TECHNICAL BRIEF

AB 1970

Mental Health or Substance Use Disorders

CHBRP

About the Technical Brief

This document provides details on the analytical foundation for CHBRP's analysis of AB 1970. While the main report synthesizes key findings for immediate policy consideration, this document is designed to support a deeper understanding of the background of the topic of the legislation and CHBRP's methodology and research in conducting its analysis. It contains the data sources, methods, assumptions, and other bill-specific considerations necessary for legislative staff, fiscal analysts, and other stakeholders to fully understand the scope and impact of the proposed measure.

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Acronyms and Terminology

Acronyms

AB – Assembly Bill

ACA – Affordable Care Act

AUD – alcohol use disorder

CA – California

CalPERS – California Public Employees' Retirement System

CDC – Centers for Disease Control and Prevention

CDI – California Department of Insurance

CHBRP – California Health Benefits Review Program

COHS – County Organized Health System

DEA – U.S. Drug Enforcement Administration

DHCS – Department of Health Care Services

DMHC – Department of Managed Health Care

ED – emergency department

EHB – essential health benefits

FDA – U.S. Food and Drug Administration

HRSA – Health Resources and Services Administration

LAI – long-acting injectables

MAUD – medications for alcohol use disorder

MOUD – medications for opioid use disorder

MHPAEA – Mental Health Parity and Addiction Equity Act

NDC – national drug code

OUD – opioid use disorder

PA – prior authorization

SMI – serious mental illness

SAMHSA – Substance Abuse and Mental Health Services Administration

SB – Senate Bill

SDOH – social drivers of health

SNRI – serotonin and norepinephrine reuptake inhibitors

SSRI – selective serotonin reuptake inhibitors

SUD – substance use disorder

TAR – treatment authorization request

Terminology

CHBRP uses the following terminology for this analysis:

Coverage-related:

Prior authorization (PA):[1] Also known as precertification, prior approval, or prospective review, PA is a utilization management technique commonly used by health insurance carriers to ensure that a given medical intervention meets the insurance plan or policy's criteria for coverage (Newcomer et al., 2017). PA was developed as a tool for insurers to assess the appropriateness of treatment that would result in a hospital admission or a high-cost procedure (Resneck, 2020). The primary uses of PA include:

- **Coverage evaluation:** Allows evaluation of whether a test, treatment, or service is medically necessary and otherwise covered.
- **Safety:** Acts as a safeguard to confirm that a patient's medications are compatible and provides an opportunity to check that proper diagnostic testing has been completed to ensure patient safety prior to use of a requested treatment. PA also reduces inappropriate patient care by stopping unsafe or low-value care that is inconsistent with the most recent clinical evidence.

[1] More information about prior authorization is available in CHBRP's 2023 analysis *Prior Authorization in California*.

- **Cost control:** Imposition of PA for nonpreferred medications can encourage the use of preferred medications that can be procured at lower price.

Step therapy: Also known as "fail-first" protocols, step therapy may be applied to prescription medications by health plans and insurers to control costs, ensure medication compatibility, and manage safety. Health plans/insurers may use step therapy protocols to apply clinical guidelines established by professional societies and other recognized organizations to treatment plans. They require an enrollee to try and fail one or more medications prior to receiving coverage for the initially prescribed medication. Step therapy protocols usually recommend starting with a medication that is less expensive (generics) and/or has more "post-marketing safety experience" (PBMI, 2015).

- **Step therapy** as defined for this bill in Insurance code 10123.201: "Step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

Utilization management: Utilization management techniques are used by health plans and insurers to control costs, ensure medication compatibility, and manage safety. Examples include benefit coverage requirements related to prior authorization, step therapy, quantity limits, and limits related to the age or sex of the enrollee (such as prescription-only infant formula or prostate cancer screening for men).

SMI/SUD-related and/or bill specific:

FDA-labeled indications and implicit step therapy: The FDA-approved labeling for a drug defines its indicated uses, recommended dosing, and any prerequisites for use. For certain serious mental illness (SMI) and substance use disorder (SUD) medications (e.g., long-acting injectables [LAIs]), the FDA label itself may require that a patient first be established on an oral formulation of the same medication before transitioning to the injectable form. This is intended to assess tolerability and confirm therapeutic response prior to initiating a longer-acting formulation. In this way, the FDA label functions as a form of implicit step therapy, as it mandates a prior treatment step before the drug can be appropriately initiated. For example, the labeling for some LAI antipsychotics requires an oral stabilization period before the first injection is administered. Payers and utilization management programs may reference these FDA-labeled prerequisites when establishing PA or TAR criteria, meaning that clinical step therapy requirements may be grounded in, and consistent with, the drug's own approved labeling rather than solely imposed by the health plan.

Medical benefit: Drugs that are physician-ordered and administered under the supervision of a physician, generally in a hospital, clinic, or infusion center, are typically covered through the medical benefit. This coverage includes the associated hospital stay or office visit. In the context of SMI and SUD, this often applies to medications such as LAI antipsychotics (e.g., administered in a clinic setting), intravenous or intramuscular treatments, and medically supervised detoxification agents.

Medi-Cal Rx: The pharmacy benefit program for Medi-Cal. Medi-Cal Rx is administered by the Department of Health Care Services (DHCS) and covers outpatient prescription drugs for Medi-Cal beneficiaries. For SMI and SUD, this includes coverage of antipsychotics, mood stabilizers, medications for OUD, and other behavioral health drugs dispensed at the pharmacy.

Medi-Cal medical benefit (drug coverage): Certain drugs administered in a clinical setting continue to be covered under the medical benefit in Medi-Cal, rather than through Medi-Cal Rx. These include physician-administered medications such as LAI antipsychotics given in a provider's office, infusion therapies, and drugs administered during an inpatient stay or outpatient visit.

Pharmacy benefit: Covers outpatient prescription drugs, typically those filled at a retail pharmacy, mail-order pharmacy, or specialty pharmacy. For individuals with SMI and SUD, this commonly includes oral antipsychotics, mood stabilizers, antidepressants, and medications for opioid use disorder (OUD) such as buprenorphine or naltrexone in oral or film form.

Serious mental illness: As defined in subdivision (b) of Section 5600.3 of the Welfare and Institutions Code,[2] includes schizophrenia, bipolar disorder, post-traumatic stress disorder, as well as major affective disorders or other severely disabling mental disorders.

Treatment authorization request (TAR): A PA mechanism used in Medi-Cal to request approval for certain medications, services, or levels of care before they are provided. TARs apply to both the medical and pharmacy benefits, meaning they may be required for physician-administered drugs billed during an office visit or clinical setting, as well as for outpatient drugs dispensed through Medi-Cal Rx. In the context of SMI and SUD, TARs are particularly relevant for LAI antipsychotics administered in a clinical setting, where clinical criteria must be met.

[2] Welfare and Institutions Code Section 5600.3 (2025). https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=WIC&sectionNum=5600.3.

Legislative Text Analyzed

CHBRP analyzed AB 1970 Mental Health or Substance Use Disorders, as amended on March 24, 2026 per the request of the California Assembly Committee on Health. The text analyzed is copied below.

SECTION 1. Section 1367.202 is added to the Health and Safety Code, to read:

1367.202. (a) Notwithstanding any other law, a health care service plan contract that is issued, amended, or renewed on or after January 1, 2027, shall not impose step therapy as a prerequisite to authorizing coverage of any prescription drug used for the treatment of a serious mental illness or substance use disorder.

(b) For purposes of this section, the following definitions apply:

(1) "Serious mental illness" has the same meaning as "serious mental disorder" as defined in subdivision (b) of Section 5600.3 of the Welfare and Institutions Code.

(2) "Step therapy" means the same as defined in Section 10123.201 of the Insurance Code.

(3) "Substance use disorder" means a substance-related and addictive disorder, as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders.

(c) This section shall apply to Medi-Cal managed care plan contracts only to the extent that the State Department of Health Care Services obtains any necessary federal approvals, and federal financial participation under the Medi-Cal program is available and not otherwise jeopardized.

(d) This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

(e) For purposes of this section, the prohibition on step therapy shall not apply when the United States Food and Drug Administration-labeled indications and usage of a drug indicate that some prior medication must be taken.

(f) This section does not apply to a specialized health care service plan contract that covers only dental or vision benefits or a Medicare supplement contract.

SEC. 2. Section 10123.1931 is added to the Insurance Code, to read:

10123.1931. (a) Notwithstanding any other law, a health insurance policy that is issued, amended, or renewed on or after January 1, 2027, shall not impose step therapy as a prerequisite to authorizing coverage of any prescription drug used for the treatment of a serious mental illness or substance use disorder.

(b) For purposes of this section, the following definitions apply:

(1) "Serious mental illness" has the same meaning as "serious mental disorder" as defined in subdivision (b) of Section 5600.3 of the Welfare and Institutions Code.

(2) "Step therapy" means the same as defined in Section 10123.201 of the Insurance Code.

(3) “Substance use disorder” means a substance-related and addictive disorder, as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders.

(c) For purposes of this section, the prohibition on step therapy shall not apply when the United States Food and Drug Administration-labeled indications and usage of a drug indicate that some prior medication must be taken.

(d) This section does not apply to dental-only or vision-only health insurance, Medicare supplement insurance, or nonhealth disability insurance policies.

SEC. 3.

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.

Policy Framework

This brief provides additional material to support the findings and recommendations presented in CHBRP's *Analysis of Assembly Bill 1970 Mental health or substance use disorders*.[3] The following sections contain details on the California and federal landscape. While this information is essential to the completeness of the analysis, it has been placed in this separate brief to maintain the flow of the main report. Readers are encouraged to consult this material for deeper insights into existing laws and technical details that informed the analysis and conclusions of the main report.

California Policy Landscape

Mental Health Parity

California law[4] requires plans and policies to cover all mental health and substance use disorders listed in the most recent edition of either the *International Classification of Disease* or the *Diagnostic and Statistical Manual of Mental Disorders* at parity with other medical services. This requirement is similar to those specified by the federal Mental Health Parity and Addiction Equity Act (MHPAEA, see below), but applies to all health insurance plans and policies subject to either the Health and Safety Code or the Insurance Code. Plans and policies that provide hospital, medical, or surgical coverage are required to provide coverage for medically necessary treatment of mental health and substance use disorders, under the same terms and conditions applied to other medical conditions.

Previous California Legislation

A variety of bills related to step therapy in general and for other specific medical conditions have been introduced and enacted over the past several years, but none related to the prohibition of step therapy for prescription drugs to treat SMI or substance use disorder (SUD). Examples are described below.

- SB 40, enacted in 2025, prohibited health plans and insurers from imposing step therapy as a prerequisite to authorizing coverage of insulin.
- AB 347 requires health care service plans, effective January 1, 2022, to expeditiously grant step therapy exceptions within specified time periods when use of the prescription drug required under step therapy is inconsistent with good professional practice. Under AB 347, California health plans must have a clear and accessible step therapy exception process.
- AB 374, enacted in 2015, requires compliant override procedures when step therapy protocols are applicable to an outpatient prescription drug benefit. The legislation authorized a request for an exception to a health plan or insurer's step therapy process for prescription drugs to be submitted in the same manner as a request for prior authorization (PA) for prescription drugs, and requires the plan or insurer to respond to the request in the same manner as a request for PA for prescription drugs. The bill requires the Department of Managed Health Care (DMHC) and the Department of Insurance (CDI) to include a provision for step therapy exception requests in the uniform PA form specified above.
- SB 306, effective July 1, 2026, requires DMHC and CDI to report statistics on covered health care services subject to PA and the rate at which they are approved or modified. The bill requires the departments to identify the health care services approved at a rate that meets or exceeds the threshold rate of 90%, and, on or before July 1, 2027, publish a list of the services identified. Beginning no later than January 1, 2028, the bill requires that a plan or insurer cease requiring PA for the most frequently approved covered health care services.

[3] Available on www.chbrp.org in Completed Analyses
[4] HSC §1374.72; INS §10144.5 and 10123.15.

Several other bills have been introduced in the California legislature in 2026, including:

- AB 1887, which would prohibit plans and insurers from imposing PA, step therapy, or other utilization review for a drug prescribed for the treatment of a rare disease, as specified, unless a biosimilar, interchangeable biologic, or generic version of the drug is available.
- SB 950, which would require plans and insurers to include coverage for all medically necessary treatments or medications, as determined by a health care provider, approved by the U.S. Food and Drug Administration (FDA) for the treatment of Alzheimer's disease or other related dementia, and it would prohibit plans and insurers from imposing step therapy protocols as a prerequisite to authorizing that coverage.
- SB 1023, which would prohibit plans and insurers from subjecting antiretroviral drugs, drug devices, or drug products that are medically necessary for the prevention of HIV/AIDS to PA or step therapy.

Federal Policy Landscape

Federal Mental Health Parity and Addiction Equity Act

The federal Mental Health Parity and Addiction Equity Act (MHPAEA) addresses parity for behavioral health benefits.[5] The MHPAEA requires that when mental health or SUD services are covered, cost-sharing terms and treatment limits be no more restrictive than the predominant terms or limits applied to medical/surgical benefits. Furthermore, for any behavioral health benefits that are covered, coverage must be provided in all classification of benefits (inpatient in-network benefits, prescription drug benefits, emergency care benefits, etc.) in which comparative medical/surgical benefits are provided. The law protects enrollees from facing greater restrictions on access to behavioral health benefits as compared to medical/surgical benefits. The MHPAEA directly applies to large-group health insurance, but the Affordable Care Act (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 described previously,[6] although the state law applies to some plans and policies not captured in the MHPAEA.

Additional information regarding MHPAEA and other federal mental health legislation is available in the 2020 analysis of SB 855 Mental Health Parity (CHBRP, 2020).

Consolidated Appropriations Act

The Consolidated Appropriations Act of 2023 removed the federal requirement for practitioners to apply for a special waiver prior to prescribing buprenorphine for the treatment of opioid use disorder (OUD) (SAMHSA, 2024b). Now, any health care professional who has a U.S. Drug Enforcement Administration (DEA) registration for Schedule III controlled medications (such as acetaminophen with codeine) can prescribe buprenorphine. This Act also removed the limits on the number of patients a practitioner may treat (SAMHSA, 2024b). With these changes, more providers will be able to prescribe buprenorphine to more patients, which may result in increased patient access to buprenorphine.

However, pharmacies must comply with federal and state dispensing regulations for buprenorphine as a Schedule III controlled substance, and suppliers of controlled substances must monitor and report any orders of opioid products that are atypically large, unusual, or considered suspicious (Qato et al., 2022). As a result of these regulations and risk of liability for opioid diversion, suppliers, pharmacies, and pharmacists may restrict supply and dispensing of buprenorphine at pharmacies. The barriers related to dispensing regulations include delayed or suspended buprenorphine shipments to pharmacies, buprenorphine not stocked in pharmacy inventories, and buprenorphine prescriptions declined and not filled (Qato et al., 2022).

[5] Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as amended by the ACA.
[6] HSC Section 1374.72; INS Section 10144.5 and 10123.15.

Federal and state policies and other barriers have limited adolescents' access to medications for OUD. Prior to 2024, federal policies required persons younger than aged 18 years to demonstrate two prior OUD treatment attempts without medication before methadone can be initiated; even when adolescents meet these requirements, it is rare for methadone clinics to allow access (Hadland et al., 2018; SAMHSA, 2024c).

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 AB 1970 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[7,8]

Essential health benefits

In California, nongrandfathered[9] individual and small-group health insurance is generally required to cover EHBs.[10] In 2027, approximately 11.5% of all Californians will be enrolled in a plan or policy that must cover EHBs.[11]

States may require state-regulated health insurance to offer benefits that exceed EHBs.[12,13,14,15] Should California do so, the state could be required to defray the cost of additionally mandated benefits for enrollees in health plans or policies purchased through Covered California, the state's health insurance marketplace. However, state benefit mandates specifying provider types, cost sharing, or other details of existing benefit coverage would not meet the definition of state benefit mandates that could exceed EHBs.[16,17] It should be noted that federal guidance establishes the "State" as the entity that would identify when a state benefit mandate exceed EHBs;[18] thus, DMHC and CDI would determine whether the benefit would require defrayal of costs.

AB 1970 does not change the coverage requirement; it only addresses step therapy for the drugs used to treat SMI and SUDs, so the proposed mandate would not exceed the current definition of EHBs in California.

[7] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to qualified health plans sold in Covered California — to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website.
[8] Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.
[9] A grandfathered health plan is "a group health plan that was created — or an individual health insurance policy that was purchased — on or before March 23, 2010. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers."
[10] For more detail, see CHBRP's issue brief *Essential Health Benefits: An Overview of Benefits, Benchmark Plan Options, and EHBs in California*.
[11] See CHBRP's resource *Sources of Health Insurance in California*.
[12] ACA Section 1311(d)(3).
[13] 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.
[14] However, as laid out in the Final Rule on EHBs U.S. Department of Health and Human Services (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.
[15] In February 2026, HHS released a proposed rule that would alter what benefits would be determined to exceed EHBs. The conclusions in this analysis of AB 1970 are subject to change based on the final language of the regulations. U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2027; and Basic Health Program. Proposed Rule. Federal Register, Vol. 91, No. 28. February 11, 2026.
[16] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and qualified health plan issuers would be responsible for calculating the cost that must be defrayed. 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.
[17] As of 2024, Maine, Massachusetts, Minnesota, Montana, Utah, and Virginia mandate benefits that exceed EHBs (GAO, 2024). For more information about defrayal, refer to CHBRP's issue brief *Essential Health Benefits: Exceeding EHBs and the Defrayal Requirement*.
[18] Essential Health Benefits Final Rule. Federal Register, Vol. 87. No. 27. February 25, 2013.

Background on Serious Mental Illness and Substance Use Disorder

Serious Mental Illness and Substance Use Disorder

AB 1970 addresses treatment for SMI among adults and does not address serious emotional disturbance (SED)[19] among youth. These categories of mental illness are described below.

Serious mental illness (SMI) is defined as a diagnosable mental, behavioral, or emotional disorder (within the past year) in a person aged 18 years or older that substantially interferes with their life and ability to function (SAMHSA, 2024a). For the purpose of this bill, SMI includes but is not limited to schizophrenia, bipolar disorder, post-traumatic stress disorder, and major affective disorders or other severely disabling mental disorders.

Schizophrenia spectrum and other psychotic disorders including schizotypal (personality) disorder are defined by abnormalities in one or more of the following five domains: delusions, hallucinations, disorganized thinking (speech), grossly disorganized or abnormal motor behavior (including catatonia), and negative symptoms (APA, 2022a). **Bipolar and related disorders** are mental health conditions characterized by periodic, intense emotional states affecting a person's mood, energy, and ability to function (APA, 2024). **Major affective disorders,** including major depressive disorder, are defined as significant mental health conditions that result in severe mood disturbances (Serafini et al., 2021). Major affective disorders are associated with high morbidity and negative outcomes, including suicidal behavior (Serafini et al., 2021). **Schizoaffective disorder** is among the most frequently misdiagnosed psychiatric disorders in clinical practice (Wy and Saadabadi, 2023). It involves symptoms of both schizophrenia (such as hallucinations or delusions) and major mood episodes (including depression or mania) that occur over a prolonged period and are not caused by substance use or another medical condition (Wy and Saadabadi, 2023).

Substance use disorder (SUD) is a chronic substance-related and addictive condition shaped by both environmental and genetic factors (APA, 2022b). It includes disorders associated with the following 10 classes of drugs: alcohol; caffeine; cannabis; hallucinogens; inhalants; opioids; sedatives, hypnotics, or anxiolytics; stimulants (amphetamine-type substances, cocaine, and other stimulants); tobacco; and other (or unknown) substances. When taken in excess, these drugs activate the brain's reward system, reinforcing use and producing feelings of pleasure or a "high." Research suggests that some individuals may exhibit neurobiological vulnerabilities such as reduced self-control before substance use begins, while substance use itself can further impair brain mechanisms related to inhibition and decision-making (Aliev et al., 2015; Koob and Volkow, 2016; Lucantonio et al., 2012; Paschen-Moffitt et al., 2011).

Because step therapy is most common for newer, higher-cost medications, the analysis of AB 1970 focuses on the following subcategories of substance-related and addictive disorders: **opioid use disorder and alcohol use disorder. Opioid use disorder (OUD)** is a chronic disease characterized by a pattern of opioid use that leads to problems or distress (Lu et al., 2024). **Alcohol use disorder (AUD)** is a medical condition characterized as a problematic pattern of alcohol use leading to clinically significant impairment or distress (NIAAA, 2025). OUD and AUD can be mild, moderate, or severe, depending on the number of symptoms a patient has experienced in the previous 12 months.

Serious Mental Illness and Substance Use Disorder Prevalence in California

CHBRP reports the most recent data available and cites national data when California data are unavailable.

[19] Serious emotional disturbance (SED) is defined as a diagnosable mental, behavioral, or emotional disorder (within the past year) in a person aged younger than 18 years that results in functional impairment that substantially interferes with or limits the child's role or functioning in family, school, or community activities (SAMHSA, 2024a).

See Table 1 for prevalence rates of SMI and SUDs in California (SAMHSA, 2025b; SAMHSA, 2023). Between 2022 and 2023, 31.4% of California adults had a mental illness or SUD in the past year (KFF, n.d.-b). More than 1.2 million adults in California live with an SMI (DHCS, n.d.).

Table 1. Prevalence Rates of Serious Mental Illness and Substance Use Disorders in California, 2021–2023

Condition	Estimated Prevalence Rate	Year
Serious mental illness in past year (aged 18 and older)	5.3%	2021-2023
Substance use disorder in past year (aged 12 and older)	16.7%	2021-2023
Alcohol use disorder in past year (aged 12 and older)	10.43%	2022-2023
Opioid use disorder in past year (aged 12 and older)	1.86%	2022-2023
Serious mental illness and substance use disorder co-occurrence (aged 18 and older)	2.13%	2022-2023

Sources: California Health Benefits Review Program (CHBRP), 2026; SAMHSA, 2025b; SAMHSA, 2023.

Serious Mental Illness Prevalence and Mortality

Estimates of the prevalence of schizophrenia and related psychotic disorders in the United States range between 0.25% and 0.64% (NIMH, n.d.-b).[20] An estimated 2.8% of U.S. adults had bipolar disorder in the past year, with an estimated 4.4% of U.S. adults experiencing bipolar disorder at some time in their lives (NIMH, n.d.-a). An estimated 21.0 million adults in the United States had at least one major depressive episode, representing 8.3% of all U.S. adults (NIMH, 2023). Although the exact prevalence of schizoaffective disorder is not known, experts estimate that it ranges from 0.2% to 0.5% (NIMH, n.d.-b).

In 2023, suicide was the 11th leading cause of death overall in the United States, claiming the lives of over 49,300 people (CDC, 2023; NIMH, 2025). There were 6,902 violent deaths to Californians in 2020, 60 percent of which were due to suicide (4,143). The rate of death by suicide was 10.4 suicides per 100,000 individuals (CDPH, 2023). California's suicide rate remained relatively stable from 2015 to 2019 and was consistently lower than both the national rate and the Healthy People 2030 target (12.8 per 100,000) (Holt and Hahn, 2022). Suicide rates varied by county in California. The 2017 to 2019 suicide rate per 100,000 population ranged from a high of 37.3 in Trinity County to a low of 6.2 in Imperial County (Holt and Hahn, 2022).

Substance Use Disorder Prevalence and Mortality

Opioid use disorder

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 (GAO, 2018). In addition to a greater risk of mortality and premature mortality, people with OUD are at a higher risk for developing cardiac dysrhythmias; respiratory depression; impairment in daily function (Blanco et al., 2013); and contraction of infections including HIV, hepatitis (A, B, and C), tuberculosis, and endocarditis, which lead to increased use of health care services to treat those conditions (SAMHSA, 2015; Tsui et al., 2014).

[20] Schizophrenia is typically diagnosed in the late teen years to early 30s and tends to emerge earlier in males (late adolescence to early 20s) than females (early 20s to early 30s).

OUD prevalence in California was 1.86% among people aged 12 years and older in in 2022 and 2023 (SAMHSA, 2023). The number of opioid-related overdose deaths in California has increased over the last decade, driven by fentanyl-related overdose deaths (CDPH, 2025a). In 2021, 7,175 Californians died from an opioid-related overdose, which was an increase of 119% from 2019 (CDPH, 2025a). In 2024, 5,462 deaths were related to any opioid overdose and 4,770 deaths were related to fentanyl overdose in California (CDPH, 2026). In 2024, 17,083 emergency department (ED) visits were related to any opioid overdose in California (CDPH, 2026).

Alcohol use disorder

AUD is the third leading cause of preventable mortality in the United States. It is responsible for 1 in 5 deaths among U.S. adults aged 20 to 49 (CDC, 2025). 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 in California was 10.43% among people aged 12 or older in 2022 and 2023 (SAMHSA, 2023). In 2021, more than half (55%) of California adults reported consuming at least one alcoholic beverage in the past 30 days, 16% reported binge drinking, and 6% reported that they drank heavily (CDPH, 2024a). An average of 18,984 adult California residents aged 20 and older died per year due to excessive alcohol use from 2020 to 2021 (CDPH, 2024a). Approximately 62% of deaths resulted from chronic causes (cancer, heart disease, and diseases of the liver, gallbladder, and pancreas), and almost 38% of deaths resulted from acute causes (injuries, violence, and motor vehicle crashes) (Jiménez et al., 2023). These deaths led to an average of 472,361 years of potential life lost per year, shortening the lives of those who died by an average of more than 25 years (CDPH, 2024a).

Serious Mental Illness and Substance Use Disorder Co-Occurrence

Co-occurring mental illness and SUDs are common in the United States. Adults with mental illness in the United States are more likely to use illicit drugs, binge drink, and are at a higher risk of developing an SUD compared to those without mental illness (SAMHSA, 2019). Similarly, individuals with SUDs are particularly vulnerable to developing mental health conditions and other costly chronic diseases like HIV, hepatitis C, heart disease, and chronic pain (SAMHSA, 2024a). Common risk factors contribute to both substance use and mental illness, including an individual's genes, social environment, and other life circumstances like traumatic experiences (NIDA, 2024).

Approximately 21.2 million U.S. adults had a co-occurring SUD and any mental illness in 2024. Roughly 33% of adults aged 18 and over in the United States with any mental illness also have an SUD (SAMHSA, 2024d). An analysis of 2015 national mental health outcome measures reported to SAMHSA found that 34.4% of California adults who were utilizing county mental health services had co-occurring SMI and SUD (Holt and Looby, 2018). Diagnosing and treating co-occurring substance use and other mental disorders is complex because patients may have overlapping symptoms and symptoms that are more persistent, severe, and resistant to treatment compared with patients who have either disorder alone (NIDA, 2024)

Chronic and Relapsing Nature of Serious Mental Illness and Substance Use Disorders

SMI and SUDs are long-term chronic illnesses involving substantial functional impairment over multiple symptom domains (Evans et al., 2016). Patients with SMI and SUDs often have complex and chronic treatment needs (Evans et al., 2016). People with SUDs often have periods of remission and relapse and typically require long-term treatment consisting of multiple episodes of treatment over several years (Dennis and Scott, 2007; Proctor and Herschman, 2014). Overall, successful SUD recovery typically requires an average of two to five rounds of treatment (Kelly et al., 2019). Many other patients do not have long-term complete abstinence, but treatment can reduce the severity and intensity of use and harms associated with use. Many patients are never able to achieve long-term recovery. Therefore, treatment goals not only focus on abstinence, but also on reducing harm from the negative consequences of substance abuse. It is possible for a patient who has more than one SUD to be in recovery from one type of SUD, but not another. Health care professionals

note that relapse and return to opioid or alcohol use 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, 2020). For many persons with OUD or AUD, maintenance treatment plans are recommended to sustain abstinence (Walter and Soyka, 2016).

Treatments for Serious Mental Illness and Substance Use Disorders

Treatments for Serious Mental Illness

The treatment of SMI can involve pharmacotherapy, psychotherapy, or a combination of both. CHBRP interprets AB 1970 to apply generally to psychopharmacology provided by licensed providers including psychiatrists, pharmacists, and psychiatric clinical nurse specialists; other types of treatments including psychotherapy are not included in this analysis.

There are many different types of SMI treatments of varying levels of care, visit lengths, in both inpatient and outpatient settings, and in-person or telehealth. Relevant drug classes for treating SMI include mood stabilizers, antipsychotics, and antidepressants. Based on a review of prescription drugs used to treat SMI that are most likely to be subject to step therapy, the following medications are the focus of CHBRP's analysis (see Table 2): **atypical antipsychotics, long-acting injectable (LAI) antipsychotics, and atypical antidepressants**. The type of medication prescribed depends on a variety of factors including patient need, condition, and possible contraindications with other medication use.

Antipsychotics are a class of drugs that mainly treat psychosis-related conditions and symptoms. Antipsychotics work by altering how certain brain signals, known as neurotransmitters, influence feelings and behavior (Cleveland Clinic, 2024). Antipsychotics treat a range of mood disorders, such as schizophrenia, schizoaffective disorder, bipolar disorder, mania, and major depressive disorder. **Atypical antipsychotics** are also known as **second generation antipsychotics**. These medications are serotonin-dopamine antagonists — meaning they block receptors like serotonin and dopamine while activating other serotonin and dopamine receptors. Atypical antipsychotics treat symptoms of schizophrenia; acute mania; major depressive disorder with psychotic features; severe agitation; borderline personality disorder; and substance-induced psychotic disorder (Chokhawala and Stevens, 2023). **Long-acting injectable (LAI) antipsychotics** are alternative formulations of first- and second-generation antipsychotics that are administered via injection by a health professional (Clauss and Daws, 2022). LAI antipsychotics are increasingly used to manage both chronic and first-episode psychosis and are recommended for those with previous problems with adherence.

Antidepressants are a group of drugs used to treat the symptoms of depression and prevent future occurrences. This class of medications aims to support the ability to maintain a normal daily routine. They are also taken to relieve symptoms such as restlessness, anxiety, and sleep problems, and to prevent suicidal thoughts. These medications are often combined with psychotherapy (IQWiG, 2024). The beginning of a major depressive episode is often a symptom of most mood disorders, and the usual first response is antidepressant monotherapy (but typically not recommended for bipolar disorders) (Shim et al., 2017). **Atypical antidepressants** fall outside of the main classes of antidepressants and are commonly prescribed for individuals who have tried other types of antidepressants that didn't work. They can also be used as a first-line treatment depending on symptoms and co-occurrent mental health conditions in addition to depression. They also help with depression by affecting different chemical messengers (neurotransmitters) used to communicate between brain cells (Mayo Clinic, 2019). In California, two atypical antidepressants that are administered orally are subject to step therapy protocols (vortioxetine and vilazodone).

Treatments for Substance Use Disorders

The treatment of SUD can involve pharmacotherapy, psychotherapy, or a combination of both. Treatment may include prescription medications, counseling, residential treatment programs, and peer support groups like Alcoholics Anonymous and Narcotics Anonymous (SAMHSA, 1997). There are many different types of SUD treatments, of varying levels of care, visit lengths, in both inpatient and outpatient settings, and in-person or telehealth. In California, the majority of clients in SUD treatment receive outpatient care (Kelleher et al., 2025). About 72% of California's SUD treatment facilities had programs tailored for clients diagnosed with co-occurring mental illness and SUDs (Kelleher et al., 2025).

Based on a review of prescription drugs used to treat SUDs that are most likely to be subject to step therapy, the following medications are the focus of CHBRP's analysis (see Table 2).

Opioid use disorder treatment

Medications for OUD (also called MOUD) relieve cravings, prevent withdrawal symptoms, and block the euphoric effects of illicit opioids (APA, 2025). Similar to the majority of chronic diseases, there is no cure for OUD or any other addiction. Instead, the goal of treatment with MOUD is to reduce the psychological (brain) and physical (body) symptoms that cause the continued use of illicit opioids. Some persons with OUD may require long-term medication treatment to ensure sustained recovery.

LAI for the treatment of OUD include **buprenorphine** and **naltrexone** (Garett and Young, 2022; Mackey et al., 2020). Buprenorphine may be administered as **buprenorphine hydrochloride (HCl)** or **buprenorphine extended-release (ER)**. The primary difference between buprenorphine HCl and buprenorphine ER is their duration of action and delivery method. The HCl method requires more frequent dosing (e.g., every 3-12 hours or daily) and the ER method is administered weekly or monthly. The **extended-release injectable formulation for naltrexone** is approved for the treatment of OUD and is administered every 4 weeks, or once a month, by a health care practitioner. Extended-release naltrexone is approved for preventing relapse after detoxification. **Naloxone hydrochloride (HCl)** is a lifesaving, nonaddictive medication used to rapidly reverse opioid overdoses (Medline Plus, 2019). It displaces opioids from receptors in the brain to restore normal breathing.

Alcohol use disorder treatment

Medications for AUD (also called MAUD) include FDA-approved pharmacological treatments employed to manage dependence on alcohol, reduce consumption, and prevent relapse (SAMHSA, 2025a). These medications most commonly function by limiting the pleasure of alcohol or causing a negative reaction to alcohol (SAMHSA, 2025a). **Extended-release naltrexone** can also be used to treat AUD. Naltrexone binds to the endorphin receptors in the body, blocking the effects and feelings of alcohol (SAMHSA, 2025c). Naltrexone reduces alcohol cravings and the amount of alcohol consumed.

Nationally, 1.6% of adults with AUD used medications for treatment in 2019, and 4.6% of adults who had AUD received any treatment in 2021 (Han et al., 2021; NIAAA, 2026).

Table 2. Categories and Medications Included in CHBRP AB 1970 Analysis

Category	Generic Name	Drug (Branded)	Included in AB 1970 Analysis*
Substance use disorder (SUD)			
	buprenorphine HCl/naloxone HCl	Suboxone	Yes
	buprenorphine ER	Sublocade	Yes
	naltrexone ER	Vivitrol	Yes
	buprenorphine extended release	Brixadi	
	naltrexone oral		
	disulfiram		
	acamprosate		

Category	Generic Name	Drug (Branded)	Included in AB 1970 Analysis*
Serious mental illness (SMI)			
Atypical (second-generation) antipsychotic (oral)	brexpiprazole	Rexulti	Yes
	cariprazine	Vraylar	Yes
	lumateperone	Caplyta	Yes
	olanzapine/samidorphan	Lybalvi	Yes
	iloperazone	Fanapt	Yes
	xanomeline/trospium chloride	Cobenfy	Yes
	aripiprazole		
	risperidone		
	paliperidone		
	olanzapine		
	quetiapine		
	clozapine		
	ziprasidone		
	lurasidone		
	asenapine		
First-generation antipsychotic (oral)	haloperidol		
	fluphenazine		
	chlorpromazine		
	perphenazine		
	thiothixene		
Long-acting injectable (LAI) antipsychotic	aripiprazole ER	Abilify Maintena	
	aripiprazole	Abilify Asimtufii	
	aripiprazole lauroxil	Aristada	Yes
	paliperidone palmitate	Invega	Yes
	risperidone	Perseris	
	risperidone	Uzedy	

Category	Generic Name	Drug (Branded)	Included in AB 1970 Analysis*
Mood stabilizers (oral)	lithium		
	valproate / divalproex		
	lamotrigine		
	carbamazepine		
	oxcarbazepine		
Antidepressants: SSRIs (oral)	sertraline		
	fluoxetine		
	paroxetine		
	citalopram		
	escitalopram		
	fluvoxamine ER		
Antidepressants: SNRIs (oral)	venlafaxine		
	desvenlafaxine		
	duloxetine		
	milnacipran		
	levomilnacipran	Fetzima	
Atypical antidepressant (oral)	vortioxetine	Trintellix	Yes
	vilazodone	Viibryd	Yes
	trazodone		
	mirtazapine		
	bupropion		

Source: California Health Benefits Review Program, 2026.
Note: *Drugs were chosen for inclusion in this analysis of AB 1970 based on CHBRP's survey of carriers.
Key: ER = extended release; HCl = hydrochloride; SNRI = serotonin and norepinephrine reuptake inhibitors; SSRI = selective serotonin reuptake inhibitors.

Step Therapy and Treatment of Serious Mental Illness and Substance Use Disorder

Step therapy or "fail-first" protocols are one type of several utilization management protocols (Nayak and Pearson, 2014) applied to prescription medications by health plans and insurers to control costs, ensure medication compatibility, and manage safety. They require an enrollee to try and fail one or more medications prior to receiving coverage for the initially prescribed medication. They are also an effective enforcement tool for clinical recommendations and guidelines. Health plans and insurers use them to apply clinical guidelines established by professional societies and other recognized organizations, such as American Society of Addiction Medicine and the National Comprehensive Cancer Network,

respectively. In addition, step therapy protocols are used to enforce the FDA indication for use of a medication in relation to other medication therapy trials or failures.

Step therapy protocols usually require starting with a medication that is less expensive (generics) and/or has more "post-marketing safety experience" (PBMI, 2015). In addition, they sometimes require starting with a less potent medication or dosage, perhaps with fewer side effects, and graduating to more potent medications as necessary (e.g., from prescription Motrin to OxyContin to treat pain). Generally, more expensive medications are covered when the patient fails to respond to the medication required by step therapy (PBMI, 2018). Similar to other utilization management protocols, step therapy policies vary among plans and insurers. As formularies are updated based on the introduction of new treatments and medical guidelines, step therapy requirements are added to new medications as appropriate.

Disparities[21] in Serious Mental Illness and Substance Use Disorders

Disparities are noticeable and preventable or modifiable differences between groups of people. Health insurance benefit mandates or related legislation may impact disparities. Where intersections between health insurance benefit mandates and social determinants or systemic factors exist, CHBRP describes relevant literature.

CHBRP found literature identifying disparities in disease outcomes and access to care for SMI and SUDs by race and ethnicity, sex and gender, gender identity and sexual orientation, age, income, and geography.

Race and Ethnicity

In 2019, American Indian and Alaska Native adults in California experienced the highest rates of SMI (6.8%) among racial and ethnic groups, followed by Black Californians (5.3%) (Holt and Hahn, 2022). Schizophrenia was the leading cause of hospitalizations and ED visits for Black Californians, with rates more than three times those of any other racial and ethnic groups (CDPH, 2024b). People of color may be overrepresented in specific diagnosed mental health conditions due partly to implicit provider bias and diagnostic criteria that fail to incorporate patients' lived experiences (CDPH, 2024b). For example, Black individuals may receive a misdiagnosis of schizophrenia when expressing symptoms related to other mood disorders or post-traumatic stress disorder (CDPH, 2024b).

Black Californians had the highest rate of nonfatal ED visits for opioids excluding heroin in 2023. American Indian/Alaska Native and Black Californians had the highest rates of nonfatal ED visits for heroin in 2023 (CDPH, 2023). Black Californians had the highest rate of opioid-related hospitalizations in 2023 and experienced the highest percentage increase of all groups from 2018 to 2023 (222%) (CDPH, 2023). American Indian/Alaska Native Californians had the highest rates of drug- and alcohol-induced deaths in 2020, while Asian, Native Hawaiian, and Pacific Islander Californians had the lowest (Kariisa et al., 2022). In 2023, American Indian/Alaska Native Californians had the highest rate of opioid overdose deaths followed by Black Californians (CDPH, 2023). The admission rate for state- and county-contracted SUD programs was highest among American Indian and Alaska Native Californians in state fiscal year 2023 (CDPH, 2024b).

In 2019, 31% of White persons with OUD received medications for treatment compared to 20% of Black or other non-Latino multiracial groups and 15% of Latino persons (Mauro et al., 2022). Prescribing practices changed significantly for opioid use disorder (buprenorphine and LAI naltrexone) after the start of the COVID-19 pandemic, with a 30.5% decrease for buprenorphine and 10.5% decrease of LAI naltrexone across all races/ethnicities. However, decreases were greater for Black, Latino, and Asian persons in regard to buprenorphine prescription fills compared to White persons (Nguyen et al., 2022). Racial disparities in overdoses have emerged with greater increases among Black and Latino persons (Furr-Holden et al., 2021). In California, the opioid-related overdose death rate was highest among American Indian/Alaskan Native and Black persons compared to White persons, and health care utilization for opioid-related overdoses in the ED and hospitalization were highest among Black persons during 2021 (CDPH, 2026).

[21] Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population (Wyatt et al., 2016).

Disparities exist for AUD prevalence and outcomes by race/ethnicity nationally and in California. Nationally, American Indian/Alaskan Native persons have the highest prevalence of AUD (SAMHSA, 2022b). Latino and Black persons have relatively lower rates of AUD than do White persons. However, ethnic and racial disparities exist for alcohol-related diseases, problems, and deaths in these groups (NIAAA, 2018). For example, Latino and Black persons have a higher risk for developing alcohol-related liver disease and subsequent cirrhosis mortality than White persons. In California, alcohol-induced death rates during 2016 were twice as high for American Indian/Alaskan Native persons compared to all other racial/ethnic groups (Holt and Hahn, 2022).

Sex and Gender[22]

In 2019, females living in California were slightly more likely than males to experience SMI, at 15% compared to 11.1% (Holt and Hahn, 2022). From 2017 to 2019, males were over three times as likely as females to die by suicide in California (Holt and Hahn, 2022).

The rates of both alcohol- and drug-induced deaths were nearly three times higher among males than females in California (Hirschi, 2021; Jiménez et al., 2023). The admission rate for state- and county-contracted SUD programs was higher for males than females in 2023 (Kelleher et al., 2025). Men have higher rates of both alcohol-induced deaths and opioid-related overdose deaths with rates two to three times higher compared to females (Holt and Hahn, 2022; CDPH, 2025a). Men in California also have higher rates of opioid-related overdose ED visits and hospitalizations compared to women (CDPH, 2025a). Women with OUD often present to treatment with more co-occurring mental health and SUDs and life instability compared to men (Huhn et al., 2019; Leone et al., 2017; Vo et al., 2016). Men with OUD are more likely to present to treatment with persistent drug use and risky drug-related behavior compared to women (Huhn et al., 2019). Men have higher rates of alcohol attributable death compared to women (Jiménez et al., 2023). Women with AUD have increased risk of developing alcohol-related heart disease, cancer, and liver disease and have higher rates of co-occurring psychiatric disorders compared to men with AUD (Erol and Karpyak, 2015). Compared to men, women with AUD experience alcohol cravings as a way to cope with negative emotion and stress (Peltier et al., 2019) and are more likely to have family or spouse history of AUD (Khan et al., 2013). Women with AUD are less likely to receive treatment compared to men (7.9% vs. 9.2%) (McCrady et al., 2020).

OUD and opioid-related deaths are increasingly impacting pregnant individuals in the United States, largely due to the recent introduction of fentanyl (Goldman-Mellor et al., 2025). In California, the prevalence of prenatal OUD doubled between 2010 and 2022 (Goldman-Mellor et al., 2025). Between 2020 and 2022, 7.3% of pregnant Californians reported any alcohol use during their third trimester (CDPH, 2025b). Maternal mental health challenges also impact Californians during their perinatal period. Approximately 14.8% of pregnant Californians reported prenatal depression symptoms, and 14.1% reported depression symptoms during postpartum in 2020 to 2022 (CDPH, 2025b).

Gender Identity and Sexual Orientation[23]

In 2020, lesbian, gay, and bisexual adult OUD prevalence was 2.4% (SAMHSA, 2022a). Opioid misuse (heroin, prescription opioid misuse) prevalence was 6.7% for lesbian, gay, and bisexual persons compared to 3.4% for the general population in the United States (SAMHSA, 2022a). Among lesbian, gay, and bisexual adults with opioid misuse in the past year, 11.9% also reported heavy alcohol use in the past month (SAMHSA, 2022a). In the United States, there is limited availability of LGBTQ-specific OUD treatment programs. Of the programs or facilities that advertised both medications for OUD and LGBTQ special programs for OUD treatment, 24% actually offered those services (Paschen-Wolff et al., 2022). In 2020, lesbian, gay, or bisexual adults had higher rates of AUD compared to the general population in the United States (aged 18 to 25 years: 23.8% vs. 15.6%; aged 26 and older: 20.8% vs. 10.3%) (SAMHSA, 2022a). Among lesbian, gay, or

[22] CHBRP uses the National Academies of Sciences, Engineering, and Medicine distinction between "sex" and "gender": "'Sex' refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. 'Gender' refers to a multidimensional construct that links gender identity, a core element of a person's individual identity; gender expression, which is how a person communicates their gender to others; and social and cultural expectations about status, characteristics, and behavior that are associated with sex traits." (NASEM, 2022)

[23] CHBRP defines gender identity as one's internal sense of one's own gender, or the gender in which a person identifies, whether it be male, female, or nonbinary. Gender identity and sexual orientation are different facets of one's identity; an individual's gender does not determine a person's sexual orientation (i.e., a person's emotional, romantic, or sexual attraction to other people) (ACOG, 2024).

bisexual adults with SMI, 25.2% reported heavy alcohol use in the past month (SAMHSA, 2022a). The National Institute on Drug Abuse reports a series of statistics regarding disparities in alcohol misuse/abuse according to sexual orientation (NIDA, 2017). 2013 survey data from the U.S. Census Bureau showed that 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).

Age

The average annual rate of SUDs for young adults (aged 18 to 25) was more than three times the rate for adolescents (aged 12 to 17) (SAMHSA, 2024a). Almost 30 percent of young adults reported binge alcohol use in the past month (SAMHSA, 2024a). The rate of cocaine use in the past year by young adults was almost twice the rate of older adults (SAMHSA, 2024a). Adults aged 18 to 25 had higher rates of co-occurring SUD and SMI than adults in other age groups (SAMHSA, 2024a). In 2020, both drug- and alcohol-induced death rates were highest for adults aged 36 to 64 (CDC, 2024). The admission rate for state- and county-contracted SUD programs was highest among adults aged 26 to 35 living in California in fiscal year 2023 (Kelleher et al., 2025). In California, young adults aged 18 to 25 years had a higher rate of AUD compared to adults aged 26 and older (16.4% vs. 10.4%) (SAMHSA, 2023). Adolescents experience disparities in access to OUD treatment compared to adults. Many adolescents do not receive treatment for OUD in the United States, and when they do receive treatment, only about 1 in 4 receive timely administration of buprenorphine, methadone, or naltrexone (Hadland et al., 2018). In 2019, the National Survey on Drug Use and Health (NSDUH) found that no adolescents (aged 12–17 years) received medications for OUD (Mauro et al., 2022). In 2016 and 2017, 5.4% of Californians aged 12 years and older reported needing but not receiving AUD treatment (9.9% among those aged 18–25 years) (SAMHSA, n.d.).

Income

The prevalence of SMI was highest among Californians with the lowest incomes. Nearly one in 12 (8.5%) California adults in families with incomes below 100% of the federal poverty level had SMI (Holt and Hahn, 2022). Between 2021 and 2022, Californians with Medicaid were nearly twice as likely to have an SMI than Californians with private insurance (KFF, n.d.-a).

Geography

SMI and SUD remain major concerns in rural communities across the United States, including in California (Southwest Rural Health Research Center, 2025). For example, opioid-related mortality (overall and fentanyl specific) disproportionately affects rural north coast counties in California (CDPH, 2026). Individuals living in rural areas face disparities in behavioral health care access stemming from various infrastructural and social factors such as poverty, uninsurance, lack of reliable transportation, limited access to broadband, hospital closures, and mental health professional shortage gaps (Danon et al., 2025; Guerrero et al., 2025). For example, 65% and 47% of rural counties in the United States lack a resident psychiatrist and psychologist, respectively, compared to 27% and 19% of metropolitan counties (Danon et al., 2025).

Twenty-five counties in California have no adult acute psychiatric beds (Holt and Hahn, 2022). The number of licensed mental health professionals per population also varies considerably by region in California. The Greater Bay Area's rates were higher than the state average for almost all licensed mental health professions, while the Inland Empire and San Joaquin Valley regions had rates that were lower than average for almost all licensed mental health professions (Holt and Hahn, 2022).

Summary of Disparities

Disparities in SMI and SUD in California are pronounced across race, ethnicity, gender, sexual orientation, age, income, and geography, and are influenced by social drivers of health. American Indian, Alaska Native, Black, Latino, and

multiracial populations experience higher rates of SMI, substance-related hospitalizations, and overdose deaths, with disparities compounded by limited access to treatment and provider bias. Men face higher rates of substance-related mortality, while women experience more co-occurring disorders and barriers to treatment; LGBTQ+ individuals have elevated rates of substance use. Younger adults and low-income populations show higher prevalence of SMI and SUD, while many adolescents and adults experience delayed or unmet treatment needs. Addressing these disparities requires considering both health coverage policies and social factors such as housing, education, and income that shape risk and access to care.

Barriers to Accessing Prescription Drugs for Serious Mental Illness and Substance Use Disorders

System- or Policy-Level Barriers

Prior authorization

Utilization management includes step therapy, PA, and quantity limits. Recent empirical evidence suggests that PA is associated with delayed access, delayed care, and decreased patient satisfaction and outcomes (Busis et al., 2024). PA requirements for medications prescribed for SUDs can delay care and increase the time it takes a person to begin treatment for several days (60% wait at least 1 business day and 26% wait at least 3 business days [AMA, 2018]). A delay in beginning medication treatment can mean a prolonged period that the patient experiences withdrawal, the person loses readiness to begin treatment, and periods of forced abstinence and return to use (AMA, 2022; Latronica, 2021). Qualitative and survey data show that among prescribers of buprenorphine, insurance PA requirements are a common barrier to prescribing buprenorphine (Andraka-Christou et al., 2022; Haffajee et al., 2019; Marino et al., 2019). PA requirements can also limit the use of specific medication formulations that might be preferred by some patients due to side effect profiles or effectiveness (Latronica, 2021). In 2021, 17.5% of commercial formularies required PA for extended-release buprenorphine injection compared to 5.4% that required PA for immediate release buprenorphine products (Nguyen et al., 2022).

In addition to PA, insurance coverage limitations for medication for SUDs through formularies (i.e., only certain or no medications covered) and step therapy ("fail first") requirements can cause delays in beginning treatment and loss of motivation to begin treatment for some patients (Andraka-Christou and Capone, 2018; Latronica, 2021). When medications or certain formulations of medications are not included on formularies, the patient will have a period of waiting when providers will need to find a different appropriate formulation covered under the plan and policy, and if PA or step therapy is required, additional delay in care will occur (Andraka-Christou and Capone, 2018). LAI naltrexone is not always included on plan formularies, and patients would have to pay out of pocket or have PA requirements that other medications for SUDs do not require (Alanis-Hirsch et al., 2016).

Federal restrictions on prescribing and dispensing buprenorphine

As noted in the *Policy Framework* section, the Consolidated Appropriations Act of 2023 removed the federal requirement that limited the prescription of buprenorphine for OUD (SAMHSA, 2024b). Now any health care professional who has a DEA registration for Schedule III controlled medications (such as acetaminophen with codeine) can prescribe buprenorphine. This Act also removed the limits on the number of patients a practitioner may treat (SAMHSA, 2024b). The barriers related to dispensing regulations include delayed or suspended buprenorphine shipments to pharmacies, buprenorphine not stocked in pharmacy inventories, and buprenorphine prescriptions declined and not filled (Qato et al., 2022).

Provider-Level Barriers

Provider supply and location

Insurance coverage does not guarantee access to care for behavioral health. Access to care is also affected by the supply of providers. Patients report a variety of challenges in accessing needed or preferred behavioral health providers, as well as dissatisfaction with their insurance in the availability of mental health and SUD providers (Panchal and Lo, 2024). There were nearly 100,000 mental health professionals in California in 2020, unevenly distributed across the state (measured by per capita ratios) (Holt and Hahn, 2022). In 2023, only 203 patient care physicians (less than one per 100,000 population) were board certified in addiction medicine or addiction psychiatry in California (Kelleher et al., 2025). California had 98,941 licensed mental health professionals in 2020, with only 4,660 of those being licensed psychiatrists (Holt and Hahn, 2022). The distribution of different mental health professionals by county varies drastically per 100,000 population. The Greater Bay Area's rates were higher than the state average for almost all mental health professions (including licensed psychiatrists), while the Inland Empire and San Joaquin Valley regions had rates that were lower than average for almost all mental health professions (Holt and Hahn, 2022). Provider supply, including geographic access to existing providers as well as the number of appropriate providers per capita, and provider attitudes are barriers to treatment (Sharma et al., 2017). In California, there are providers available to prescribe medications for OUD treatment in almost every county, but most counties (around 30) have fewer providers per capita than the national average of 9.7 prescribing providers per 100,000 residents (Haffajee et al., 2019).

Patients may face supply issues or geographical barriers to accessing LAI naltrexone or buprenorphine ER, as it needs to be injected in a medical office (clinic) rather than dispensed at a pharmacy. The medical office (clinic) would need to order and store the medication and have staff available for the injection, and the patient would need to make an appointment and travel to the medical office (Sharma et al., 2017). According to the SAMHSA Opioid Treatment Program (OTP) Directory, there are 168 OTPs in California (SAMHSA, 2026). Typically, AUD treatment occurs in specialty care settings such as rehabilitation facilities, mental health centers, and non–health care settings such as peer support groups. Barriers to initiating treatment for persons with AUD include accessibility to these facilities and the referrals needed (Mintz et al., 2021).

Provider willingness

Provider willingness to treat SUDs can also be limited; not all providers are comfortable prescribing medications to treat these conditions due to a lack of clinical knowledge and SUD education in medical school and residency, lack of office space and support resources, time pressure, PA requirements, financial sustainability, concern of diversion, and personal beliefs or stigma against treating SUDs (Campopiano et al., 2024; Dhanani et al., 2022; Garrett and Young, 2022; Haffajee et al., 2019; Marino et al., 2019; McNeely et al., 2018; Mintz et al., 2021; Williams et al., 2018). Although most pharmacists are willing to dispense buprenorphine, there are often barriers and pharmacists reported discomfort with dispensing of buprenorphine when potential risk factors for diversion were present (Hill et al., 2023). Community-based pharmacists identified insurance PA, difficulty reaching prescribers with questions, concerns about buprenorphine diversion, and DEA investigation risk as the biggest barriers to dispensing buprenorphine. Policies and perceived barriers also vary by type of pharmacy. Independent pharmacies have more restrictive policies in place than commercial pharmacies (Hill et al., 2023).

Administrative burden

Health care providers have reported several administrative barriers to provision of pharmacological treatments due to PA processes. For example, in an observational study conducted with a sample of primary care and medicine subspeciality group practices in Tucson, Arizona, five PA pain points were described from prescribers and their staff: (1) information transfer gaps; (2) format disparities; (3) outdated technologies; (4) care consequences; and (5) workarounds (Bhattacharjee et al., 2019). In a PA physician survey conducted by the American Medical Association, findings included major administrative workloads due to PA, leading to diverted time from patient care. The study found that physicians spent on average 13 hours per week on PA tasks, with 60% of practices not having staff dedicated solely to PA tasks (AMA, 2024). Approximately 93 to 94% of physicians reported PA delaying access to necessary care for their patients, with 94% saying PA had a negative impact on clinical outcomes (AMA, 2024). Recent empirical evidence suggests that PA is also associated with provider burnout (Busis et al., 2024).

Patient-Level Barriers

Patient-level barriers for seeking, beginning, or continuing SMI or SUD treatment include stigma, previous experience with treatment, knowledge gaps, logistical barriers, and inconsistent treatment access (Mackey et al., 2020).

Stigma and knowledge

Stigma and negative treatment experiences are commonly identified by patients seeking treatment for SMI and SUDs (Mackey et al., 2020; Mintz et al., 2021). The stigma of and the ability to acknowledge their SMI or SUD may reduce their desire or ability to seek care, even more so for those who have co-occurring SMI and SUD (Fisher et al., 2017; Jones et al., 2015; Verissimo and Grella, 2017). The stigma against medications for SUDs can be due to beliefs that they are a "crutch" or the person is weak or a failure for needing them (Mackey et al., 2020). Concern for stigma or legal-related consequences of seeking treatment might deter some persons from seeking treatment (Corrigan and Nieweglowski, 2018), despite the fact that the Americans with Disabilities Act (ADA) prevents discrimination against persons with SUD who are in recovery and who do not engage in illegal drug use or alcohol use while working, and it includes protection during recovery when medications are prescribed for treatment (ADA, 2026; Foreman et al., 2000). It also provides protection for persons with past OUD with a "record of disability" (ADA, 2026). Prior experience with OUD treatment is also a barrier to initiating treatment if previous experiences were negative.

Additional patient-level barriers are related to knowledge deficits or gaps, which include where to obtain care, lack of education about medications for treatment, misconceptions of the medications, and uncertainty of what to expect with long-acting buprenorphine and naltrexone (Garett and Young, 2022; Mackey et al., 2021).

Inconsistent treatment access

Among California adults with any mental illness, 36.8% reported receiving mental health services, which include treatment, counseling, or prescription medication during the past year, lower than the national rate of 43.6% (Holt and Hahn, 2022). While adults in California with SMI were more likely to receive treatment, 40% did not get any (Holt and Hahn, 2022). Approximately 5.7% of Californians reported needing mental health treatment or counseling but not being able to get it; of these, over a third (36%) reported not receiving treatment due to cost (Holt and Hahn, 2022). Approximately 10.4% of Californians experienced a delay or did not get their prescription medicine in 2024 (CHIS, 2024). In 2024, roughly 4 in 10 (41.8%) California teens experienced a delay or did not get the needed mental health care in the past 12 months (CHIS, 2024).

Summary of Barriers

Access to treatment for SMI and SUDs is impeded by system- and provider-level barriers. Insurance requirements such as PA, formulary restrictions, and step therapy delay initiation of medications, reducing patient readiness and continuity of care. Federal regulations and pharmacy practices can further limit access to medications like buprenorphine and naltrexone, while provider shortages, uneven geographic distribution, and provider discomfort treating SUDs constrain availability. Patient-level barriers, including stigma, prior negative treatment experiences, logistical challenges, and knowledge gaps further reduce engagement with care.

Societal Impact of Serious Mental Illness and Substance Use Disorders in California

The societal impact discussed here is relevant to a broader population than AB 1970 impacts, as AB 1970 would affect the health insurance of a subset of Californians (see *Policy Framework* section). See the *AB 1970 Impacts: Benefit Coverage and Cost* section in CHBRP's *Analysis of Assembly Bill 1970 Mental health or substance use disorders* for estimates of direct cost impacts for the specific population targeted by AB 1970.

The presence of SMI and SUD in California and the United States has direct and indirect economic and societal costs.

In 2020, U.S. mental health spending was projected to reach $238 billion — about 6% of total health care spending — with public payers such as Medicaid covering the majority of costs (Holt and Hahn, 2022). Public payers were projected to pay for 63% of mental health expenditures, compared to 53% of overall health expenditures (Holt and Hahn, 2022). SMI is particularly costly, with an estimated lifetime economic burden of about $1.85 million per person (with a diagnosis by the age of 25). Direct medical costs account for 12 to 47% of the economic burden of SMI, with approximately 53 to 84% of SMI's burden coming indirectly from lost productivity, unemployment, and early mortality (Hedt, 2019). In California, Medicaid financed 41% of hospitalizations for SMI in the state in 2014 (Hedt, 2019). While the state spent about $2.9 billion on county-based adult mental health services in 2021, estimates suggest more than $12 billion would be required to provide evidence-based care to all eligible residents in need (RAND, 2025).

The California Department of Public Health (CDPH) estimates that SUDs in California produce an estimated economic loss of over $230 billion annually. Illicit drugs and misuse of prescription opioids account for $18 billion, and alcohol accounts for $45 billion in direct health care costs (Jiménez et al., 2013). The remaining $155 billion accounts for indirect costs, such as lost work productivity and crime (Jiménez et al., 2013). In 2010, California taxpayers spent $35.0 billion due to excessive alcohol use, and when adjusted for inflation, the estimate increased to $47.3 billion in 2022 (NCDAS, n.d.). In California, SUDs result in significant mortality, with an estimated 25,000 deaths due to alcohol and illicit substances annually (CDC, 2025; CDPH, 2025a).

Summary of Social Impact of Serious Mental Illness and Substance Use Disorders in California

SMI and SUDs in California and the United States create substantial economic and societal costs, with lifetime costs of SMI estimated at $1.85 million per person with a diagnosis by the age of 25 and SUD-related losses in California exceeding $230 billion annually. Public payers, including Medicaid, cover the majority of these costs, yet current spending falls far short of what would be needed to provide evidence-based care to all residents in need. Beyond direct medical costs, most of the economic burden stems from lost productivity, crime, and early mortality, with SUDs contributing to an estimated 25,000 deaths annually in California.

Medical Effectiveness

As discussed in the *Policy Framework* section, AB 1970 would prohibit a plan or policy from imposing step therapy as a prerequisite to authorizing coverage of any prescription drug used for the treatment of SMI or SUD, as defined. The prohibition on step therapy does not apply when the FDA-labeled indications and usage of a drug indicate that some prior medication must be taken. This medical effectiveness review summarizes findings from evidence[24] on the impact of step therapy requirements for prescription drugs used to treat SMI and SUDs, focusing on utilization of these drugs, health outcomes, and utilization of other health care services. This medical effectiveness review also compares the effectiveness of branded drugs that are often subject to step therapy with generic drugs in the same drug category.

Serious mental illness, as defined in subdivision (b) of Section 5600.3 of the Welfare and Institutions Code,[25] includes schizophrenia, bipolar disorder, post-traumatic stress disorder, and major affective disorders or other severely disabling mental disorders.

Substance use disorder, as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders, includes opioid use disorder, alcohol use disorder, and tobacco use disorder.

Research Approach and Methods

The search related to step therapy requirements was limited to studies published in the United States from 2020 to the present because CHBRP had previously conducted thorough literature searches on step therapy topics in 2020 for AB 2144, in 2015 for AB 374, and in 2013 for AB 899.[26] Study designs included systematic reviews and/or meta-analyses, controlled clinical trials, and non-randomized comparative studies. The search related to the comparative effectiveness of prescription drugs used to treat SMI and SUDs was similarly limited to studies from 2020 to present, but it included studies published in the United States and internationally. Study designs were limited to systematic reviews and/or meta-analyses.

A total of 19 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on how step therapy requirements for prescription drugs used to treat SMI or SUDs impact utilization of these drugs, health outcomes, or utilization of other health care services or they did not focus on the comparative effectiveness of these drugs. CHBRP identified a number of studies focused on prior authorization (PA) but did not include those studies in this review because there was no indication that step therapy was a prerequisite for PA. 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 CHBRP's Medical Effectiveness Analysis and Research Approach document.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[27] 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.

[24] Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence in the Medical Effectiveness Analysis and Research Approach document, in the absence of peer-reviewed literature on well-designed randomized controlled trials (RCTs) that is fully applicable to the analysis, CHBRP's hierarchy of evidence allows for the inclusion of other evidence.
[25] Welfare and Institutions Code Section 5600.3 (2025). https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=WIC&sectionNum=5600.3.
[26] Studies of the effects of step therapy requirements for prescription drugs used to treat SMI or SUDs were identified through searches of PubMed, Cochrane Library, Web of Science, Embase (Elsevier), and PsycInfo (ProQuest). The search was limited to abstracts of studies published in English and conducted in the United States.
[27] Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. See CHBRP's website for more information.

Key Questions

1. In persons with an SMI and/or SUD, what is the impact of step therapy requirements for prescription drugs compared to no step therapy requirements on:
    a. Utilization of these drugs?
    b. Health outcomes?
    c. Utilization of other health care services?
2. In persons with an SMI and/or SUD, what is the comparative effectiveness of:
    a. Orally administered formulations of branded atypical antipsychotics compared to generic orally administered atypical antipsychotics?
    b. Orally administered formulations of branded antidepressants compared to generic orally administered antidepressants?
3. What are the harms of orally administered formulations of branded atypical antipsychotic drugs compared to generic orally administered atypical antipsychotics and orally administered formulations of branded antidepressants compared to generic orally administered antidepressants?

Methodological Considerations

Some of the included studies discuss the impact of step therapy requirements in conjunction with other restrictions, such as formulary exclusions and PA requirements. Therefore, it is not possible to determine the magnitude of effect attributable to step therapy requirements solely.

Several studies were wholly or partially funded by pharmaceutical companies and/or were authored by researchers with financial relationships to pharmaceutical companies.

The evidence presented in this medical effectiveness review represents a limited number of studies directly comparing one prescription drug used to treat SMI to another. Most evidence comes from network meta-analyses, in which indirect comparisons are made between findings from studies that compare a drug used to treat SMI to a placebo.

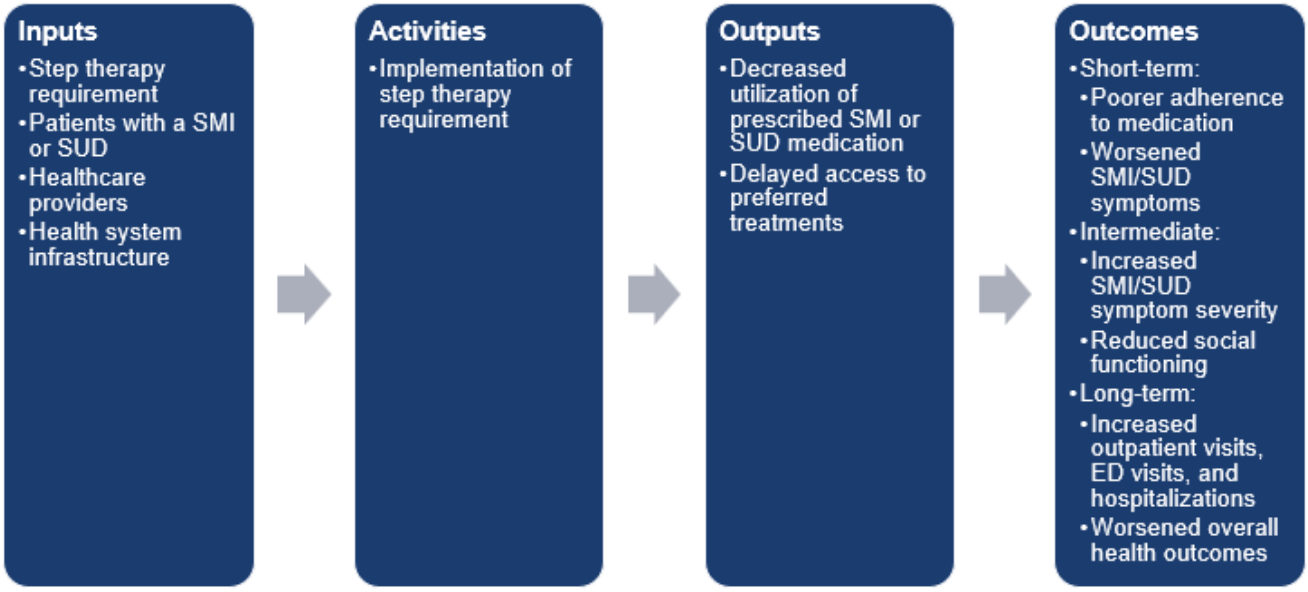
CHBRP did not identify any studies regarding the effects of step therapy requirements for prescription drugs used to treat SUDs or the comparative effectiveness of prescription drugs used to treat SUDs.

Outcomes Assessed

Primary outcomes assessed for step therapy requirements include utilization of prescription drugs to treat SMI or SUDs; health outcomes (e.g., mental health crises, overdoses, symptom severity, relapse); and utilization of other health care services (e.g., outpatient visits, ED visits, hospitalizations). Figure 1 presents a logic model illustrating the relationship among these outcomes. Step therapy requirements may lead to decreased utilization of a drug prescribed to treat an SMI or SUD. Decreased utilization and thus poorer adherence may lead to more severe symptoms and other negative health outcomes. People with more severe symptoms of SMI or SUDs may have more outpatient visits, ED visits, and/or hospitalizations.

Primary outcomes assessed for the comparative effectiveness of prescription drugs used to treat SMI or SUDs include impact on symptoms, social functioning, utilization of other health care services, discontinuation, adverse events, and other health outcomes (e.g., weight gain, use of antiparkinsonian medication, akathisia, prolactin elevation, QTc prolongation, sedation, anticholinergic side effects).

Figure 1. Logic Model for Primary Outcomes Assessed for Step Therapy Requirements



Source: California Health Benefits Review Program, 2026.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effects of step therapy requirements for prescription drugs used to treat SMI and SUDs and the comparative effectiveness of such drugs that are often subject to step therapy. Each section regarding effectiveness is accompanied by a corresponding figure. The title of the figure indicates the treatment for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a treatment based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms are included in the box below.

The following terms are used to characterize the body of evidence regarding an outcome:

Very strong evidence (formerly called *clear and convincing evidence*) indicates that there are multiple studies of a treatment and the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective. Conclusions are unlikely to be altered by additional evidence.

Strong evidence (formerly called *preponderance of evidence*) indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective. Conclusions could be altered with additional strong evidence.

Some evidence (formerly called *limited evidence*) indicates that a small number of studies have limited generalizability to the population of interest and/or the studies have a serious methodological concern in research design or implementation. Conclusions could be altered with additional evidence.

Conflicting evidence (formerly called *inconclusive evidence*) indicates that of the studies of equal quality, the number suggesting the treatment is effective is similar to the number of those suggesting the treatment is not effective.

Not enough research (formerly called *insufficient evidence*) indicates that (1) there are no studies of the treatment **or** (2) the available studies are not of high quality, meaning there is not enough evidence available to know whether or not a treatment is effective. *Not enough research* does not indicate that a treatment is not effective.

Effects of Step Therapy Requirements for Prescription Drugs Used to Treat SMI

Effects on utilization of prescription drugs that require step therapy

In a previous step therapy analysis (AB 2144), CHBRP identified four studies on step therapy requirements for prescription drugs used to treat SMI (two studies on antidepressants and two studies on atypical antipsychotics). The studies found that utilization of drugs that require step therapy (e.g., branded drugs) decreased after step therapy requirements were enforced while utilization of first line/preferred drugs (e.g., generic drugs) increased (Dunn et al., 2006; Farley et al., 2008; Mark et al., 2010; Soumerai et al., 2008). One study (Soumerai et al., 2008) found that patients who initiated atypical antipsychotics while step therapy protocols were in place experienced greater risk of treatment discontinuity than patients who initiated treatment before step therapy. Additional evidence also suggests that step therapy requirements decrease use of prescription drugs used to treat conditions other than SMI (Delate et al., 2005; Suehs et al., 2015; Udall et al., 2013; Yokoyama et al., 2007).

Dunn et al. (2006) studied the impact of a generics-first step-therapy protocol on antidepressants in a health maintenance organization in an integrated health system. Utilization of generic antidepressants increased after the implementation of step therapy while utilization of branded antidepressants decreased. Overall utilization of antidepressants decreased slightly after implementation of step therapy, which was influenced by external factors such as the FDA issuing safety advisories during the study period about the risk of suicidality associated with antidepressants and decreased antidepressant utilization in the broader market.

A retrospective observational study by Farley et al. (2008) examined the impact of a step therapy policy for atypical antipsychotics in Georgia's Medicaid program where patients were required to fail on typical antipsychotics before receiving an atypical antipsychotic.[28] The policy led to a significant decrease in atypical antipsychotic expenditures among patients with schizophrenia (indicating a reduction in utilization of atypical antipsychotics) and a significant increase in typical antipsychotic expenditures (indicating a shift in prescription patterns).

Mark et al. (2010) analyzed the effects of antidepressant step therapy protocols in employer-sponsored health plans in a retrospective observational study. Utilization of generic antidepressants increased while utilization of branded antidepressants decreased. The number of antidepressant days supplied decreased following implementation of step therapy, but this effect reversed over time. Among the potential reasons for this decrease, the study suggested that physicians may have initially been unaware of the new step therapy protocols and continued prescribing medications that were no longer covered under the plan, potentially discouraging patients from filling prescriptions when they learned about the lack of coverage.

Soumerai et al. (2008) studied the impact of step therapy on use of atypical antipsychotics following step therapy implementation in Maine's Medicaid program. Use of preferred antipsychotics increased while use of nonpreferred antipsychotics decreased during the study period. Patients who initiated atypical antipsychotics while step therapy protocols were in place experienced greater risk of treatment discontinuity than patients who initiated treatment before step therapy.

One retrospective observational study of commercial health insurance claims by Nabulsi et al. (2025; n=1,698) compared adult patients with major depressive disorder whose initial cariprazine (Vraylar) claim was approved with those whose initial cariprazine claim was rejected for a formulary-related reason (e.g., step therapy). Patients in the rejected cohort were delayed an average of 4.5 months before receiving another atypical antipsychotic after initial cariprazine claim rejection, 31.6% waited an average of 6 months before receiving cariprazine, and 68.4% never received cariprazine. The

[28] Atypical antipsychotics are also known as second-generation antipsychotics. Typical antipsychotics are also known as first-generation antipsychotics.

rejected cohort was slightly more likely to switch from one antidepressant to another during follow-up. Step therapy requirements accounted for 4.6% of cariprazine claim rejections.[29]

In another retrospective observational study of commercial health insurance claims by Laliberté et al. (2024; n=4,662), outcomes for adults with bipolar I disorder whose initial cariprazine claim was approved were compared with outcomes for those whose claim was rejected for a formulary-related reason. Among patients in the rejected cohort, 76.8% never received cariprazine, 34.7% never received any atypical antipsychotic during follow-up, 16.3% never received any mood stabilizer/anticonvulsant, and 13.6% never received any bipolar I-related medication. The average treatment delay was 6 months for cariprazine and 4 months for another atypical antipsychotic. Step therapy requirements accounted for 4.4% of cariprazine claim rejections.[29]

Summary of findings regarding the effects of step therapy requirements on utilization of prescription drugs used to treat SMI: There is *some evidence* based on six studies that step therapy requirements decrease utilization of prescription drugs for SMI that require step therapy. In a previous bill analysis (AB 2144), CHBRP identified four studies on step therapy for prescription drugs used to treat SMI; these studies found that utilization of drugs that require step therapy decreased after step therapy was implemented. One study found that step therapy increased the risk of discontinuing treatment with any antipsychotic, and one found a decrease in the number of days supplied for any antidepressant. Two retrospective observational studies cited delays and decreased utilization of cariprazine (Vraylar) or any atypical antipsychotic after an initial cariprazine claim was rejected; however, claims were rejected for a number of formulary-related reasons and step therapy accounted for only a small percentage of those claim rejections.

Effects on health outcomes

CHBRP did not identify any studies regarding the effects of step therapy requirements for prescription drugs used to treat SMI on health outcomes.

Effects on utilization of other health care services

CHBRP's analysis for AB 2144 concluded that findings regarding the impact of step therapy requirements on the utilization of other health care services were inconsistent. One of the included studies reported on step therapy for antidepressants and the other discussed antipsychotic drugs. Mark et al. (2010) reported that step therapy for antidepressant drugs was associated with a greater number of outpatient office visits, ED visits, and hospitalizations. Farley et al. (2008) reported a decline in outpatient visits following step therapy implementation for atypical antipsychotics by Georgia's Medicaid program.[30]

Nabulsi et al. (2025) found that all-cause and mental health–related hospitalizations were 61% and 89% higher, respectively, for the rejected cohort versus the approved cohort (all-cause: risk ratio [RR] 1.61, 95% confidence interval [CI] 1.15-2.32, p=0.012; mental health–related: RR 1.89, 95% CI 1.18-2.89, p=0.016). ED and outpatient visit rates were similar. Step therapy requirements accounted for 4.6% of cariprazine claim rejections.[29]

Laliberté et al. (2024) reported that all-cause and mental health–related hospitalizations were 22% and 24% higher, respectively, for the rejected cohort versus the approved cohort (all-cause: RR 1.22, 95% CI 1.01-1.48, p=0.024; mental health–related: RR 1.24, 95% CI 1.01-1.55, p=0.044). ED and outpatient visit rates were similar. Step therapy requirements accounted for 4.4% of cariprazine claim rejections.[29]

Summary of findings regarding the effects of step therapy requirements for prescription drugs used to treat SMI on utilization of other health care services: There is *some evidence* based on three studies that step therapy

[29] Given that claims were rejected for various formulary-related reasons and the data were not disaggregated by rejection reason, the results from this study may not fully capture the specific impact of step therapy requirements.
[30] Farley et al. (2008) found that expenditures for outpatient visits increased despite the decrease in the number of outpatient visits, suggesting that providers may have been reimbursed more per visit. The authors suggest that outpatient payments may have increased to offset the increased administration burden of complying with step therapy policies,

requirements for prescription drugs used to treat SMI are associated with increased hospitalizations. However, in two of the studies, cariprazine (Vraylar) claims were rejected for a number of formulary-related reasons and step therapy accounted for only a small percentage of those claim rejections.

Effects of Step Therapy Requirements for Prescription Drugs Used to Treat SUDs

CHBRP did not identify any studies regarding the effects of step therapy requirements for prescription drugs used to treat SUDs.

Comparative Effectiveness of Branded Versus Generic Drugs Used to Treat SMI

The comparative effectiveness of branded versus generic drugs for each category presented in Table 3 are discussed below. Per responses to CHBRP's survey of the largest (by enrollment) providers of health insurance in California, most branded atypical antipsychotics and antidepressants are subject to step therapy while most generic atypical antipsychotics and antidepressants are not. Therefore, branded drugs are compared to generic drugs in this medical effectiveness review.

Table 3. List of Branded and Generic Drugs Included in Comparative Effectiveness Review

Category	Branded Drugs	Generic Drugs
Atypical (second-generation) antipsychotic	Caplyta (Lumateperone)	Aripiprazole
	Cobenfy (Xanomeline/Trospium Chloride)	Asenapine
	Fanapt (Iloperidone)	Lurasidone
	Lybalvi (Olanzapine/Samidorphan)	Olanzapine
	Rexulti (Brexpiprazole)	Paliperidone
	Vraylar (Cariprazine)	Quetiapine
		Risperidone
		Ziprasidone
Antidepressants		
Atypical antidepressants	Trintellix (Vortioxetine)	Bupropion
		Mirtazapine
		Trazodone
	Viibryd	Vilazodone
Selective serotonin reuptake inhibitors (SSRIs)		Citalopram
		Escitalopram
		Fluoxetine

Category	Branded Drugs	Generic Drugs
		Fluvoxamine ER
		Paroxetine
		Sertraline
Serotonin and norepinephrine reuptake inhibitors (SNRIs)	Fetzima (Levomilnacipran)	Desvenlafaxine
		Duloxetine
		Milnacipran
		Venlafaxine

Source: California Health Benefits Review Program, 2026.
Key: ER=Extended Release.

Atypical antipsychotics

Overall Symptoms – Bipolar Depression

In a systematic review and network meta-analysis, Li et al. (2024; 16 randomized controlled trials [RCTs]; n=7,234) compared the efficacy and tolerability of branded atypical antipsychotics (cariprazine [Vraylar] and lumateperone [Caplyta]) with generic atypical antipsychotics (lurasidone, olanzapine, and quetiapine). The authors reported that adults with bipolar depression treated with quetiapine (generic) were significantly more likely to achieve a ≥50% improvement in depression severity from baseline on the Montgomery–Åsberg Depression Rating Scale (MADRS)[31] compared to those treated with cariprazine (branded) (OR 0.69, 95% CI 0.51 to 0.96, p<0.05).

Kadakia et al. (2021) examined the efficacy and tolerability of antipsychotics used to treat adults with bipolar depression in a network meta-analysis of 18 RCTs (n=7,969) that included comparisons of a branded antipsychotic (cariprazine) versus generic antipsychotics (aripiprazole, lurasidone, olanzapine, quetiapine, and ziprasidone). Generic drugs quetiapine (mean change -0.30, 95% credible interval [CrI] -0.49 to -0.11) and lurasidone (mean change -0.38, 95% CrI -0.66 to -0.10) were associated with a significantly greater reduction in overall symptom severity compared to cariprazine (branded) as measured by the Clinical Global Impression for Bipolar Disorder – Severity scale (CGI-BP-S)[32]. Generic drugs quetiapine (odds ratio [OR] 1.44, 95% CrI 1.08 to 1.91) and lurasidone (OR 2.38, 95% CrI 1.38 to 3.85) were also significantly more likely to achieve a ≥50% improvement on MADRS compared to cariprazine (branded).

Overall Symptoms – Schizophrenia

Studies in the following meta-analyses used scales such as the Positive and Negative Syndrome Scale (PANSS)[33] or Brief Psychiatric Rating Scale (BPRS)[34] to measure overall symptoms of schizophrenia.

In a systematic review and meta-analysis of 45 RCTs (n=11,238) studying the efficacy of antipsychotics used to treat adults with schizophrenia, Leucht et al. (2023) compared a branded antipsychotic (iloperidone [Fanapt]) with generic antipsychotics (aripiprazole, asenapine, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone).

[31] The Montgomery–Åsberg Depression Rating Scale (MADRS) is a clinical assessment tool used to measure the severity of depressive symptoms (Fantino & Moore, 2009).
[32] The Clinical Global Impression for Bipolar Disorder – Severity scale (CGI-BP-S) is a clinical assessment tool used to measure the severity of bipolar disorder symptoms, including manic, depressive, and overall symptoms (Busner & Targum, 2007).
[33] The Positive and Negative Syndrome Scale (PANSS) is a clinical assessment tool used to measure the severity of schizophrenia symptoms. It focuses on positive symptoms, negative symptoms, and general psychopathology, which includes symptoms such as anxiety, depression, and cognitive impairment (Kay et al., 1987).
[34] The Brief Psychiatric Rating Scale (BPRS) is a clinical assessment tool used to measure psychiatric symptoms in individuals with schizophrenia or other SMI. It focuses on psychotic and mood-related symptoms (Overall and Gorham, 1962).

Generic drugs lurasidone (standard mean difference [SMD] -0.49, 95% CI -0.85 to -0.13), olanzapine (SMD -0.32, 95% CI -0.49 to -0.15), risperidone (SMD -0.20, 95% CI -0.39 to -0.01), and aripiprazole (SMD -0.16, 95% CI -0.32 to -0.01) were associated with a significantly greater reduction in overall symptoms compared to iloperidone (branded).

In another systematic review and meta-analysis looking at how responses differ between subgroups — one being the general population of patients with schizophrenia — Leucht et al. (2022) compared antipsychotics used to treat patients with schizophrenia (537 RCTs, n=76,382). Risperidone (generic) was significantly better at reducing overall symptoms than cariprazine (branded) in the general population of patients with schizophrenia subgroup (SMD -0.34, 95% CI -0.53 to -0.15).

Schneider-Thoma et al. (2022) conducted a systematic review and meta-analysis of 100 RCTs (n=16,812) that compared branded antipsychotics (brexpiprazole, cariprazine, and iloperidone) with generic antipsychotics (aripiprazole, asenapine, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone). No significant differences in overall symptoms were observed between the drugs.

In a systematic review and network meta-analysis involving 402 RCTs (n=53,463), Huhn et al. (2020) compared the efficacy and tolerability of branded antipsychotics (brexpiprazole [Rexulti], cariprazine, and iloperidone) with generic antipsychotics (aripiprazole, asenapine, lurasidone, olanzapine, paliperidone, risperidone, quetiapine, and ziprasidone) among adults with schizophrenia. The generic drugs demonstrated greater effectiveness in reducing overall symptoms than the branded drugs. Specifically, olanzapine (generic) was associated with significantly greater reductions in overall symptoms compared to branded drugs cariprazine (SMD -0.21, 95% CrI -0.37 to -0.06), iloperidone (SMD -0.23, 95% CrI -0.35 to -0.11), and brexpiprazole (SMD -0.30, 95% CrI -0.45 to -0.15). Risperidone (generic) was also associated with significantly greater reductions in overall symptoms compared to branded drugs cariprazine (SMD -0.21, 95% CrI -0.36 to -0.05), iloperidone (SMD -0.22, 95% CrI -0.34 to -0.10), and brexpiprazole (SMD -0.29, 95% CrI -0.45 to -0.14). Similarly, paliperidone (generic) was associated with significantly greater reductions in overall symptoms compared to brexpiprazole (branded) (SMD -0.23, 95% CrI -0.40 to -0.06).

Positive Symptoms — Schizophrenia

Positive symptoms of schizophrenia refer to an excess or distortion of normal function (e.g., delusions and hallucinations) (Ruiz-Castañeda et al., 2022). Studies in the following meta-analyses used scales such as the PANSS or BPRS to measure positive symptoms of schizophrenia.

Leucht et al. (2022) reported that risperidone (generic) was associated with a significantly greater reduction in positive symptoms of schizophrenia compared to cariprazine (branded) among the general population of patients (SMD 0.39, 95% CI 0.20 to 0.58).

Huhn et al. (2020) demonstrated that generic antipsychotics (aripiprazole, asenapine, olanzapine, paliperidone, risperidone, quetiapine, and ziprasidone) were more effective in reducing positive symptoms of schizophrenia compared to branded antipsychotics (brexpiprazole, cariprazine, and iloperidone). Specifically, risperidone (generic) significantly reduced positive symptoms compared to branded drugs cariprazine (SMD -0.30, 95% CrI -0.46 to -0.15), iloperidone (SMD -0.31, 95% CrI -0.45 to -0.17), and brexpiprazole (SMD -0.44. 95% CrI -0.59 to -0.29). Similarly, olanzapine (generic) significantly reduced positive symptoms compared to branded drugs cariprazine (SMD -0.23, 95% CrI -0.38 to -0.08), iloperidone (SMD -0.23, 95% CrI -0.38 to -0.09), and brexpiprazole (SMD -0.36, 95% CrI -0.51 to -0.21). Paliperidone (generic) also significantly reduced positive symptoms compared to branded drugs cariprazine (SMD -0.23, 95% CrI -0.41 to -0.05), iloperidone (SMD -0.24, 95% CrI -0.41 to -0.06), and brexpiprazole (SMD -0.36, 95% CrI -0.54 to -0.19). Additionally, generic drugs asenapine (SMD -0.30, 95% CrI -0.50 to -0.10), ziprasidone (SMD -0.25, 95% CrI -0.43 to -0.08), quetiapine (SMD -0.25, 95% CrI -0.43 to -0.08), and aripiprazole (SMD -0.21, 95% CrI -0.37 to -0.05) significantly reduced positive symptoms compared to brexpiprazole (branded).

Negative Symptoms — Schizophrenia

Negative symptoms of schizophrenia refer to a reduction or absence of normal function (e.g., anhedonia, social withdrawal) (Correll and Schooler, 2020). Studies in the following meta-analyses used scales such as the PANSS or BPRS to measure negative symptoms of schizophrenia.

Leucht et al. (2022) did not find any significant differences in negative symptoms of schizophrenia between cariprazine (branded) and risperidone (generic).

Huhn et al. (2020) found that olanzapine (generic) was associated with significantly greater reductions in negative symptoms of schizophrenia compared to brexpiprazole (branded) (SMD -0.20, 95% CrI -0.32 to -0.08). In addition, generic drugs olanzapine (SMD -0.23, 95% CrI -0.35 to -0.11), asenapine (SMD -0.20, 95% CrI -0.37 to -0.03), risperidone (SMD -0.20, 95% CrI -0.37 to -0.03), and paliperidone (SMD -0.15, 95% CrI -0.30 to -0.01) were associated with significantly greater reductions in negative symptoms of schizophrenia compared to iloperidone (branded).

Depression Symptoms — Schizophrenia

Studies in the following meta-analysis used scales such as the PANSS, BPRS, or MADRS to measure depressive symptoms of schizophrenia.

Huhn et al. (2020) determined that olanzapine (generic) significantly reduced depression symptoms among individuals with schizophrenia compared to brexpiprazole (branded) (SMD -0.21, 95% CrI -0.37 to -0.06).

Social Functioning — Schizophrenia

Studies in the following meta-analysis used scales such as the Personal and Social Performance scale (PSP) to measure how well a person is functioning in daily life across multiple domains.

Huhn et al. (2020) reported that generic drugs olanzapine (SMD -0.28, 95% CrI -0.52 to -0.04) and paliperidone (SMD -0.26, 95% CrI -0.46 to -0.07) were associated with significantly better social functioning outcomes than brexpiprazole (branded).[35]

Utilization of Other Health Care Services

Schneider-Thoma et al. (2022) found that cariprazine (branded) was associated with significantly greater odds of rehospitalization for psychiatric reasons than generic drugs olanzapine (OR 6.15, 95% CrI 1.39 to 27.12) and quetiapine (OR 5.07, 95% CrI 1.26 to 20.43).

Summary of findings regarding the comparative effectiveness of branded versus generic atypical antipsychotics used to treat bipolar disorder and schizophrenia: There is *some evidence* based on two studies that branded atypical antipsychotics (e.g., cariprazine [Vraylar]) are less effective than generic atypical antipsychotics (e.g., lurasidone, quetiapine) at reducing symptoms related to bipolar disorder. There is *some evidence* based on three studies that branded atypical antipsychotics (e.g., brexpiprazole [Rexulti], cariprazine, iloperidone [Fanapt]) are less effective than generic atypical antipsychotics (e.g., aripiprazole, asenapine, lurasidone, olanzapine, paliperidone, risperidone, quetiapine, ziprasidone) at reducing overall, positive, and negative symptoms of schizophrenia; reducing depression symptoms; and improving social functioning. One study found that cariprazine (branded) was associated with greater odds of rehospitalization for psychiatric reasons than olanzapine (generic).

[35] Higher scores on social functioning scales such as the PSP represent better social functioning, while lower scores represent worse social functioning. In the context of this study, lower SMD values favor the reference treatments – olanzapine and paliperidone.

Figure 2. Level of Evidence of the Effectiveness of Branded Versus Generic Atypical Antipsychotics Used to Treat Bipolar Disorder

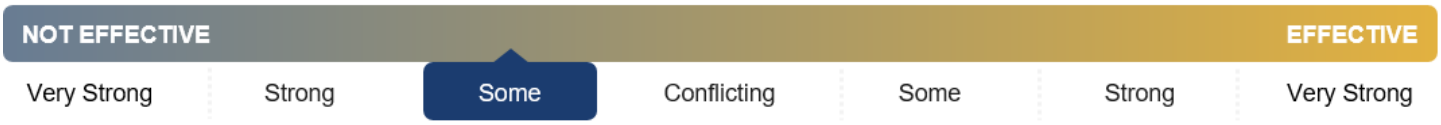
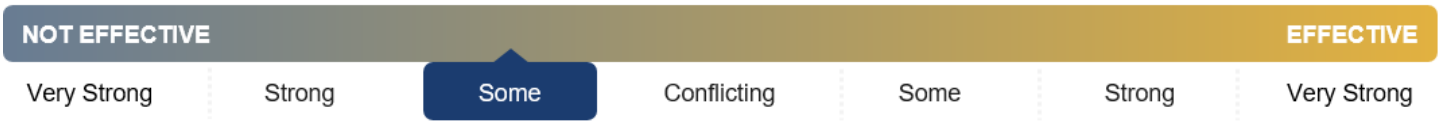


Figure 3. Level of Evidence of the Effectiveness of Branded Versus Generic Atypical Antipsychotics Used to Treat Schizophrenia



Antidepressants

Overall Symptoms — Major Depressive Disorder

Barbosa et al. (2024) examined a branded atypical antidepressant – vortioxetine (Trintellix) – versus generic serotonin and norepinephrine reuptake inhibitors (SNRIs; desvenlafaxine, duloxetine, and venlafaxine) and generic selective serotonin reuptake inhibitors (SSRIs; escitalopram, sertraline, and paroxetine) in a systematic review and meta-analysis of 17 RCTs with study durations of 6 or 8 weeks and involving adults with major depressive disorder (n=4,708). No significant differences in symptom reduction were observed between vortioxetine (branded) and generic SNRIs or generic SSRIs.

Zhang et al. (2022) conducted a systematic review and meta-analysis of vortioxetine (branded) versus generic SNRIs (duloxetine and venlafaxine) and generic SSRIs (sertraline and escitalopram) for the treatment of major depressive disorder in adults (20 RCTs; n=8,547). Although vortioxetine (branded) had no significance difference in symptom reduction compared to generic SNRIs in general, there was a significant difference favoring vortioxetine (branded) over duloxetine (generic SNRI) (RR 0.86, 95% CI 0.79 to 0.94, p=0.001), measured as ≥50% improvement on an observer-rated depression scale such as MADRS. There was no significant difference in symptom reduction between vortioxetine (branded) and generic SSRIs, and no significant difference in remission rates between vortioxetine (branded) and generic SNRIs or generic SSRIs. The study duration for each study was either 6 or 8 weeks.

Relapse Rate — Major Depressive Disorder

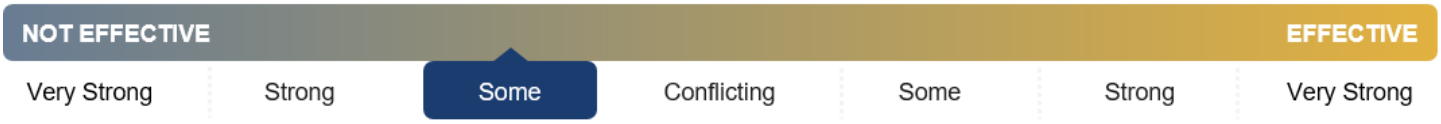
Kishi et al. (2023) evaluated the efficacy of various antidepressants used to treat adults with major depressive disorder during the maintenance phase – which refers to the period when symptoms have significantly been reduced or remission has been achieved but treatment is continued to prevent relapse or reoccurrence of depressive episodes (34 RCTs, n=9,384). In each trial, patients were stabilized on an antidepressant during the initial open-label phase and then randomized to receive the same antidepressant or a placebo. Across all drugs examined, vortioxetine (branded) was associated with a significantly greater risk of major depressive disorder relapse at six months compared to generic SSRI sertraline (RR 3.13, 95% CrI 1.46 to 6.88). By contrast, branded SNRI levomilnacipran (Fetzima) was associated with a significantly lower risk of relapse at six months compared to generic SSRI sertraline (RR 0.26, 95% CrI 0.11 to 0.57).[36]

Summary of findings regarding the comparative effectiveness of branded versus generic antidepressants used to treat major depressive disorder: There is *some evidence* based on three studies that there is no difference between the branded atypical antidepressant vortioxetine (Trintellix) and generic SNRIs (e.g., desvenlafaxine, duloxetine, venlafaxine) or generic SSRIs (e.g., escitalopram, sertraline, paroxetine) on symptom reduction at 6 or 8 weeks among adults with major depressive disorder. That is, vortioxetine (branded) is not more effective at symptom reduction at 6 or 8 weeks than

[36] None of the health insurance carriers surveyed by CHBRP reported requiring step therapy for levomilnacipran (Fetzima).

certain generic SNRIs or generic SSRIs. There is *some evidence* based on one study that vortioxetine (branded) is not more effective at reducing risk of major depressive disorder relapse at six months compared to sertraline (generic SSRI).

Figure 4. Level of Evidence of the Effectiveness of Branded Versus Generic Antidepressants Used to Treat Major Depressive Disorder



Comparative Effectiveness of Prescription Drugs Used to Treat SUDs

CHBRP did not identify any studies regarding the comparative effectiveness of prescription drugs used to treat SUDs.

Harms of Prescription Drugs Used to Treat SMI

Atypical antipsychotics

Discontinuation

Li et al. (2024) did not find any significant differences in odds of all-cause discontinuation between branded atypical antipsychotics (cariprazine and lumateperone) and generic atypical antipsychotics (lurasidone, olanzapine, and quetiapine).

Schneider-Thoma et al. (2022) reported that olanzapine (generic) was associated with significantly lower odds for all-cause discontinuation than brexpiprazole (branded) (OR 3.02, 95% CrI 1.07 to 6.91). Similarly, generic drugs olanzapine (OR 3.89, 95% CrI 1.38 to 9.04) and risperidone (OR 3.26, 95% CrI 1.13 to 7.43) were associated with significantly lower odds for all-cause discontinuation than cariprazine (branded).

Kadakia et al. (2021) did not find any significant differences in odds of all-cause discontinuation, discontinuation due to adverse events, or discontinuation due to lack of efficacy between cariprazine (branded) and aripiprazole, olanzapine, quetiapine, ziprasidone, or lurasidone (generics).

Huhn et al. (2020) demonstrated that generic atypical antipsychotics (aripiprazole, olanzapine, paliperidone, and risperidone) were associated with lower risk for all-cause discontinuation compared to branded atypical antipsychotics (brexpiprazole, cariprazine, and iloperidone). Specifically, olanzapine (generic) was associated with significantly lower risk for all-cause discontinuation than branded drugs iloperidone (RR 0.91, 95% CrI 0.85 to 0.98), brexpiprazole (RR 0.84, 95% CrI 0.79 to 0.92) and cariprazine (RR 0.83, 95% CrI 0.78 to 0.88). Paliperidone (generic) was also associated with significantly lower risk for all-cause discontinuation than branded drugs brexpiprazole (RR 0.85, 95% CrI 0.79 to 0.93) and cariprazine (RR 0.83, 95% CrI 0.77 to 0.91). Similarly, risperidone (generic) was associated with significantly lower risk for all-cause discontinuation than branded drugs brexpiprazole (RR 0.89, 95% CrI 0.83 to 0.97) and cariprazine (RR 0.87, 95% CrI 0.81 to 0.94). Lastly, aripiprazole (generic) was associated with significantly lower risk for all-cause discontinuation than cariprazine (branded) (RR 0.88, 95% CrI 0.76 to 0.98).

Weight Gain

Li et al. (2024) reported that lumateperone (branded) was associated with significantly lower odds of ≥7% weight gain compared to generic drugs lurasidone (OR 0.00, 95% CrI 0.00 to 0.30), olanzapine (OR 0.00, 95% CrI 0.00 to 0.03), and quetiapine (OR 0.00, 95% CrI 0.00 to 0.25). Cariprazine (branded) was also associated with significantly lower odds of ≥7% weight gain compared to olanzapine (generic) (OR 0.05, 95% CrI 0.01 to 0.41).

Leucht et al. (2022) did not find any significant differences in weight gain between cariprazine (branded) and risperidone (generic).

Schneider-Thoma et al. (2022) determined that cariprazine (branded) was associated with significantly less weight gain than olanzapine (generic) (MD -2.57 kg, 95% CrI -4.75 to -0.56).

Kadakia et al. (2021) found that generic drugs olanzapine (mean change 2.24 kg, 95% CrI 1.66 to 2.80) and quetiapine (mean change 0.52 kg, 95% CrI 0.07 to 0.96) were associated with significantly greater weight gain compared to cariprazine (branded). Olanzapine (generic) was also associated with significantly greater odds of ≥7% weight gain compared to cariprazine (branded) (OR 24.93, 95% CrI 3.35 to 95.57).

Huhn et al. (2020) reported mixed findings regarding weight gain. Cariprazine (branded) was associated with significantly less weight gain than generic drugs quetiapine (MD -1.20 kg, 95% CrI -2.11 to -0.31) and olanzapine (MD -2.05 kg, 95% CrI -2.87 to -1.24). Similarly, brexpiprazole (branded) was associated with significantly less weight gain than olanzapine (generic) (MD -1.57 kg, 95% CrI -2.43 to -0.73). However, ziprasidone (generic) was associated with significantly less weight gain than branded drugs brexpiprazole (MD -1.36 kg, 95% CrI -2.30 to -0.40) and iloperidone (MD -2.33 kg, 95% CrI -3.13 to 1.53). Likewise, generic drugs lurasidone (MD -1.86 kg, 95% CrI -2.72 to -0.99), aripiprazole (MD -1.65 kg, 95% CrI -2.47 to -0.84), and risperidone (MD -0.74 kg, 95% CrI -1.46 to -0.03) were associated with significantly less weight gain than iloperidone (branded).

Akathisia

Akathisia, a side effect of antipsychotic drugs, is a neuropsychiatric syndrome that manifests as restlessness (Patel and Marwaha, 2023).

Kadakia et al. (2021) did not find any significant differences in akathisia between cariprazine (branded) and aripiprazole, quetiapine, or lurasidone (generics).

Huhn et al. (2020) reported mixed findings regarding akathisia. Iloperidone (branded) was associated with significantly less risk of akathisia compared to generic drugs ziprasidone (RR 0.34, 95% CrI 0.07 to 0.94), risperidone (RR 0.26, 95% CrI 0.05 to 0.77), and lurasidone (RR 0.16, 95% CrI 0.03 to 0.50). Similarly, brexpiprazole (branded) was associated with significantly less risk of akathisia compared to generic drugs risperidone (RR 0.50, 95% CrI 0.26 to 0.85) and lurasidone (RR 0.31, 95% CrI 0.14 to 0.57). However, generic drugs olanzapine (RR 0.30, 95% CrI 0.20 to 0.51), quetiapine (RR 0.32, 95% CrI 0.20 to 0.58), and paliperidone (RR 0.42, 95% CrI 0.25 to 0.83) were associated with significantly less risk of akathisia compared to cariprazine (branded).

Use of Antiparkinsonian Medication

Researchers typically measure use of antiparkinsonian medication as an indicator of extrapyramidal symptoms such as parkinsonism, akathisia, and tardive dyskinesia[37], which are side effects of antipsychotic drugs (Burgyone et al., 2004).

Schneider-Thoma et al. (2022) reported that olanzapine (generic) was associated with lower odds of using antiparkinsonian medication compared to cariprazine (branded) (OR 12.3, 95% CrI 1.18 to 52.29).[38]

Huhn et al. (2020) found that generic drugs olanzapine (RR 0.45, 95% CrI 0.29 to 0.89) and quetiapine (RR 0.47, 95% CrI 0.29 to 0.96) were associated with significantly less risk of using antiparkinsonian medication compared to cariprazine (branded).

[37] Parkinsonism is a broad term for neurological syndromes that manifest as movement disorders such as rigidity and tremors; Parkinson's disease is the most common condition that causes this syndrome (Shrimanker et al., 2024). Tardive dyskinesia is a neurological condition that causes involuntary, repetitive, and uncontrollable body movements, typically in the face, tongue, lips, trunk, or limbs (Raza and Mars, 2026).
[38] The wide confidence interval suggests uncertainty about the magnitude of the difference in odds of using antiparkinsonian medication.

Prolactin Elevation

Prolactin is a hormone primarily produced by the pituitary gland. High prolactin levels, or hyperprolactinemia, is a side effect of antipsychotic drugs. Hyperprolactinemia is associated with adverse conditions such as irregular or absent menstrual cycles in women and infertility in both sexes (Tewksbury and Olander, 2016).

Schneider-Thoma et al. (2022) reported that brexpiprazole (branded) significantly reduced prolactin levels compared to generic drugs paliperidone (MD -51.88, 95% CrI -73.96 to -30.55) and ziprasidone (MD -25.35, 95% CrI -38.63 to -14.87). Cariprazine (branded) also significantly reduced prolactin levels compared to generic drugs paliperidone (MD -54.13, 95% CrI -77.00 to -31.45) and ziprasidone (MD -27.60, 95% CrI -42.29 to -15.08).

Kadakia et al. (2021) did not find any significant differences in prolactin levels between cariprazine (branded) and aripiprazole, quetiapine, or lurasidone (generics).

Huhn et al. (2020) reported mixed findings regarding changes in prolactin levels. Cariprazine (branded) significantly reduced prolactin compared to generic drugs olanzapine (MD -7.66, 95% CrI -14.29 to -1.04), asenapine (MD -8.24, 95% CrI -16.10 to -0.35), lurasidone (MD -10.24, 95% CrI -17.37 to -3.10), risperidone (MD -41.17, 95% CrI -47.74 to -34.63), and paliperidone (MD -51.71, 95% CrI -59.44 to -43.99). Brexpiprazole (branded) significantly reduced prolactin compared to generic drugs lurasidone (MD -6.09, 95% CrI -12.24 to -0.03), risperidone (MD -37.03, 95% CrI -42.56 to -31.51), and paliperidone (MD -47.57, 95% CrI -54.43 to -40.71). Iloperidone (branded) significantly reduced prolactin compared to generic drugs risperidone (MD -33.19, 95% CrI -39.51 to -26.79) and paliperidone (MD -43.73, 95% CrI -51.35 to -36.15). However, aripiprazole (generic) significantly reduced prolactin compared to branded drugs brexpiprazole (MD -8.05, 95% CrI -13.28 to -2.88) and iloperidone (MD -11.89, 95% CrI -18.78 to -4.94).

QTc Prolongation

QTc prolongation, a side effect of antipsychotic drugs, is a heart condition marked by delayed cardiac repolarization[39] that can lead to life-threatening complications (Chohan et al., 2015).

Schneider-Thoma et al. (2022) did not find any significant differences in QTc prolongation between brexpiprazole (branded) and lurasidone, paliperidone, quetiapine, or ziprasidone (generics).

Huhn et al. (2020) reported mixed findings regarding QTc prolongation. Brexpiprazole (branded) caused significantly less QTc prolongation than generic drugs quetiapine (MD -4.89, 95% CrI -9.04 to -0.82), olanzapine (MD -5.75, 95% CrI -9.78 to -1.73), risperidone (MD -6.23, 95% CrI -10.10 to -2.44), and ziprasidone (MD -11.16, 95% CrI -15.26 to -7.26). Cariprazine (branded) also caused significantly less QTc prolongation than generic drugs olanzapine (MD -5.74, 95% CrI -10.98 to -0.72), risperidone (MD -6.22, 95% CrI -11.01 to -1.58), and ziprasidone (MD -11.15, 95% CrI -16.33 to -6.12). However, generic drugs lurasidone (MD -9.14, 95% CrI -12.45 to -5.76), aripiprazole (MD -7.37, 95% CrI -11.22 to -3.56), paliperidone (MD -5.73, 95% CrI -10.35 to -0.97), and quetiapine (MD -3.50, 95% CrI -6.78 to -0.05) caused significantly less QTc prolongation than iloperidone (branded).

Sedation

Sedation refers to the drowsiness and decreased alertness caused by antipsychotic drugs (Reeve et al., 2025).

Leucht et al. (2022) did not find any significant differences in sedation between cariprazine (branded) and risperidone (generic).

Huhn et al. (2020) determined that branded atypical antipsychotics (brexpiprazole, cariprazine, and iloperidone) were less sedating than generic atypical antipsychotics (asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone). Specifically, cariprazine (branded) was significantly less sedating than generic drugs lurasidone (RR 0.59, 95% CrI 0.31 to

[39] Cardiac repolarization is the process during which heart muscle cells return to a resting state after contracting.

0.88), risperidone (RR 0.56, 95% CrI 0.31 to 0.88), asenapine (RR 0.47, 95% CrI 0.35 to 0.78), olanzapine (RR 0.41, 95% CrI 0.22 to 0.66), ziprasidone (RR 0.39, 95% CrI 0.21 to 0.65), and quetiapine (RR 0.35, 95% CrI 0.18 to 0.57). Iloperidone (branded) was also significantly less sedating than generic drugs asenapine (RR 0.54, 95% CrI 0.39 to 0.97), olanzapine (RR 0.52, 95% CrI 0.28 to 0.84), ziprasidone (RR 0.50, 95% CrI 0.28 to 0.78), and quetiapine (RR 0.45, 95% CrI 0.23 to 0.74). Similarly, brexpiprazole (branded) was significantly less sedating than quetiapine (generic) (RR 0.56, 95% CrI 0.27 to 0.99).

Anticholinergic Side Effects

Antipsychotic drugs are associated with anticholinergic side effects, such as "dry mouth, constipation, urinary retention, bowel obstruction, dilated pupils, blurred vision, increased heart rate, and decreased sweating" as well as "impaired concentration, confusion, attention deficit, and memory impairment." (Lieberman, 2004)

Huhn et al. (2025) reported that brexpiprazole (branded) was associated with significantly less risk for anticholinergic side effects than generic drugs olanzapine (RR 0.36, 95% CrI 0.15 to 0.73) and quetiapine (RR 0.18, 95% CrI 0.07 to 0.37). Cariprazine (branded) was also associated with significantly less risk for anticholinergic side effects than quetiapine (generic) (RR 0.38, 95% CrI 0.19 to 0.66).

Summary of findings regarding the harms of branded versus generic atypical antipsychotics: There is *some evidence* based on two studies that generic atypical antipsychotics (e.g., olanzapine, quetiapine) are associated with less risk of using antiparkinsonian medication compared to branded atypical antipsychotics (e.g., cariprazine). There is *some evidence* based on one study that branded atypical antipsychotics (e.g., brexpiprazole, cariprazine) are associated with less risk for anticholinergic side effects than generic atypical antipsychotics (e.g., olanzapine, quetiapine). There is *conflicting evidence* regarding all-cause discontinuation (four studies), akathisia (two studies), prolactin elevation (three studies), QTc prolongation (two studies), and sedation (two studies). There is also *conflicting evidence* regarding weight gain (five studies). Of note, in the three studies that reported statistically significant changes in weight between the atypical antipsychotics, the actual weight changes (in kg) were small.

Antidepressants

Discontinuation

Barbosa et al. (2024) cited no significant differences in all-cause discontinuations, discontinuations due to lack of efficacy, or discontinuations due to adverse events between vortioxetine (branded) and generic SSRIs (escitalopram, sertraline, and paroxetine). Findings were similar for generic SNRIs (desvenlafaxine, duloxetine, and venlafaxine), except vortioxetine (branded) was associated with a statistically lower risk of discontinuation due to adverse events compared to generic SNRIs (RR 0.71, 95 % CI 0.51 to 1.00, p=0.05).

Kishi et al. (2023) found that vortioxetine (branded) was associated with a significantly greater risk for discontinuation due to adverse events compared to generic SNRIs desvenlafaxine (RR 4.04, 95% CrI 1.12 to 18.33) and venlafaxine (RR 3.63, 95% CrI 1.00 to 14.21).

Zhang et al. (2022) determined that there were no significant differences in discontinuations due to adverse events between vortioxetine (branded) and generic SNRIs (duloxetine and venlafaxine) or generic SSRIs (escitalopram and sertraline) in general, but vortioxetine (branded) was associated with significantly lower risk for discontinuation due to adverse events compared to generic SNRI venlafaxine (RR 0.42, 95% CI 0.26 to 0.67, p<0.001).

Adverse Events

Vijayan et al. (2025) reported no significant differences in risk of adverse events between vortioxetine (branded) and generic SNRIs (duloxetine and venlafaxine).

Barbosa et al. (2024) found that compared to generic SNRIs, vortioxetine (branded) was associated with a significantly lower risk of experiencing at least one adverse event (RR 0.92, 95 % CI 0.85 to 0.98, p=0.02): constipation (RR 0.46, 95 % CI 0.35 to 0.62, p<0.001), decreased appetite/weight loss (RR 0.37, 95 % CI 0.20 to 0.71, p=0.003), dizziness (RR 0.56, 95 % CI 0.43 to 0.74, p<0.001), dry mouth (RR 0.50, 95 % CI 0.41 to 0.61, p<0.001), fatigue (RR 0.53, 95 % CI 0.38 to 0.74, p<0.001), hyperhidrosis (RR 0.34, 95 % CI 0.23 to 0.49, p<0.001), insomnia (RR 0.61, 95 % CI 0.45 to 0.83, p=0.001), palpitation/tachycardia (RR 0.36, 95 % CI 0.16 to 0.79; p=0.01), sexual dysfunction in men (RR 0.07, 95 % CI 0.01 to 0.35, p=0.001), and somnolence (RR 0.41, 95 % CI 0.28 to 0.59; p<0.001). There were no significant differences observed between vortioxetine (branded) and generic SSRIs in general for risk of experiencing at least one adverse event, but vortioxetine (branded) was associated with a significantly higher risk of nausea/vomiting than generic SSRIs (RR 1.99; 95 % CI 1.21 to 3.27, p=0.006).

Kishi et al. (2023) reported that vortioxetine (branded) was associated with a significantly higher risk of nausea/vomiting than generic atypical antidepressant bupropion (RR 7.80, 95% CrI 1.07 to 86.22) and generic SSRIs citalopram (RR 5.20, 95% CrI 1.47 to 20.75) and fluoxetine (RR 3.89, 95% CrI 1.19 to 14.46).

Zhang et al. (2022) determined that vortioxetine (branded) was associated with significantly fewer adverse events than generic SNRIs in general (RR 0.90, 95% CI 0.86 to 0.94, p<0.001). Specifically, vortioxetine (branded) had fewer adverse events than generic SNRI duloxetine (RR 0.89, 95% CI 0.84 to 0.95, p< 0.001).

Summary of findings regarding the harms of branded versus generic antidepressants: There is *some evidence* based on one study that there are no differences between the branded atypical antidepressant vortioxetine (Trintellix) and generic SNRIs (e.g., desvenlafaxine, duloxetine, venlafaxine) or generic SSRIs (e.g., escitalopram, sertraline, paroxetine) in all-cause discontinuations or discontinuations due to lack of efficacy. There is *some evidence* based on three studies that vortioxetine (branded) has a lower risk of discontinuation due to adverse events compared to generic SNRIs, but not generic SSRIs based on two studies. There is *conflicting evidence* based on three studies regarding vortioxetine (branded) and generic SNRIs for risk of adverse events. There is *some evidence* based on two studies that vortioxetine (branded) is associated with a significantly higher risk of nausea/vomiting than generic atypical antidepressants (e.g., bupropion) and generic SSRIs (e.g., citalopram, fluoxetine).

Summary of Findings

CHBRP found *some evidence* that step therapy requirements for prescription drugs used to treat SMI decrease utilization of those drugs and increase hospitalizations. However, these findings should be interpreted with caution because some of the studies analyzed older atypical antipsychotic drugs that are no longer subject to step therapy. CHBRP did not identify any direct evidence on the effect of step therapy requirements for prescription drugs used to treat SMI on health outcomes. The association between step therapy and increases in hospitalizations provides indirect evidence that step therapy is associated with increased severity of SMI symptoms.

CHBRP found *some evidence* that branded atypical antipsychotics are less effective than generic atypical antipsychotics at reducing symptoms related to bipolar disorder. CHBRP found *some evidence* that branded atypical antipsychotics are less effective than generic atypical antipsychotics at reducing overall, positive, and negative symptoms of schizophrenia; reducing depression symptoms; and improving social functioning among persons with schizophrenia.

CHBRP found *some evidence* that there is no difference between vortioxetine (branded atypical antidepressant) and generic SNRIs or generic SSRIs on symptom reduction at 6 or 8 weeks among adults with major depressive disorder. CHBRP found *some evidence* that vortioxetine (branded) is associated with greater risk of major depressive disorder relapse at six months compared to generic SSRIs.

CHBRP did not identify any studies regarding the effects of step therapy requirements for prescription drugs used to treat SUDs, nor any studies regarding the comparative effectiveness of prescription drugs used to treat SUDs.

Findings regarding the harms of branded versus generic atypical antipsychotics and branded versus generic antidepressants are mixed. CHBRP found *some evidence* that generic atypical antipsychotics are associated with less risk of using antiparkinsonian medication compared to branded atypical antipsychotics and *some evidence* that branded atypical antipsychotics are associated with less risk for anticholinergic side effects than generic atypical antipsychotics. CHBRP found *some evidence* that there are no differences between vortioxetine (branded) and generic SNRIs or generic SSRIs in all-cause discontinuations or discontinuations due to lack of efficacy. CHBRP found *some evidence* that vortioxetine (branded) has a lower risk of discontinuation due to adverse events compared to generic SNRIs but there were no differences between vortioxetine (branded) and generic SSRIs. CHBRP found *some evidence* that vortioxetine (branded) is associated with a significantly higher risk of nausea/vomiting than generic atypical antidepressants and generic SSRIs.

Cost Impact Analysis: Data Sources, Caveats, and Assumptions

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc., the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[40] 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 on CHBRP's website.[41]

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

Analysis-Specific Data Sources

Current step therapy requirements for enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represented 72% of commercial enrollees with health insurance that can be subject to state benefit mandates. In addition, CalPERS and DHCS were queried regarding related benefit coverage.

For this analysis, CHBRP relied on Current Procedural Terminology (CPT®) codes to identify relevant services: CPT copyright 2022 American Medical Association (AMA). All rights reserved. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the AMA.

Health Cost Guidelines

The health cost guidelines (HCGs) are a health care pricing tool used by actuaries in many of the major health plans in the United States. The guidelines provide a flexible but consistent basis for estimating health care costs for a wide variety of commercial health insurance plans. It is likely that these organizations use the HCGs, among other tools, to determine the initial premium impact of any new mandate. Thus, in addition to producing accurate estimates of the costs of a mandate, we believe the HCG-based values are also good estimates of the premium impact as estimated by the HMOs and insurance companies.

The highlights of the commercial HCGs include:

- Specific major medical, managed care, and prescription drug rating sections and guidance with step-by-step rating instructions.
- Other helpful analysis resources such as inpatient length of stay distribution tables, Medicare Severity-Adjusted Diagnosis Related Group (MS-DRG) models, and supplementary sections addressing EHBs and mandated benefits, experience rating, and individual and small-group rating considerations.
- Presentation of loosely and well-managed nationwide utilization and cost information by Milliman benefit-aligned service categories used throughout the Rating Structures — inpatient hospital services for both loosely and well-managed care delivery systems are also supported by DRG level utilization and cost benchmarks.

[40] CHBRP's authorizing statute requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[41] See CHBRP's Cost Impact Analysis landing page; in particular, see *Cost Impact Analyses: Data Sources, Caveats, and Assumptions*.

- Annual updates address emerging regulatory considerations such as health care reform and mental health parity requirements.
- Annually updated benefit descriptions used in the HCG service categories.
- Annually updated medical trend assumptions and considerations.
- Presentation of two sets of nationwide area factors to facilitate development of area-specific claim costs, including separate utilization and charge level factors by type of benefit, state and Metropolitan Statistical Area for first-dollar coverage, and composite factors by deductible amount.
- Claim Probability Distributions (CPDs) by type of coverage that contain distributions of claim severity patterns for unique combinations of benefits and member types (adult, child, composite member).
- The Prescription Drug Rating Model (RXRM), an automated rating tool that provides a detailed analysis of prescription drug costs and benefits.

Consolidated health cost guidelines sources database

Milliman maintains benchmarking and analytic databases that include health care claims data for nearly 60 million commercial lives and over 3 million lives of Medicaid managed care data. This dataset is routinely used to evaluate program impacts on cost and other outcomes.

Detailed Cost Notes Regarding Analysis-Specific Caveats and Assumptions

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable.

The population subject to AB 1970 includes DMHC-regulated commercial insurance plans, CDI-regulated policies, and CalPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act that offer outpatient pharmacy coverage. Medi-Cal enrollees have pharmacy drug coverage through Medi-Cal Rx, and CHBRP determined Medi-Cal Rx does not have step therapy for any drug on its formulary.

CHBRP assumed step therapy only applies to drugs received through an enrollee's pharmacy benefit, and that drugs received through the medical benefit do not have a step therapy utilization management mechanism.

Methodology and Assumptions for Baseline Utilization

Branded SMI and SUD prescription drugs

- CHBRP identified branded atypical antidepressants, atypical antipsychotics, and drugs to treat SUD, as well as corresponding National Drug Codes (NDCs). See Table 2 for the list of drugs that are included in this analysis.
- CHBRP calculated annual 30-day scripts per 1,000 enrollees for these brand SMI and SUD pharmacy drugs in aggregate using NDC and Milliman's proprietary 2024 Consolidated Health Cost Guidelines™ Sources Database (CHSD).
- The annual 30-day scripts per 1,000 enrollees was trended from 2024 to 2027 using a 2.5% pharmacy utilization trend based on the 2025 Milliman Health Cost Guidelines.

Generic SMI and SUD prescription drugs

- CHBRP identified the following generic antidepressants, antipsychotics, or drugs for SUD as well as corresponding NDCs:

- amitriptyline, amoxapine, bupropion, chlordiazepoxide, citalopram, clomipramine, desipramine, desvenlafaxine, doxepin, duloxetine, escitalopram, fluoxetine, fluvoxamine, mirtazapine, nefazodone, nortriptyline, paroxetine, perphenazine, phenelzine, sertraline, tranylcypromine, trazodone, aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, clonidine, and naloxone

- CHBRP calculated annual 30-day scripts per 1,000 enrollees for these generic SMI and SUD pharmacy drugs in aggregate using NDCs and CHSD.
- The annual 30-day scripts per 1,000 enrollees was trended from 2024 to 2027 using a 2.5% pharmacy utilization trend based on the 2025 Milliman Health Cost Guidelines.

Methodology and Assumptions for Baseline Cost

- CHBRP calculated the average cost per 30-day script for brand and generic SMI and SUD pharmacy drugs using CHSD. The average commercial cost per 30-day script was trended from 2024 to 2027 using a 9.75% pharmacy cost trend based on the 2025 Milliman Health Cost Guidelines.

Methodology and Assumptions for Baseline Cost Sharing

- CHBRP calculated the average cost sharing per 30-day script for brand and generic SMI and SUD pharmacy drugs from CHSD and adjusted the cost sharing for benefit differences within each line of business. The average commercial cost sharing per 30-day script was trended from 2024 to 2027 using a 9.75% pharmacy cost trend based on the 2025 Milliman Health Cost Guidelines.

Methodology and Assumptions for Postmandate Utilization

- CHBRP assumed a 1% increase in brand SMI and SUD users and 1% increase in brand SMI and SUD scripts as a result of AB 1970.
- CHBRP assumed a corresponding decrease in users and scripts of generic SMI and SUD pharmacy drugs.
- The postmandate utilization change relied solely on brand or generic status and does not consider specific SMI or SUD indication.

Methodology and Assumptions for Postmandate Cost

- CHBRP assumed the average cost per script would not change as a result of AB 1970.

Methodology and Assumptions for Postmandate Cost Sharing

- CHBRP assumed the average cost sharing per script would not change as a result of AB 1970. The composite average cost sharing across a population would change due to a projected change in the mix of drugs being prescribed.

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits by comparing the benefits provided by self-insured health plans or policies (which are not regulated by the 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.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS have the largest number of enrollees. No information was obtained regarding whether 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 plans and insurers 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.

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CHBRP is an independent program administered and housed by the University of California, Berkeley, under the Office of the Vice Chancellor for Research. A group of faculty, researchers, and staff complete the analysis that informs 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** works with Task Force members in preparing parts of the analysis, and manages external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with an independent actuarial firm, **Milliman, Inc.**, 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. Information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at chbrp.org.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at chbrp.org.

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