

# Expediting Psychedelic-Assisted Treatment Adoption in Clinical Settings

## Executive Summary for Policymakers

### BACKGROUND

The U.S. is in the midst of a long-standing mental health crisis, tragically exacerbated by the Covid-19 pandemic<sup>1</sup>. While current treatments for mental health and substance use disorders (MH/SUDs) help some patients, many patients continue to suffer even with repeated attempts at treatment. Progress in developing more effective pharmacologic treatment for MH/SUDs over the past 30 years has been frustratingly limited<sup>2</sup>.

Over the last several years, however, a new class of drugs—psychedelics—have demonstrated promising efficacy and safety results in multiple late-phase clinical trials<sup>3</sup>. These trials test psychedelic-assisted therapy (PAT), which is different from typical mental health treatments in that a PAT treatment cycle is comprised of three stages: preparatory psychotherapy, a supervised dosing session, and integrative support or psychotherapy. Trial participants receive one to three doses of a psychedelic combined with psychotherapy. Many experience symptom improvement for many months following treatment and, in some cases, complete remission. 3,4-methylenedioxy-methamphetamine (MDMA) (for treatment of post-traumatic stress disorder) and psilocybin (for treatment of major depressive disorder and treatment resistant depression) are currently in late-phase clinical trials and are likely to become the first two psychedelic medicines approved for the treatment of MH/SUDs.

As exciting as these developments are, the path to real-world usage remains lengthy and challenging. In [Expediting Psychedelic-Assisted Treatment Adoption in Clinical Settings](#), BrainFutures identifies and provides recommendations to address three pressing policy issues, using a shared set of foundational principles, as well as critical and timely next steps.

### PRINCIPLES TO ADVANCE PAT FROM CLINICAL TRIAL TO REAL WORLD PATIENTS

As the PAT field prepares for FDA-approval of psychedelic compounds to be utilized in PAT, BrainFutures emphasizes the importance of a shared set of foundational principles to guide the next phase of the field's development:

- PAT must be **accessible** to all patients who qualify for, and would benefit from, such care
- PAT must be **affordable** for all patients who qualify for, and would benefit from, such care
- PAT must meet **high quality** standards to ensure optimal patient outcomes

### POLICY CHALLENGES TO THE PROVISION OF ACCESSIBLE, AFFORDABLE, HIGH-QUALITY PAT

#### 1. Ensure Accessibility in FDA Approval and Safety Requirements

For any New Drug Application, FDA reviews a drug's safety profile and risk-benefit ratio. For some drugs, the FDA may determine that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure the benefits of the drug outweigh its risks. Should the FDA determine that a REMS is necessary for psychedelics, **BrainFutures recommends** that such strategies be:

- Balanced against the principle of wide access
- Contextualized against the high emotional, social, and economic costs of the targeted conditions
- Consistent with or comparable to those established for existing treatments (with similar risk and safety profiles to psychedelics) for the targeted conditions
- Consistent with generally accepted medical and behavioral quality assurance practices

See report for full references.

<sup>1</sup> SAMHSA, 2021; Whitney & Peterson, 2019; Panchal et al., 2021

<sup>2</sup> Insel, 2022; Sky, 2022

<sup>3</sup> Sky, 2022

- Open to the establishment of quality standards by psychedelic professional organizations

## 2. **Ensure Affordability in Payer Coverage and Payment Decisions**

Public and private health insurance coverage of PAT is a prerequisite to equitable access. To ensure PAT is affordable for patients, **BrainFutures recommends** coverage and payment policies:

- Follow a path of wider and more comprehensive insurance coverage than has traditionally marked mental health benefits
- Limit out-of-pocket requirements for patients
- Comply with both the financial requirement and treatment limitation provisions of the Mental Health Parity and Addiction Equity Act, particularly for non-quantitative treatment limitations
- Ensure the psychedelic compound and psychotherapy are adequately reimbursed and the coverage is coordinated between behavioral health and pharmaceutical benefits

- Utilize a uniform coding strategy

## 3. **Ensure PAT meets High Quality Standards to Ensure Optimal Patient Outcomes**

As is the standard with all physical and behavioral healthcare, PAT stakeholders and independent experts must come together to establish standards for the delivery of high-quality care. To ensure PAT meets high quality standards to ensure optimal patient outcomes, **BrainFutures recommends:**

- Establishment of a certification authority for training programs and providers, including ethical standards
- Harmonization and standardization of a core training curricula
- Establishment of a collaborative group of stakeholders and independent experts to identify a measurement-based approach to PAT, and identification of a set of key quality measures

## **NEXT STEPS**

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In the near-term, the PAT field must align approaches in four key areas:

- **Standards of Care:** Designation of a specialty association(s) to set standards of care for PAT providers
- **Program Accreditation:** Designation of a body to offer independent accreditation of PAT education programs
- **Provider Certification:** Designation of a certification board to offer independent evaluation and verification of a provider's skills and expertise relative to PAT
- **Reimbursement Strategy:** Alignment of stakeholders around a unified coding strategy and implementation plan to facilitate payer coverage determinations, simplify coding and billing processes, and improve access to care

Fortunately, the resources to execute on these goals exist within the PAT community. The key next step is for a trusted entity to identify these capacities within the PAT stakeholder community, and to build consensus around assignment of key responsibilities to identified organizations. BrainFutures looks forward to being a part of this collective team, as together we accelerate the psychedelic therapy field into accessible, affordable, high-quality adoption.

BrainFutures is a national nonprofit dedicated to assessing and advancing the practical applications of new scientific understanding of the brain. We offer rigorous assessment of—and education about—brain-based interventions that target specific segments of society. By providing objective, evidence-based information about what works and clearing policy and practice pathways, we aim to maximize human potential and ameliorate pressing societal challenges.