MDMA-Assisted Psychotherapy for Post-Traumatic Stress Disorder: Effectiveness and Value

Public Meeting — May 30, 2024

Meeting materials available at: https://icer.org/assessment/ptsd-2024

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INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

NEW ENGLAND CEPAC
AN ICER PROGRAM
COMPARATIVE EFFECTIVENESS PUBLIC ADVISORY COUNCIL

Patient Experts

Diana Chao, Executive Director, Letters to Strangers

- *Diana serves as an advisor on the Mental Health America Youth Council, who has received funding from healthcare companies. Letters to Strangers has received a $5000 donation from an executive member at Pfizer as a private individual donation.*

Naomi M. Mathis, Assistant National Legislative Director, Disabled American Veterans

- *No conflicts to disclose.*

Clinical Experts

Jessica Maples-Keller, PhD, Assistant Professor, Emory University School of Medicine

- *Dr. Maples-Keller has received funding from healthcare companies, such as COMPASS Pathways and Multidisciplinary Association of Psychedelic Studies (MAPS) for research trials on MDMA-assisted exposure therapy for PTSD.*

Joar Øveraas Halvorsen, cand.psychol., PhD, Associate Professor and Consultant Clinical Psychologist, Norwegian University of Science and Technology, St. Olav's University Hospital

- *No conflicts to disclose.*

ICER Speakers

Sarah K. Emond, MPP
President & CEO

Reem A. Mustafa, MD, MPH, PhD
Evidence Author

David Rind, MD, MSc
Senior Management Lead

Steven D. Pearson, MD, MSc
Special Advisor

Brett McQueen, PhD
Lead Modeler

Why are we here today?

I have a lot of nightmares. They have to do with what happened to me. There are places that remind me of my trauma and there are people that remind me of my trauma, and I would avoid those at all costs. So basically, I just wanted to be alone. I don't want to try to explain it to people. I didn't want to have to go over my experiences every single time. I trusted no one, even my own family. I started believing that I didn't deserve help, that I didn't deserve to be happy.

Person with PTSD
(https://www.ptsd.va.gov/apps/AboutFace/)

Why Are We Here Today?

- What happens the day these treatments receive FDA approval?
- Questions about:
  - What are the risks and benefits?
  - How do new treatments fit into the evolving landscape?
  - What are reasonable prices and costs to patients, the health system, and the government?
  - What lessons are being learned to guide our actions in the future?

The Impact on Rising Health Care Costs for Everyone

DIAGNOSIS: DEBT

100 Million People in America Are Saddled With Health Care Debt

By Noam N. Levey

JUNE 16, 2022

Why Delaware is eying a 27% premium hike on state employees' health insurance

Amanda Fries

Delaware News Journal

Published 4:35 a.m. ET Feb. 1, 2024 | **Updated 9:29 p.m. ET Feb. 6, 2024**

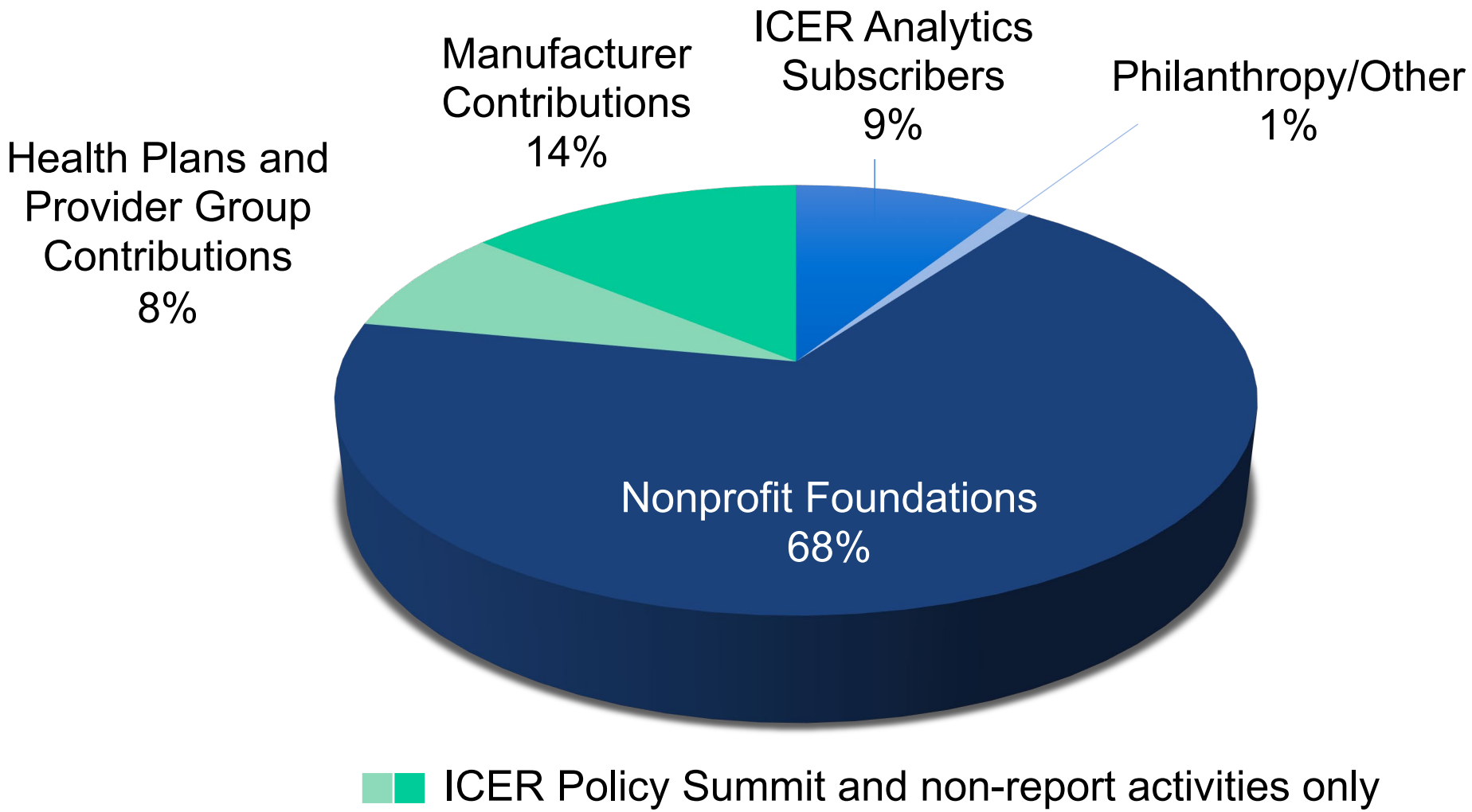
100 Million People in America Are Saddled With Health Care Debt (KFF Health News)

Why Delaware is eying a 27% premium hike on state employees' health insurance (Delaware Online)

Organizational Overview

- New England CEPAC
- Institute for Clinical and Economic Review (ICER)

Funding 2024



How Was the ICER Report Developed?

- Scoping with guidance from patients, clinical experts, manufacturers, and other stakeholders
- ICER evidence analysis in collaboration with University of Kansas Medical Center and cost-effectiveness modeling in collaboration with University of Colorado Anschutz Medical Campus
- Public comment and revision
- Expert reviewers
  - Diana Chao, BA, Letters to Strangers
  - Arash Javanbakht, MD, Wayne State University School of Medicine
  - Dominic Trépel, PhD, Trinity College Dublin
- How is the evidence report structured to support NE CEPAC voting and policy discussion?

Value Assessment Framework: Long-Term Value for Money

Agenda (ET)

10:00 AM	Meeting Convened and Opening Remarks
10:20 AM	Presentation of the Clinical Evidence
11:00 AM	Presentation of the Economic Model
11:40 AM	Public Comments and Discussion
12:15 PM	Lunch Break
12:50 PM	NE CEPAC Deliberation and Vote
1:50 PM	Break
2:00 PM	Policy Roundtable Discussion
3:30 PM	Reflections from New England CEPAC
4:00 PM	Meeting Adjourned

Presentation of the Clinical Evidence

Reem A. Mustafa, MD, MPH, PhD

Professor of Medicine, Division of Nephrology and Hypertension

Director, Outcomes and Implementation Research, University of Kansas Medical Center

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Key Collaborators

Team Role	Assigned Team Member
Research Lead	Dmitriy Nikitin, MSPH
Research Assistant	Emily Nhan, BA

Disclosures

Financial support provided to Dr. Mustafa from the Institute for Clinical and Economic Review (ICER)

Dr. Mustafa and other members of ICER (Nikitin, Nhan) have no conflicts to disclose defined as more than $10,000 in healthcare company stock or more than $5,000 in honoraria or consultancies relevant to this report during the previous year from health care manufacturers or insurers.

Post-Traumatic Stress Disorder (PTSD)

- PTSD is a complex psychiatric disorder associated with substantial disability and poor quality of life. It can involve nightmares, flashbacks, intrusive thoughts, and avoidance of trauma reminders
- In the US, about 13 million adults (5%) experience PTSD symptoms annually
- In 2018, the total economic burden beyond normal healthcare costs for PTSD in the US was $232.2 billion ($19,630 per individual)
- PTSD is more prevalent in certain subgroups: women, veterans, racial/ethnic groups

Insights from Discussions with Patients

- ICER reached out to over 20 clinicians, 15 patient advocacy organizations, and hosted a focus group and interviews with individual patients
- PTSD makes daily activities extremely difficult for some patients, burdening patients and caregivers
- Accessing trauma-focused psychotherapies is challenging, with high dropout rates
- Despite trying various treatments, many still report persistent PTSD symptoms

Insights from Discussions with Patients

- Patients express concerns over lack of new FDA-approved PTSD treatments in 20 years
- Some patients self-medicate or experiment with illegal/unproven compounds out of desperation
- Patients perceive that successful therapy reduces symptom severity, builds coping skills, alleviates suicidality, and fosters autonomy without medication reliance

FDA: Food and Drug Administration, PTSD: posttraumatic stress disorder

Standard of Care and Management

Trauma-focused Psychotherapy

- Prolonged Exposure Therapy
- Cognitive Behavioral Processing Therapy
- Cognitive Processing Therapy
- Eye Movement Desensitization and Reprocessing

Pharmacotherapy

- Paroxetine
- Sertraline
- Venlafaxine
- Fluoxetine

New Therapy: MDMA-Assisted Psychotherapy

- Midomafetamine (3,4-Methylenedioxymethamphetamine) capsules to be used in combination with psychological interventions, including psychotherapy and other supportive services from a health care provider
- The MDMA-AP protocol in the trials requires approximately 42 hours of therapy with two therapists per patient (84 therapist hours) and doses range from 80 to 180 mg of MDMA per session
  - Three 90-minute preparation sessions
  - Three 8-hour MDMA-AP assisted sessions
  - Nine 90-minute integration sessions
- FDA: Advisory Committee Meeting June 4, and expected decision by August 14, 2024

FDA: Food and Drug Administration, MDMA: Midomafetamine, MDMA-AP: MDMA-assisted psychotherapy, mg: milligram, PTSD: posttraumatic stress disorder

Scope of Review

- **Population**
  - Adults diagnosed with moderate-to-severe PTSD
- **Intervention**
  - MDMA-AP (Lykos Therapeutics, Inc.)
- **Comparator**
  1. Lykos-specific non-assisted psychotherapy (LSNAP). LSNAP served as control arm in pivotal trials but is not an established form of standalone psychotherapy
  2. Short-term trauma-focused psychotherapies for PTSD (e.g., Prolonged Exposure, Cognitive Behavioral Therapy)

LSNAP: Lykos-specific non-assisted psychotherapy, MDMA: Midomafetamine, MDMA-AP: MDMA-assisted psychotherapy, PTSD: posttraumatic stress disorder

Clinical Evidence

Key Clinical Trials

Trial	N	Age, mean years	PTSD duration, mean years	PTSD severity, %	CAPS-5, mean score	Prior lifetime MDMA use, %
MAPP1	90	41	14.1	Severe: 100%	44.1	32.2%
MAPP2	104	39.1	16.2	Moderate: 27% Severe: 73%	39.1	46.2%

CAPS-5: Clinician-Administered PTSD Scale for DSM-5, MDMA: Midomafetamine, n: number, N: total number, PTSD: posttraumatic stress disorder

Maintenance of Blinding

- The psychoactive and physiological effects of MDMA make it difficult to maintain blinding of participants and therapists
- In MAPP2 trial:
  - 94% of participants in the MDMA-AP arm correctly guessed their assigned treatment
  - 75% of participants in the LSNAP arm did so
- An informal evaluation of the MAPP1 trial indicated comparable findings
- Maintenance of blinding among trial therapists was not assessed in either the MAPP1 or MAPP2 trials

LSNAP: Lykos-specific non-assisted psychotherapy, MDMA: Midomafetamine

Primary Treatment Goals: Reduction in PTSD Symptoms

- Clinician-Administered PTSD Scale for DSM–5 (CAPS-5)
  - 30-item questionnaire (0-80 total score) corresponding to the DSM-5 diagnosis for PTSD. Requires the identification of a single index trauma to serve as the basis of symptom inquiry
  - Primary outcome: Change from baseline through 18 weeks
    - Responder (≥10-point decrease on CAPS-5),
    - Loss of Diagnosis (no longer meeting symptom criteria),
    - Remission (loss of diagnosis and a total CAPS-5 score of ≤11)

CAPS-5: Clinician-Administered PTSD Scale for DSM-5, DSM-5: The Diagnostic and Statistical Manual of Mental Disorders (5th ed), PTSD: posttraumatic stress disorder

Question 1: Reduction in PTSD Symptoms

- The CAPS-5 score changed [Mean difference (MD) -10.18 (95% CI -13.80, -6.56)] in the MDMA-AP versus LSNAP study arm
  - No established clinically meaningful threshold on CAPS-5, collaborator agreement with FDA established 10 points as clinically meaningful
- The standardized effect size (Cohen's d) between the two groups was 0.8, suggesting a large treatment effect size
- Patients treated with MDMA-AP may be more likely than LSNAP to:
  - Be treatment responders RR 1.32
  - Achieve loss of diagnosis RR 1.7
  - Meet criteria for remission RR 2.86

CAPS-5: Clinician-Administered PTSD Scale for DSM-5, CI: confidence interval, LSNAP: Lykos-specific non-assisted psychotherapy, MD: mean difference, MDMA-AP: MDMA-assisted psychotherapy, PTSD: posttraumatic stress disorder, RR: relative risk

Durability of Treatment Effect

- Phase III trial participants showed reduction in PTSD symptoms two months after the final experimental session, demonstrating short-term health benefit
- Long-term follow-up data from MAPP1 and MAPP2 trials are not yet available

PTSD: posttraumatic stress disorder

Harms

- Common adverse events with MDMA-AP included muscle tightness, decreased appetite, bruxism, hyperhidrosis, fatigue, restlessness, and insomnia
- Transient increases in blood pressure, body temperature, and heart rate were observed with MDMA-AP
- Limited evidence on risk of MDMA abuse or cardiac events due to short-term (18 weeks) follow-up

MDMA: Midomafetamine, MDMA-AP: MDMA-assisted psychotherapy, PTSD: posttraumatic stress disorder

Harms: Risk of Suicide Ideation

- High baseline risk of suicidal ideation (~90% of trial participants with positive lifetime suicidal ideation) - Risk of suicide ideation (RR: 0.89; 95% CI 0.64 to 1.24) with MDMA-AP vs LSNAP
- MDMA-AP lowered the risk of treatment withdrawals (RR: 0.32)
    - Higher rates of discontinuation occurred in the LSNAP arms of the MAPP1 and 2 trials (16% in both MAPP1 and 2) compared to the MDMA-AP arms (1.9 and 8.7%)
- At least one known instance, a participant who suspected they were receiving LSNAP treatment withdrew from the study

CI: confidence interval, MDMA-AP: MDMA-assisted psychotherapy, RR: relative risk

Harms: Therapist Misconduct

- There have been concerns that MDMA heightens suggestibility and lowers judgement and for this reason in the phase II and III trials there were pairs of therapists (male and female) to reduce this risk
- Despite these measures, in the phase II trial there was a widely-reported serious event where a therapist sexually assaulted a patient
- Led to suspension of Phase II study to review safety and compliance

Other Outcomes of Interest

- Due to the considerable uncertainties about these seemingly positive trials, we will not discuss the results of secondary and exploratory outcomes (e.g., functional disability, depression symptoms, alcohol abuse...etc.)

Question 2: MDMA-AP vs TFPs

Differences in study design, baseline medication use, patient criteria, and therapies themselves make direct comparisons of effectiveness between MDMA-AP and other TFP challenging:

- MDMA-AP has demonstrated a moderate to large treatment effect size for reducing PTSD symptoms, similar to some TFPs vs usual care
- Around 40% of MDMA-AP participants achieved PTSD remission, compared to ~53-63% remission rates reported for CBT in a meta-analysis
- Treatment discontinuation rates were lower for MDMA-AP (5%) compared to some TFPs (13-30% dropout)
- MDMA-AP protocol is more resource-intensive (42 hrs, 2 therapists) compared to typical TFP delivery (8-20 hrs, 1 therapist)

CBT: cognitive behavioral therapy, LSNAP: Lykos-specific non-assisted psychotherapy, MDMA-AP: MDMA-assisted psychotherapy, PTSD: posttraumatic stress disorder, TFP: trauma-focused psychotherapy

Concerns About Conduct of MDMA-AP Trials

- ICER spoke to a therapist and a small number of patients involved in the MAPP trials, and experts familiar with the research space. We heard concerns about the conduct of the trials by Lykos Therapeutics including design choices affecting result interpretation and potential misconduct
- Strong prior beliefs about psychedelics' value among trial participants and therapists
  - Pressures to report favorable outcomes
  - Severe negative outcomes being downplayed/underreported
- Instances of patients prevented from participating in long-term follow-up

Controversies and Uncertainties

- Trials likely unblinded, making control comparison difficult
- Potential biases in reporting benefits/harms – see Section 2.1
- CAPS-5, while commonly used, may not fully capture PTSD changes for certain populations
- Small samples/short follow-up may underestimate harms
- Implementing MDMA-AP could be very challenging for healthcare systems

CAPS-5: Clinician-Administered PTSD Scale for DSM-5, MDMA-AP: MDMA-assisted psychotherapy, PTSD: posttraumatic stress disorder

Benefits Beyond Health and Special Ethical Priorities

- Substantial unmet need despite currently available treatments
- Women, veterans and racial/ethnic minority groups in the US have a higher burden of PTSD. If efficacious, MDMA-AP may have potential to reduce health disparities
- The extent to which MDMA-AP may impact caregivers' quality of life and functioning is unclear, due to uncertainty around the therapy's effectiveness in reducing patients' PTSD symptoms

MDMA-AP: MDMA-assisted psychotherapy, PTSD: posttraumatic stress disorder, US: United States

Summary

- The MAPP trials showed improvements in many patients treated with MDMA-AP, with few short-term harms
- While this suggests MDMA-AP could be an important addition to PTSD treatment options, there are concerns about the validity and generalizability of the results
- Multiple experts believe additional trials are needed to prove the benefits outweigh potential harms, despite being hopeful about using psychedelics for PTSD
- ICER cannot assess the frequency of misreporting benefits and/or harms, and thus the overall net benefit of MDMA-AP. We continue to believe that it is vital that regulatory bodies investigate these issues since ICER is unable to assess them
- Comparative studies of MDMA-AP against gold-standard TFP are necessary to evaluate its efficacy and guide clinical implementation

ICER Evidence Ratings for MDMA-AP

Treatment	Comparator	Population	Evidence Rating
MDMA-AP	Lykos Specific Non-Assisted Psychotherapy	Adults with moderate to severe PTSD	I
	Short-term Trauma Focused Psychotherapy	Adults with moderate to severe PTSD	I

I: Insufficient – Any situation in which the level of certainty in the evidence is low

Comments

"One hundred and nine therapists and principal/co-investigators contributed to the Phase 3 trials of MDMA-AP for PTSD. To our knowledge, none of them were consulted before the preliminary report was issued. However, this group is in the strongest position to describe the studies and address accusations related to inappropriate study design and conduct. In the absence of such input, a number of assertions in the ICER report represent hearsay, and should be weighted accordingly."

Comments

- ICER Report: *"Some patients were prevented from entering the long-term follow-up study and felt this was done to keep these negative outcomes out of the data set"*
- Principal Investigator: "*This is untrue. No participants were prevented from entering the phase 3 long-term follow-up study (MPLong)."*
- ICER Response: *"We had first-hand reports of such events. We cannot be certain that these reports were accurate, but we do wonder whether [the PI] is certain that this could not have occurred."*

Questions?

Presentation of the Economic Evidence

Brett McQueen, PhD

Associate Professor

University of Colorado Anschutz Medical Campus

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Key Review Team Members

Team Role	Assigned Team Member
Modeler(s) and Economics Lead	R. Brett McQueen
Modeling team member	Antal Zemplenyi
Modeling team member	Mike DiStefano

Disclosures

Financial support provided to the University of Colorado from the Institute for Clinical and Economic Review (ICER)

R. Brett McQueen has no conflicts to disclose defined as more than $10,000 in healthcare company stock or more than $5,000 in honoraria or consultancies relevant to this report during the previous year from health care manufacturers or insurers.

Objective

PTSD

This exploratory analysis compared the cost-effectiveness of MDMA-AP to no short-term intervention for PTSD as estimated by the effectiveness of the control arm of the randomized trial (LSNAP).

MDMA: 3,4-methylenedioxymethamphetamine, MDMA-assisted psychotherapy, PTSD: Post-traumatic stress disorder; LSNAP: Lykos-specific non-assisted psychotherapy

Unmet Need

Condition	Absolute evLY Shortfall	Proportional evLY Shortfall
PTSD	7.4	21%
Other Example Conditions		
Major Depressive Disorder	9.7	32%
Multiple Sclerosis	18.9	52%
Osteoporosis	2.6	19%

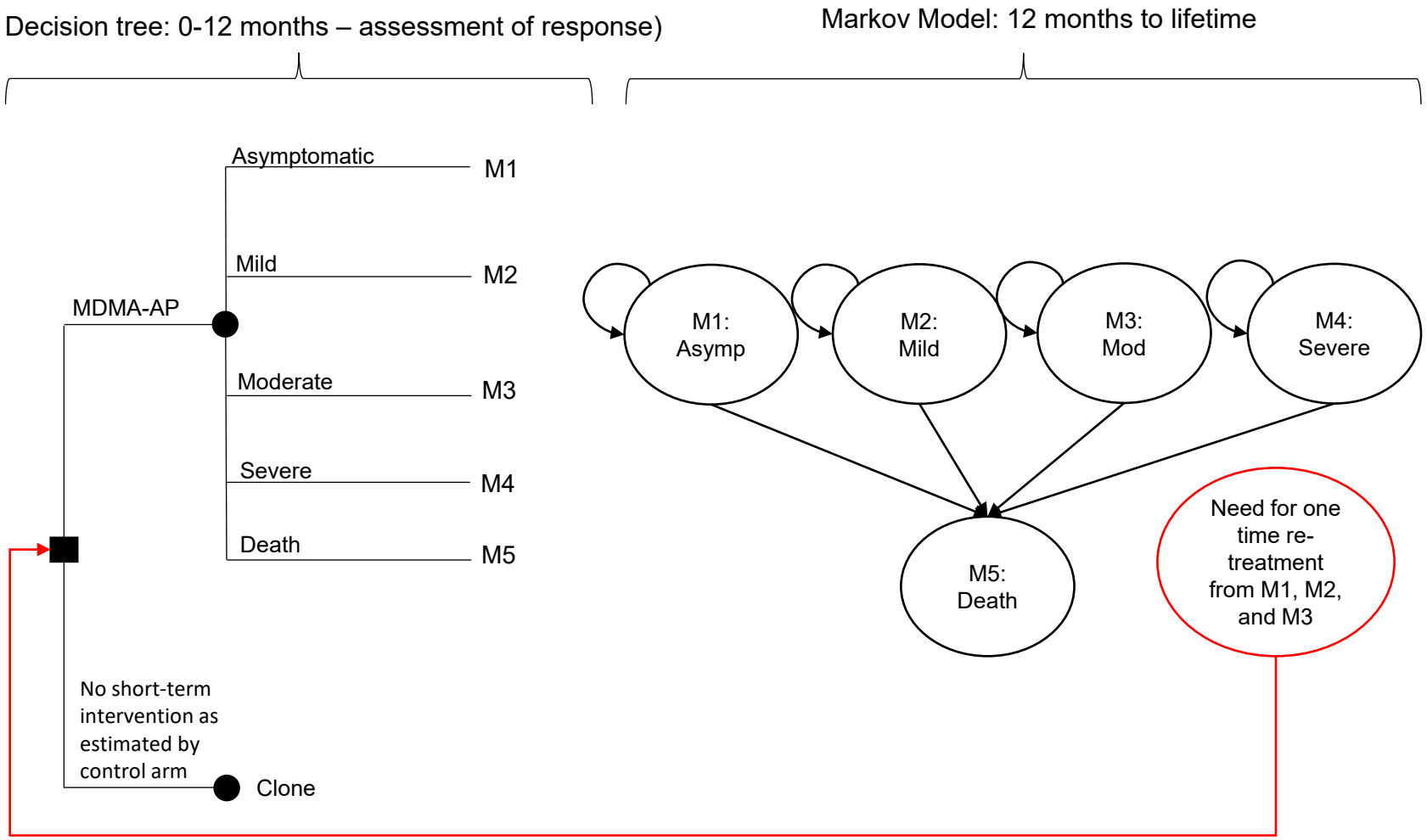
Methods in Brief

Methods Overview

Methods	Summary
Model	Decision tree and Markov cohort model
Setting	United States
Perspective	Health Care Sector Perspective and Modified Societal Perspective
Time Horizon	Lifetime
Discount Rate	3% per year (costs and outcomes)
Cycle Length	1 year
Primary Outcome	Cost per quality-adjusted life year (QALY) gained; equal value of life years gained

evLY: equal value of life years gained, QALY: quality-adjusted life years

Model Schematic



MDMA: 3,4-methylenedioxymethamphetamine, MDMA-assisted psychotherapy, M: Markov state, asymp = asymptomatic

Key Assumptions

- The cost of standard of care reflected real-world treatment scenarios instead of protocol driven assumptions on treatment without MDMA
- Simulated CAPS-5 scores from recent phase III trial evidence to generate post-intervention effectiveness for health state distributions in model
- Utilities across PTSD severity distributions from the first phase III trial were used to estimate treatment effects on quality of life outcomes at follow-up for both arms of the model

Key Model Inputs: Initial and post-trial state distributions (PTSD severity)

PTSD Health State	Baseline Distribution	Post-Trial Distribution		Source
		MDMA-AP	Placebo	
Asymptomatic	0%	46.2%	21.4%	Mitchell et al. 2023 and authors' calculation
Mild	0%	23.9%	27.3%	
Moderate	26.92%	20.0%	25.7%	
Severe	73.08%	9.9%	25.7%	

PTSD: Post-traumatic stress disorder, MDMA: 3,4-methylenedioxymethamphetamine, MDMA-assisted psychotherapy

Key Model Inputs: Costs

Direct Costs	Input†	Source
Cost of intervention (MDMA + Lykos-specific manualized therapy)*	$23,117	Marseille et al. 2020; Mitchell et al. 2023; CPT codes
Asymptomatic health state	$4,830	Davis et al. 2022; Walker et al. 2003 ; National Institute of Mental Health: PTSD statistics 2007; authors' calculation
Mild health state	$9,670	
Moderate health state	$13,340	
Severe health state	$19,720	

MDMA: 3,4-methylenedioxymethamphetamine, MDMA-assisted psychotherapy
*Using a placeholder price of $10,000 per treatment course for MDMA drug costs. Intervention costs also include the costs of Lykos-specific non-assisted psychotherapy.
†Inputs varied in sensitivity analyses

Key Model Inputs: Utilities

PTSD Health State	Input†	Source
Asymptomatic	0.90	Marseille et al. 2022
Mild	0.83	
Moderate	0.74	
Severe	0.61	

PTSD: Post-traumatic stress disorder
† Inputs varied in sensitivity analyses

Key Model Inputs: Retreatment and Mortality

Parameter	Input†	Source
Annualized retreatment rate (one time within the first 5 years)	6%	Benitez et al. 2012
PTSD all-cause mortality risk	RR: 1.47 (95% CI: 1.06-2.04)	Nilaweera et al. 2023
PTSD suicide mortality risk	RR: 2.09 (95% CI: 1.11-3.94)	Akbar et al. 2022; calibration to Centers for Disease Control data on deaths by suicide

PTSD: Post-traumatic stress disorder
† Inputs varied in sensitivity analyses

Results

Exploratory Results

Drug	Intervention Costs	Non-Intervention Costs	Total Cost	PTSD-Related Deaths by Suicide per 100,000 people	QALYs	Life Years	evLYs
MDMA-AP*	$28,000	$207,000	$235,000	478	17.5	21.50	17.5
Placebo	$0	$267,000	$267,000	697	16.2	21.48	16.2

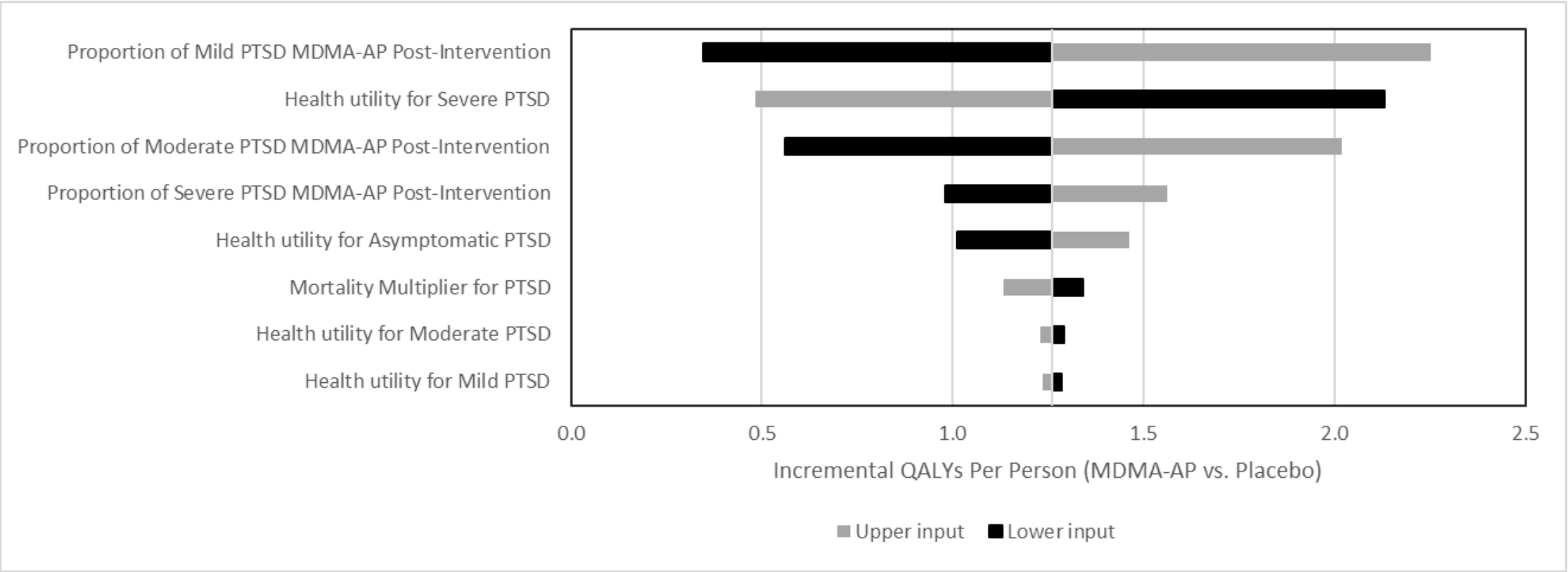
PTSD: Post-traumatic stress disorder evLYs: equal value of life years, QALYs: quality-adjusted life years, MDMA: 3,4-methylenedioxymethamphetamine, MDMA-assisted psychotherapy
*Using a placeholder price of $10,000 per treatment course for MDMA drug costs. Intervention costs also include the costs of Lykos-specific non-assisted psychotherapy.

Exploratory Incremental Results

Drug	Cost per QALY Gained	Cost per Life Year Gained	Cost per evLY Gained	Cost per death by suicide averted
MDMA-AP* vs. placebo	Less costly, more effective	Less costly, more effective	Less costly, more effective	Less costly, more effective

MDMA: 3,4-methylenedioxymethamphetamine, MDMA-assisted psychotherapy, evLYs: equal value of life years, QALYs: quality-adjusted life years
*Using a placeholder price of $10,000 per treatment course for MDMA drug costs. Intervention costs also include the costs of Lykos-specific non-assisted psychotherapy.

One Way Sensitivity Analyses



MDMA: 3,4-methylenedioxymethamphetamine, MDMA-assisted psychotherapy, PTSD: Post-traumatic stress disorder

Probabilistic Sensitivity Analysis

Drug	Cost-Effective at $50,000 per QALY and evLY	Cost-Effective at $100,000 per QALY and evLY	Cost-Effective at $150,000 per QALY and evLY
MDMA-AP*	100%	100%	100%

MDMA: 3,4-methylenedioxymethamphetamine, MDMA-assisted psychotherapy, QALY: quality-adjusted life years
*Using a placeholder price of $10,000 per treatment course for MDMA drug costs. Intervention costs also include the costs of Lykos-specific non-assisted psychotherapy.

Scenario Analyses

Treatment	Exploratory Result	Scenario Analysis 1: Modified Societal Perspective	Scenario Analysis 2: Time Horizon of 3 Years	Scenario Analysis 3: Time Horizon of 5 Years
MDMA-AP*	Less costly, more effective	Less costly, more effective	$157,000 per QALY and evLY	$81,000 per QALY and evLY

MDMA: 3,4-methylenedioxymethamphetamine, MDMA-assisted psychotherapy, QALY: quality-adjusted life years
*Using a placeholder price of $10,000 per treatment course for MDMA drug costs. Intervention costs also include the costs of Lykos-specific non-assisted psychotherapy.

Limitations

- Data regarding the impact of MDMA-AP in terms of a change in the distribution of PTSD across stages of severity was requested from Lykos Therapeutics and not provided
- No observed treatment effect estimates on health-related quality of life utility scores available from the MAPPS trials
- No evidence on MDMA-AP versus other short-term trauma focused therapies

Comments Received

- Inclusion of costs and benefits of spillover effects of PTSD, e.g., substance abuse disorders
- Real-world mortality and other inputs across PTSD severity states
- Caregiver burden in modified societal perspective

Conclusions

- Exploratory analysis of MDMA-AP provides clinical benefit in terms of gains in QALYs, evLYs, and deaths by suicide as compared to no short-term intervention
- Key drivers were short-term improvements in PTSD-related symptoms and quality of life by severity of PTSD-related symptoms

Questions?

Public Comment and Discussion

Sarah McNamee, MSW, MScA
MAPP1 Research Participant, Social Worker, Psychotherapist

Conflicts of Interest:

- *Sarah works as a research assistant at McGill university, where professors/labs may receive funding from health care companies.*

00 : 05 : 00

Lily Ross, MDiv, PhD
Independent Researcher, Journalist

Conflicts of Interest:

- *No conflicts to disclose.*

00 : 05 : 00

Molly Richardson
Patient Expert

Conflicts of Interest:

- *No conflicts to disclose.*

00 : 05 : 00

Jesse Gould
President and Founder, Heroic Hearts Project

Conflicts of Interest:

- *No conflicts to disclose.*

00 : 05 : 00

Neşe Devenot, PhD
Senior Lecturer, Johns Hopkins University

Conflicts of Interest:

- *No conflicts to disclose.*

00 : 05 : 00

Meaghan Buisson, BSc
Independent Researcher

Conflicts of Interest:

- *No conflicts to disclose.*

00 : 05 : 00

Lunch

Meeting will resume at 12:50 PM ET

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Voting Questions

Clinical Evidence

Patient Population for all questions: *Adults with a diagnosis of moderate-to-severe PTSD; patients may be receiving ongoing therapy and/or medications such as SSRI antidepressants.*

slido

1. Is current evidence adequate to demonstrate that the net health benefit of MDMA-AP is superior to that of not treating with MDMA-AP?

ⓘ Start presenting to display the poll results on this slide.

slido

2. Is the current evidence adequate to demonstrate that the net health benefit of MDMA-AP is superior to that of short-term trauma-focused psychotherapies (TFP)?

ⓘ Start presenting to display the poll results on this slide.

Benefits Beyond Health and Special Ethical Priorities

To help inform judgments of overall long-term value for money, please indicate your level of agreement with the following statements:

slido

3. There is substantial unmet need despite currently available treatments.

ⓘ Start presenting to display the poll results on this slide.

slido

4. This condition is of substantial relevance for people from a racial/ethnic group that have not been equitably served by the healthcare system.

ⓘ Start presenting to display the poll results on this slide.

To help inform judgments of overall long-term value for money, please indicate your level of agreement with the following statements based on the relative effects of MDMA-AP versus not treating with MDMA-AP:

slido

5. The treatment is likely to produce substantial improvement in caregivers' quality of life and/or ability to pursue their own education, work, and family life.

ⓘ Start presenting to display the poll results on this slide.

slido

6. The treatment offers a substantial opportunity to improve access to effective treatment by means of its mechanism of action or method of delivery.

ⓘ Start presenting to display the poll results on this slide.

Long-Term Value for Money

slido

Given the available evidence on comparative clinical effectiveness and incremental cost effectiveness, and considering benefits beyond health and special ethical priorities, what is the long-term value for money of MDMA-AP versus not treating with MDMA-AP?

ⓘ Start presenting to display the poll results on this slide.

Break

Meeting will resume at 2:00PM ET

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Policy Roundtable

Policy Roundtable

Participant	Conflict of Interest
Diana Chao, Executive Director, Letters to Strangers	Diana serves as an advisor on the Mental Health America Youth Council, who has received funding from healthcare companies. Letters to Strangers has received a $5000 donation from an executive member at Pfizer as a private individual donation.
Peter Glassman, MBBS, MSc, Chair, Medical Advisory Panel, VA Pharmacy Benefits Management Services	Peter Glassman is a full-time employee at the U.S. Department of Veterans Affairs.
Jessica Maples-Keller, PhD, Assistant Professor, Department of Psychiatry and Behavioral Sciences, Emory University School of Medicine	Dr. Maples-Keller has received funding from healthcare companies, such as COMPASS Pathways and Multidisciplinary Association of Psychedelic Studies (MAPS) for research trials on MDMA-assisted exposure therapy for PTSD.
Naomi M. Mathis, Assistant National Legislative Director, Disabled American Veterans	No conflicts to disclose.
Joar Øveraas Halvorsen, cand.psychol., PhD, Associate Professor and Consultant Clinical Psychologist, Norwegian University of Science and Technology, and St. Olav's University Hospital	No conflicts to disclose.
Marina Sehman, PharmD, CSP, Clinical Director, IPD Analytics	Marina Sehman is a full-time employee at IPD Analytics.

New England CEPAC Council Reflections

Next Steps

- Meeting recording posted to ICER website next week
- Final Report published on or around June 27th, 2024
    - Includes description of New England CEPAC votes, deliberation, policy roundtable discussion
- Materials available at: https://icer.org/assessment/ptsd-2024

Adjourn

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