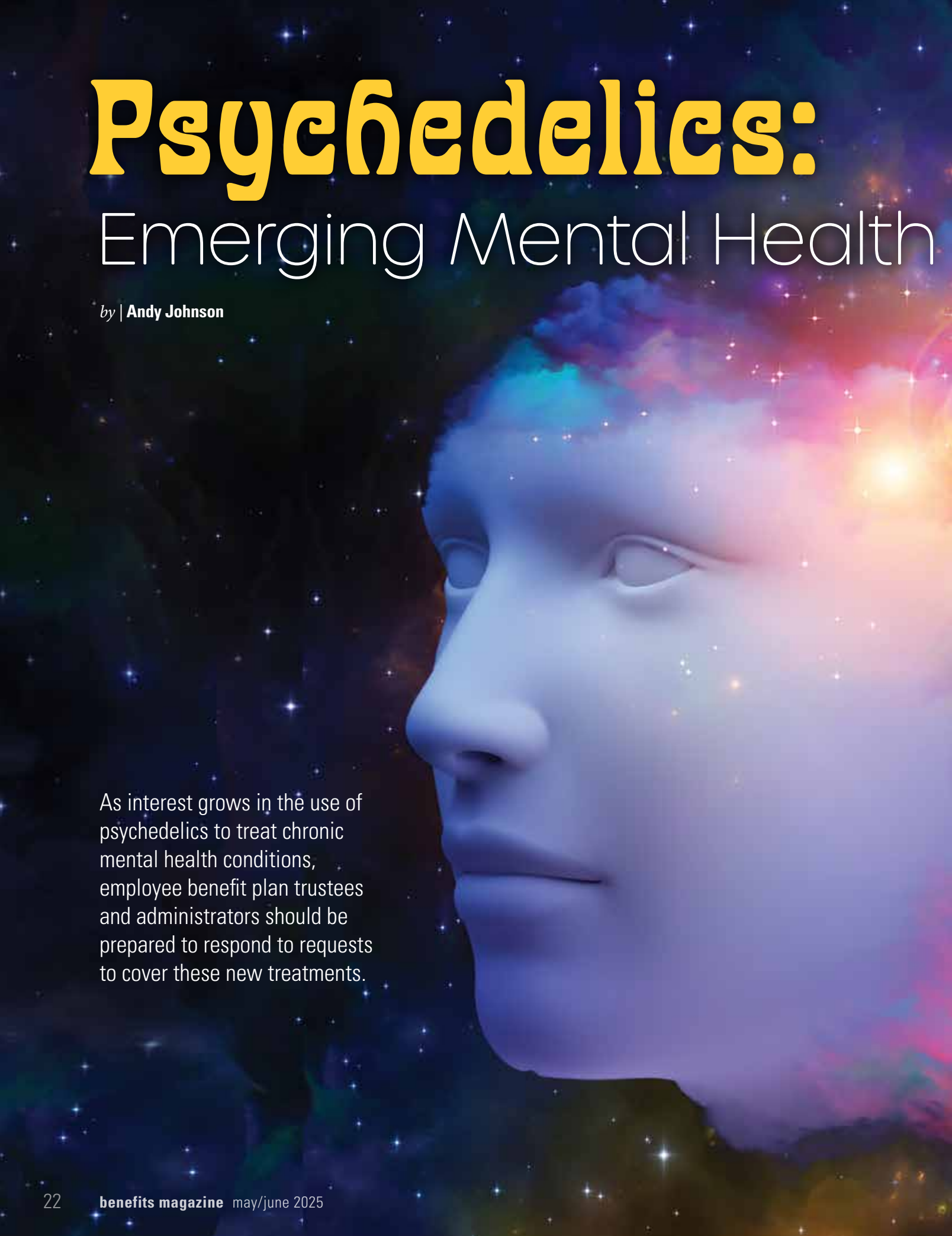
Psychedelics: Emerging Mental Health

by | **Andy Johnson**



As interest grows in the use of psychedelics to treat chronic mental health conditions, employee benefit plan trustees and administrators should be prepared to respond to requests to cover these new treatments.

Treatment Option?

benefits MAGAZINE

Many people associate psychedelics with the "Tune In, Turn On, Drop Out" movement of the 1960s. However, this class of drugs is gaining new attention—this time as promising treatments for some of the most chronic mental health conditions. The groups now eager to discover the potential hidden benefits of these substances include drug manufacturers, venture capitalists, and top-tier universities such as Johns Hopkins, Harvard, Yale, Stanford and Oxford.

Psychedelics and Mental Health

Researchers started looking into the potential of psychedelics to treat mental illnesses as far back as the 1940s with the discovery of lysergic acid diethylamide (LSD). However, LSD and other psychedelics were made Schedule I substances by the federal government following problems with abuse of LSD in the 1960s.[1]

The renewed focus on psychedelics stems from research and anecdotal reports highlighting their efficacy in treating treatment-resistant depression (TRD), post-traumatic stress disorder (PTSD) and substance abuse, as well as their potential for rapidly reducing suicidality. A short list of substances being researched includes ketamine, a drug approved by the Food and Drug Administration (FDA) for use in anesthesia; 3,4-methylenedioxymethamphetamine (MDMA), commonly known as ecstasy or molly; psilocybin, also known as magic mushrooms; and LSD. A quick online search reveals that, worldwide, there are currently more than 600 clinical trials involving psychedelics being conducted at over 300 universities and institutions.

In addition to educational institution research, the U.S. military is also exploring the medical uses of psychedelics. Both the Department of Defense (DOD) and the Department of Veterans Affairs (VA) are funding studies on psychedelic therapy for treating active-duty service members and veterans with PTSD.[2]

So, why the interest in psychedelics despite their illicit past? The short answer is that the currently available medications are ineffective for a significant portion of people suffering from TRD and PTSD. *Treatment-resistant depression* is defined as major depressive disorder that remains unmanageable despite treatment attempts with at least two different antidepressants. It is estimated to affect more than 30% of individuals receiving medication for depression. In addition, the VA estimates that more than 20% of veterans who served after 1990 will experience PTSD at some point in their lives.[3] PTSD also occurs in many nonveterans due to trauma, whether recent or experienced during childhood.

Focus on Ketamine

Ketamine is the only medication categorized as a psychedelic that is currently legal and available nationwide. Introduced in the early 1960s, ketamine was FDA-approved as an injectable anesthetic in 1970 and has been marketed for human use since then. It has also been used off-label to treat various mood disorders, depression and other chronic ailments. In 2005, researchers began studying ketamine's ability to treat depression, PTSD, anxiety disorders and substance use disorders. Ketamine has distinguished itself by its rapid onset, effectiveness in treatment-resistant cases and lower relapse rates compared with traditional antidepressants.[4]

Ketamine's Action in the Brain

Research studies have noted several effects on the brain when low doses of ketamine are introduced. Two major effects involve the processes of neurogenesis and neuroplasticity, which occur for approximately 72 hours after taking ketamine. *Neurogenesis* refers to the generation of new neurons, while *neuroplasticity* describes the brain's ability to form and reorganize synaptic

takeaways

- Psychedelics—including ketamine; 3,4-methylenedioxymethamphetamine (MDMA), commonly known as ecstasy or molly; psilocybin, also known as magic mushrooms; and lysergic acid diethylamide (LSD)—are gaining renewed attention as a possible treatment option for chronic mental health conditions.
- Treatment-resistant depression (TRD) and post-traumatic stress disorder (PTSD) are among the conditions for which psychedelics may hold promise.
- Ketamine is the only medication categorized as a psychedelic that is currently legal and available nationwide, and studies have demonstrated its efficacy in treating severe depression. Effectiveness varies from patient to patient.
- Employee benefit plan sponsors and administrators should educate themselves on psychedelic treatments and determine what services their plans will cover.

connections. Rodent studies have shown that ketamine can promote both the growth of new nerve cells (neurogenesis) and the sprouting of new connections between existing neurons (neuroplasticity).[5]

Ketamine treatment has also been found to help patients by reducing *ruminations*—repetitive, distracting thoughts about the past and future.[6] During ketamine treatments, patients often report feeling more present and in tune with themselves and free from negative and critical thinking.

Multiple studies have demonstrated ketamine's efficacy in treating severe depression. In one large study, intravenous ketamine was compared with the "gold standard" treatment for severe depression—electroconvulsive therapy (ECT)—with ketamine producing better outcomes. Researchers found that 55% of those receiving ketamine and 41% of those receiving ECT experienced at least a 50% improvement in their depressive symptoms and quality of life. ECT was associated with memory loss and musculoskeletal adverse effects, whereas ketamine did not produce these side effects.[7]

Ketamine-Based Treatments

In 2019, a nasal spray derived from ketamine and sold under the brand name Spravato® (esketamine) received FDA approval for treating depression in adults. Otherwise, the only current FDA-approved use of ketamine is for anesthesia. However, ketamine-based treatments have been legal in every state through off-label prescriptions for various mental health conditions.

Ketamine can also be administered via infusion or in lozenge form. Some providers solely administer ketamine, while others practice ketamine-assisted therapy (KAT), which combines ketamine infusions with psychotherapy to help patients process their experiences. In addition, while many clinics administer ketamine infusions on site, some providers offer at-home treatments through lozenges or self-injection.

Ketamine clinics can operate legally as long as the health care providers dispensing ketamine have a Drug Enforcement Agency (DEA) registration to administer the treatments, along with any other required state licensing for medical practice. Ketamine is increasingly being incorporated into inpatient psychiatric treatment protocols, and outpatient ketamine clinics are rapidly expanding across the United States. The U.S. ketamine clinic market was valued at $3.41 billion in 2023 and is projected to grow at an annual rate of over 10% from 2024 to 2030.[8]

As with all psychiatric treatments, the effectiveness of ketamine varies from patient to patient. Ketamine therapy is not recommended for patients with a history of psychosis, and there are concerns about long-term use. It should only be used for patients who have not had success with other treatment methods.

One thing is clear: Ketamine-based treatments are rapidly becoming a tool in psychiatric care. It is crucial to note that ketamine should always be administered under the supervision of a trained medical professional. Most people are familiar with the death of actor Matthew Perry and the involvement of ketamine in that tragedy. While Perry had been receiving ketamine-assisted treatments, it was determined that the ketamine in his system at the time of his death had not been administered by a health care professional but was instead obtained illegally from a local dealer.[9]

Psychedelics and Benefit Plans

In January 2024, new coverage and reimbursement codes from the American Medical Association went into effect that included codes for FDA-legalized psychedelic-assisted therapies. While these are temporary codes assigned to emerging technologies, services and procedures, having a CPT code makes it easier for health care providers to seek reimbursement and could improve access to psychedelic therapies. The data collected from their use could eventually lead to the establishment of permanent CPT codes.

The growing interest in psychedelics as a treatment modality and the rapid expansion of ketamine clinics are important developments for benefit plan administrators. Plan sponsors should collaborate with consultants and legal counsel to educate themselves on these treatments, including those that are

learn more

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currently available, such as ketamine, and those that are on the horizon, like MDMA and psilocybin.

Plans should determine which services they will cover (e.g., in-clinic/in-office versus at-home treatments) and whether safeguards, such as prior authorizations, need to be in place to prevent fraud and abuse. In addition, as fiduciaries, trustees and administrators should carefully evaluate the costs associated with different ketamine treatment modalities, since prices can vary significantly.

The cost of ketamine treatment varies depending on the type of administration, location and clinic. Ketamine infusions for depression typically cost between $400 and $800 per treatment.[10] Patients typically receive a series of six treatments over two to three weeks or four treatments over one to two weeks. KAT may cost slightly more due to additional psychotherapy session charges. The cost of administering Spravato is estimated to range from $18,500 to more than $45,000 during the first year of use since patients receive multiple treatments weekly during that time.[11] These costs may continue into the next year as well. Plans may want to explore partnering with one or more of the current ketamine therapy vendors to obtain both guidance and preferential pricing for these services.

The sidebar provides additional information on legal considerations for covering psychedelics for employee benefit plans.

Conclusion

The renewed interest in psychedelics for mental health treatment represents a paradigm shift in addressing some of the most persistent and debilitating behavioral health conditions. With ongoing research and growing evidence of their efficacy, substances such as ketamine, MDMA, psilocybin and LSD may hold promise for individuals who have struggled to find relief through traditional treatment methods. As this field continues to evolve, benefit plans that provide access to these treatments need to ensure that they are safe and appropriately managed to support those in need.

bio

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Editor's Note: The following is excerpted from a blog post by Barbara J. Zabawa, president of the Center for Health and Wellness Law, LLC. The blog post originally appeared on the website of the International Foundation's sister organization, the Wellness Alliance.

Legal Considerations When Covering Psychedelics

What are some legal considerations for employers and plan sponsors as they encounter requests to offer psychedelic medicine to treat depression and improve employee mental well-being?

Parity Issues

If psychedelics, especially those that are legal, are available but not offered by employee benefit plans, could plan sponsors be accused of discriminating against employees with mental illness? Group health plans that cover weight loss drugs like Ozempic® but do not cover psychedelic drugs to treat treatment-resistant depression may need to demonstrate that the method it used to decline prescription drug coverage for a mental health disorder is no more restrictive than the method it uses to cover a drug to treat diabetes and/or obesity.[1]

Provider Standards

Psychedelic administration should occur alongside guided therapy from highly trained therapists. In the clinical trials for 3,4-methylenedioxymethamphetamine (MDMA) to treat posttraumatic stress disorder (PTSD), the participant drug is administered by trained therapists who guide the participant's experience through scripted sessions that also allow for improvisation.[2] Thus, for psychedelic treatment to be effective and safe, plan sponsors should ensure that the individuals who administer the psychedelic drugs are properly trained. Failing to use properly trained practitioners to administer the drugs and provide the requisite therapy could

increase the chance of inappropriate use, abuse, harm and therefore liability to the employer. Employers will need some way to verify that the individuals administering the psychedelics are properly trained and have adequate liability insurance for themselves. Employers should also ensure that their own liability insurance covers the use and administration of psychedelic treatment to employees.

State vs. Federal Legal Compliance

Some state and local governments may allow for psychedelic use for depression before federal law permits it. For example, the State of Oregon has decriminalized medical and (effectively) recreational use of psilocybin. Municipalities including Oakland, Santa Cruz, and Arcata, California; Ann Arbor, Michigan; and Somerville, Cambridge, and Northampton, Massachusetts have passed legislation decriminalizing psychedelics.[3]

Legalizing more psychedelic drugs for medical use could follow a similar pattern as legalization of marijuana. Marijuana is still illegal at the federal level, but many states have legalized it. Psychedelic legalization seems to be following a similar path, with state and local governments taking action before the federal government. Employers that conduct business in states or localities that permit the use of psychedelics to treat depression may still need to consider federal law, specifically the Controlled Substances Act. Employers will need to weigh the legal risk of violating federal law while trying to help employees who may need mental health treatment with psychedelics.

Offering Psychedelics Through an EAP or On-Site Clinic May Trigger HIPAA/ACA and HSA Compliance Issues

The recent Food and Drug Administration (FDA) approval of Spravato requires that people taking the drug be monitored in a doctor's office for at least two hours and have their experience entered into a registry.[4] Indeed, according to one study, "training and clinical oversight is necessary to ensure safety and also therapeutic efficacy for this divergent class of treatments."[5] Thus, offering psychedelics such as ketamine should be more than just listing it on the group health plan's formulary. Plans that consider offering this treatment for depression and/or PTSD will also need to ensure that proper clinical protocols are followed, including ensuring that a trained clinician oversees the drug's administration and use.

If an employer offers this treatment through an employee assistance program (EAP) or on-site clinic, this more involved treatment would likely represent significant benefits in the nature of medical care, thus requiring employers to comply with the Health Insurance Portability and Accountability Act (HIPAA) and the Affordable Care Act (ACA) market reforms if offered through an EAP, and the treatment could jeopardize health savings account (HSA) eligibility for employees.

The legal issues above are just some examples that plan sponsors should consider as they are approached by various stakeholders about offering psychedelic treatment for employees suffering from depression or PTSD. This is an evolving area of law, and employers should engage competent legal counsel to help them navigate their way to a benefit plan that makes the most sense for them and their employees.

Endnotes

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