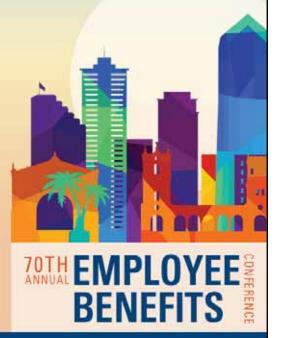
# Psychedelics— A Panel Discussion

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## **Overview and Goals**

- The science of psychedelic therapies
  - Efficacy, uses, contraindications
- Case study
- Applications in health promotion and mental health care in the workforce

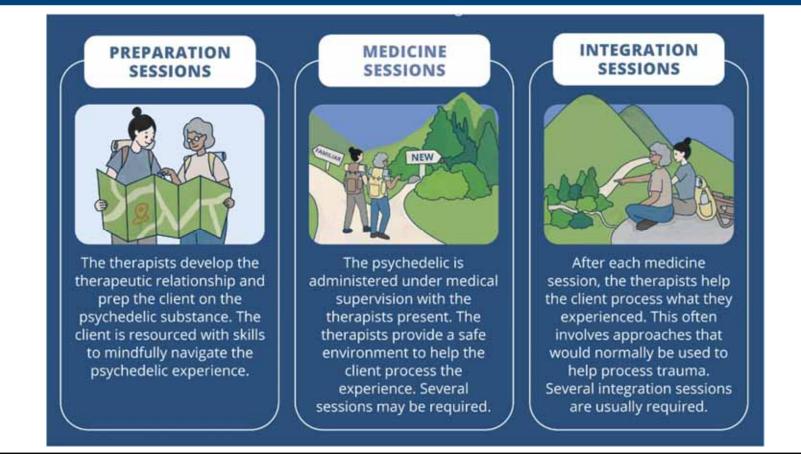
# Psychedelics & Psychotherapy

The Healing Potential of Expanded States

## Psychedelic-Assisted Psychotherapy

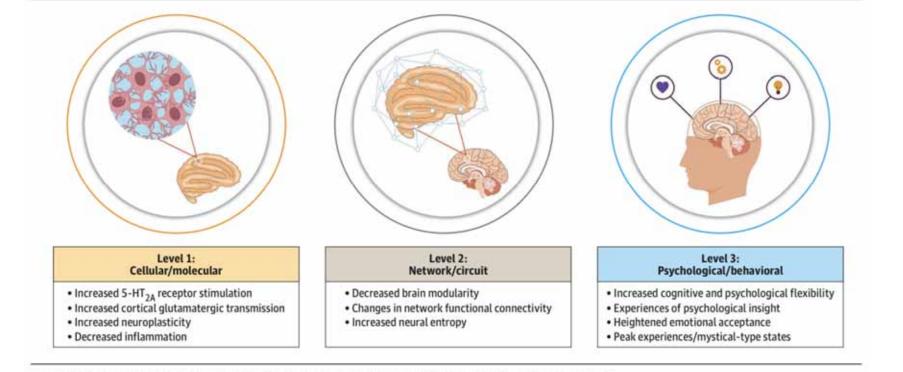
- Psychedelic-assisted psychotherapy combines the use of substances like psilocybin or MDMA with professional psychotherapy to treat mental health conditions such as depression, substance use disorder, PTSD, and anxiety.
- Research has shown promising results, with some studies demonstrating rapid and long-lasting improvements in symptoms after just one or a few treatment sessions, potentially offering a cost-effective alternative to traditional long-term therapies and medications for employees struggling with mental health issues.

## How Is It Done?



## How Does It Work?

### Figure. How Does Psychedelic Therapy Work?



Proposed therapeutic mechanisms of psychedelic drugs are grouped by level of analysis. 5-HT<sub>2A</sub> indicates serotonin<sub>2A</sub>.

Aday et al., 2023

## What Medicines Show Promise/Efficacy?

- Psilocybin
- MDMA
- Ketamine
- LSD
- Ayahuasca
- Ibogaine
- Mescaline
- 5-MeO-DMT

## Psilocybin Mushrooms: Efficacy and Uses

- Major depressive disorder and treatment-resistant depression
- Substance use disorders (e.g., Alcohol use disorder and tobacco addiction)



• End-of-life anxiety/mood disorders

## MDMA (3,4-Methylenedioxymethamphetamine)

 MDMA-assisted psychotherapy has shown significant efficacy for treating post-traumatic stress disorder (PTSD)



## Ketamine

- NMDA receptor antagonist with an anesthetic-dissociative effect
  - Used to treat pain, mental health, and substance abuse disorders



- due to its rapid-acting analgesic and antidepressant effects
- Substantial evidence for its antidepressant qualities, including as an intervention for acute, suicidal depression and treatment-resistant depression

## Key Risks

- 1. Challenging psychological experiences: Psychedelics can trigger difficult emotions, memories, or thought patterns that may be distressing.
- 2. Transient anxiety, paranoia, or panic reactions during the acute drug effects.
- 3. Potential for abuse or dependence, particularly with ketamine.
- 4. Risk of Hallucinogen Persisting Perception Disorder (rare).
- 5. Cardiovascular effects: Temporary increases in blood pressure and heart rate.
- 6. Cognitive and perceptual changes that could impair functioning or decision-making during and shortly after use.
- 7. Physical side effects like nausea, headaches, jaw clenching (with MDMA)

## Mitigating Risk

- Careful screening and preparation of patients. Some contraindications for those with
  - A personal or family history of psychosis or bipolar disorder
  - Cardiovascular issues
- A controlled, supportive setting
- Close monitoring during drug administration
- Integration therapy afterwards
- Using pure, laboratory-grade substances in carefully measured doses

### Case Study: Group Ketamine-Assisted Psychotherapy



## **Overview of Pilot Treatment Study**

- Adult participants (N = 29) were recruited to participate in GroupKAP, providing informed consent for both treatment and research
- Cohorts of 5-8 individuals per group
- Pre-tests, intervention, post-tests, follow-up

## Assessments

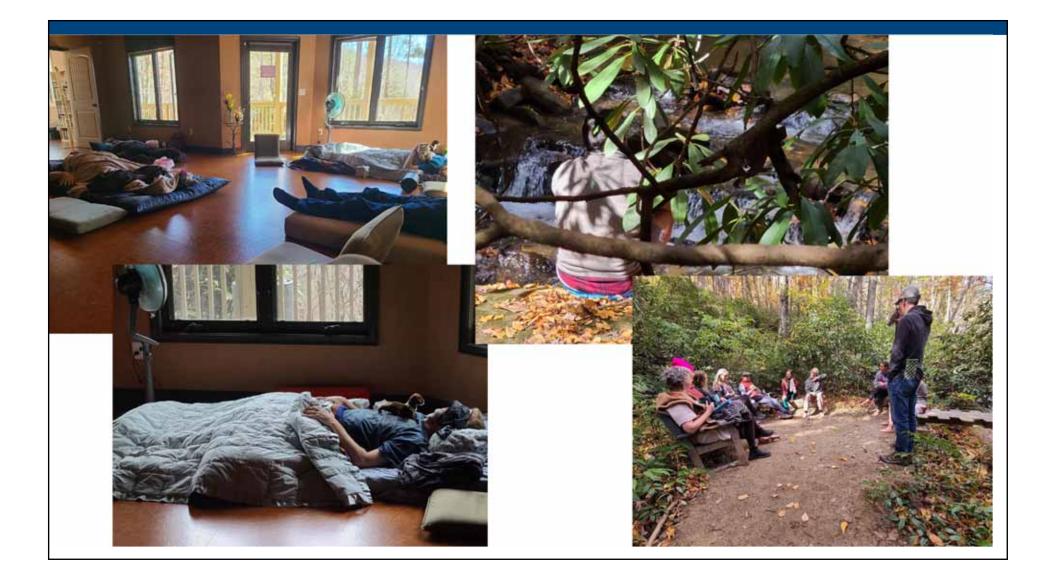
- DASS-21: Assesses depression, anxiety and stress
- Self-leadership scale: Examines 8 Cs of self-leadership: confidence, connectedness, calmness, clarity, creativity, curiosity, courage, and compassion

36. Henry JD, Crawford JR. The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample. *Br J Clin Psychol*. 2005;44(Pt 2):227-239.

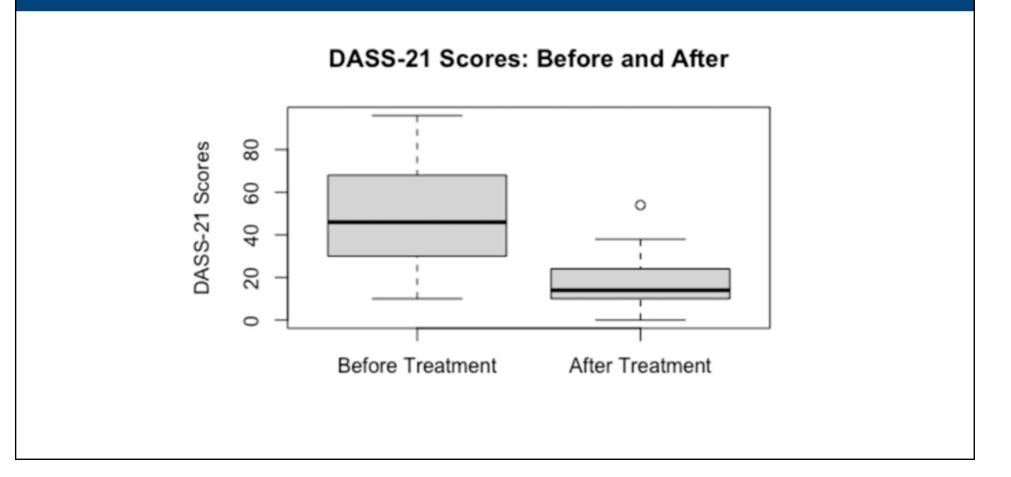
37. Steinhardt MA, Dolbier CL, Mallon MW, Adams DT. The development and validation of a scale for measuring self-leadership. *J Self-Leadership*. 2003;1:20-31.

## Treatment

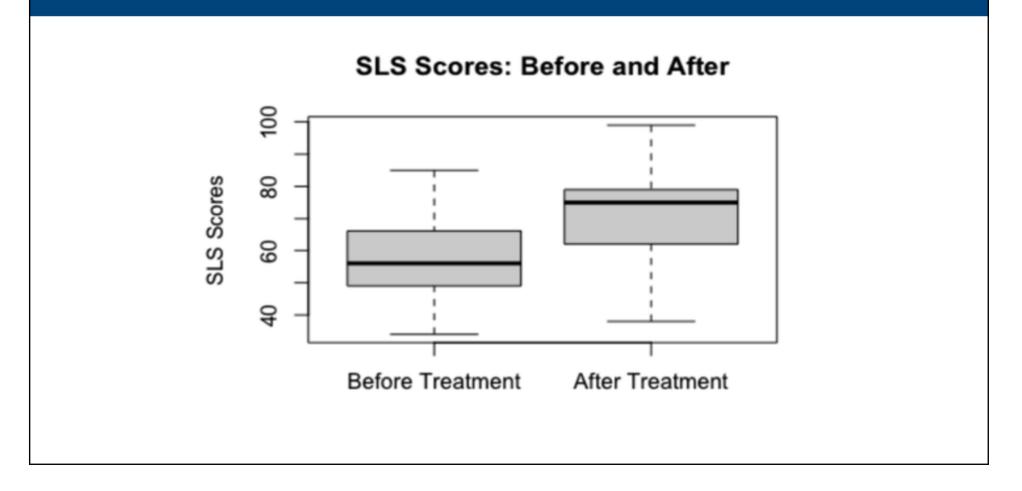
- Opening circle (intentions, set and setting)
- 200-400mg oral ketamine (lozenge)
- 1-2 hours of medicine experience
- Integration activities in the afternoon
- Online integration two days later
  - Group therapy with Internal Family Systems (IFS)
- 4 med sessions; 4 integrations sessions



## **Results: Depression, Anxiety and Stress**



## **Results: Self-Leadership**



IHP, January 2024	
American Journal of Health Promotion	
	Impact Factor:
Free access Other First published online Decemb	per 21, 2023
Psychedelic Healing: A Historical, Empirica	l, and Personal Account
Robert Swoap, PhD 🖾 View all authors and affiliations	
Volume 38, Issue 1 https://doi-org.proxy191.nclive.org/10.	1177/08901171231210806e

## **Equity and Access Issues**

## Access

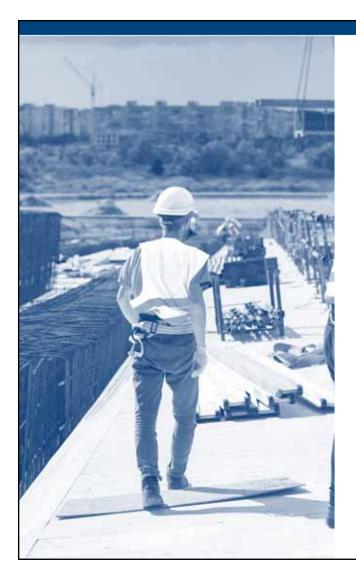
- Mental health disparities exist at global, national and local levels
- Marginalized groups are disproportionately affected by mental distress
- Low SES is related to both poor mental health outcomes and limitations in accessing care, with poverty being both a causal factor and a consequence of mental health difficulties

Spriggs et al., 2023

## Access in Clinical Trials

- Inadequate representation of marginalized groups within modern research settings; both in participants of clinical trials and in many research teams
- Cost can be prohibitive once approved

## Application in Health Promotion and in the Workforce



- 23% of adults experienced a mental illness in the past year
- >5% reported experiencing serious thoughts of suicide
- The Building Trades are especially impacted

### 54%

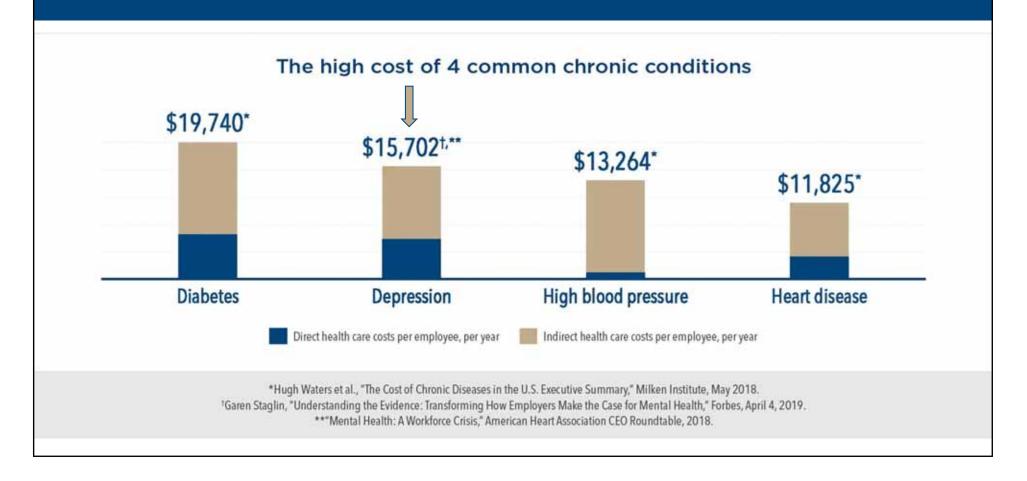
of union workers report high levels of job-related stress

### 83%

of workers have experienced a moderate to severe mental health issue

- Risk Factors
- Culture and stigma
- Psychosocial and occupational stressors
- High volume of narcotic prescriptions

## **Depression as a Chronic Condition**



## Mental Health Multiplier Effect

 Mental health and physical health are fundamentally linked. Medical claims are multiplied when comorbid mental health conditions are present.



57%

Of "high-cost" patients also have a mental health or substance use disorder (Milliman) 50%

Increased risk of obesity and diabetes if employee has depression 4.5x

Higher cost of diabetes treatment when

depression is present than the treatment of diabetes alone.

## The Hidden Crisis: Addiction and Suicide in Construction

- 150% more likely to be diagnosed with a substance-use disorder than other full-time workers
  - 12% alcohol use disorder
  - 14.3% substance use disorder
- Highest suicide rate of all industries
  - 4.5x greater than the national average

American Journal Of Industrial Medicine, <u>Https://Doi.Org/10.1002/Ajim.23340</u> Substance Abuse And Mental Health Administration, <u>Https://Www.Samhsa.Gov/Data/Data-we-collect/Nsduh-national-survey-drug-use-and-health</u>



# Mental illness is the "silent killer" in the building trades industry

## Stigma Still Remains an Issue...

78% Shame and stigma between the stigma stigma between the stigma betw

However, executives are willing to or already attempting to address this issue...

93% of all survey respondents recognize that addressing mental health at work is a sound business practice.

psychiatry.org



## However, Even When Funds Invest in Mental Health, Current Treatment Options Are Ineffective for Many



#### Sources:

American Psychological Association, https://www.apa.org/ptsd-guideline/ patients-and-families/length-treatment Fortune, 2022, https://fortune.com/2022/08/02/top-employee-benefits-companies-will-offer-2023/ Journal of Clinical Psychopharmacology, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3119579/ Biological psychiatry, https://pubmed.ncbi.nlm.nih.gov/12706951/#:~:text=Treatment%2D resistant%20depression%20(TRD),adequate%20response%20following%20antidepressant%20treatment

## 50%

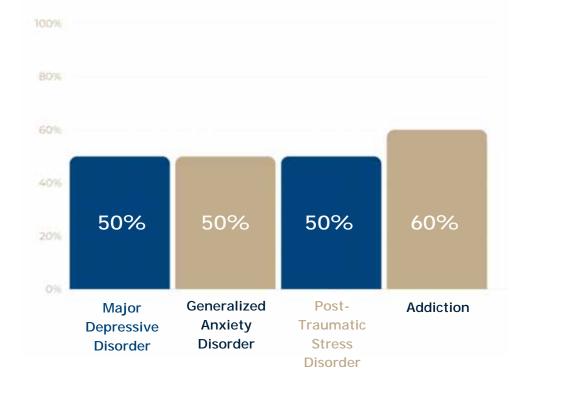
of therapy-goers will experience improvement only after 15 to 20 sessions

60%

don't achieve an adequate response following antidepressant treatment 58%

of people taking SSRIs experience moderately severe side effects Further, many individuals are entirely resistant to current treatments options like medication and therapy

### **Treatment Resistant Population**



Sources:

Johns Hopkins, <u>https://www.hopkinsmedicine.org/health/conditions-and-diseases/mood-disorders/treatment-resistant-depression</u> Mental Health Clincian, 2020, <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7653736/</u>

National Academies Press; 2014, <u>https://www.ncbi.nlm.nih.gov/books/NBK224874/#:~:text=It%20has%20been%20suggested%20that,%25%20 (Green%2C%202013)</u> Nida, 2023, <u>https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/treatment-recovery</u>

### New treatments are available now...

Ketamine-Assisted Therapy (KAT) Ketamine-assisted therapy uniquely combines a low dose of ketamine with psychotherapy for enhanced and sustained outcomes.

About Ketamine:

- FDA-approved anesthetic
- 50 years of proven safety
- 25 years of supporting evidence for the treatment of mental health

A Different Approach:

- Ketamine used to enhance the outcomes and effectiveness of therapy
- Sustained outcomes by enhancing neuroplasticity
- Addresses the root cause rather than masking symptoms like SSRIs
- Effective for treatment-resistant conditions

**Delivery Mechanism:** 

- Short-term treatment protocol (6 sessions)
- Administered by a clinician
- Integration with a therapist
- Enthea is a specialized mental health network available nationwide

KAT is effective for addiction, PTSD, anxiety, depression and treatmentresistant cases

Clinical Research and Supporting Evidence

- Addiction: Ketamine shows great promise as a treatment for various addictions (Source: <u>Ezquerra-Romano et al., 2022</u>).
- Alcohol Use Disorder: 86% abstinence at 6-month follow-up (Source: <u>Awakn Life Sciences</u>)
- Substance Use Disorder: Results from various clinical studies suggest that ketamine facilitates abstinence across multiple substances of abuse, such as cocaine, heroin and alcohol (Source: <u>Jones et al., 2018</u>)
- Depression, Anxiety, and PTSD: KAT produced a significant reduction in depression, anxiety, and PTSD symptoms after only 4-6 KAT sessions, with sustained effects at 6-month follow-up (Source: <u>Yermus et al., 2023</u>)
- PTSD: 86% of those screened for PTSD at baseline screened negative for PTSD after a 12-week KAT treatment (Source: <u>Dames et al., 2022</u>)
- Anxiety: 91% of patients treated with KAT reported clinically significant reductions in generalized anxiety at 3-month follow-up (Source: <u>Dames et al.</u>, <u>2022</u>)
- General Functioning: 92% of patients reported significant life and work functionality improvements after 12 weeks of KAT treatment (Source: <u>Dames et</u> <u>al., 2022</u>)
- Suicidality: Ketamine-assisted therapy only treatment that works in as little as 24 hours (Source: <u>Yale Medicine, 2022</u>)

## The Patient Journey Includes Clinical Support and Monitoring Each Step of the Way, Beginning With a Thorough Screening and Evaluation Process

- Initial Evaluation: Clinical assessments ensure treatment appropriateness, safety and to personalize the care plan.
- Preparation Sessions: Up to three sessions where the clinician helps the patient understand the treatment process.
- Medicine Sessions: Up to six ketamine administration sessions, each combined with therapy under the guidance of a trained clinician.
- Integration Sessions: Up to eight sessions focused on integrating the insights and experiences from the KAT sessions into daily life. Additional sessions available as needed.



## Despite Its Proven Effectiveness and Strong Safety Profile, Coverage for Generic Ketamine Is Sparse

- Current insurance coverage as an anesthetic; coverage for stand-alone therapy
- Insurance coverage for mental health (KAT) slowly being adopted (coverage under the VA/DOJ) but sparse for unions and employers
- High cost of FDA approval creates barriers
  for approval of other indications
- Brand-name ketamine covered through high cost (up to \$45K annually), lower efficacy and no therapy—Chronic medication



## Member Experience With Conventional Coverage Yields Painful/Costly Outcomes

This scenario underscores the need for effective mental health benefits to prevent crises and support both members and funds.



Sam has been struggling with severe depression

Limited coverage: Coverage for SSRIs and talk therapy

Ineffective treatment: No improvement from multiple antidepressants



His condition worsens, leading to a crisis

Escalating issues: Depression deepens, alcohol use increases requiring rehab

**High-cost care**: His fund incurs significant costs due to his inpatient rehab stay



He takes on debt to seek alternative care

**Out-of-pocket** costs: Sam pays for alternative therapies not covered by insurance

Self Medicates: Uses alcohol and other substances to cope



Sam takes an extended leave

**Unplanned absence**: Extended leave, straining his team and reducing productivity

Disability claim: Sam can't come back to work, and files a disability claim



## KAT Patient Experience Yields Optimal Outcomes



Sam has been struggling with severe depression

Enrolls in ketamine-assisted therapy (KAT) through Enthea which his fund offers Sam receives a thorough evaluation and is approved for KAT.



Sam begins treatment with Enthea's support

Sam receives a personalized treatment plan: Sessions are tailored to his needs, with full coverage and ongoing support from Enthea.



Sam experiences rapid recovery

Within hours of treatments Sam feels relief.

After a few sessions, Sam sees a 65% reduction in symptoms, discontinues antidepressants, reduces drinking and limits only to social settings.



Positive impact on Sam's work and life

Sam returns to work more focused and productive.

Sam's mental health is restored, allowing him to thrive both personally and professionally.



## Case Study

In 2021, a manufacturing company partnered with Enthea, a company helping unions cover ketamine- assisted therapy as a mental health benefit. The CEO is a successful beneficiary of KAT and offered the new benefit to all employees and adult dependents at no cost. They had 7% utilization (note, standard utilization is 7%). Outcomes are as follows:

$\bigcirc$	86% Improvement	Post-traumatic stress disorder	PCL-5	Average 25.25-point reduction in symptom severity
	65% Improvement	Major depressive disorder	•Average 19.26-point reduction i•• <td< th=""></td<>	
(FF)	67% Improvement	Generalized anxiety disorder	GAD-7	Average 7.57-point reduction In symptom severity
	80% no	o longer on antidepressants at 3-	month	follow up

## What Are Patients Saying?

"The work I did in just one session equated to years of therapy."

"The ketamine treatments and integrations have lifted me out of the darkest depression, saved me from suicidal ideation, and given me new perspective, new hope, new tools, and new motivation to use those tools. I no longer feel doomed."



"It was literally a life changer. I had been on every antidepressant on the market, and they either didn't work, or I build up resistance to them. After my first ketamine treatment, I noticed a difference; by my third, my depression was basically done. I felt emotions I hadn't (joy, love, happiness) for the first time in a decade. I would highly recommend this being a standard of care."

## Bringing KAT to Your Workforce

### Empower Your Workforce Today

Invest in the mental health and safety of your workforce with proven, innovative treatments that are cost effective.

## Cost comparison:



## New Models of Care Are Available That Allow Unions to Cover Ketamine-Assisted Therapy Through an Ancillary Benefit

### Best practices, safe protocols and high-quality care

Approach: Lower-cost, higher-efficacy treatments with a short-term approach (up to 6 doses) rather than ongoing medication.

Generic ketamine, an FDA-approved medication prescribed off-label for mental health conditions—A common practice, as about 1 in 5 prescriptions are prescribed off-label by doctors. Administered in a short-term treatment of six sessions combined with psychotherapy, making it a more cost-effective approach compared to esketamine.

A recent study found that intravenous ketamine (generic) was more 3x more effective than intranasal esketamine (brand name Spravato) for treating depression

### Reimbursement for Root-cause Mental Health: Supporting Funds in Providing Access to Ketamine-Assisted Therapy as an Ancillary Benefit



### Conventional Insurance

### Esketamine

- Brand name; spray
- Chronic use, clinical efficacy; higher cost

Spravato (Esketamine) a o related form of Ketamine

It's FDA Approved for

Treatment Resistant Depression

## National network of specialized providers (through Enthea)

with therapy

• Higher clinical efficacy; lower cost; short term

Ancillary/Add-On

**Employee Benefit** 

Generic ketamine combined

### Psilocybin-assisted therapy (Enthea only)

Coverage in select states where legal



# Overview of Available Treatment Options (Enthea)

Treatment		Target indication	FDA Status	Insurance coverage	Regulatory status
Ketamine- assisted therapy	Dissociative anesthetic administered by clinician followed by therapy	Addiction, PTSD, depression, anxiety, suicidality	FDA-approved medicine	Enthea/VA/DOJ- select carriers (case by case)	Legal in all 50 states
Stellate Ganglion Block (Optional)	Anesthetic administered by clinician followed by therapy	Addiction, PTSD depression, anxiety, suicidality	FDA approved medicine	Enthea/VA/DOJ/ Magellan Health	Legal in all 50 states
Psilocybin- assisted Therapy (Optional)	Naturally occurring psychedelic compound in certain mushrooms species.	Addiction (NUD, SUD, AUD, OUD), depression, PTSD anxiety, existential distress in terminally ill patients.	Breakthrough therapy status Phase III clinical trials (2025)	Enthea TPA	Legal in OR and CO Psychedelic therapy clinical trials in VA ( <u>source</u> )

## Key Takeaways



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Session Evaluation

