of receiving SUD treatment. Mohlman et al. (2016) indicated reductions in inpatient, emergency, medical specialist, and imaging services and increases in PCP visits and surgical specialist visits. Any side effects or harms associated with increased use of SUD medications are not measurable in terms of increased health service use or spending. The Mohlman et al. (2016) study included data on utilization offsets that would have included additional office visits or services that may have resulted from both minimal side effects (i.e., redness or swelling at injection sites) and larger harms, like increased risk of overdose when patients treated with naltrexone who discontinue treatment may be sensitive to lower doses of opioids, which could increase their risk of overdose (SAMHSA, 2015). In general, the utilization and cost offsets calculated in this report take into consideration added health services use and spending, regardless of whether it is associated with the direct cost of the treatment or additional services associated with side effects. Please see *Medical Effectiveness* section for literature on other harms.

Unit costs were estimated using a combination of the Mohlman estimates, CHSD data, and relationships between commercial and Medi-Cal unit costs. CHBRP relied upon CHSD data for commercial and Medi-Cal utilization and cost estimate. There is no assumed differential in average cost per service pre- and postmandate.

Table 8. Selected Offsets: Avoided Inpatient Days, Inpatient Detoxification, and Emergency Department Visits

	Average Utilization Change per SUD Treatment User	Commercial Unit Cost	Medi-Cal Unit Cost
OUD Inpatient Days	-1.46	\$8,360	\$3,356
OUD Detox Days	-1.46	\$1,379	\$2,795
OUD ED Visits	-1.04	\$3,723	\$400
AUD Inpatient Days	-0.436	\$9,285	\$3,308
AUD Detox Days	-0.457	\$1,433	\$2,682
AUD ED Visits	-0.044	\$4,225	\$393

Source: California Health Benefits Review Program, 2019.

Generally, the literature suggests that OUD treatment with methadone, buprenorphine, naloxone, or naltrexone lead to better outcomes and reduced overall spending when compared with no use (McCarty, 2010; Tkacz, 2014). Despite sizeable costs of OUD medication services, the recipients in the articles mentioned above experienced 43% lower spending on average for inpatient and outpatient services. These studies suggest in aggregate that OUD medication services are likely to result in short- and long-

term savings (see the *Long-Term Impacts* section). CHBRP used literature focused on utilization change due to OUD medication treatment to inform its cost model estimates.

To estimate the cost offsets for OUD medication likely to occur due to SB 11. CHBRP relied on one article that isolates the impact of Medication-Assisted Treatment (MAT) on health services utilization in the Vermont Medicaid program (Mohlman et al., 2016). The article suggests that increases in MAT are offset by decreases in spending on inpatient days and stays, emergency room visits, and imaging. However, Mohlman et al. found an increase in the use of other services, including surgical appointments and primary and specialty care services.

CHBRP applied estimated utilization and cost offsets based on published evidence (Mohlman et al., 2016; Mark et al., 2010) on the impact of OUD-related medication and counseling treatment on emergency room use, inpatient services, outpatient physician services, inpatient detoxification, and other OUD-related services. There is evidence that TUD prescription medications, specifically Varenicline, are prescribed less often than indicated and that adherence is low, despite existing coverage by insurance benefits (Burke et al., 2016). For both OUD and AUD, CHBRP estimates that use of outpatient counseling services would increase by 0.5 visit per year for new users, although it would be subject to prior authorization and other utilization review unlike the FDA-approved medications covered by SB 11.

These cost offsets for new users only are reflected in Table 1 and the estimates for expenditures and premium changes in 2019.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies would remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Postmandate Changes in the Number of Uninsured Persons²²

Because the change in average premiums does not exceed 1% for any market segment (see Table 10. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2019), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 11.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of SB 11.

²² See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

Currently, the carved out Medi-Cal benefit for OUD and AUD is used to deliver some of the services covered by SB 11. Medi-Cal does cover all of the OUD and AUD medications and services, with limited utilization management restrictions. Due to the duplication in coverage proposed by SB 11 and comprehensive coverage of the FDA-approved drugs for OUD and AUD that already exists in the Medi-Cal fee-for-service carve-out with limited utilization management, CHBRP only estimated an increase in Medi-Cal managed care plans covering new use of auto-injector naloxone due to the treatment authorization request requirements in Medi-Cal fee-for-service and the relative high cost of the drug. By removing any prior authorization requirement and moving it to tier 1 of the formulary, obtaining the auto-injector version of naloxone will be much easier in Medi-Cal managed care plans due to SB 11. CHBRP anticipates other OUD will continue to be delivered through the fee-for-service carve-out, which is not impacted by SB 11.

Table 9. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2019

	DMHC-Regulated						CDI-Regulated			TOTAL
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
Enrollee Counts										
Total enrollees in plans/policies subject to state mandates (d)	9,371,000	3,117,000	2,081,000	887,000	6,832,000	678,000	214,000	133,000	120,000	23,433,000
Total enrollees in plans/policies subject to SB 11	9,371,000	3,117,000	2,081,000	887,000	6,832,000	678,000	214,000	133,000	120,000	23,433,000
Premium Costs										
Average portion of premium paid by Employer	\$482.65	\$343.93	\$0.00	\$505.74	\$276.66	\$808.46	\$557.12	\$459.26	\$0.00	\$103,945,637,000
Average portion of premium paid by Employee	\$122.24	\$158.45	\$588.53	\$82.33	\$0.00	\$0.00	\$175.81	\$167.30	\$459.20	\$36,625,181,000
Total Premium	\$604.88	\$502.38	\$588.53	\$588.07	\$276.66	\$808.46	\$732.93	\$626.56	\$459.20	\$140,570,818,000
Enrollee Expenses										
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$48.13	\$111.60	\$159.72	\$50.14	\$0.00	\$0.00	\$133.93	\$176.39	\$112.74	\$14,896,952,000
Enrollee expenses for noncovered benefits (e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total Expenditures	\$653.02	\$613.98	\$748.25	\$638.21	\$276.66	\$808.46	\$866.86	\$802.95	\$571.95	\$155,467,770,000

Source: California Health Benefits Review Program, 2019.

Note: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the exchange.

(b) As of September 2017, 56% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2019.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; COHS=County Operated Health Systems; MCMC = Managed Care Medi-Cal

Table 10. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2019

	DMHC-Regulated						CDI-Regulated			TOTAL
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
Enrollee Counts										
Total enrollees in plans/policies subject to state Mandates (d)	9,371,000	3,117,000	2,081,000	887,000	6,832,000	678,000	214,000	133,000	120,000	23,433,000
Total enrollees in plans/policies subject to SB 11	9,371,000	3,117,000	2,081,000	887,000	6,832,000	678,000	214,000	133,000	120,000	23,433,000
Premium Costs										
Average portion of premium paid by Employer	\$0.0940	\$0.1765	\$0.0000	\$0.0530	\$0.0112	\$0.0112	\$0.2191	\$0.0506	\$0.0000	\$19,394,000
Average portion of premium paid by Employee	\$0.0238	\$0.0813	\$0.2221	\$0.0086	\$0.0000	\$0.0000	\$0.0692	\$0.0185	\$0.6218	\$12,461,000
Total Premium	\$0.1179	\$0.2578	\$0.2221	\$0.0616	\$0.0112	\$0.0112	\$0.2883	\$0.0691	\$0.6218	\$31,855,000
Enrollee Expenses										
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	-\$0.0238	-\$0.1099	-\$0.1372	-\$0.0167	\$0.0000	\$0.0000	-\$0.1245	-\$0.0329	-\$0.2939	\$11,184,000
Enrollee expenses for noncovered benefits (e)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total Expenditures	\$0.0941	\$0.1479	\$0.0849	\$0.0449	\$0.0112	\$0.0112	\$0.1638	\$0.0362	\$0.3280	\$20,671,000
Postmandate Percent Change										
Percent change insured premiums	0.0195%	0.0513%	0.0377%	0.0105%	0.0041%	0.0014%	0.0393%	0.0110%	0.1354%	0.0227%
Percent Change total expenditures	0.0144%	0.0241%	0.0113%	0.0070%	0.0041%	0.0014%	0.0189%	0.0045%	0.0573%	0.0133%

Source: California Health Benefits Review Program, 2019.

Note: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the exchange.

(b) As of September 2017, 56% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2019.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans).

Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; COHS=County Operated Health Systems; MCMC = Managed Care Medi-Cal

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 11 addresses the benefit coverage of enrollees who have a pharmacy benefit that covers a medication that is FDA-approved for treatment of a substance use disorder (SUD). For these enrollees' health insurance, SB 11 would mandate coverage of all FDA-approved medications for substance use disorders. SB 11 would require these medications to be placed on the lowest tier of the formulary and would prohibit use of prior authorization and step therapy utilization management tools for these medications. The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate).

This section estimates the short-term impact of SB 11 on health outcomes and potential population disparities. See *Long-Term Impacts* for discussion of premature death, economic loss, and social determinants of health.

Estimated Public Health Outcomes

There are FDA-approved prescription medications for three substance use disorders: opioid use disorder (OUD), alcohol use disorder (AUD), and tobacco use disorder (TUD). As presented in *Medical Effectiveness* (Figure 13), there is clear and convincing evidence of effectiveness for most of the FDA-approved SUD medications. The OUD, AUD, and TUD medications promote treatment retention, prevent relapse, and improve birth outcomes. Additionally, evidence shows OUD medications reduce illicit use opioid use (misuse of prescription opioids or use of heroin and illicitly manufactured fentanyl); reverse opioid overdose thus reducing associated mortality; and reduce risk behaviors associated with transmission of HIV or Hepatitis C (see *Long-Term Impacts* section for further discussion about morbidity and mortality). CHBRP's medical effectiveness review found limited evidence regarding the impact of prohibiting utilization management strategies on reducing enrollee barriers to care.

As presented in *Benefit Coverage, Utilization, and Cost Impacts*, CHBRP estimates a marginal increase of up to 10,800 people with OUD, AUD, or TUD newly accessing FDA-approved medications to treat their disorders were SB 11 implemented. Please note, concomitant use of medications by some enrollees may occur, and so these enrollee estimates reflect an upper bound.

Opioid Use Disorder (OUD)

Given the effectiveness of all five OUD medications (buprenorphine (-naloxone), methadone, and naltrexone for maintenance treatment; lofexidine for withdrawal; and naloxone for overdose reversal), CHBRP anticipates an increase in opioid overdose reversals and maintenance treatment for the 3,100 enrollees with OUD projected to have new access to these FDA-approved medications. Corresponding decreases in illicit opioid use, opioid overdose and its associated mortality, poor maternal-infant outcomes, and a reduction in behaviors associated with elevated risk of hepatitis B and C, and HIV (unprotected sex and shared injection drug equipment).

Improving access to OUD treatment is especially important for reducing risk of hepatitis B and C and HIV. A minority of people with OUD become injection drug users (IDU) either to improve the high from misused prescription opioids or because they have turned to heroin, which is cheaper and easier to obtain than prescription opioids (NIDA, 2018). National estimates of hepatitis C infection rates among IDU ranges from 60% to 90% (Tsui et al., 2014) indicating a high likelihood of transmitting the infection when sharing contaminated drug equipment. In 2015, about 18% of California females with HIV contracted the infection through IDU (opioid and other drugs) compared with 5% of HIV+ males (although males comprise 88% of

the HIV population) (CHDP, 2015). Based on the evidence, injection drug users who take medications to treat OUD could avert contracting HIV and/or hepatitis C and prevent transmission to others.

In addition to the preventable health burdens, pharmacotherapy for OUD also reduces use of health services. The *Background on Substance Use Disorders and Benefit Coverage, Utilization, and Cost Impacts* sections described research showing decreased emergency room use and hospitalizations for patients being treated for OUD as compared with patients with untreated OUD (Mohlman et al., 2016). In the case of SB 11, CHBRP estimates that in the first year postmandate, there would be cost offsets attributable to fewer OUD-related services per OUD user. Specifically, 1.46 fewer days in both OUD inpatient days and OUD detox days, plus one less OUD-related ED visit per OUD user (see Table 8 in the *Benefit Coverage, Utilization, and Cost Impacts* section for estimated changes).

The public health impact of SB 11 within a year postmandate may be limited for several reasons. In addition to a relapse rate of 40% to 60% (see *Background on Substance Use Disorders* section), other significant attitudinal and structural barriers contribute to lower OUD treatment rates than OUD treatment needs. As discussed in the *Background on Substance Use Disorders* section, patient attitudinal barriers are strong deterrents to seeking treatment. Namely the nature of addiction precludes some people with OUD from recognizing their need for help, with an estimated 11% seeking treatment in the first year after onset of the disorder and 24% within 10 years of onset (Blanco et al., 2013). OUD stigma from family, friends, and employers produces another significant barrier, as does provider willingness to prescribe and treat. Moreover, structural barriers prevent some who seek medication treatment from obtaining it due to a mismatch between the supply of trained providers and health care settings, and patient demand (Clemens-Cope et al., 2018; Knudsen et al., 2017).

In the first year postmandate, CHBRP estimates that about 3,100 enrollees with newly compliant benefit coverage would use FDA-approved prescription drugs for the treatment of opioid use disorder, 40%-60% of whom may experience relapse. As supported by clear and convincing evidence, outcomes of such treatment would include reducing illicit opioid use, opioid overdose and associated mortality, acquisition and transmission of hepatitis C and HIV, and poor maternal-infant outcomes. Among those new users, SB 11 would also increase maintenance treatment retention and increase overdose reversals (through the use of naloxone).

Impact on disparities

Disparities are differences between groups that are modifiable, and insurance benefit mandates that impose coverage parity among state-regulated plans and policies may change an existing disparity.²⁷ As presented in the *Background on Substance Use Disorders* section, disparities occur within many demographic categories in California. Disparities in opioid overdose mortality rates, hospitalizations, and emergency department use exist among racial/ethnic groups (highest among whites and Native Americans); age cohorts (highest among ages 25-35 yrs); and by gender (males have two times the mortality rate of females). The LGBT population is twice as likely as the heterosexual population to report misusing prescription opioids.

The demographic composition of the estimated 3,100 enrollees projected to start OUD treatment medication(s) is undefined; therefore, the impact of SB 11 on existing disparities in opioid use, mortality, and related health services use is unknown.

Alcohol Use Disorder (AUD)

As presented in *Medical Effectiveness*, there is clear and convincing evidence that two of the three²³ FDA-approved AUD medications (acamprosate and naltrexone) are effective in reducing alcohol consumption or supporting abstinence from alcohol. There is insufficient evidence of effectiveness for outcomes related to quality of life, injury, and mortality (Jones et al., 2014). As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP estimates about 2,200 enrollees with newly SB 11-compliant benefit coverage will use FDA-approved medications for the treatment of AUD.

There is well-established evidence of a causal link between alcohol misuse/abuse and higher rates of injury, cancers, fetal alcohol spectrum disorder, stroke, cardiovascular disease, liver cirrhosis, high risk behaviors, and other physical and mental health conditions (Rehm et al., 2010; NIAAA, 2019). Although longitudinal studies on the effectiveness of these medications improving health outcomes is lacking, epidemiologic evidence indicates that reductions in alcohol consumption would translate to lower rates of acute and chronic conditions such as fetal alcohol spectrum disorder; miscarriage; AUD-associated injury and mortality (e.g., motor vehicle accidents, falls, suicides, sexual assault); and risky sexual behavior leading to unintended pregnancy or sexually transmitted infections (CDC, 2018) (see the *Long-Term Impacts* section for discussion of cardiovascular and liver disease and cancer).

Two examples of the negative health effects of untreated AUD include poor pregnancy outcomes and injuries/accidents:

- Pregnant women who misuse/abuse alcohol increase the risk of poor birth outcomes. Fetal alcohol spectrum disorder (FASD), defined by permanent physical and intellectual disabilities and/or behavioral problems in newborns, is caused exclusively by alcohol. In 2014, SAHMSA showed that, nationally, 2.7% of pregnant women aged 15 to 44 reported binge drinking, and 0.3% reported heavy drinking, which greatly increases the risk of FASD. SAMSHA also reported that about 200,000 cases of FASD occur annually in the U.S. Studies from specific U.S. sites report the prevalence of FASD ranging between 20 to 50 cases per 1,000 births annually (NIAAA, 2018).
- Alcohol misuse/abuse also causes a significant number of injuries/accidents. The CDC hosts the Alcohol-related Disease Impact database, which reports the number of alcohol-attributable deaths due to excessive alcohol consumption. In California, of the 5,113 acute causes of death, more than 1,000 motor vehicle deaths; 1,000 homicides; 800 suicides; and 600 falls resulting in death were alcohol related in 2012 (CDC, 2013).

Treating AUD with medication may help decrease the incidence of these negative health outcomes. Additionally, higher rates of emergency room use and hospitalizations are also associated with AUD (see *Background* section). In the case of SB 11, CHBRP estimates cost offsets associated with reduction in AUD related services. Specifically, about a half day reduction in AUD inpatient days and a half day reduction in AUD detox days per AUD patient (see Table 8 in Cost section for estimated changes).

As discussed in the *Background on Substance Use Disorders* section, attitudinal barriers are strong deterrents to seeking treatment. First, the nature of addiction precludes some people with AUD from recognizing their need for help. Additionally, stigma from family, friends, and employers may also play a role in patient reluctance to initiating and maintaining a treatment regimen (Fisher et al., 2016; Jones et

²³ Naltrexone, which helps manage withdrawal symptoms and blocks effects of alcohol and opioids; and acamprosate, which helps reduce cravings, are found to be effective; whereas there is insufficient evidence of the effectiveness of disulfiram.

al., 2015; Verissimo and Grella, 2017). Finally, many providers are reticent to prescribe medication to treat AUD, despite more than 10 years of provider education campaigns from government entities and the American Medical Association (Jonas et al., 2014; SAMSHA, 2015). Reasons for provider nonparticipation include prior training to refer to patients with AUD to specialty treatment centers, lack of familiarity with medications, systemic division between physical and behavioral health care, and limited referral options to specialty treatment clinics for their patients (provider-of-last resort) (SAMSHA, 2015; Wessell et al., 2014). Wessell et al. found that key facilitators to increasing primary care providers' prescribing AUD medication included provider exposure to evidence and case studies, receptive patients, early successful patient outcomes, and low cost (generic oral naltrexone) availability of AUD medication (Wessell et al., 2014).

In the first year postmandate, CHBRP estimates that approximately 2,200 enrollees with newly compliant benefit coverage would use FDA-approved prescription drugs for the treatment of alcohol use disorder, of which 50% or more may experience relapse within the first year of treatment. Based on clear and convincing evidence that two of the three FDA-approved AUD medications are effective in reducing alcohol consumption, CHBRP projects that these enrollees would experience decreases in negative health outcomes such as injuries/accidents and poor pregnancy outcomes in the first year postmandate.

Impact on disparities

As described in the *Background on Substance Use Disorders* section, AUD-related disparities among racial/ethnic groups exist in California with whites and Native Americans exhibiting the highest rates of heavy drinking, although Hispanics and blacks have higher rates of alcohol-related liver disease and cirrhosis mortality. Similar to other substance use disorders, younger cohorts (ages 18-34 years) report higher rates of heavy drinking as compared with other ages; similarly, the LGBT population reported higher rates of binge drinking than the heterosexual population.

The demographic composition of the estimated 2,200 enrollees projected to start AUD treatment medication(s) is undefined; therefore, the impact of SB 11 on reducing existing disparities in alcohol use, pregnancy outcomes, injuries/accidents, and related health services use is unknown.

Tobacco Use Disorder (TUD)

As presented in *Medical Effectiveness*, there is clear and convincing evidence that all three FDA-approved TUD medications are effective in promoting smoking cessation. As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, CHBRP estimates that there would be about 5,500 enrollees with newly SB 11 compliant benefit coverage will use FDA-approved medications for the treatment of TUD.

Smoking is a known cause of significant morbidity and mortality. A deep and comprehensive literature link smoking to a multitude of conditions and diseases including cancers, cardiopulmonary disease, and poor birth outcomes (HHS, 2014). A comprehensive epidemiological study reported that about 50% of deaths from 12 types of cancer are attributable to smoking, with more than 80% of lung cancer deaths attributable to smoking (Siegel et al., 2015). Despite having the second lowest smoking rate in the U.S. (11.3%), lung cancer remains the leading cause of cancer deaths in California with more than 12,000 deaths occurring in 2014 (ACS, 2017; CDC, 2017). (See the *Long-Term Impacts* section for more discussion of long-term effects of smoking.) Additionally, secondhand smoke increases non-smokers' risk of developing lung cancer, bronchitis, and pneumonia; exacerbating asthma; and causing poor birth outcomes (CDPH, 2018) all of which can lead to an increase in preventable health services utilization. California has the lowest prevalence rate nationally of women who smoke any time during pregnancy (about 2%) according to analysis of 2014 birth certificates (Curtin et al., 2016).

Public health campaigns, smoking policy changes (tobacco taxation, tobacco sales restrictions, workplace restrictions, etc.), and the ACA-requirement for coverage of cessation therapies by many plans and policies have contributed the second lowest state-smoking rate (11.4%) in the U.S. Table 3 shows the prevalence of smoking cessation methods that California smokers reported using (one or more) to quit smoking in the past year (based on the 2016-2017 California Adult Tobacco Survey) (CDPH, 2018). Data from the 2017 California Health Information Survey reports a smaller percentage (55%) of smokers quit for one or more days in the past year (CHIS, 2017). Research has shown that former smokers recalled an average of 4.7 quit attempts before successfully abstaining (CDPH, 2018).

CHBRP estimates that about 5,500 enrollees with newly compliant benefit coverage would use FDA-approved prescription drugs for the treatment of tobacco use disorder, some of whom will relapse within the first year of treatment initiation. This estimate is supported by clear and convincing that the three FDA-approved medications are effective in increasing quit rates and sustaining abstinence. Thus, reductions in poor birth outcomes and smoking-exacerbated conditions (e.g., asthma and heart attacks) would be expected in the first year post-mandate. (See *Long-Term Impacts* for discussion of premature mortality.)

Impact on disparities

Disparities are differences between groups that are modifiable, and insurance benefit mandates that impose coverage parity among state-regulated plans and policies may change an existing disparity. As described in the *Background on Substance Use Disorders* section, there are disparities in smoking prevalence by gender, race/ethnicity, age, and sexual orientation.

The demographic composition of the estimated 5,500 enrollees projected to start TUD treatment medication(s) is undefined; therefore, the impact of SB 11 on reducing existing disparities in tobacco use, and tobacco-related health outcomes is unknown.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact²⁴ of SB 11, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

Long-term utilization of FDA-approved OUD medications could increase as OUD prevalence increases in the state. CHBRP estimates that the level of use per user per year predicted in 2019 (see Table 1) would not change over time, but utilization overall would increase with additional use of opioids. Due to continuing structural and attitudinal barriers (see the *Background on Substance Use Disorders* section), CHBRP does not forecast that the level of those with OUD receiving services would increase to more than 22% per year.

As new medications approved by the FDA are adopted in clinical practice, shifts in utilization could occur. For example, the new lofexadine for OUD approved in late 2017 could alter the market for buprenorphine administration and increase use of the injectable version over sublingual versions (FDA, 2017). Currently, no paid claims are present to investigate current use, few plans have started covering the medication, and CHBRP's context expert suggested physicians are not yet prescribing the medication readily.

In the case of AUD and TUD treatment, there is very low baseline utilization of the FDA-approved medications for the two conditions. Because plans reported few restrictions to obtaining these medications, it appears physicians and patients are not using them frequently to treat AUD or TUD and therefore CHBRP does not expect long-term changes in prescribing practices or patient use.

Cost Impacts

OUD maintenance treatment needs with FDA-approved medication would continue and possibly increase if incidence of OUD increases over time. The constraints on the supply of providers (Clemans-Cope et al., 2018) would limit the level of increase associated with new users. However, new, more expensive brand-name medications coming to market are required to be covered by SB 11 without utilization management, which could result in long-term shifts in use towards more expensive options, which would increase per user costs and per unit costs for certain medications. However, if those medications are more effective than current OUD medications, they could come with cost offsets and increased adherence that would limit average cost increases. Currently, lofexidine is not being readily prescribed but that could change over a longer timeline.

CHBRP does not anticipate increased long-term spending on AUD or TUD if prevalence rates do not increase substantially and if practice patterns do not change, which will not necessarily be changed by SB 11 given existing coverage and use of TUD and AUD medications.

²⁴ See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Shifts for Medi-Cal

CHBRP anticipates that the prohibition on prior authorizations and step therapy will make auto-injector naloxone relatively easier to access by Medi-Cal beneficiaries enrolled in DMHC-regulated plans. In addition, the lack of prior authorization and step therapy requirements could, in future years, shift some Medi-Cal beneficiaries who would have chosen to access coverage for OUD through fee-for-service Medi-Cal carve-out programs to access newer, more expensive FDA-approved medications like lofexidine through a Medi-Cal managed care plan due to the SB 11-compliant absence of utilization management tools that would limit their ability to obtain the services through the carve-out (i.e., Treatment Authorization Requests). CHBRP does not anticipate this would happen for most OUD drugs which are already comprehensively covered by Medi-Cal fee-for-service with limited or no utilization management and no cost sharing.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments) while other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12-months postmandate) to the public's health that would be attributable to the mandate, including impacts on social determinants of health, premature death, and economic loss.

In the case of SB 11, CHBRP estimates that up to 10,000 enrollees would newly access FDA-approved prescription drug treatments for SUD in the first year of the mandate. For the portion of these and future new users who are able to sustain abstinence, SB 11 would contribute to reductions in substance use-related morbidity and mortality such as cardiovascular disease, cancer, HIV and hepatitis C. (See the *Public Health Impacts* section for discussion of potential reductions in acute conditions such as poor birth outcomes and injuries.)

As discussed in the *Background on Substance Use Disorders* and *Public Health Impacts* sections, a key barrier to abstinence for any substance use disorder is patient interest and readiness to abstain. CHBRP anticipates the demand for treatment of OUD, AUD, and TUD would continue as relapsed patients attempt abstinence again and first-time initiators would join the pool of patients seeking care. The SB 11 mandate to place the FDA-approved medications (Table 4) on tier 1 of formularies and remove insurer utilization management tools would continue to facilitate prescription medication treatment for some enrollees whose insurance did not previously offer coverage due to those barriers.

However, limited patient readiness for SUD treatment and the demand-supply mismatch for OUD and AUD treatment remain significant barriers to care. Other policy options to address the (under) supply of properly distributed buprenorphine-waivered and methadone providers may improve in the future as newly funded provider training programs take effect through the California Department of Public Health and Department of Health Care Services (CDPH, 2016) and as California's 58 counties implement the new Drug Medi-Cal Organized Delivery System for Medi-Cal beneficiaries (Joshi et al., 2017).

Impacts on the Social Determinants of Health²⁵

Taken as a whole, treatment of SUDs is inextricably linked bi-directionally with many important social determinants of health (SDoH). SDoH, such as quality of built environment, proximity to crime, educational opportunities, self-efficacy, and income levels can influence a person's risk for substance use disorders (Mooney et al., 2018; Sudhinaraset et al., 2016). Conversely, substance use disorders can also alter a person's baseline SDoH namely through the consequences of addiction, such as involvement with the criminal justice system, job loss, unstable housing or family situations, and discrimination against those with treated or untreated substance use disorder (Krebs et al., 2016).

Periodically, health insurance mandates may influence social determinants of health (SDoH), which can mediate health inequities. The impact of SB 11 on SDoH is unknown; however, it stands to reason that for those enrollees who are adherent to OUD or AUD prescription medication treatment could see reduced interactions with the criminal justice system and/or improvements in family and housing stability.

Impacts on Premature Death

Premature death is often defined as death occurring before the age of 75 years (Cox, 2006). There are an estimated 5,700 years of potential life lost (YPLL) before age 75 per 100,000 Californians (United Health Foundation, 2019). Overdose deaths, injuries/accidents, chronic diseases, and violence related to OUD, AUD and TUD are contributing factors to that rate.

OUD: Opioid-related mortality is considered a public health crisis, with more than 2,000 unintentional opioid deaths occurring in California in 2016 (Clemans-Cope et al., 2018; HHS, 2018). In terms of years-of-life-lost (YLL), Tomes et al. estimated the national burden of opioid deaths in 2016 represented 1 in 65 deaths (5.2 YLL/1,000 population), or about a quarter of the YLL due to cancer, the second leading cause of death in the U.S. Males experience twice the rate of YLL as females (7.0 YLL/1,000 population versus 3.4 YLL/1,000 population); and the opioid-related YLL for males aged 25-34 years (18.1/1,000 population) represented about a quarter of all YLL in the U.S. in 2016 (Tomes, et al., 2018).

AUD: The CDC reported the "average annual alcohol attributable years of life lost" as 823/100,000 Californians. Fifty-four alcohol conditions were included in the calculation including acute and chronic conditions such as motor vehicle accidents, cancers, and cardiovascular diseases (Gonzales et al., 2014). California males experienced triple the rate of YLL as compared with their female counterparts (1,215/100,000 versus 434/100,000). Blacks had the highest YLL (1,187/100,000), followed by Hispanics (915/100,000), whites (858/100,000), Alaska Native/American Indian (691/100,000) and Asians (309/100,000) (Gonzales et al., 2014).

TUD: Max et al. estimated that 17.1 years of potential life were lost per smoker due to smoking-related disease in California with no statistical difference between males and females (Max et al., 2009). Causes of premature death included premature birth, low birth weight, sudden infant death syndrome (SIDS), respiratory stress syndrome, lung cancer, heart disease, and asthma.

There is evidence that smoking cessation can reverse negative health effects from tobacco and can produce similar reductions in morbidity and mortality that would be achieved through pharmaceutical interventions commonly prescribed for heart disease patients (Critchley and Capewell, 2003; Suskin et al., 2001). Other studies show that smoking cessation can boost life expectancy; cessation at age 35

²⁵ For more information about SDoH, see CHBRP's publication *Incorporating Relevant Social Determinants of Health into CHBRP Benefit Mandate Analyses* at http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

years resulted in a predicted additional 7 to 8 years of life for men and a predicted additional 6 to 7 years of life for women (Jha et al., 2013; Taylor et al., 2002).

The quantitative long-term impact of SB 11 on premature death associated with OUD, AUD, and TUD is unknown; however, it stands to reason, based on the effectiveness of FDA-approved medications, that there would be a reduction in premature deaths for those enrollees who undergo treatment for their substance use disorder(s).

Economic Loss

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amounts (i.e., valuation of a population's lost years of work over a lifetime). In addition, morbidity associated with the disease or condition of interest can also result in lost productivity by causing a worker to miss days of work due to illness or acting as a caregiver for someone else who is ill.

The National Institute of Drug Abuse reports that substance abuse in the U.S. produces an estimated economic loss of \$740 billion annually. Illicit drugs (including opioids) and misuse of prescription opioids account for \$37 billion, alcohol accounts for \$27 billion, and tobacco accounts for \$168 billion in direct health care costs. The remaining \$507 billion accounts for indirect costs, such as lost work productivity and crime (NIDA, 2017 April).

CHBRP is unable to estimate the impact of SB 11 on the economic loss associated with substance use disorders in California.

APPENDIX A TEXT OF BILL ANALYZED

On December 6, 2018, the California Senate Committee on Health requested that CHBRP analyze the benefit mandate included SB 11 (see sections 2 and 4).

SENATE BILL

No. 11

Introduced by Senator Beall

December 3, 2018

An act to add Sections 1374.77 and 1374.78 to the Health and Safety Code, and to add Sections 10144.41 and 10144.42 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 11, as introduced, Beall. Health care coverage: mental health parity.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires health care service plan contracts or health insurance policies issued, amended, or renewed on or after July 1, 2000, to provide coverage for the diagnosis and medically necessary treatment of severe mental illnesses, as defined, and of serious emotional disturbances of a child, as specified, under the same terms and conditions applied to other medical conditions.

Existing federal law, the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), requires group health plans and health insurance issuers that provides both medical and surgical benefits and mental health or substance use disorder benefits to ensure that financial requirements and treatment limitations applicable to mental health or substance use disorder benefits are no more restrictive than the predominant requirements or limitations applied to substantially all medical and surgical benefits. Existing

state law subjects nongrandfathered individual and small group health care service plan contracts and health insurance policies that provide coverage for essential health benefits to those provisions of the MHPAEA.

This bill would require a health care service plan and a health insurer to submit an annual report to the Department of Managed Health Care or the Department of Insurance, as appropriate, certifying compliance with state and federal mental health parity laws, as specified. The bill

would require the departments to review the reports submitted by health care service plans to ensure compliance with state and federal mental health parity laws, and would require the departments to make the reports and the results of the reviews available upon request and to post the reports and the results of the reviews on the departments' Internet Web site. The bill would also require the departments to report to the Legislature the information obtained through the reports and the results of the review of the reports and on all other activities taken to enforce state and federal mental health parity laws.

Existing law authorizes a health care service plan and a health insurer to utilize formularies, prior authorization, step therapy, or other reasonable medical management practices, as specified, in the provision of outpatient prescription drug coverage.

The bill would prohibit a health care service plan and a health insurer that provides prescription drug benefits for the treatment of substance use disorders from, among other things, imposing any prior authorization requirements on, or any step therapy requirements before authorizing coverage for, a prescription medication approved by the federal Food and Drug Administration for the treatment of substance use disorders.

Because a willful violation of the bill's provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Digest Key

Vote: MAJORITY. Appropriation: NO. Fiscal committee: YES. Local program: YES

Bill Text

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1374.77 is added to the Health and Safety Code, to read:

1374.77. (a) A health care service plan shall submit an annual report to the department on or before March 1 of each year certifying compliance with Sections 1374.72, 1374.76, and 1374.78, and the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law 110-343), hereafter referred to as the MHPAEA, its implementing regulations, and all related federal guidance. The department shall make the report available upon request and shall post the report on the department's Internet Web site.

(b) A health care service plan shall include, but not be limited to, all of the following information in the annual report required pursuant to subdivision (a):

(1) A description of the process used to develop or select the medical necessity criteria for mental health and substance use disorder benefits and the process used to develop or select the medical necessity criteria for medical and surgical benefits.

(2) Identification of all nonquantitative treatment limitations (NQTLs) that are applied to both mental health and substance use disorder benefits and medical and surgical benefits within each classification of benefits.

(3) The results of an analysis that demonstrates that for the medical necessity criteria described in paragraph (1) and for each NQTL identified in paragraph (2), as written and in operation, the processes, strategies, evidentiary standards, or other factors used in applying the medical necessity criteria and each NQTL to mental health and substance use disorder benefits within each classification of benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the medical necessity criteria and each NQTL to medical and surgical benefits within the corresponding classification of benefits. At a minimum, the results of the analysis shall do all of the following:

(A) Identify the factors used to determine that an NQTL will apply to a benefit, including factors that were considered, but rejected.

(B) Identify and define the specific evidentiary standards used to define the factors and any other evidence relied upon in designing each NQTL.

(C) Provide the comparative analyses, including the results of the analyses performed to determine that the processes and strategies used to design each NQTL, as written, and the written processes and strategies used to apply the NQTL to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes and strategies used to design each NQTL, as written, and the written processes and strategies used to apply the NQTL to medical and surgical benefits.

(D) Provide the comparative analyses, including the results of the analyses performed to determine that the processes and strategies used to apply each NQTL, in operation, for mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes or strategies used to apply each NQTL, in operation, for medical and surgical benefits.

(E) Disclose the specific findings and conclusions reached by the health care service plan that the results of the analyses described in this paragraph indicate that the health care service plan is in compliance with the MHPAEA, its implementing regulations, and all related federal guidance.

(c) A report submitted to the department pursuant to this section shall not include any information that may individually identify insureds, including, but not limited to, medical record numbers, names, and addresses.

(d) The department shall review the reports submitted by health care service plans pursuant to subdivision (a) to ensure compliance with this section, Sections 1374.72, 1374.76, and 1374.78, and the MHPAEA, its implementing regulations, and all related federal guidance. The department shall make the results of the review available upon request and shall post the review of the reports on the department's Internet Web site.

(e) (1) The department shall annually report to the Legislature the information obtained through the reports and the results of the review of the reports and on all other activities taken to enforce this section, Sections 1374.72, 1374.76, and 1374.78, and the MHPAEA, its implementing regulations, and all related federal guidance.

(2) The California State Auditor shall review the department's implementation of this section, and shall report its findings from the review to the Legislature.

(3) A report submitted pursuant to this subdivision shall be submitted in accordance with Section 9795 of the Government Code.

(f) For purposes of this section, "nonquantitative treatment limitations" or "NQTL" means those limitations described in the implementing regulations of the MHPAEA.

SEC. 2. Section 1374.78 is added to the Health and Safety Code, to read:

1374.78. Notwithstanding any other law, a health care service plan that provides prescription drug benefits for the treatment of substance use disorders shall place all prescription medications approved by the federal Food and Drug Administration (FDA) for the treatment of substance use disorders on the lowest tier of the drug formulary developed and maintained by the health care service plan, and shall not do any of the following:

(a) Impose any prior authorization requirements on any prescription medication approved by FDA for the treatment of substance use disorders.

(b) Impose any step therapy requirements before authorizing coverage for a prescription medication approved by the FDA for the treatment of substance use disorders.

(c) Exclude coverage for any prescription medication approved by the FDA for the treatment of substance use disorders and any associated counseling or wraparound services on the grounds that those medications and services were court ordered.

SEC. 3. Section 10144.41 is added to the Insurance Code, to read:

10144.41. (a) A health insurer shall submit an annual report to the department on or before March 1 of each year certifying compliance with Sections 10144.4, 10144.42, and 10144.5, and the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Public Law 110-343), hereafter referred to as the MHPAEA, its implementing regulations, and all related federal guidance. The department shall make the report available upon request and shall post the report on the department's Internet Web site.

(b) A health insurer shall include, but not be limited to, all of the following information in the annual report required pursuant to subdivision (a):

(1) A description of the process used to develop or select the medical necessity criteria for mental health and substance use disorder benefits and the process used to develop or select the medical necessity criteria for medical and surgical benefits.

(2) Identification of all nonquantitative treatment limitations (NQTs) that are applied to both mental health and substance use disorder benefits and medical and surgical benefits within each classification of benefits.

(3) The results of an analysis that demonstrates that for the medical necessity criteria described in paragraph (1) and for each NQTL identified in paragraph (2), as written and in operation, the processes, strategies, evidentiary standards, or other factors used in applying the medical necessity criteria and each NQTL to mental health and substance use disorder benefits within each classification of benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the medical necessity criteria and each NQTL to medical and surgical benefits within the corresponding classification of benefits. At a minimum, the results of the analysis shall do all of the following:

(A) Identify the factors used to determine that an NQTL will apply to a benefit, including factors that were considered, but rejected.

(B) Identify and define the specific evidentiary standards used to define the factors and any other evidence relied upon in designing each NQTL.

(C) Provide the comparative analyses, including the results of the analyses performed to determine that the processes and strategies used to design each NQTL, as written, and the written processes and strategies used to apply the NQTL to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes and strategies used to design each NQTL, as written, and the written processes and strategies used to apply the NQTL to medical and surgical benefits.

(D) Provide the comparative analyses, including the results of the analyses performed to determine that the processes and strategies used to apply each NQTL, in operation, for mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes or strategies used to apply each NQTL, in operation, for medical and surgical benefits.

(E) Disclose the specific findings and conclusions reached by the health insurance policy that the results of the analyses described in this paragraph indicate that the health insurance policy is in compliance with the MHPAEA, its implementing regulations, and all related federal guidance.

(c) A report submitted to the department pursuant to this section shall not include any information that may individually identify insureds, including, but not limited to, medical record numbers, names, and addresses.

(d) The department shall review the reports submitted by health insurers pursuant to subdivision (a) to ensure compliance with this section, Sections 10144.4, 10144.42, 10144.5, and the MHPAEA, its implementing regulations, and all related federal guidance. The results of the review shall be made available upon request and shall be posted on the department's Internet Web site.

(e) (1) The department shall annually report to the Legislature the information obtained through the reports and the results of the review of the reports, and on all other activities taken to enforce this section, Sections 10144.4, 10144.42, and 10144.5, and the MHPAEA, its implementing regulations, and all related federal guidance.

(2) The California State Auditor shall review the department's implementation of this section, and shall report its findings from the review to the Legislature.

(3) A report submitted pursuant to this subdivision shall be submitted in accordance with Section 9795 of the Government Code.

(f) For purposes of this section, "nonquantitative treatment limitations" or "NQTL" means those limitations described in the implementing regulations of the MHPAEA.

SEC. 4. Section 10144.42 is added to the Insurance Code, to read:

10144.42. Notwithstanding any other law, a health insurer that provides prescription drug benefits for the treatment of substance use disorders shall place all prescription medications approved by the federal Food and Drug Administration (FDA) for the treatment of substance use disorders on the lowest tier of the drug formulary developed and maintained by the health insurer, and shall not do any of the following:

(a) Impose any prior authorization requirements on any prescription medication approved by FDA for the treatment of substance use disorders.

(b) Impose any step therapy requirements before authorizing coverage for a prescription medication approved by the FDA for the treatment of substance use disorders.

(c) Exclude coverage for any prescription medication approved by the FDA for the treatment of substance use disorders and any associated counseling or wraparound services on the grounds that those medications and services were court ordered.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

This appendix describes methods used in the medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of the effects of prescription medications approved by the United States Food and Drug Administration (FDA) for the treatment of substance use disorders were identified through searches of Web of Science, PubMed, the Cochrane Library, EMBASE, Scopus, and PsycINFO. Websites maintained by the following organizations were also searched: Agency for Healthcare Research and Quality (AHRQ), Scottish Intercollegiate Guideline Network, International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, and the National Institute for Health and Care Excellence (NICE).

The search was limited to abstracts of studies published in English.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

For studies on tobacco use disorder, the search was limited to studies published from 2014 to present (AHRQ Evidence Review synthesized literature through July 2014). For studies on opioid use disorder, the search was limited to studies published from January 2018 to present (CHBRP report AB 2384 synthesized literature through December 2017). For studies on alcohol use disorder, the search was limited to studies published from November 2013 to present (AHRQ Evidence Review synthesized literature through October 2013). Of the 947 articles found in the literature review, 65 were reviewed for potential inclusion in this report on SB 11, and a total of 56 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they were of poor quality, did not report findings from clinical research studies, or did not address use of prescription medication for substance use disorders.

CHBRP also reviewed literature on how prior authorization and step therapy affect substance abuse disorder treatment (including opioid abuse disorder, alcohol abuse disorder, and tobacco use disorder) utilization.

CHBRP did not review literature on the effectiveness of any prescription medication for substance use disorders that is not approved by the FDA for the treatment of substance use disorders.

Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.²⁶ To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;

²⁶ Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence;*
- *Inconclusive evidence; and*
- *Insufficient evidence.*

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Search Terms

Smoking cessation	Drug abuse
Smoking prevention	Medication assisted therapy
Smoking cessation agents	Medication assisted treatment
Tobacco cessation	Methadone
Tobacco use cessation	Naloxone
Varenicline	Naltrexone
Bupropion hcl	Narcotic dependence
Nicoderm CQ	Opiate substitution treatment
Nicorette	Opiates
Nicotrol	Opioid-related disorders/therapy
Nicotine replacement therapy	Opioid treatment
Alcoholism	Opioids
Alcohol disorders	Opioid use disorders
Disulfiram	Prior authorization
Acamprosate	Step therapy
Lofexidine	Utilization management
Bupreorphine	
Buprenorphine plus naloxone	

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, the University of California, Davis and the University of Maryland, as well as the contracted actuarial firm, Milliman, Inc. (Milliman).²⁷

Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.²⁸

This appendix describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

Analysis-Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions specifically relevant to the requirements for pharmacy benefit coverage of outpatient medications for the treatment of substance use disorder (SUD) per SB 11. The impact of SB 11 is limited to medications related to the treatment of opioid use disorder (OUD), alcohol use disorder (AUD) and tobacco use disorder (TUD); these are the three SUDs for which the FDA has approved medications as treatments.

A number of analytic assumptions are mentioned in the *Policy Context* section of the report.

Following are descriptions of methodology and additional assumptions used to develop the estimates of cost impacts:

- SUD prescription drugs used National Drug Codes (NDC) codes and reviewed by a content expert. Additionally, the SUD drug list excluded pain-related use of certain medications and only focused on the medication for SUD based on a content expert's review.
 - CHBRP excluded AUD drugs gabapentin and topiramate due to the high prevalence of for non-AUD conditions.
 - Other SUD medications which are not available through a pharmacy benefit as outpatient prescription drugs due to the need for a clinician to be involved for injections, etc., such as naltrexone intramuscular, were also excluded from the analysis.
 - CHBRP excluded lofexedine from the analysis. This drug received FDA approval in May 2018 and based on CHBRP's content expert's opinion, is not yet in widespread use by clinicians. It is not expected to have a cost impact in 2019 that is attributed to SB 11.

²⁷ CHBRP's authorizing statute, available at www.chbrp.org/docs/authorizing_statute.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

²⁸ See *2017 Cost Impact Analyses: Data Sources, Caveats, and Assumptions*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Table 11. Outpatient Prescription Medications for SUD and Overdose Reversal Medications

Substance Use Disorder	Category	Drug Name (Generic)	Drug Name (Brand)	Formulation
Opioid	Maintenance	Buprenorphine	Subutex	Sublingual Tablet
	Maintenance	Buprenorphine	N/A	Sublingual Tablet
	Maintenance	Buprenorphine	Probuphine	Subdermal Implant
	Maintenance	Buprenorphine XR	Sublocade	SubQ pre-filled syringe
	Maintenance	Buprenorphine; Naloxone	N/A	Sublingual Tablet
	Maintenance	Buprenorphine; Naloxone	Bunavail	Buccal Film
	Maintenance	Buprenorphine; Naloxone	Suboxone	Sublingual Film
	Maintenance	Buprenorphine; Naloxone	Zubsolv	Sublingual Tablet
	Maintenance	Naltrexone	N/A	Tablet
	Emergency	Naloxone	Narcan	Nasal Spray
	Emergency	Naloxone	Evzio	Auto-injector Solution
	Emergency	Naloxone	N/A	Injection Solution
Alcohol	Maintenance	Acamprosate	Campral	Tablet DR
	Maintenance	Disulfiram	Antabuse	Tablet
	Maintenance	Naltrexone	N/A	Tablet
Smoking Cessation	Maintenance	Nicotine	Nicoderm CQ	Patch 24 Hour
	Maintenance	Nicotine	Nicorette	Gum
	Maintenance	Nicotine	Nicorette	Lozenge
	Maintenance	Nicotine	Nicotrol	Inhaler
	Maintenance	Varenicline	Chantix	Tablet
	Maintenance	Bupropion HCL SR	Zyban	Tablet SR 12 Hour

Source: California Health Benefits Review Program, 2019.

The following tables list the HCPCS and CPT codes used to identify counseling services for Substance Use Disorders.

Table 12. CPT/HCPCS Codes Used for Behavioral Therapy Services for Substance Abuse

CPT/HCPCS Code	Description
99406 – 99407, 4000F - 4004F, G0436 - G0437, G9016, G9458, G9906, D1320, C9801 - C9802, G8402, G8453	Smoking and Tobacco Use Cessation Counseling
4158F, 4320F, G0443, G9621, T1006	Alcohol Use Counseling
4306F	Opioid Use Counseling
H0004	Behavioral Health Counseling
H0005, H0015	Alcohol and/or Drug Counseling

Source: California Health Benefits Review Program, 2019.

CHBRP used the Substance Use Disorder diagnosis codes to identify the Substance Use Disorder Outpatient Drug users in Milliman’s proprietary 2016 Consolidated Health Cost Guidelines Sources Database (CHSD), which contains both Commercial and Medi-Cal claims and encounters.

Table 13. Diagnosis Codes Used for Substance Use Disorder

Diagnosis Code (ICD-10)	Description
F10.10-F10.99	Alcohol Abuse/Dependence/Use
F11.10-F11.99	Opioid Abuse/Dependence/Use
F17.200-F17.2999	Nicotine Dependence

Source: California Health Benefits Review Program, 2019.

CHBRP identified all individuals with SUD diagnosis codes throughout the year to establish a baseline estimate of the number of diagnosed individuals with a SUD. CHBRP relied upon the NDC codes to establish the utilization levels for each medication dosage and formulation prescribed for treatment of a SUD. CHBRP used the CPT/HCPCS codes to identify SUD counseling for members identified as using one or more of the specified SUD medications.

Baseline medication unit costs were trended at an annual rate 7.5% per year from 2016 to 2019 (Milliman 2018 Commercial Health Cost Guidelines™). The 7.5% trend represents the 2017 drug trends for the commercial enrollees represented within the report. As the increase in utilization seems unlikely to impact it, the unit cost per script is expected to be unchanged by SB 11, postmandate.

Based on 2017 Mental Health and Substance Abuse Treatment Trends analysis performed by Truven Health Analytics (Health Leaders Media, 2017), baseline behavioral therapy services unit cost were trended at an annual rate 10% per year from 2016 to 2019. The analysis projects utilization rates per 1,000 enrollees changing postmandate due to the removal of utilization management and for the inclusion on tier 1 of plan formularies for some enrollees (see Table 13). Baseline utilization rates per 1,000 were developed based on CHSD data for members who use SUD medications.

Postmandate Offset Services – Inpatient, Outpatient, and Professional

There are likely to be changes in the utilization of non-SUD-related services as a result of receiving SUD treatment. Mohlman et al. (2016) indicated reductions in inpatient days and emergency department visits associated with treatment of opioid use disorder. Mark et al. (2010) provided estimated reductions in detoxification days, inpatient days and emergency department visits associated with use of medications to treat alcohol use disorder.

Unit costs were estimated using a combination of the Mohlman estimates, CHSD data, and relationships between commercial and Medi-Cal unit costs. CHBRP relied upon CHSD data for commercial and Medi-Cal utilization and cost estimate. SB 11 will not cause a significant change in average cost per service postmandate.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits SB 11 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares the benefits provided by self-insured health plans or policies (which are not regulated by DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements for treatment or service. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

APPENDIX D PHARMACY BENEFITS AND STATE-LEVEL MANDATES

As noted in Table 1, for 2019, CHBRP estimates that approximately 1.4% of enrollees in plans regulated by the California Department of Managed Health Care (DMHC) or policies regulated by the California Department of Insurance (CDI) have no pharmacy benefit and 3.0% of these enrollees have pharmacy benefit coverage that is not regulated by DMHC or CDI.

Table 14. Pharmacy Benefit Coverage, 2019

Enrollees in DMHC-Regulated Plans and in CDI-Regulated Policies	
<i>Total</i>	
Enrollee Counts	
Total enrollees in plans/policies subject to state Mandates (a)	23,433,000
Pharmacy Benefit Coverage	
DMHC or CDI regulated brand name and generic medication coverage	95.5%
DMHC or CDI regulated generic only coverage	0.1%
No pharmacy benefit	1.4%
Other pharmacy benefit	3.0%

Source: California Health Benefits Review Program, 2019.

Notes: (a) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organization

Additional detail about the presence and absence of pharmacy benefit coverage in various market segments is presented below, in Table 15, Table 16, and Table 17.

Relevant State and Federal Law

- A number of overlapping state and federal laws require broad pharmacy benefit coverage or coverage for particular medications, but the requirements are not applicable to all forms of health insurance
- Some (but not all) small group and individual market health care service plans and health insurance policies are required to provide coverage for medications as part of coverage for Essential Health Benefits (EHBs).²⁹
- Some (but not all) large group, small group, and individual market health care service plans and health insurance policies are required to provide pharmacy benefit coverage for particular medications as part of preventive services, but not for all medications.³⁰
- Some state-level mandates, applicable to some or all plans and policies regulated by DMHC or CDI, require pharmacy benefit coverage for particular medications. For example, there is a mandate that requires coverage for insulin and prescription medications for the treatment of diabetes but does not require coverage for medications that treat diabetes-related conditions.³¹

However, this mix of laws does not require that all enrollees in plans and policies regulated by DMHC or CDI have a pharmacy benefit.

Presence or Absence of Pharmacy Benefit Coverage for Outpatient Medications and Related Regulation

Pharmacy benefit coverage of medications was estimated through surveys and queries. For enrollees in the privately funded markets regulated by DMHC and CDI, coverage was determined by responses to a survey of the largest providers of health insurance in California. Responses to this survey represent 95% of enrollees in these markets. The California Public Employees' Retirement System (CalPERS) was queried regarding coverage among DMHC-regulated plan enrollees associated with CalPERS. The California Department of Health Care Services (DHCS) was queried about coverage among Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

From this information, CHBRP concluded that most enrollees have pharmacy benefit coverage through their DMHC-regulated plan or CDI-regulated policy. These enrollees' pharmacy benefit is generally used when acquiring medications at an outpatient pharmacy or mail order service. When pharmacy benefit coverage is handled through a subcontracting pharmacy benefit management (PBM) organization, the plan or policy, licensed by DMHC or CDI, requires the subcontracting PBM to comply with relevant state-level health insurance benefit mandates.

As pharmacy benefit coverage is not universally required, some enrollees in DMHC-regulated plans and CDI-regulated policies have no pharmacy benefit. Although these enrollees' health insurance covers prescription medications delivered during a hospital (or other facility) admission and some prescription medications that are dispensed through a clinician's office, these enrollees' health insurance would not generally help them acquire medications intended for outpatient use. As noted above, there are some

²⁹ California Health & Safety Code: 1367.005, 1367.006, 1367.0065; California Insurance Code: 10112.27, 10112.28, 10112.285; Federal Affordable Care Act of 2010: Section 1301, 1302, and Section 1201 modifying Section 2707 of the PHSA

³⁰ California Health & Safety Code: 1367.002; California Insurance Code: 10112.2; Federal Affordable Care Act of 2010: Section 1001 modifying Section 2713 of the PHSA

³¹ California Health & Safety Code: 1367.51 and California Insurance Code: 10176.61

medication-specific exceptions, such as insulin, but coverage would be limited to those specific outpatient medications.

In terms of alternate regulation, some enrollees who have no pharmacy benefit through their DMHC-regulated plan or CDI-regulated policy still do have a pharmacy benefit — but have it through another source, one that is not regulated by DMHC or CDI. Such a circumstance can occur if, for example, an employer arranges for a large group plan to exclude pharmacy benefit coverage and then contracts separately with a PBM to administer a pharmacy benefit. In this example, the PBM is not a subcontractor to a plan or insurer; it is directly contracting with the employer. If the contracting PBM is not licensed by either DMHC or CDI, it is not subject to state-level health insurance benefit mandates (see enrollees with “other pharmacy benefit” in the tables in this appendix).

Table 15. Pharmacy Benefit Coverage in the Large Group and Publicly Funded Markets, 2019

	DMHC-Regulated Plans					CDI-Regulated Policies	
	Privately Funded Large Group		Publicly Funded Plans			Privately Funded Large Group	
	Grand-fathered	Non-Grand-fathered	CalPERS HMOs (a)	MCMC (Under 65) (b)	MCMC (65+) (b)	Grandfathered	Non-Grand-fathered
Enrollee Counts							
Total enrollees in plans/policies subject to state mandates (c)	1,860,000	7,511,000	887,000	6,832,000	678,000	5,000	209,000
Pharmacy Benefit Coverage							
DMHC or CDI regulated brand name and generic medication coverage	95.9%	90.5%	79.5%	100.0%	100.0%	80.3%	86.8%
DMHC or CDI regulated generic only coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
No pharmacy benefit	3.8%	3.0%	0.0%	0.0%	0.0%	14.9%	2.2%
Other pharmacy benefit	0.3%	6.5%	20.5%	0.0%	0.0%	4.8%	11.0%

Source: California Health Benefits Review Program, 2019.

Notes: (a) As of September 2017, 56% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2019.

(b) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS..

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care.

Table 16. Pharmacy Benefit Coverage in the DMHC-regulated Small Group and Individual Markets, 2019

	Privately Funded Small Group				Privately Funded Individual			
	Grand-fathered	Non-Grand-fathered Covered California(a)	Non-Grand-fathered Mirror Plans (b)	Other Non-Grand-fathered	Grand-fathered	Non-Grand-fathered Covered California(a)	Non-Grand-fathered Mirror Plans (b)	Other Non-Grand-fathered
Enrollee Counts								
Total enrollees in plans/policies subject to state mandates (c)	355,000	49,000	687,000	2,026,000	103,000	1,157,000	611,000	210,000
Pharmacy Benefit Coverage								
DMHC regulated brand name and generic medication coverage	99.9%	100.0%	100.0%	100.0%	90.7%	100.0%	100.0%	100.0%
DMHC regulated generic only coverage	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
No pharmacy benefit	0.0%	0.0%	0.0%	0.0%	9.3%	0.0%	0.0%	0.0%
Other pharmacy benefit	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: California Health Benefits Review Program, 2019.

Notes: (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called “Covered California.”

(b) “Mirror Plans” are qualified health plans (QHPs) available outside of Covered California.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees’ Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care.

Table 17. Pharmacy Benefit Coverage in CDI-regulated Small Group and Individual Markets, 2019

	Privately Funded Small Group				Privately Funded Individual			
	Grand-fathered	Non-Grand-fathered Covered California (a)	Non-Grand-fathered Mirror Plans (b)	Other Non-Grand-fathered	Grand-fathered	Non-Grand-fathered Covered California (a)	Non-Grand-fathered Mirror Plans (b)	Other Non-Grand-fathered
Enrollee Counts								
Total enrollees in plans/policies subject to state mandates (c)	1,000	3,000	23,000	106,000	186,000	3,000	22,000	26,000
Pharmacy Benefit Coverage								
CDI regulated brand name and generic medication coverage	96.5%	100.0%	100.0%	100.0%	50.9%	100.0%	100.0%	100.0%
CDI regulated generic only coverage	0.0%	0.0%	0.0%	0.0%	39.1%	0.0%	0.0%	0.0%
No pharmacy benefit	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	0.0%
Other pharmacy benefit	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: California Health Benefits Review Program, 2019.

Notes: (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called “Covered California.”

(b) “Mirror Plans” are qualified health plans (QHPs) available outside of Covered California.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

Key: CalPERS HMOs = California Public Employees’ Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Operated Health Systems; MCMC = Medi-Cal Managed Care.

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A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **Milliman USA**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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