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Navigating Insurance & Reimbursement Pathways in Psychedelic Therapy

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Disclosures

- My spouse/partner and I have the following relevant financial relationship with a commercial interest to disclose:
 - I hold stock options in CB Therapeutics
 - I have served as an advisor/consultant for Abbvie, CB Therapeutics, Compass Pathways, EBSCO Industries, Janssen Pharmaceuticals, Livanova, MindMed, and TD Cowen
 - I have received research funding from Abbott, Compass Pathways, MindMed and Reunion Neuroscience

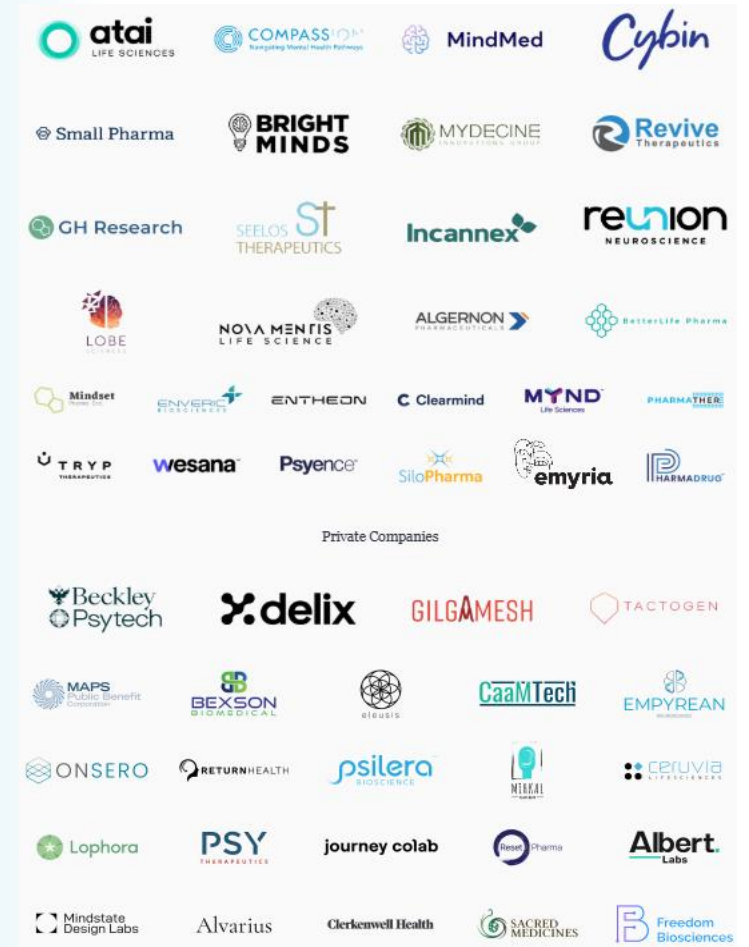
Where are we in psychedelic drug development?



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- Many psychedelic biotechs working towards FDA approval
- 08/2024: FDA declined to approve MDMA for PTSD, asked for another trial
- 08/2025: Abbvie acquires Gilgamesh Pharmaceuticals' lead investigational asset, bretisilocin (GM-2505)
- Late 2026/Early 2027: FDA will likely consider New Drug Application for psilocybin for treatment resistant depression



Psychedelic Alpha, 2025



Post-approval considerations

- Affordability is crucial for broad accessibility of psychedelic-assisted therapy (PAT)
 - Concerns about development of parallel cash-based ecosystem
- Protocols can include 40 hours or more of therapist time per patient
 - More therapy than many therapy patients receive in entire year
- Securing payor coverage is as critical as clinical trial outcomes and regulatory progress
 - Larger upfront cost for PAT for insurers compared to monthly medication
 - Insurers often differentiate between covering medication and therapeutic process that accompanies it, so PAT coverage may prove challenging



Anticipating challenges to PAT access

- PAT will be expensive: round of MDMA assisted therapy (MDMA-AT) estimated at ~\$12,000 per patient
- MDMA-AT breaks even at 3.8 years
 - Americans typically switch health insurance plans every 3-4 years
- Lack of trained therapists
 - MAPS aims to train 25,000 MDMA-assisted therapists by 2030
- Logistical and staffing needs (two trained therapists per session, treatment room setup, care and specialty pharmacy coordination needs, REMS requirements, etc)
 - These, along with uniquely complex medical coding, have slowed esketamine uptake
- Expect particularly limited access marginalized communities, including rural areas

Finn Partners, 2016; Marseille et al, 2022; MacMillan et al, 2023; Ostrovsky & Barnett, 2024



Esketamine billing codes

Site of Care	Activity	Payer	Potential Coding Options	Potentially Applicable Add-on Codes
Provider Purchases SPRAVATO® From an Authorized Distributor and Bills for Drug and Services				
Physician Office	Treatment visit and drug	Medicare	G2082 or G2083*	N/A
		Non-Medicare	G2082 or G2083*	Payer discretion
			99202-99205; 99212-99215 Drug: S0013 or J3490	Prolonged Clinical Staff Services: 99415; 99416 Prolonged Service: 99417
Hospital Outpatient Department (HOPD)	Treatment visit and drug	Medicare	G2082 or G2083*	N/A
		Non-Medicare	G2082 or G2083*	Payer discretion
			99202-99205; 99212-99215 Drug: S0013 or J3490	Prolonged Clinical Staff Services: 99415; 99416 Prolonged Service: 99417
Provider Acquires SPRAVATO® From a REMS-Certified Pharmacy† and Bills for Services				
Physician Office	Treatment visit	Medicare	99202-99205; 99212-99215	Prolonged Clinical Staff Services: 99415; 99416 Prolonged Service: G2212
		Non-Medicare		Prolonged Clinical Staff Services: 99415; 99416 Prolonged Service: 99417
Hospital Outpatient Department (HOPD)	Treatment visit	Medicare	G0463‡	N/A
		Non-Medicare	99202-99205; 99212-99215	Prolonged Clinical Staff Services: 99415; 99416 Prolonged Service: 99417



Reasons for optimism

- Insurance coverage for esketamine is relatively good
- Billing codes for psychedelic treatment approved by American Medical Association
- Self-funded employers could be significant catalyst for expanding payor coverage for PAT
- Many companies increasing investments in mental health



U.S. Chamber of Commerce

Topics

Topics / Health Care /

New Survey of American Businesses Shows Employers Are Acting to Support Growing Demand for Mental Health Services

Ninety four percent of employers report making new investments in care for mental health and substance use disorders.

Barnett 2024; US Chamber of Commerce, 2023

Improving mental health benefits landscape



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- Enthea, third-party administrator of health insurance plans, offers ketamine as ancillary benefit, charging patients extra for coverage.
 - Has recently partnered with Fluence to expand its network of KAP providers by increasing reimbursement for Fluence-trained clinician services

BUSINESS

Psychedelic therapy is moving to the next frontier: workplace perk



By [Tara Bannow](#) and [Olivia Goldhill](#) Dec. 6, 2022

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Fluence, 2024

Psychedelic monitoring billing codes



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- Category III CPT codes for psychedelic monitoring approved by AMA in 2023
 - Category III CPT codes are for emerging treatments only
 - No assigned relative value units (RVUs)
 - Will convert to Category I codes upon FDA approval and be allotted RVUs
- Available to use as of January 2024
- Can potentially use for ketamine-assisted therapy

0820T	Continuous in-person monitoring and intervention (e.g. psychotherapy, crisis intervention), as needed, during psychedelic medication therapy; first physician or other QHP, each hour	Physician or other QHP	60 min
+0821T	Continuous in-person monitoring and intervention (e.g. psychotherapy, crisis intervention), as needed, during psychedelic medication therapy; second physician or other qualified health care professional, concurrent with first physician or other QHP, each hour	Physician or other QHP	60 min
+0822T	Continuous in-person monitoring and intervention (e.g. psychotherapy, crisis intervention), as needed, during psychedelic medication therapy; clinical staff under the direction of a physician or other QHP, concurrent with the first physician or other QHP, each hour	Clinical staff	60 min

Barnett & Ostrovsky, 2023; MacMillan et al, 2023; Ostrovsky & Barnett, 2024

Psychedelic monitoring billing codes



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- Not intended for use in preparation and integration sessions. Would need to use standard psychotherapy billing codes.
- Duration of these sessions may pose billing challenges
 - 90 min long in some study protocols
 - No billing code for 90 min psychotherapy session that can be applied by all clinicians who can bill for psychotherapy
 - Only clinicians who can utilize evaluation and management (E&M) codes, such as physicians and nurse practitioners, can bill for 90 min sessions
 - 90 min psychotherapy billing code for use by all clinicians who can bill for psychotherapy in development

MacMillan et al, 2023

A role for innovative payment mechanisms?



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- Insurers may be hesitant to provide coverage until long-term cost efficacy demonstrated
- However, possibility of sustained response or remission from only a few treatments may spur payment innovation in this case
- Innovative payment mechanisms used for high-cost treatments such as gene therapies could be applied to PAT
 - Outcomes-based payments
 - Installment payments

Jørgensen & Kefalas, 2021



Potential cost-reduction approaches

- Accompany psychedelics with psychological support rather than psychotherapy
- Group preparation and integration
 - Group therapy saved 50.9% of clinician costs for MDMA-PTSD and 34.7% for psilocybin-MDD, or \$3,467 and \$981 per patient, respectively.
- Group/simultaneous psychedelic administration
- Single therapist/monitor

Gasser, 2022; Goodwin et al, 2024; Marseille et al, 2023; Rucker et al, 2022; von Rotz et al, 2022



Final thoughts

- Will take years to train enough PAT providers, build infrastructure, and optimize PAT manufacturer-payer-pharmacy-provider-patient interactions
- Clinicians should expect stringent prior authorization requirements early on
- Off-label use unlikely to be covered by insurers due to costs, as with esketamine for bipolar depression



Thank you!

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