



Clinical TMS Society's Statement on Level of Evidence for Single-Day TMS combined with Medications

Effective: December 2025

Due for Review: December 2026

The mission statement of the Clinical Transcranial Magnetic Stimulation Society (CTMSS) is to optimize clinical practice, support research, and increase access to high-quality, evidence-based Transcranial Magnetic Stimulation (TMS).

CTMSS seeks to clarify the level of evidence required to make claims of efficacy in direct-to-consumer/patient advertising. Claims based on pre-clinical data (including animal data, in-vitro, computational, modelling data etc.), theoretical papers on the possible mechanisms of a treatment, other non-published, non-peer reviewed reports, retrospective chart reviews, and preliminary open-label data do not meet the threshold to recommend an intervention as a clinical treatment. The CTMSS discourages direct-to-consumer/patient advertising of interventions that do not have sufficient evidence of efficacy.

In support of helping providers and patients choose evidence-based care, the CTMSS advises caution regarding an advertised protocol known as Optimized, Neuroplasticity-Enhanced techniques in Depression (ONE-D). This protocol involves twenty sessions of 600-pulses intermittent theta burst stimulation sessions delivered in 1 day, along with specific oral medications, d-cycloserine (125 mg) and lisdexamfetamine (20 mg), which are administered in the morning before stimulation.

Various clinics are making broad claims about ONE-D's efficacy, without clarification that the evidence is very preliminary. The AMPA TMS device used to deliver ONE-D is FDA cleared through the 510(k) pathway for standard clinical treatment. However, the ONE-D protocol itself was not FDA cleared.

As of December 2025, the evidence consists of one peer-reviewed journal article and one abstract, and these are insufficient to support efficacy. Both are retrospective case series, the first with 32 participants at two private clinics (Vaughn 2024) and the second with 8 participants in a primary care office (Nanos 2025). Typically, a retrospective case series would be seen as a preliminary finding, which would be followed by more rigorous studies.

Ethical guidelines recommend patients be provided with evidence-based education materials regarding the off-label status of a proposed treatment, the state of knowledge about the risks and benefits, and a clear statement that the proposed treatment has not been approved nor cleared for the condition(s) for which it is being offered (Oberman 2025).

While there is significant potential for clinical efficacy of single-day TMS protocols, and/or medication-assisted TMS protocols, to be established in the future, the current low level of evidence does not meet the threshold to recommend the clinical application of ONE-D over more evidence-based approaches. Therefore, if clinics are advertising or promoting their use of ONE-D, the off-label nature and low-level of evidence should be transparent in communications with patients.

References:

Nanos, G. (2025). Accelerated One-Day TMS Protocol in a Primary Care Setting: Real-World Efficacy and Safety for Major Depressive Disorder and Generalized Anxiety Disorder. *Transcranial Magnetic Stimulation*, 3.

Oberman, L. M., Leuchter, A., & Lisanby, S. H. (2025). Marketing and Promotion of Off-Label Uses of Repetitive Transcranial Magnetic Stimulation Treatment. *Transcranial Magnetic Stimulation*, 100197.

Vaughn, D. A., Marino, B., Engelbertson, A., Dojnov, A., Weiss, N., Vila-Rodriguez, F., ... & Downar, J. (2024). Real-world effectiveness of a single-day regimen for transcranial magnetic stimulation using Optimized, Neuroplastogen-Enhanced techniques in Depression (ONE-D).