The purpose of this document is to provide guidance to members drafting insurance appeal letters. Alterations to this document reflect the views and opinions of the author and do not necessarily reflect the views of the Clinical TMS Society, its affiliates, or its employees.

Physician Supervision of TMS treatment

Transcranial magnetic stimulation (TMS) is a non-invasive treatment cleared by the United States Food and Drug Administration (FDA) for adult patients with major depressive disorder. TMS is considered extremely safe, with the very rare side effect of seizure in fewer than 1 per 60,000 treatments[1] or fewer than 6 in 10,000 patients.[2] Like many medical treatments, TMS is prescribed and managed by a physician, but the treatments themselves are administered by non-physician technicians. The standard TMS course includes 36 sessions administered by a qualified TMS technician.[3]

A qualified TMS technician is one who has undergone device-specific training. The technician administers the treatment independently and is generally the only person in the room with the patient during treatments. The Clinical TMS Society highly recommends that in addition to the device manufacturers' training, TMS technicians undergo emergency first responder training. This includes, but is not limited to, cardiopulmonary (CPR) or basic life support (BSL) and Health Insurance Portability and Accountability act (HIPAA) compliance.[4] The attending physician must be available in case of an emergency, either in person or by phone. The prescribing physician is ultimately responsible for treatment plan management and must be accessible. When these requirements are met, qualified technicians and other clinical staff members may safely administer TMS sessions without direct, onsite physician supervision.

The ability to delegate TMS device operation is vital to clinical ability to provide effective and timely treatment for patients in need. Any insurance policy that requires direct, onsite physician supervision severely limits patient access to TMS, and creates an unnecessary drain on clinical resources. We therefore urge you to reconsider onsite physician supervision policies which can result in prolonged suffering and reduced treatment access for patients in need.

References

1. Tendler A, Harmelech T, Gersner R, Roth Y. Seizures provoked by H-coils from 2010 to 2020. Brain Stimul. Nov 2020;14(1):66-68. doi:10.1016/j.brs.2020.11.006

2. Lerner AJ, Wassermann EM, Tamir DI. Seizures from transcranial magnetic stimulation 2012-2016: Results of a survey of active laboratories and clinics. Clin Neurophysiol. 08 2019;130(8):1409-1416. doi:10.1016/j.clinph.2019.03.016

3. Office of Device Evaluation, U., 2011. *Repetitive Transcranial Magnetic Stimulation (Rtms) Systems - Class II Special Controls Guidance For Industry And FDA Staff*. [online] U.S. Food and Drug Administration. Available at: <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/repetitive-transcranial-magnetic-stimulation-rtms-systems-class-ii-special-controls-guidance> [Accessed 14 November 2020].

4. Perera T, George MS, Grammer G, Janicak PG, Pascual-Leone A, Wirecki TS. The Clinical TMS Society Consensus Review and Treatment Recommendations for TMS Therapy for Major Depressive Disorder. *Brain Stimul*. 2016 May-Jun 2016;9(3):336-346. doi:10.1016/j.brs.2016.03.010