



## Five Fast Facts on ICER and our PTSD Report:

1. **ICER is a completely independent organization.**
2. **ICER has no regulatory power; we are a non-profit research organization.**
3. **ICER holds public meetings to discuss the effectiveness of all kinds of treatments as part of our report process.**
4. **ICER evaluated one very specific therapy for PTSD developed by Lykos Therapeutics; ICER has not reviewed MDMA in general.**
5. **The issues ICER outlined with the Lykos Therapeutics trials have been well-documented by news outlets.**

**Have time to learn more?** The Institute for Clinical and Economic Review ([ICER](#)) is an independent, non-profit research institute that conducts evidence-based reviews of health care interventions, including prescription drugs, other treatments, and diagnostic tests. ICER is independently funded — over 75% of our funding comes from charitable foundations and other independent sources. [Click here](#) to find out more about our funding.

**We want patients of all kinds – veterans and non-veterans – to have access to evidence-based treatments. Our goal is ensuring fair access to treatments at a fair price. In fact, since 2017, ICER and the VA have collaborated [to ensure better access to and lower costs of prescription drugs](#) for our nation’s veterans.**

In collaboration with patients, clinical experts, and other key stakeholders, ICER’s team of scientists analyzes the available evidence on the benefits and risks of these interventions to measure their clinical value and suggest fair prices. ICER also regularly reports on the barriers to care for patients and recommends solutions to ensure fair access to prescription drugs.

Our process for reviewing a new treatment—as we did with our recent MDMA-AP review—takes place over eight months and is fully transparent. We have two public comment periods and a public meeting. You can learn more about our process [here](#) and see [public comments](#) on the ICER’s MDMA-AP Draft Report and our response to public comments [here](#).

As a part of ICER’s public meeting process to discuss the effectiveness and value of a treatment, ICER allows external stakeholders such as patient advocates, clinicians, manufacturers, and others to provide a five-minute oral public comment. Consistent with our commitment to transparency, any individual or organization that provides feedback on our review is listed in our [report](#) (see page iii). **Individuals who comment at our public meeting are not involved in the conduct of our research. Neither our external reviewers nor the individuals or organizations involved in the public meeting are responsible for any part of the ICER report, which is solely the work of ICER.** These external stakeholders can discuss their perspectives about the ICER



report, the lived experience of patients and caregivers, or any other aspect of the condition or treatment they would like to highlight.

In the case of our MDMA-AP review, ICER reviewed the specific use of MDMA by one organization – Lykos Therapeutics. We had many questions about the clinical trials conducted by Lykos. ICER has not reviewed MDMA in general – we analyzed the results of these specific trials by this one pharmaceutical company. Nothing in the ICER report indicates that MDMA is not potentially useful for PTSD.

In the case of Lykos' MDMA-AP, [our report found](#) that, *“Despite two randomized trials of MDMA-AP, functional unblinding in the trials and additional concerns around trial design and conduct led to ICER concluding that the publicly available evidence is insufficient to assess the balance of benefits and harms.”* As such, ICER concluded that the current publicly available evidence is insufficient to assess the overall net benefit of MDMA-AP developed by Lykos.

The issues with the clinical trials have been well documented by other sources: [STAT: The inside story of how Lykos' MDMA research went awry](#)