

# Expediting Psychedelic-Assisted Treatment Adoption in Clinical Settings

## Executive Summary for Stakeholders

### BACKGROUND

The field of psychedelic-assisted therapy (PAT) is at an inflection point. The promise of psychedelic compounds raises great hope for PAT's potential to relieve pain and suffering for millions of patients struggling with mental health and substance use disorders (MH/SUDs), and the first of these drugs could be approved by the FDA as early as 2023. Yet PAT, which combines extended psychotherapy sessions with a psychedelic compound, does not fit neatly into the U.S. healthcare regulatory and reimbursement framework. In [Expediting Psychedelic-Assisted Treatment Adoption in Clinical Settings](#), BrainFutures identifies several regulatory and reimbursement challenges that stakeholders must now solve to successfully integrate PAT into the existing healthcare delivery infrastructure.

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

- 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, the 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 for the targeted conditions with similar risk and safety profiles
- Consistent with generally accepted medical and behavioral healthcare quality assurance practices
- Open to the establishment of quality standards by the field of clinicians, national certification bodies, accrediting agencies, and professional practitioner 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 in order to maximize patient access to treatment, appropriately reimburse prescribers, practitioners, and manufacturers, and simplify coding and billing for payers, providers, and patients

### 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, initial provider certification, and ongoing recertification of provider competencies, including ethical standards and codes of conduct required by each provider's professional license

- Harmonization and standardization of a core training curricula, with psychedelic compound-specific modules, to be endorsed by professional associations and adopted by all training programs
- Establishment of a collaborative group of stakeholders and independent experts to identify a measurement-based approach to PAT
- Identification of a set of key quality measures, including both process and outcome measures, to encourage provider transparency and accountability

## 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, including standards of quality, medical or clinical practice guidelines, medical review criteria, and performance measures
- **Program Accreditation:** Designation of a body to offer independent accreditation of PAT education programs, set standards for effective training, and monitor compliance with those standards
- **Provider Certification:** Designation of a certification board to offer independent evaluation and verification of a provider's skills and expertise relative to PAT, to update certification criteria as the specialty evolves, and to provide patients with a trusted credential to help identify qualified providers
- **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; development of parity education materials and briefing documents as free resources to stakeholders to support collective advocacy efforts

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.