MENTAL HEALTH WEEKLY Essential information for decision makers

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After first gaining popularity during the 1960s and 1970s, psychedelics are acquiring much renewed interest in the mental health field. Much of the ongoing research with psychedelic substances, like MDMA and psilocybin, are now showing promise as part of mental health treatment plans for depression and post-traumatic stress disorder. See top story, this page

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Psychedelic therapies continue to be seen as big trend in MH treatment

Research is revealing that psychedelics are showing promise as mental health treatment for depression and post-traumatic stress disorder (PTSD). Psychedelic therapies continue to be studied in clinical trials around the country.

USA Today reported Jan. 7 that for anyone unfamiliar with psychedelics being used for mental health treatment, this year will change that, and experts predict this treatment will be seen as an emerging wellness trend.

In a Jan. 5 *New York Times* article, "The Promises and Perils of Psychedelic Health Care," Kat Eschner reported that some of the most prominent universities in the world are studying four substances in particular: psilocybin, ketamine, MDMA

Bottom Line...

MDMA may be one of the first psychedelic therapies to be approved by the FDA, says a psychedelic researcher.

and LSD. The bulk of available research suggests these substances hold promise as part of larger treatment plans, according to the article.

According to Eschner, psychedelics remain expensive and difficult to gain access to legally, unless someone is part of a research study for mental health purposes.

Meanwhile, news about upcoming clinical trials continues to emerge. The Pacific Neuroscience Institute located at Providence Saint

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North Dakota ramps up eligibility in change to Medicaid plan amendment

North Dakota officials continue to make adjustments to the state's Medicaid behavioral health program, first implemented in a state plan amendment last February. The most recent changes to North Dakota's Medicaid 1915(i) state plan amendment include an eligibility score adjustment that should expand access to home- and community-based services for a broader range of

Bottom Line...

Among the most recent changes to its Medicaid 1915(i) state plan amendment, North Dakota is adjusting eligibility standards in order to serve more individuals whose needs have not yet reached a crisis level.

individuals with mental health needs.

Under the change to the state plan amendment that was approved by the Centers for Medicare & Medicaid Services (CMS) last month, the state is lowering the minimum comprehensive score on the World Health Organization Disability Assessment Schedule (WHODAS) for 1915(i) eligibility from 50 to 25. The WHODAS measures individuals' functional needs in six domains: cognition, mobility, self-care, social interaction, life activities and community participation. The state's Medicaid 1915(i) state plan amendment program administrator told MHW that the move down from 50, a level that denotes fairly significant

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John's Health Center in Santa Monica, California, on Jan. 12 announced it has activated a new psilocybin clinical trial and has begun participant enrollment. The PSIL201 study is investigating the safety and efficacy of psilocybin for major depressive disorder. It will evaluate the potential antidepressant effects of a one-time dose of psilocybin.

"This is going to be a pivotal year for psychedelic medications toward opening up access, but we have a long way to go," Reid Robison, M.D., MBA, chief medical officer and co-founder of Cedar Psychiatry — a wholly owned subsidiary of Novamind, a mental health company specializing in psychedelic medicine, told *MHW*.

Robinson, a psychedelic psychiatrist, said he has directed more than 200 clinical trials looking for new and improved psychedelics. Psychedelics, he noted, can best be used in conjunction as part of comprehensive mental health treatment along with a supportive team. He initially began working with ketamine in 2011, when it was being studied as an antidepressant.

MDMA progress

Robison pointed to an ongoing clinical trial series he says is one of the most important research studies going on right now. The research, involving the use of psychedelic-assisted therapy, is showing promise and significant implications for patients with severe, chronic PTSD and could potentially move the needle further toward Food and Drug Administration (FDA) approval (see *MHW*, May 17, 2021).

Regarding the MDMA trial, the majority of individuals who received this treatment no longer met the criteria for PTSD, even six months down the road, Robison said. According to the study, two months after treatment, 67% of participants in the MDMA group no longer qualified for a diagnosis of PTSD, com-

'I believe MDMA will likely be the first psychedelic medication approved by the FDA. It may even happen this year.'

Reid Robison, M.D., MBA

The research, from the Multidisciplinary Association for Psychedelic Studies (MAPS), is part of an ongoing clinical trial series expanding on the results of a previous trial that found 3,4-methylenedioxy-methamphetamine (MDMA)-assisted therapy to be an effective and cost-saving treatment for PTSD.

"I believe MDMA will likely be the first psychedelic medication approved by the FDA," said Robison. "It may even happen this year." Once approved, clinicians and therapists will need specialized training and infrastructure to provide patient treatment. pared with 32% in the placebo group. That "meaningful data represents big news," Robison said. He indicated that he is working with MAPS on psychedelic research examining eating disorders.

Psilocybin is being studied for treatment-resistant depression and is an active psychedelic compound found in magic mushrooms. Research has found it proving to be effective at treating such conditions as depression, PTSD and drug dependency. Psilocybin is also considered to be on the "fast track" by the FDA, said Robison, adding that MDMA is a little further along in the process.



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MDMA represents a new paradigm in mental health treatment, he noted. "We're going for a cure rather than just treating symptoms," he said.

Robison pointed to another prominent psychedelic researcher, Matthew W. Johnson, Ph.D. at Johns Hopkins, who was awarded a federal grant last September to study psilocybin for smoking cessation.

State activities

Legislation has been introduced in some states to continue the research. The Pennsylvania Health Benefits of Psilocybin Act was introduced in October and is making its way to the state's health committee. The proposed bill creates a framework for clinical studies of psilocybin (see story, page 6). Robison said he is encouraged about the Pennsylvania bill. "More initiatives like that

are needed," he said. "We're seeing more show up in creative ways."

Oregon legalized psychedelic-assisted therapy in 2020. Denver has decriminalized the use of psychedelic medications, and other cities are following suit. According to Marijuana Moment, following a 2019 campaign by local activists, Denver became the first city in the United States to decriminalize psilocybin possession.

Robison said it was a very important step that individuals pursuing psychedelic medications will not get prosecuted; however, they are not given information about how to access the medications in a good way.

Much more work is needed for psychedelic therapy use, he noted. The medications need to be registered in a database and tracked, especially because of safety risks, he said. "It will still require patience and persistence in opening up access to people who need it, especially diverse and marginalized populations," said Robison.

Meanwhile, Spravato (esketamine) is available now and prescribed in many clinics across the country, he noted. "They do have an important place in [psychedelic] medications and can be extremely useful tools for the right client at the right setting," said Robison.

"I really believe some of these medications are going to be a game changer for the field," said Robison. •

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Lawyers set to deliver settlement for MH underpayment claims

Following settlement of a class-action lawsuit filed in 2017, in which plaintiffs challenged United-Health's tiered reimbursement policy, Zuckerman Spaeder released an announcement last week that the U.S. District Court for the Eastern District of New York ordered final approval of the settlement that will provide relief for more than 110,000 mental health patients/insureds represented by the firm.

According to Doe v. UnitedHealth Group, United used the reimbursement policy to reduce payments for certain out-of-network behavioral health services provided by psychologists and master's-level counselors and social workers. More specifically, the policy reduced allowed reimbursement amounts by 25% for psychotherapy services provided by out-of-network psychologists and by 25% or 35% for out-of-network master's-level counselors and social workers. The plaintiffs alleged that United's policy violated the Employment Retirement Income Security Act (ERISA) and the federal Mental

Bottom Line...

The litigation achieved a change in UnitedHealth's tiered reimbursement policy. The insurer no longer uses the policy and has committed to not reinstating it for United and Oxford plans.

Health Parity Act.

"The insurer violated mental health parity law and ERISA because it discriminated against behavioral health therapeutic services," Andrew N. Goldfarb, a partner at Zuckerman Spaeder, told *MHW*. "There were no comparable reductions on the medical, surgical side."

Regarding the tiered reimbursement policy, "we're very pleased with this settlement in which United did stop the tiered reimbursement policy, as part of the litigation, in 2019," Goldfarb stated. As part of the settlement, United committed to not reinstating the tiered reimbursement policy for United and Oxford plans.

As a result of the lawsuit and settlement, United, considered the

largest insurer in the country, will pay \$10 million to compensate for these underpayments, Goldfarb not-ed. "We're very proud of the size of the payment," said Goldfarb.

Tiered reimbursement practices

"The New York Attorney General's Office (NYAG) and the U.S. Department of Labor (DOL) were also investigating United's practices related to tiered reimbursement — the same practices at issue in our suit," said Goldfarb. "All of the parties were able to participate in the negotiation to resolve our private suit on a class basis, as well as the potential enforcement actions by the NYAG and DOL."

The settlement is a significant one for patients covered by United-administered plans, he said. "We're hopeful to eliminate that disparity for people seeking behavioral health services under United plans," said Goldfarb.

"If you take a step back, there Continues on next page