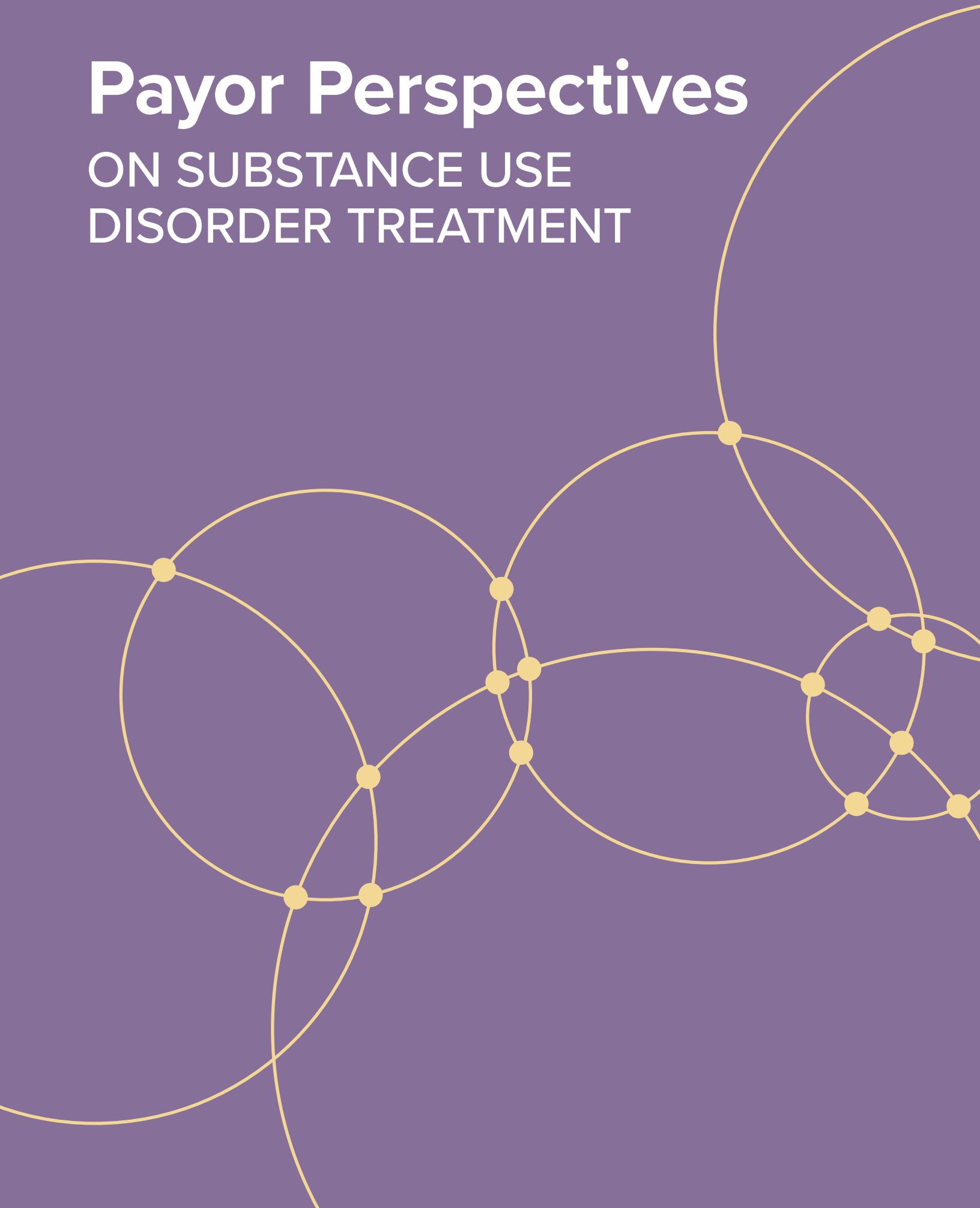


# Payor Perspectives

ON SUBSTANCE USE  
DISORDER TREATMENT



# List of Abbreviations

<b>ASAM</b>	American Society of Addiction Medicine
<b>CDC/NCHS</b>	Centers for Disease Control and Prevention's National Center for Health Statistics
<b>CMS</b>	Center for Medicare and Medicaid Services
<b>CDER</b>	Center for Drug Evaluation and Research
<b>ED</b>	Emergency Department
<b>MCO</b>	Managed Care Organization
<b>MAT</b>	Medication Assisted Treatment
<b>MOUD</b>	Medications for Opioid Use Disorder
<b>OTP</b>	Opioid Treatment Programs
<b>OUD</b>	Opioid Use Disorder
<b>P&amp;T Committee</b>	Pharmacy and Therapeutics Committee
<b>SAMHSA</b>	Substance Abuse and Mental Health Services Administration
<b>SUD</b>	Substance Use Disorder
<b>WHO</b>	World Health Organization

## Executive Summary

On Thursday, March 11, 2021, the Reagan-Udall Foundation for the FDA (FDA Foundation) convened, in conjunction with the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA), a roundtable on “Payor Perspectives on Substance Use Disorder Treatment.” The purpose of the roundtable was to hear different key stakeholders’ perspectives on health insurance coverage of pharmacological treatments for substance use disorder (SUD). Given concerns regarding access to SUD treatment, particularly pharmacological treatment, the FDA wanted to understand in more granularity the factors that impact the availability of treatment, particularly health insurance coverage, for individuals with SUD. This information could potentially help inform the development and evaluation of new treatments for SUD, particularly treatments for stimulant use disorder (StUD), for which specific medications have not yet been approved by FDA.

In response to this request, the FDA Foundation convened a group of stakeholders from the health insurance sector, patient groups, recovery support organizations, health economists, clinicians, and government officials to discuss the dynamics of SUD treatment from the payor perspective. This closed-door discussion allowed for candid sharing of views, particularly from those involved in the financial support of both pharmacological and psychosocial therapy for individuals with SUD. Following “Chatham House” rules, the participants shared their personal and professional experiences in supporting such treatment in a frank and open manner. Among the high-level takeaways of this meeting, we heard:

- FDA labeling impacts payor decisions but does not, by itself, determine health insurance coverage. Other factors come into play, including deliberations by internal committees within the payor organizations (both private and public) and negotiations with the product sponsor or manufacturer. Payors consider real-world evidence about the effectiveness of the product, and, separately, the extent to which the FDA label reflects the “lived experience” of individuals with SUD.
- Cost-effectiveness studies of medications for SUD, specifically medications for opioid use disorder (MOUD), with or without accompanying psychosocial therapy, indicate that benefits of medications for SUD far outweigh the costs. The benefits generally accrue in the form of lower overall healthcare costs, despite higher outpatient and prescription costs. Other economic benefits include increased productivity and less premature mortality.
- SUD is increasingly viewed by payors as a chronic disease. Facilitating the maintenance of pharmacologic treatment for individuals with SUD leads to fewer relapses and thus lowers overall costs for payors and society as a whole. Recognizing that individuals\* change health plans periodically, managing these transitions smoothly between plans with fewer disruptions and/or sudden increases in out-of-pocket costs leads to fewer adverse medical events and lower costs to payors. Labeling that emphasizes the importance of adherence, chronically, could be beneficial.
- As the medical and economic benefits of pharmacotherapy have been increasingly accepted, and the recognition that SUD is a chronic disease has grown, benefit and payment design practices that served to limit access to MOUD are gradually being phased out. However, there still exist some barriers to access in the form of state and Federal regulations designed initially to prevent abuse or misuse of opioids. Some of

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\* For the purposes of this white paper, “beneficiaries” refer to participants in government-supported health insurance programs such as Medicaid, while “enrollees” refer to participants in commercial insurance programs. “Individuals” applies when referring to both.

these barriers are being reconsidered; for example, the Department of Health and Human Services released new practice guidelines in April 2021 that exempt many prescribers from federal certification requirements, including training, that are part of the process for obtaining a waiver to treat up to 30 patients with buprenorphine.

- While Medicaid is still the largest insurer of individuals with SUD, the United States is seeing an increase in the numbers of individuals with SUD who are enrolled in Medicare, reflecting an aging of this population.

The perspectives of payors are useful in understanding the entire ecosystem of healthcare in the United States, particularly behavioral/mental health, which in many ways is treated separately from physical health. Convenings such as the March 11 roundtable serve to inform FDA and applicants how FDA approval and content of labeling may impact access to those medications and contribute to the broader FDA mission to protect and advance public health.

This activity is one part of a multi-part Foundation project related to substance use disorder. The multi-part project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an overall award of \$197,943 of federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit [FDA.gov](https://www.fda.gov).

## ABOUT THE REAGAN-UDALL FOUNDATION FOR THE FDA

The Reagan-Udall Foundation for the FDA (FDA Foundation) is an independent 501(c)(3) created by Congress to advance regulatory science to help the U.S. Food and Drug Administration accomplish its mission. The FDA Foundation works to improve health and safety through stakeholder engagement and public-private partnerships that facilitate innovation, foster the use of real-world evidence, and identify modern tools and policies to keep pace with today's rapidly evolving science. [www.reaganudall.org](https://www.reaganudall.org)

## Introduction

At the March 11, 2021, roundtable on “Payor Perspectives on Substance Use Disorder Treatment” convened by the FDA Foundation in conjunction with FDA, participants in the meeting included stakeholders from, or with experience in, health plans, managed care organizations, state Medicaid programs, pharmacy benefits, patient advocacy groups, and Federal agencies.

The purpose of the roundtable was to gather perspectives on the coverage of pharmacotherapy for SUD. The FDA wanted to understand better the factors that impact the availability of treatment, particularly pharmacy and medical benefits of health insurance, for individuals with SUD. Understanding the dynamics of pharmaceutical benefits decision-making can help inform the development, evaluation, and labeling of treatments for SUD, particularly new treatments for stimulant use disorder (StUD) and polysubstance use.

The authorization of health plan coverage for specific medications is a question informed but not directed by FDA approval. FDA approval is the threshold requirement for coverage consideration but does not, by itself, determine whether an individual with SUD has access to medication for SUD. FDA approval typically considers a product’s safety and effectiveness in isolation. Clinical endpoints that FDA has used in reviewing and approving SUD medications are not the only endpoints that payors consider when evaluating treatments for pharmaceutical benefit coverage.

Patient advocates and providers underscored that successful SUD treatment is not the same for all; abstinence is not the sole criterion of success. Payors also consider the range of available treatments (including those not involving medication, such as behavioral therapies and device-based treatment), cost-effectiveness and real-world effectiveness of those treatments, and the needs of their covered lives/beneficiary population at an individual level. Other criteria used to determine access to medications include those intended to guide the practice of medicine, e.g., American Society of Addiction Medicine (ASAM) criteria, and those designed for cost-control reasons and/or to prevent fraud, diversion, misuse, and abuse.

## Current Status of SUD Treatments

Deaths due to drug overdose have increased sharply in recent years. According to the Centers for Disease Control and Prevention’s National Center for Health Statistics, an estimated 100,306 drug overdose deaths occurred in the 12-month period ending April 2021, an increase of 28.5% from the 78,056 deaths during the same period the year before. While the major increase was due to opioid overdose, overdose deaths from synthetic opioids, e.g., fentanyl, and stimulants also increased during this 12-month period.<sup>1</sup>

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), SUD refers to a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal.<sup>2</sup> For the purposes of this white paper, two main types of SUD are being considered—StUD and opioid use disorder (OUD). Alcohol, tobacco, and caffeine are not included unless used alongside (other) stimulants.

StUD includes the misuse of stimulant substances such as cocaine, methamphetamine, and amphetamines. Overall, prescription stimulant non-medical use (misuse and abuse) impacts about 5 million adults in the United States, mostly involving amphetamines.<sup>3</sup> The population most impacted by stimulant use is young adults (18–29 years old).<sup>4</sup> In a recent study published in *JAMA Psychiatry*, methamphetamine overdose deaths surged nearly five-fold between 2012 and 2018, with American Indians and Alaska Natives having the highest death rates overall.<sup>5</sup> Currently, there are no medications that have been demonstrated to be effective for StUD and thus none approved by FDA. Available non-pharmacological treatments for StUD include psychosocial therapy and contingency management.

OUD includes the misuse of opioid substances such as codeine, heroin, morphine, opium, and prescription drugs such as methadone, oxycodone, and hydrocodone. In 2018, an estimated 2 million people had an OUD, which includes prescription pain medication containing opiates and heroin.<sup>6</sup> Taking opioids as directed by a prescriber is not considered an OUD.

Per SAMHSA<sup>7</sup>, “Medication-assisted treatment (MAT)\* is the use of medications, in combination with counseling and behavioral therapies, to provide a ‘whole-patient’ approach to the treatment of [SUDs].” Medications for SUD are approved by FDA, and treatment programs are clinically driven and tailored to meet each individual’s needs.

Available treatments for OUD include psychosocial therapy and medications. Currently, FDA has a few approved medications for the treatment of OUD (referred to as MOUD or “medications for OUD”). Methadone<sup>8</sup>, an opioid agonist, mimics other opioids, reducing craving and pain without full effects of other opioids. Buprenorphine<sup>9</sup> is a partial opioid agonist, activating opioid receptors. As a partial agonist, rather than a full agonist like methadone or morphine, buprenorphine has properties that make it less subject to nonmedical use.

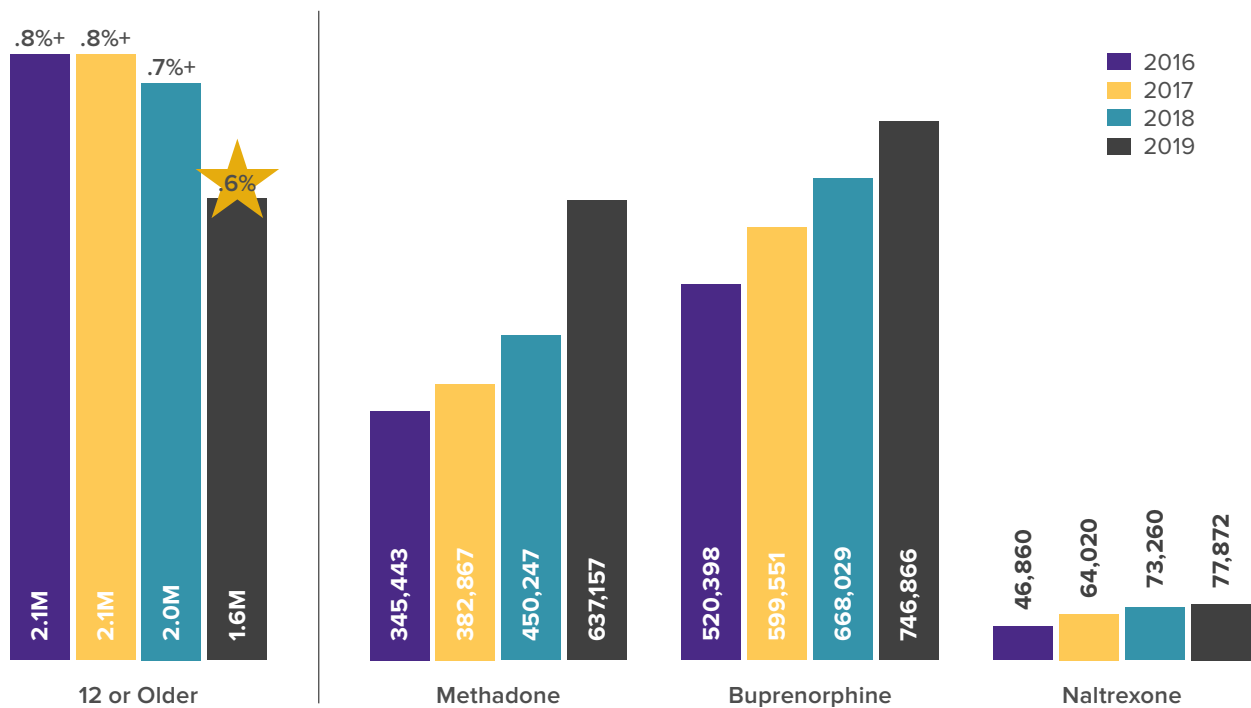
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\* “Medication-assisted Treatment” or MAT is no longer preferred terminology. Instead, “medications for opioid use disorder” or MOUD is the recommended term as it aligns with the way psychiatric medications are understood. See <https://www.drugabuse.gov/nidamed-medical-health-professionals/health-professions-education/words-matter-terms-to-use-avoid-when-talking-about-addiction> for additional insight on appropriate terminology.

Naltrexone<sup>10</sup> is the third medication approved to treat OUD and is available both in tablet and injectable formulations. Naltrexone is a highly effective opioid antagonist that tightly binds to new opiate receptors. Because it has a higher affinity for these receptors than heroin, morphine, or methadone, naltrexone displaces those drugs from receptors and blocks their effects.

Both naltrexone and buprenorphine have long-acting and short-acting formulations. Methadone can only be dispensed for OUD treatment in approved facilities, while buprenorphine and naltrexone may be prescribed and dispensed through traditional channels and with the appropriate authorization (see discussion on DATA 2000 legislation). Clinical trials indicate that all three are effective in preventing relapses post-detoxification.

According to SAMHSA, OUD has decreased steadily over the past few years, from 2.1 million individuals aged 12 and above with OUD in 2016 to 1.6 million in 2019 (see chart on left below).<sup>11</sup> Meanwhile, access to MOUD has gradually increased over the last few years (see chart on the right below). However, the need for greater access to MOUD still remains, as noted below. Results from the 2020 National Survey on Drug Use and Health were recently released. In this edition of the survey, the criteria for assessing OUD changed from DSM-IV to DSM-5, resulting in an inability to compare assessments to prior years.<sup>12</sup>



Source: SAMHSA, National Survey on Drug Use and Health, 2019

Polysubstance use is the misuse of multiple substances over time and may include a combination of both licit and illicit substances. In some cases, the individual transitions from regulated products to illicit substances or vice versa. Polysubstance use is common—if a person is having problems with one substance, they are likely using, and may be having problems with, other substances. The shifting use and availability of different substances have created a complicated landscape for developing SUD treatments generally.

# The Complex Ecosystem of Health Insurance Pharmacy Benefit Coverage of SUD Treatments

Fortunately, SUDs are treatable. But SUDs are often chronic in nature, with symptom recurrence rates similar to those for other well-characterized chronic medical illnesses, such as diabetes, hypertension, and asthma, which also have both physiological and behavioral components. Because relapse is common—and similar in consequence—across these illnesses, clinical guidelines suggest SUD should be treated like any other chronic illness.<sup>13</sup>

The United States, as well as many other countries, has had a long history of treating mental health issues separately from physical health. As a result, coverage of mental health services, including SUD treatment, has also been managed separately from coverage of physical medicine treatment. This landscape continues to change. The 2008 Mental Health Parity and Addiction Equity Act prevents group health plans and health insurance issuers that choose to provide mental health or SUD benefits from imposing less favorable benefit limitations on those benefits compared to medical/surgical benefits.<sup>14</sup> The 2010 Affordable Care Act required health plans for small groups and individuals on the health insurance exchange to cover mental health services, at a level comparable to medical services. Finally, in 2016, this same mandate was extended to Medicaid managed-care plans. Thus, applicable insurers must not charge higher copays or deductibles for mental health care.<sup>15</sup> However, some health plans, including some state Medicaid programs and state government employee plans, are able to opt out of some of the provisions in these laws, including the parity requirements.<sup>16, 17</sup>

A 2016 review of economic evaluation studies<sup>18</sup> indicated that MOUD is associated with lower total healthcare costs, despite higher outpatient and prescription costs. The costs of treatment were largely offset by lower utilization of high-cost services such as visits to the emergency department (ED) and inpatient care. In addition, there were lower criminal justice-related costs. The review concluded that methadone maintenance therapy was the most economically advantageous, but that the cost-effectiveness of buprenorphine and naltrexone, with and without contingency management and other techniques, was promising but not conclusive. See Appendix 1 for more background on economic evaluation studies.

Despite evidence of clinical and cost-effectiveness, the uptake of MOUD has not met the expectations of many. According to a study by Reutsch,<sup>19</sup> fewer than 50 percent of all patients with OUD receive MOUD of any form. Worldwide, the World Health Organization estimates that fewer than 10 percent of people who need MOUD have access to medication.<sup>20</sup> There are multiple reasons behind this lack of uptake. Doctors and other prescribers may not be adequately trained or may not be comfortable working with patients requiring MOUD. Some have identified other challenges that impact access to SUD treatment (see text box for barriers suggested by roundtable participants).

## Barriers to SUD Treatment

- The historical disconnect between healthcare and SUD treatment providers
- The lack of healthcare professionals trained to prescribe MOUD
- SUD treatment providers who do not fully embrace MOUD or simply prefer behavioral counseling and other non-pharmacological interventions
- SUD treatment providers who lack prescribing authority
- Insurance coverage parameters that serve as a barrier to access



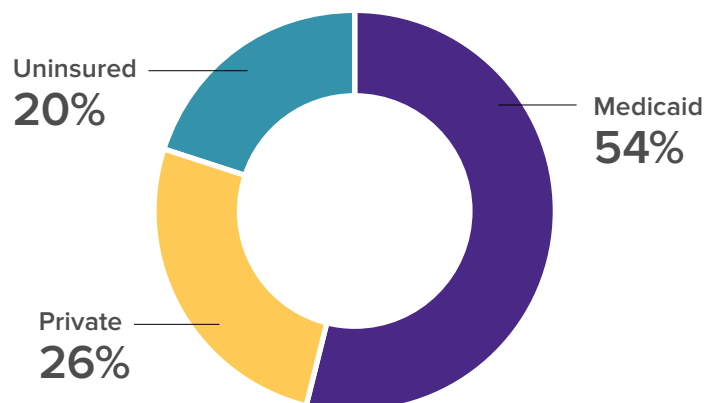
This roundtable focused on the insurance coverage component of MOUD uptake, with an intent to better understand potential payor environments for future medications for StUD. Self-pay, while not a focus of discussion during the roundtable, is also a key part of the payment ecosystem for SUD treatment. For example, one national study of ambulatory visits in which buprenorphine was prescribed found that visits by self-pay patients accounted for nearly 40 percent of all visits.<sup>21</sup> Practices preferring or only accepting self-pay patients may affect treatment uptake by limiting access to individuals who can afford out-of-pocket costs, though they may also provide a welcome degree of anonymity to individuals who would otherwise avoid treatment due to stigma-related concerns.

## Key Perspectives

As noted previously and in the appendix, the economic benefits of SUD treatment, with and without medication, are well-established. Financial support for treatment can come from multiple sources, primarily health insurance. In the United States, we have multiple forms of health insurance, both public and private, each with their own set of limits and exclusions, which adds to the complex ecosystem of pharmacy benefit coverage. Below are brief descriptions of various forms of health insurance and their intersections with SUD treatment.

**Medicaid** is the largest payor for SUD treatment.<sup>22</sup> Section 1006(b) of the SUPPORT Act requires states to provide Medicaid coverage for MOUD.<sup>23</sup> According to a 2018 report by SAMHSA<sup>24</sup>, all state Medicaid programs provide coverage for some form of MOUD, but not necessarily all forms of medication, e.g., extended-release forms. Furthermore, different states will have different combinations of benefit design limits, including prior authorization requirements and pharmacy benefits administered by managed care plans, creating a patchwork of programs and access that varies from state to state.

### Nonelderly Adults with Opioid Use Disorder Who Received Any Treatment in Past Year, by Insurance Status, 2017



#### Total Nonelderly Adults with OUD Who Received Treatment: 617,000

NOTE: Nonelderly adults are 18 to 64 years. Any treatment includes receiving drug and/or alcohol treatment at any of the following in the past year: inpatient hospital, residential rehabilitation, outpatient rehabilitation, mental health center, and private doctors' office. Excludes those in the other insurance category due to statistical unreliability.

Source: Kaiser Family Foundation *Issue Brief*, May 2019

State Medicaid programs routinely use benefit management tools to contain expenditures and guide use of medications, such as prior authorization or step-therapy. Several states require evidence that the patient is also receiving concurrent psychosocial treatment. Finally, quantity or dosing limits are common; some states impose lifetime Medicaid-funded treatment limits on SUD therapy.<sup>25</sup>

As with some private health plans, some state Medicaid programs use managed care organizations (MCOs) to administer behavioral health benefits, including pharmacy benefits, while in other states, e.g., California, SUD services are handled separately, outside of MCOs. In general, these MCOs administer benefits according to state regulations, using evidence-based guidelines, e.g., those from ASAM, to guide prior authorizations, preferred drug lists, etc.

Looking ahead, several states are in the process of developing new and innovative approaches to provide MOUD to their constituents. These include reform of existing pharmacy benefit design, as well as new incentives, programs, and demonstration projects (Section 1115). The 2008 Mental Health Parity and Addiction Equity Act is also providing greater impetus for states to expand coverage and improve access to MOUD.<sup>26</sup>

**Medicare.** In addition to Medicaid, the U.S. Government supports SUD treatment through a combination of Medicare (Part B medical insurance and Part D drug benefit). As the population of beneficiaries with SUD has aged,<sup>27</sup> the Centers for Medicare and Medicaid Services (CMS) is seeing a greater number of Medicare enrollees who are requiring chronic treatment for OUD. CMS coverage policies ensure some form of MOUD is available across all CMS programs. Starting in 2020, Medicare began to cover methadone for OUD and related services furnished by opioid treatment programs (OTP). In addition, all Medicare Advantage prescription drug plans and Medicare Part D plans have at least one MOUD product on a non-branded drug benefit tier. CMS will also cover other OUD treatment services as part of a bundled payment. These services include dispensing and administration of MOUD; substance use counseling; toxicology testing; as well as intake activities and periodic assessments. Additionally, the coverage includes substance use counseling and individual and group therapy services furnished by OTPs, either in-person or via two-way interactive audio-video technology (telehealth).<sup>28</sup>

Other U.S. Government programs that provide OUD treatment coverage include TRICARE and CHAMPVA, as well as federal block grants and discretionary grants given to state and local governments, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Pacific jurisdictions, and tribal entities for support of various treatment and recovery support programs.

**Private health plans** are another major source of financing for SUD treatments, albeit one with significant variation in the types of coverage offered. About 180 million lives are covered by an employment-based health plan, and an additional 35 million are covered by an individual plan. The majority of people with employment-based health coverage are covered under employer-funded, self-insured plans, with the risk assumed by the employer or union and claims processed by a third-party administrator.<sup>29</sup> These plan sponsors have certain latitude in coverage and benefit design by virtue of exemption from essential health benefit requirements. The 2008 Mental Health Parity and Addiction Equity Act and the 2010 Affordable Care Act have helped to improve access to addiction and mental health treatment; however, some treatment services are carved out of health insurance policies and behavioral health plans. As with Medicaid and Medicare, innovations are being tried with the goal of improving access to treatment for individuals with SUD while managing overall healthcare costs.

Payors, whether public or private, must weigh a number of considerations when designing their coverage benefits. In general, payors endeavor to offer the maximum number of benefits while remaining financially solvent. As such, payors have developed several features which they use to implement coverage programs. For SUD treatments, these features may include the requirement for prior authorization, the placement of specific treatments on a formulary or preferred drug list, and the existence of a pre-approved list of providers qualified to prescribe MOUD eligible for coverage under the plan.

Below are descriptions of two of these features.

**Pharmacy and Therapeutics (P&T) Committees** are used by State Medicaid agencies, health plans, and health systems to determine whether to place a medication on their Preferred Drug List or formulary. (Within a health system, the formulary determines what products are available in the facility. Within a payor, formularies

determine what drugs will be eligible for coverage under a health insurance plan.) Factors that a P&T Committee may consider include treatment efficacy, cost-effectiveness and cost offset, relevant policies and regulations, and ASAM guidance.

**Pharmacy Benefit Design** shapes access to pharmacotherapy. Initial coverage decisions for new treatments are a consideration with benefit design such as formulary placement, prior authorization, quantity or dosing limits, step therapy, etc. Each of these design parameters (some of which are described below) influence MOUD access and uptake—protecting against fraud and abuse and preserving plan resources, but potentially limiting individual access.

- Absence of a specific MOUD intervention on a payor formulary severely limits plan coverage for the medication. Placement on a less-preferred formulary tier requires a higher co-pay or co-insurance contribution from the enrollee, which may limit access.
- Prior authorization may require documenting the presence of specified conditions to authorize coverage for MOUD or a type of MOUD.
- Step therapy may require treatment failure of one or more interventions prior to authorizing coverage for a specific treatment.
- Quantity or dosing limits narrow insurance coverage to certain amounts of medication.

While not technically part of the pharmacy benefit coverage ecosystem, access to MOUD is impacted by state and Federal government regulations and policies. These regulations may be designed to lessen fraud, misuse or abuse of substances, whether licit or illicit, ensure that health providers and recovery support programs are qualified to provide treatment services, and/or intended to ensure a minimum standard of care within the state, whether provided by private plans or state-level Medicaid programs.

One commonly cited regulation which has recently undergone revision is enshrined in the Drug Addiction Treatment Act of 2000 (DATA 2000) legislation. Under this legislation, doctors or other prescribers intending to prescribe buprenorphine are required to complete online training and register with the Drug Enforcement Administration (DEA) to receive their “X-waiver.” This requirement limited the pool of practitioners allowed to prescribe buprenorphine to those willing to undergo the training and registration process. In April 2021, the Department of Health and Human Services issued new guidelines which allow practitioners who simply file a “Notice of Intent” to treat up to 30 patients with OUD using buprenorphine without having to make certain training-related certifications.<sup>30</sup>

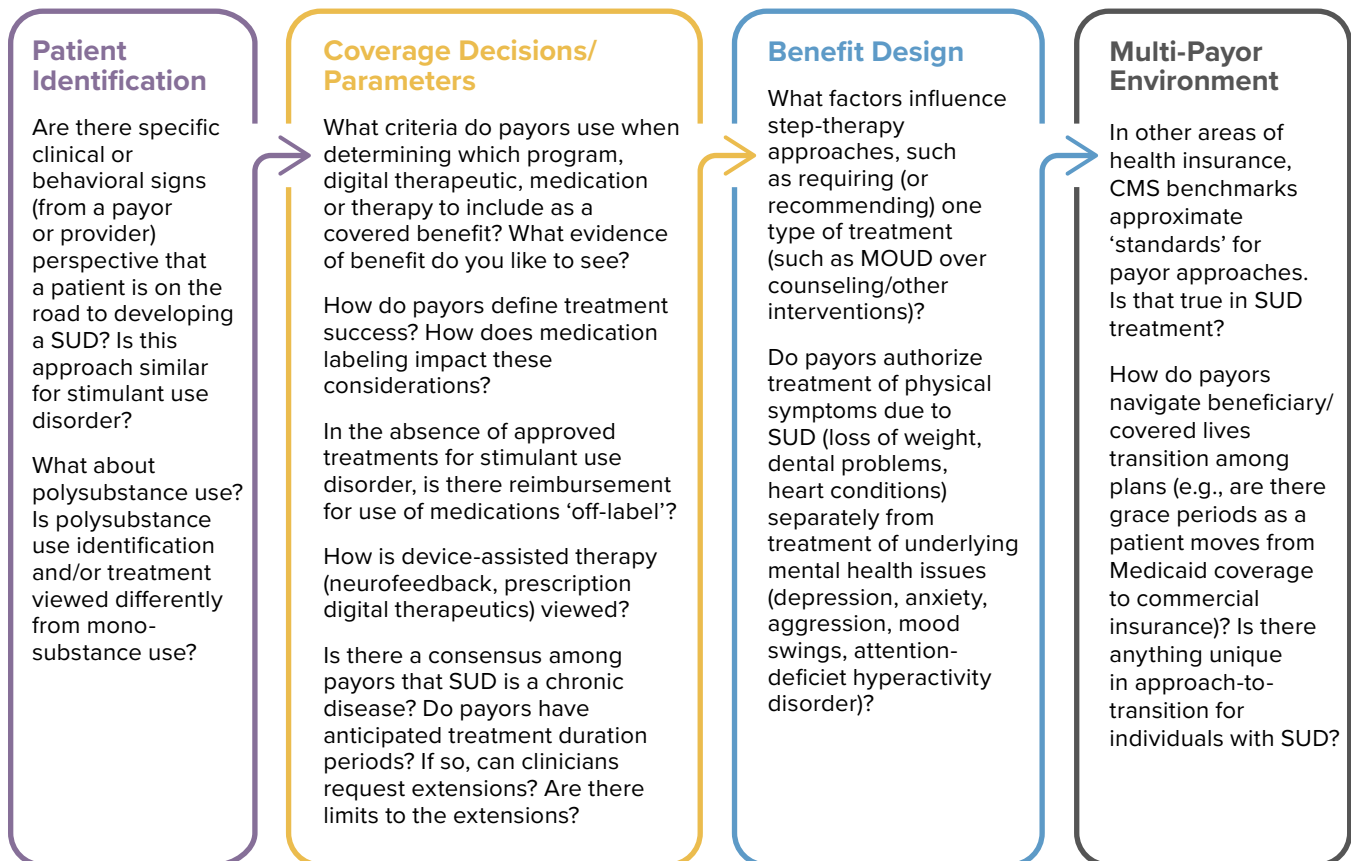
# Methodology

To gain a better understanding of the uptake of existing medications to treat SUDs, primarily MOUD, the FDA Foundation convened virtually a small group of stakeholders to share their perspectives on and experiences in SUD treatment. The group of 34 experts consisted of clinicians, health economists, individuals in recovery, treatment providers, and a variety of payors, as well as FDA and FDA Foundation staff. Among the payors, we had experts representing the experiences of large health insurers, employer-based plans, MCOs, state Medicaid agencies, and CMS. No representatives of regulated industry (e.g., pharmaceutical or medical device companies) participated in the discussion.

The meeting started with a few scene-setting presentations from clinicians, patients, and economists and then followed with an approximately 3-hour interactive dialogue. A series of questions, organized by theme, was used to structure the dialogue (see text box).

The participants provided their views and experiences. To encourage honest and candid discussion, the meeting followed “Chatham House Rules.”<sup>31</sup> Thus, no specific comments are attributed to any one person. After the meeting, the key takeaways were compiled and shared with the participants for their review and comment. Participants represented their own views reflecting on their personal or professional experiences. No attempt was made to corroborate or verify their statements.

## Discussion Questions



# Payor Perspectives and Insights Gathered

The following are the highlights and emerging themes expressed by participants.

## Impact of FDA Labeling on Payor Decisions

FDA does not have an explicit role in setting payors' policy, but the Agency's work distinctly shapes that policy. FDA-approved labeling is the initial starting point for discussions regarding whether to add a specific medication to a payor's covered drug benefits. Then the level of specificity in product labels—e.g., indications, dosing, and duration of pharmacotherapy—may be reflected in drug benefit design. Because of this influence, to the extent that FDA labeling can reflect the “lived experience” of individuals with SUD, the more likely that the treatment coverage parameters will align with that lived experience.

Factors beyond the FDA-approved label animate coverage and benefit design decisions, particularly as more evidence and experiences are gathered. Many payors require a formal review process to expand coverage to newly approved products. Thus, new product coverage decisions may lag FDA approval by several months. For example, coverage decisions may require convening a payor's P&T Committee, which typically meets on a regular schedule, e.g., every six weeks or quarterly. Alternatively, the payor and product sponsor or manufacturer may need to conduct contract negotiations, which can also take several months. Each of these processes takes place prior to providing coverage for any products to the enrollees/beneficiaries of the health insurance plan. To expedite such decisions, parties should share relevant evidence-based, non-promotional information as soon as possible, prior to FDA approval.

The payors' views of a medication can also evolve over time as additional evidence is made available, e.g., additional clinical trials, required post-marketing studies, or analyses of real-world data. In addition, various State and Federal level requirements for commercial insurance plans may introduce complexity. For example, according to one roundtable participant, nine states still require prior authorization of MOUD.

## Factors Influencing Coverage and Benefit Decisions



If payors are uncertain about a new product's benefits, initial coverage and benefit design parameters are more likely to align closely with the FDA label and not allow for deviations in use. Where stronger uncertainty exists, coverage and benefit parameters may be more limited than the FDA label. As more real-world data become available, payors and sponsors have an opportunity to reflect "lived experience" by introducing more innovation in payment design, such as initiation of pharmacotherapy in the ED as noted previously. Similarly, real-world data for pharmacotherapy can stimulate or help to expand additional benefit design changes or new innovations. Clinical study of already-approved medications can lead to payor support and adoption of benefit design incorporating new clinical guidelines/practice prior to FDA approval of a new indication. FDA labeling could also potentially influence provider payment design.

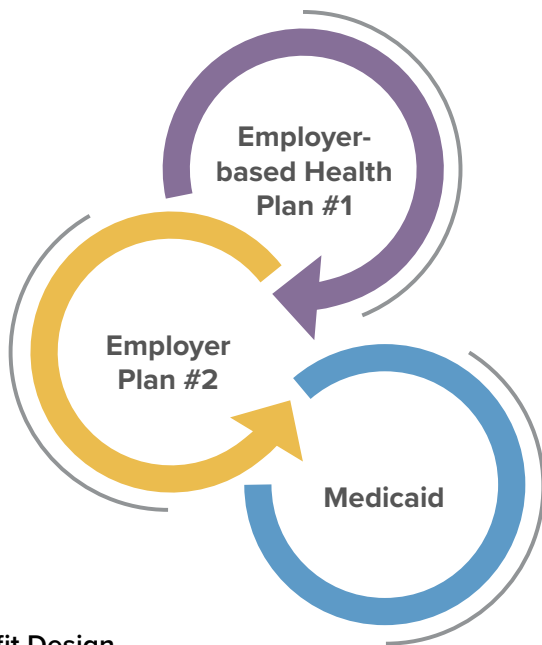
For example, participants in the roundtable observed that medication for SUD, if indicated, should be initiated as early as possible, including in the ED. Primary care physicians and ED physicians should have the ability and training to prescribe medications for SUD and/or counseling, including the consideration of financial incentives to encourage such action, which some of our participants had incorporated into their insurance benefit design. Participants also observed that lack of access to trained behavioral health professionals, particularly in EDs and in underserved parts of the country, is another reason why only a fraction of individuals with SUD have access to medication for SUD. A small, but increasing, number of both public and private payors are creating financial incentives for providers who initiate pharmacotherapy during ED visits. Recent changes in practice guidelines should enable this shift to gain momentum. Participants stated that clear FDA labeling that indicates that the immediate start of MOUD in ED settings (where the applicant has supported with requisite evidence) may further adoption of this approach.

### **The Shifting Payor Environment**

Beyond personal health impacts, individuals with SUD are costly from a societal perspective, particularly lost productivity, quality of life, and premature mortality (see [Appendix](#)). Economic studies indicate that the benefits of treatment, particularly pharmacotherapy, significantly outweigh its costs over the long term. Thus, continued innovation in new pharmacotherapies that lead to measurable improvements should be considered a good investment.

Individuals in recovery often transition from one type of insurance program to another, e.g., Medicaid to private plans, between private plans, prison health care to Medicaid or private plan, fee-for-service to managed care. Furthermore, the population of individuals with SUD is starting to age, reflected in increasing numbers enrolled in Medicare. A significant number of individuals have dual coverage of Medicaid and Medicare.

Poorly coordinated transitions between programs, abrupt changes in benefit design, and sudden increases in out-of-pocket expenses can lead to gaps in treatment and potentially trigger relapse, which can result in increased overall healthcare expenses (in addition to the obvious trauma to the individual and their families). Well-coordinated handoffs from one type of coverage to another help minimize relapses and lower costs. As an example, an enrollee in a health plan supported by Employer #1 has been successfully using MOUD and plans to accept an offer of employment from Employer #2. If Employer #2's health plan requires documentation that counseling alone was not successful prior to authorizing coverage of MOUD, requiring the enrollee to experience a counseling-only treatment failure, i.e., a relapse, it would be counterproductive both for the patient and the employer. Labeling emphasis on adherence may also be helpful in underscoring the chronic nature of SUD pharmacotherapy and the need for smooth transitions to minimize disruptions.



**Smooth Transitions** between health plans lead to:

- Continuity of Care
- Fewer relapses
- Lower costs

**Poor Transitions** with significant changes in benefit design can lead to:

- Treatment gaps
- Relapses
- Higher costs

## Benefit Design

Pharmacotherapy is commonly combined with psychosocial treatment, and some payors may require such treatment before approving pharmacotherapy. Lack of coordination between medical and drug benefit design can make meeting such requirements more complicated. Benefit design is not always accommodating to the individualized, and chronic, nature of SUD. According to one participant, pharmacotherapy (MOUD) is reaching only about 30 percent of individuals with OUD. This gap in pharmacotherapy is partly attributed to benefit design stipulations. In the past, prior authorizations, treatment limits, restrictive refill requirements, or restrictions on treatment coverage for new covered lives/beneficiaries have delayed or disrupted treatment, despite the documented medical and economic benefits of providing treatment.

These practices are increasingly being phased out, although Medicaid programs in nine states still require prior authorization, and restrictions on adolescent coverage and lifetime prescription limits still exist in some cases. Step therapy is no longer common in SUD, but quantity or days-supply limits or special prescription requirements also create coverage barriers. For example, due to restrictions on quantity, patients may be forced to refill their prescription on a weekly basis, rather than a 30-day supply, with each weekly visit requiring a separate co-pay, thus driving up out-of-pocket costs. A pro-rated co-pay may minimize this impact.

According to a few participants, while the benefits of pharmacotherapy and the need to treat SUD as a chronic disease are largely accepted in the community, the stigma of SUD still persists among some public and private payors (as well as some providers), which may influence coverage limitations and benefit design. As mentioned above, states, in some cases, put in place these policies, rather than the health plans themselves. For example, contingency management—the provision of small incentives to patients as a reward for following their treatment plan—may be restricted or prohibited by state policy. While FDA does not have a role in the adoption of contingency management, when it is possible for the FDA labeling to provide clear prescribing guidance, this can perhaps discourage such restrictive policies by emphasizing the positive benefits of consistent medication in preventing relapses.

Finally, while not a benefit design per se, some participants noted that low reimbursement rates, training requirements, stigma, and other disincentives have led to fewer qualified providers and treatment programs, in turn limiting access to quality treatment.



## Conclusions

The investment of health plan or pharmacy benefit dollars in specific medications is a question informed, but not directed, by FDA approval. While FDA approval considers a product's safety and effectiveness, payors must consider the range of available treatments (including those not involving medication, such as behavioral therapies and device-based treatment) and the needs of their covered lives/beneficiary population.

As outlined in this paper, clinical endpoints that FDA has used in reviewing and approving SUD medications are not the only endpoints that payors consider when evaluating treatments for policy coverage. Payors consider multiple factors in coverage determination, including whether conditions such as prior authorization or step therapy would be appropriate to help assure appropriate use and appropriate investment of health care coverage dollars.

Shedding light on the nature of those considerations as well as the other factors that influence pharmacotherapy access helps to inform the FDA in its mission<sup>32</sup>, which includes helping to speed innovations that make medical products for conditions such as SUD more effective, safer, and more affordable.

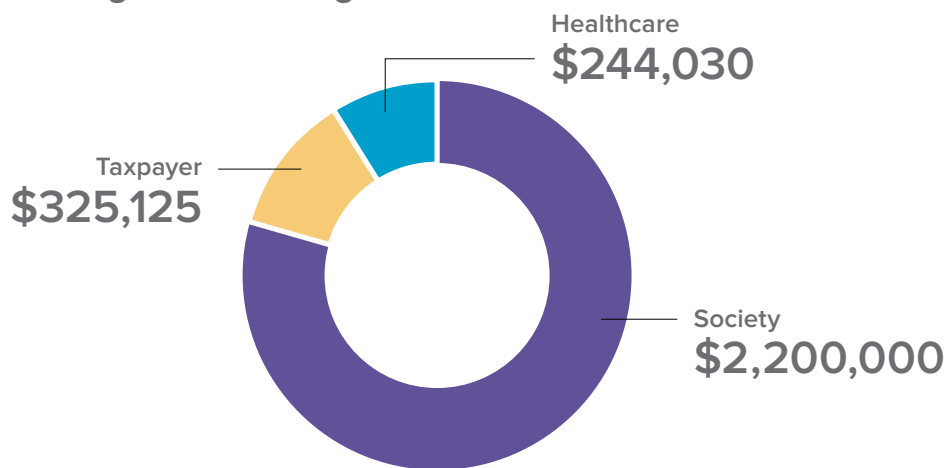
# Appendix

## ECONOMIC IMPACTS OF SUD

The full economic impact of SUD is not easy to appreciate. In the literature, the majority of economic analyses focus on OUD, with relatively few studies, and of more limited scope, focusing on other types of SUD, i.e., StUD or polysubstance use.

In a 2020 paper, Sean Murphy of Cornell Weill Medical School estimated the annual economic cost to the United States for OUD at \$786.8 billion (2018 USD), consisting of excess healthcare utilization (\$89B), premature mortality (\$60.3B), reduced workplace productivity (\$64.6B), and criminal activity (\$29.9B). The value of averting or preventing an OUD was calculated to be \$2.2 million from a societal perspective, \$325,125 from a taxpayer perspective, and \$244,030 from a healthcare perspective. The economic costs associated with OUD vary over time and by age of the individual, with peak costs to society during the ages of 35–49 and the peak value of averted OUD associated with the ages of 12 to approximately 40 years old.<sup>33</sup>

### Value of Averting or Preventing an OUD



Source: Murphy SM, *The Cost of Opioid Use Disorder and the Value of Aversion*. *Drug Alcohol Depend.* 2020;108382

A more recent paper by Curtis Florence of the Centers for Disease Control and Prevention, using a matched case-control design, pegged the societal costs of OUD and fatal opioid overdose in 2017 at \$1.02 trillion (2017 USD), with most costs associated with reduced health-related quality of life and lost productivity due to premature death, loss of work, or incarceration.<sup>34</sup>

**Economic value of treatment.** A 2016 review of economic evaluation studies, also by Murphy<sup>35</sup>, indicated that pharmacotherapy for OUD is associated with lower total healthcare costs, despite higher outpatient and prescription costs. These costs were largely offset by lower utilization of high-cost services such as visits to the ED and inpatient care. In addition, there were lower criminal justice-related costs. The study concluded that methadone maintenance therapy was the most economically advantageous, but that the cost-effectiveness of buprenorphine and naltrexone, with and without contingency management and other techniques, were promising but not conclusive.

Another study by McCollister showed that the cost of medication was modest in comparison to the cost of detoxification, a necessary precursor to MOUD with methadone, buprenorphine or naltrexone.<sup>36</sup> Furthermore, the medication cost of naltrexone extended release was higher than buprenorphine but provider and patient costs for buprenorphine were higher due to higher frequency of visits required. Overall, the per patient costs of these treatments were similar.

According to a study by Reutsch<sup>37</sup>, fewer than 50 percent of all OUD patients receive MOUD of any form, and 40-60 percent of individuals relapse within one year of discharge. Although OUD is generally regarded as a chronic relapsing disorder, treatment non-adherence is a contributing factor, with non-adherent patients relapsing at higher rates, leading to higher costs overall.

Similar analyses calculating the economic impacts of StUD or polysubstance use have not been developed. A limited study indicated that the cost of amphetamine-related hospitalization grew from \$436 million in 2003 to \$2.17 billion in 2015, with approximately half of that cost (\$1.25 billion in 2015) covered by Medicaid.<sup>38</sup> However, this study only addresses healthcare utilization and does not incorporate costs associated with premature mortality, reduced workplace productivity, and criminal activity, which are largely felt at a societal level.

As noted earlier, few economic studies have focused on StUD or polysubstance use, hindering us from appreciating the full impact of SUD, or the benefits of potential treatments. Further analysis of the economic impacts of stimulant/polysubstance use is needed. Such research would help payors and society as a whole properly assess the economic benefits of encouraging treatment of StUD as well as the costs of ignoring StUD in the population.

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