



Psychedelic-Assisted Therapy Expands Employer Options for Mental Health Treatment

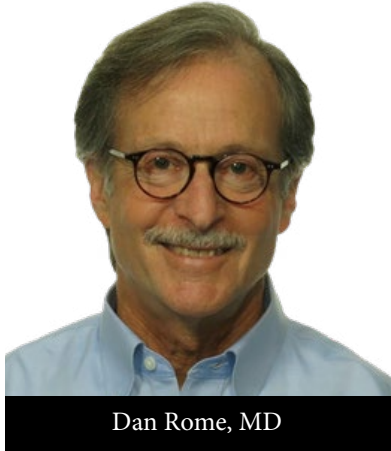
Written By Laura Carabello

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With growing mainstream media coverage surrounding Psychedelic-Assisted Therapy (PAT) and its benefits to address staggering mental health issues such as anxiety, depression, substance use disorder (SUD) and chronic, unresolved post-traumatic stress disorder (PTSD), it's no wonder that self-funded organizations are now paying attention to and adopting this treatment option.

PAT refers to therapeutic practices that involve the ingestion of a psychedelic drug, and since the early 1990s, a new generation of scientists has revived the research to support this treatment. A growing body of research is helping to dispel the social stigma surrounding "psychedelics" and employers are taking a healthcare perspective on covering this treatment as a meaningful health benefit.

As science now better understands the health and wellness improvements derived from the medicinal use of psychoactive compounds, such as Ketamine, this novel, innovative approach introduces opportunities for cost effective mental health treatment that deviates from traditional pharmacological interventions.



Dan Rome, MD

“The effectiveness of ketamine-assisted therapy has been demonstrated through multiple research studies and more than twenty years of accumulated clinical experience,” says Dan Rome, MD, chief medical officer at Enthea, the first and only licensed, turn-key third-party administrator (TPA) of psychedelic healthcare in the United States offering psychedelic healthcare as a workplace benefit.

Clinical trials have shown that ingesting a psychedelic in a carefully prescribed and monitored setting can induce an experience that is medically safe and that provokes profound, durable psychological and behavioral change.

Researchers have conducted highly regulated studies, using careful screening, therapeutic preparation, controlled settings and with trained monitors. Innovative therapies, such as Ketamine, are now FDA-approved and state-legal for use to effectively treat a range of behavioral disorders.

Several reports show that psychedelics have surged in popularity over the past few years. According to National Survey on Drug Use and Health, prepared for the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (HHS), 1.4 million Americans tried hallucinogens for the first time in 2020.

This level of enthusiasm, as reported in the *New England Journal of Medicine*, is partially the result of clinical trials showing that the drugs, notably psilocybin and ketamine, hold real promise in treating some mental health disorders, particularly depression. In fact, two states, Oregon and Colorado, have now legalized psilocybin for therapeutic use, and additional states are expected to follow suit.

Here’s the caveat: specialists who study these substances strongly urge that people only use them in supervised therapeutic settings, such as in a clinical trial or at an established ketamine clinic.

There are safety concerns attached to these substances and they are illegal outside of these venues.

Experts at Lancet advise that psychedelics have an extremely low chance of lethal overdose and there is little likelihood of addiction. As a result, authors classify them as some of the least harmful recreational drugs. But they do caution that they are not entirely without risk. Because of this, psilocybin trials and ketamine clinics have strict exclusion criteria to try to protect people who have physical or psychological vulnerabilities.

The newest research published in *Nature* offers promise that psychedelic drugs may “reopen” the brain to help it recover from trauma. Scientists at Johns Hopkins University were investigating the drugs’ effects on “critical periods” for social learning, times when the brain is more open to new information that diminish as we age. They also anticipate that the therapeutic horizon for psychedelics could expand to other opportunities to retrain the brain, including recovery from a stroke, traumatic brain injury and even hearing loss and paralysis.

Some medical professionals and researchers say that PAT can be lifesaving when other traditional medications and therapies have failed. Researchers point to their remarkable efficacy in treating conditions that are often resistant

Psychedelic Assisted Therapy

to conventional treatments, with one promising arena in the treatment of substance abuse.

Employers are often ill-equipped to address these treatment-resistant conditions and welcome proven solutions. Given the current shortage of mental health providers and compromised access to care, this option is resonating among health decision-makers.

CALL FOR MORE EDUCATION AND MARKET AWARENESS

Don McCully, founder, Medical Captive Underwriters LLC, makes a good point: “Psychedelic assisted therapy is not widely known as an excellent treatment source. Education about the groundbreaking work in this area is largely muted. Employer decision making in this area requires additional education to allow for better informed decisions. PTSD and cancer were the first disease states approached for use of PAT and both experienced amazing outcomes. This needs amplification.”



He observes the inertia in health care for adoption of new and better treatments, saying, “It took 20 years to get sleep apnea patients assigned to pulmonologists. While there are no similarities or comparison between sleep disorders and PAT psychedelic assisted therapy, this is an example of the delayed response among decision-makers.”

Emphasizing that the first step in any behavioral health treatment plan is a referral from the trusted family physician, preferably a Direct Primary Care provider, he highlights the importance of a referral for PAT from a provider with enough knowledge to pair up the patient with an estimable good fit. McCully says he has heard about a few employers that make this treatment available, noting that many first responders are aware of PAT and are incorporating it into plan offerings.

“The only way to offset the significant cost I estimate this treatment will run, it is only logical to have covered members contribute in the form of a deductible, co-pay or co-insurance,” he says.

Enthea counters this statement by demonstrating the cost-savings of ketamine-assisted therapy:



Source: 2023 Enthea

WHAT IS KETAMINE?

Ketamine is legal in the U.S. in all 50 states to clinically treat patients suffering from not only serious mental illness who have tried other medications with little or no relief, but also others who are struggling to a lesser severity.

Ketamine is a synthetic pharmaceutical compound, classified as a dissociative anesthetic. It is one of the most widely used drugs in modern medicine and is on the World Health organization’s List of Essential Medicines. It was developed in 1963, approved by the Food and Drug Administration for certain surgical procedures in 1970, and adopted by many hospitals and medical offices because of its rapid onset, proven safety, and short duration of action.



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More recently, a growing body of research has found that lower doses of ketamine may be effective to treat a variety of mental health conditions. During the 1990s, investigators at the National Institute of Mental Health started to explore the antidepressant potential of ketamine while looking for alternatives to anti-depressants, commonly known as SSRIs and SNRIs.

In conjunction with this growing body of research, ketamine clinics and clinicians have proliferated across the United States, offering ketamine sessions for a range of psychiatric disorders either using ketamine-only treatments or ketamine in conjunction with psychotherapy (i.e., KAT).

Ketamine can induce a state of sedation -- feeling calm and relaxed -- as well as relief from pain. Ketamine is an FDA-approved medical product as an injectable, short-acting anesthetic for use in humans and animals and esketamine (Spravato®; the active form of the drug) which was granted FDA-approval as a nasal spray for treatment-resistant depression.

In 1999, Ketamine became a Schedule III non-narcotic substance under the Controlled Substances Act. Ten years later, the FDA approved the S(+) enantiomer of Ketamine

(esketamine) nasal spray version (Spravato®) for treatment-resistant depression that is only available at a certified doctor's office or clinic.

According to Dr. Rome, "Unlike existing medicines, these compounds have a unique "neuroplastic" effect, meaning they put the brain in an unusually fresh, open and flexible state that is freed of long-established assumptions and routines – ways of seeing things and experiencing ourselves, others and the world around us."

He says to imagine the mind of a 2-year-old – curious, open, unburdened by anxiety and depressive thoughts: "Exploiting this neuroplastic effect combined with gently guiding talk therapy, many are finding lasting relief from depression, anxiety, PTSD and addictive disorders."

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KETAMINE-ASSISTED THERAPY (KAT)

KAT is a treatment that integrates prescribed doses of sub-anesthetic ketamine under the supervision of a clinician. Combined with integration sessions with KAT-trained therapists, this treatment improves mental health conditions. In low doses, ketamine can serve as an adjunct to psychotherapy, as it provides an opportunity for the temporary softening of psychological defenses, which may result in deeper self-reflection and psychotherapeutic processing.

Together, these components may help patients break long-standing, deeply ingrained thinking patterns associated with a variety of mental health conditions and, in turn, develop new ways of thinking and being. In this way, KAT involves the use of ketamine to enhance and deepen the therapeutic process, and the use of psychotherapy to amplify and prolong the curative effects of ketamine.

Ketamine is fast-acting and short-lived, making it very conducive to working with a therapist.



EMPLOYER ADOPTION OF PAT

A sure-fire sign that PAT has hit the self-funded community is the creation of Enthea as a TPA to help self-funded organizations, brokers, benefits consultants and other intermediaries with new choices, new and better ways to treat mental health issues that are apparent in the workplace.

Established in 2020 and thereafter re-organized as a Public Benefit Corporation, Enthea advocates for the safe and effective clinical use of psychedelics.

The Enthea approach is to offer employer-sponsored benefit plans new and better mental health treatment options that are proven to be safe. Standards of care emanate from Enthea's evidenced-based medical policy, with treatment delivered through its proprietary network of KAT/PAT therapists.

Sherry Rais, CEO and co-founder, Enthea, says, "Our goal is to make it easy for employers to expand their mental health package and offer psychedelic healthcare to their employees. Employers need and rely upon our developed protocols, guidelines and frameworks for integrating psychedelic therapy into their benefit program design. This practical perspective is vital for the industry as it moves towards broader adoption of psychedelic therapy."

Rais points to Enthea data and scores over the past year which demonstrate the impact of KAT treatment for members:



- Post-traumatic stress disorder (PTSD) diagnosis reported an average of 86% symptom reduction
- Major depressive disorder (MDD) diagnosis reported an average of 67% symptom reduction
- General anxiety disorder (GAD) diagnosis reported an average of 65% symptom reduction.

"This is astounding considering that only 15% of people who use SSRIs find them highly effective, and the SSRIs, in contrast to ketamine therapy, come with many, many unwanted side effects," says Rais.

POST TRAUMATIC STRESS DISORDER (PTSD)

PTSD is defined as a disorder that develops in some people who have experienced a shocking, scary, or dangerous event. Anyone can develop PTSD at any age, including combat veterans and people who have experienced or witnessed a physical or sexual assault, abuse, an accident, a disaster, or other serious events.

"As psychedelic treatments become better understood and widely accepted and practiced within healthcare, they will provide critical support to self-insured participants," says Rais, noting that Enthea is building a nationwide network of credentialed providers. "We vet each clinic to ensure that they are staffed by credentialed PAT providers and follow guidelines that include:

- Evidence-based medical policies for psychedelic therapies that are regularly updated based on clinical developments and FDA approvals.
- Standards of care and credentials across the network to assure quality, positive patient experiences and positive treatment outcomes.
- Easy treatment authorization and reimbursements to providers, while shielding employers from Protected Health Information.

Pharmaceutical Expertise Helps Clients Better Manage Costs



HM Insurance Group's Pharmacy Operations Team Is Essential in Helping to Assess and Address Risk

Pharmacy expertise is critical to smart claims management, especially with high-cost gene therapies now entering the market regularly. The claims associated with these high-cost treatment options can be catastrophic to self-funded employers without the right Stop Loss coverage in place.

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Helping Clients Manage High-Cost Claims

Pharmaceutical developments continue to keep everyone — carriers, brokers, and employers alike — on alert, and HM has prioritized working together to better aid in managing claims expenses without compromising care, helping to achieve improved outcomes now and in the future.

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*AM Best Company, Best's Rating Reports, August 2022.

¹HM Insurance Group's Pharmacy Focus: Elevidys – A New Gene Therapy for Duchenne Muscular Dystrophy (DMD), June 2023, hmig.com; and HM Insurance Group's Pharmacy Focus: Hemgenix® – A New Gene Therapy for Hemophilia B, December 2022, hmig.com
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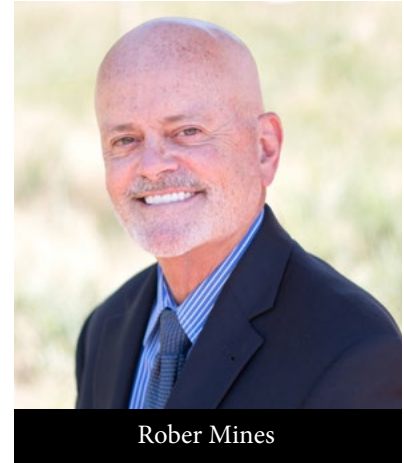
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MICRODOSING OF PSYCHEDELIC SUBSTANCES

Microdosing involves taking sub-perceptual doses of psychedelic substances, such as psilocybin-containing mushrooms, in order to experience subtle cognitive and emotional benefits without the typical hallucinogenic effects associated with higher doses.

Psilocybin or magic mushrooms are naturally occurring and are consumed for their hallucinogenic effects. They are psychedelic drugs, which means they can affect all the senses, altering a person’s thinking, sense of time and emotions.

Robert A. Mines, Ph.D., Chairman and Chief Psychology Officer of MINES and Associates, an international business psychology firm providing behavioral health services for self-insured organizations, explains, “While there has been a growing interest in microdosing, it’s important to note that the scientific research on its effects and efficacy is still limited.”



Rober Mines

Mines points to the “pros” of microdosing:

1. Enhanced Mood and Emotional Well-being: A study found that microdosers reported improvements in mood

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and emotional stability. Participants reported increased positive affect, reduced depressive symptoms, and enhanced emotional regulation.

2. **Increased Creativity and Cognitive Flexibility:** Research suggests that microdosing may enhance cognitive abilities associated with creativity. Microdosers reported improved divergent thinking, increased fluency, and enhanced cognitive flexibility, potentially leading to enhanced problem-solving skills.
3. **Heightened Focus and Productivity:** Microdosing has been associated with improved focus and concentration. Researchers found that microdosers reported increased energy levels and improved productivity, leading to enhanced work performance and efficiency.
4. **Reduction in Anxiety and Stress:** Preliminary evidence suggests that microdosing may have potential therapeutic effects on anxiety and stress. Researchers observed a reduction in anxiety symptoms among microdosers, indicating its potential as an alternative

approach for managing anxiety disorders.

Mines also cites some of the “cons”:

1. **Lack of Standardized Protocols:** One of the challenges with microdosing is the lack of standardized protocols. One study emphasized the need for careful dosage control, as individual responses to microdoses can vary. The absence of precise guidelines may lead to inconsistent effects and potential risks.
2. **Potential Side Effects:** While microdosing aims to avoid the acute psychedelic effects, some individuals may still experience side effects. One study reported increased irritability and restlessness in a subset of participants, suggesting the importance of monitoring individual responses to microdoses.
3. **Legal and Regulatory Considerations:** It’s important to note that the legal status of psilocybin-containing mushrooms varies across jurisdictions. In many places, their possession and use are still illegal. Individuals considering microdosing should be aware of the legal implications and potential risks involved.
4. **Lack of Long-Term Safety Data:** Although the existing research on microdosing is promising, the long-term safety and potential risks associated with prolonged microdosing are yet to be fully understood. Further research is needed to evaluate the potential long-term consequences and safety profile of microdosing practices.

“Microdosing with mushrooms has gained popularity due to anecdotal reports of positive experiences and potential benefits,” continues Mines. “While the available peer-reviewed literature on microdosing is still limited, it suggests potential advantages such as enhanced mood, creativity, and focus. However, it is essential to consider the lack of standardized protocols, potential side effects, legal considerations, and the need for long-term safety data.

Mines asserts that science advantages from an initial clinical observation and set of case studies through preliminary peer reviewed studies to gold standard double blind studies.

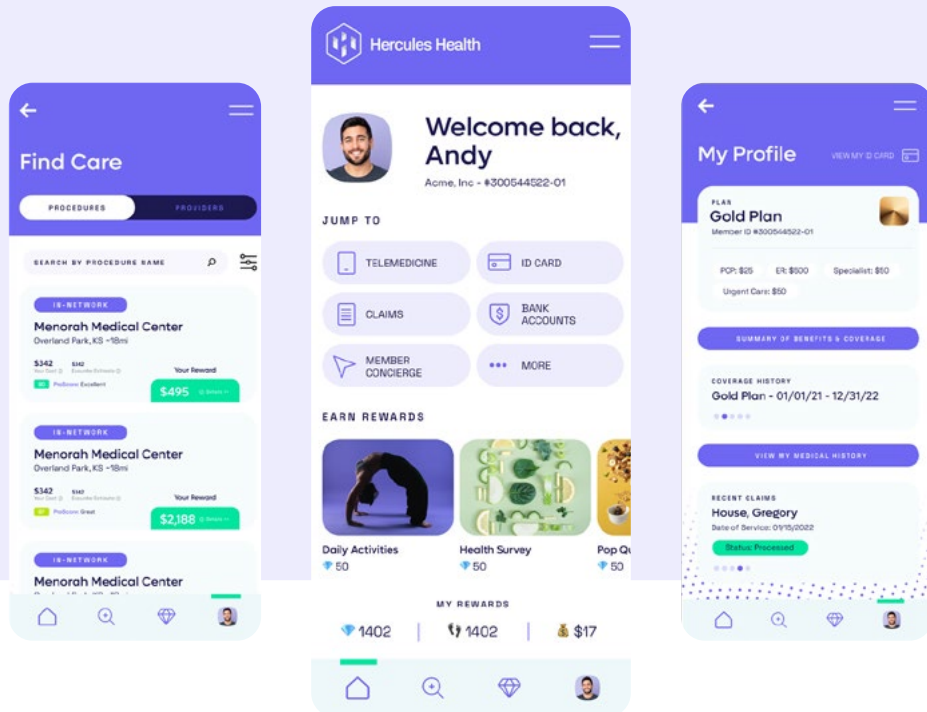
“Microdosing has received significant social media attention with many individuals self-microdosing and sharing their experiences,” he states. “How these experiences translate to treatment for depression, generalized anxiety or PTSD much less other conditions is unknown regarding the actual dosage levels. Furthermore, as in many areas of psychotropic medications, the actual causal pathways of deficiencies



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at the neurochemical level is not known in the research to date”

He says there are a number of correlational studies that associate improvement in symptoms with taking psilocybin. The basis for the effects could be a number of factors ranging from actual biochemical positive changes to placebo effects.

“We just do not know at this time,” he advises. “From the self-insurance perspective, I suggest the industry proceed with its usual caution on experimental medications. It is premature to endorse the use of microdosing until the research clarifies what does may be effective -- assuming further research does support the next step related to effectiveness, for whom, and at what dose levels, plus long term effects, and for those who it may be contraindicated.”

COMPANIES INTRODUCE PAT

“By building a provider network for safe and legal clinical pathways to psychedelic therapy, Enthea services come at a critical time when self-funded companies recognize that mental health issues are significantly impacting the workplace in terms of employee wellness, attendance and productivity,” says Rais, referring to the companies

that offer PAT to their employees via the Enthea network:

Dr. Bronner’s

Dr. Bronner’s is leading the way as an early adopter and advocate of psychedelic medicine. The US-based, family-owned company expanded its healthcare benefits as a first step in prioritizing their support of employee mental health and wellness. Founded in the U.S. in 1948, Dr. Bronner’s is the top-selling natural brand of soap in North America and a leading brand worldwide.

“The health and wellbeing of our employees is the primary driver in how we think about benefits and compensation,” explains

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Michael Bronner, president, Dr. Bronner's. "Offering coverage for ketamine-assisted therapy is in the interest of providing tools to our workforce to have the best quality of life and best options for mental health care."

Dr. Bronner's employees and their dependents receive assistance from Enthea, either electronically or by phone, to connect with a ketamine-assisted therapy provider. Once a patient/provider relationship is established, 100% of services are covered for Dr. Bronner's benefit eligible employees.

Bronner continues, "Our family and Company are no strangers to depression and anxiety. We are deeply concerned about the mental health crisis society is facing, especially in the context of the Covid-19 pandemic. Considering all our advocacy on this issue, this employee benefit is the next logical step."

Dr. Bronner's supports a number of public education efforts, advocacy organizations, and political campaigns around the country working to advance the acceptance and availability of psychedelic-assisted therapy and medicines to treat depression, anxiety, PTSD, and other conditions.

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"The reality is the vast majority of all illnesses and diseases are psychosomatic," says Jorge Yant, founder and CEO, PLEXIS Healthcare Systems. There are things that we can heal with our minds just as much as we can create with our minds. And so, tools that help expand consciousness and help you see more clearly the truth of how things are will help you just naturally heal effortlessly."

He says we're just at the beginning, adding, "I see several reports from our insurance companies that give me a sense of the types of medications and the types of services, in general, that our employees and their family members are using. It's shocking the number of people on antidepressants. Psychedelic therapeutics could change this dependency."

Yant believes that KAT, if properly administered and applied in the right setting, can be extremely helpful and useful to people, not only for mental illness issues, but also physical problems.

"We're covering the cost of the benefit which is included our very rich benefits package," he explains. "My aim is always to try to find new benefits to give our employees. A healthier healthy employee is a productive employee."

PAT: A BETTER SOLUTION FOR MENTAL HEALTH

Novel Treatment Approach: Psychedelic therapy introduces a novel treatment approach that deviates from traditional pharmacological interventions. By combining the administration of psychedelic substances, such as psilocybin, MDMA, or LSD with prescribed dosage under doctor-supervision and with therapeutic support, this treatment offers a unique and potentially more effective way to address mental health conditions. This shift from symptom management to a more holistic, transformative approach can revolutionize the field of mental healthcare.

Breakthrough in Treatment-Resistant Conditions: Psychedelic therapy has shown remarkable efficacy in treating conditions that are often resistant to conventional treatments. For example, clinical trials have



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demonstrated the potential of psychedelics in reducing symptoms of treatment-resistant depression, PTSD, addiction, and anxiety.

Accelerated Therapeutic Process: Psychedelic therapy has the potential to accelerate the therapeutic process by facilitating deep introspection, emotional breakthroughs, and heightened states of consciousness. The psychedelic experience can help individuals gain new perspectives, access repressed memories, and confront underlying emotional traumas. This accelerated process can potentially lead to profound insights, personal growth, and lasting therapeutic benefits in a shorter time frame compared to traditional therapy approaches.

Shift towards Personalized Medicine: Psychedelic therapy aligns with the growing emphasis on personalized medicine and patient-centered care. The treatment is tailored to the individual's unique needs, focusing on their personal experiences, traumas, and aspirations. This personalized approach recognizes the multidimensional nature of mental health and aims to address the underlying causes rather than merely suppressing symptoms. The shift towards personalized medicine holds the potential to revolutionize the healthcare industry, leading to more tailored and effective treatments.

Potential Cost Savings: While the cost-effectiveness of psychedelic therapy is still being studied, early evidence suggests that it may lead to tremendous cost savings in the long term. Therapy session costs are dependent on location, provider, and type of service, however, a typical session can range from \$150-\$400 per session.

By potentially reducing the need for long-term medication use, hospitalizations, and ongoing therapy sessions, PAT



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has the potential to alleviate the financial burden on individuals and healthcare systems. Health economists are calculating a \$25,000 savings per individual with effective treatment.

reported using out-of-network mental health or substance use providers “all of the time” versus only 6% for physical health care.

- Even among patients who successfully made an appointment with a new in-network mental health or substance use provider, 40% had to contact four or more providers.

Immediate access to PAT can help employers to resolve these challenges by providing a meaningful solution that can be rapidly and cost-effectively implemented. ■

PAT: ADDRESSING MENTAL HEALTH TREATMENT ACCESS CHALLENGES

Accessing mental health services remains a challenge for employees. A recent report, based on a survey of 2,794 patients conducted by NORC, a nonpartisan research organization at the University of Chicago, found:

- More than half of patients (57%) who sought mental health or substance use care were unable to access any care on at least one occasion between January 2019 and April 2022.
- Of patients in employer-sponsored health plans, 39% reported using at least one out-of-network provider for mental health or substance use outpatient care, compared to just 15% for physical health care.
- Of patients using out-of-network provider, 80%

Laura Carabello holds a degree in Journalism from the Newhouse School of Communications at Syracuse University, is a recognized expert in medical travel, and is a widely published writer on healthcare issues. She is a Principal at CPR Strategic Marketing Communications. www.cpronline.com



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