CMS Local Coverage Determination (LCD) of Transcranial Magnetic Stimulation for Massachusetts, New York, Illinois and Rhode Island

L33398

Coverage Indications and Limitations

Transcranial magnetic stimulation (TMS) is a noninvasive method of brain stimulation. The technique involves placement of a small coil over the scalp and passing a rapidly alternating current through the coil wire which produces a magnetic field that passes unimpeded through the brain. The procedure is usually carried out in an outpatient setting and does not require anesthesia or analgesia. TMS can induce a focal current in the brain and temporary modulation of cerebral cortical function. Capacitor discharge provides electrical current in alternating on/off pulses. Depending on stimulation parameters, repetitive TMS to specific cortical regions can either decrease or increase the excitability of targeted structures. It is thought that this stimulates the part of the brain that involves mood control and can ease depression.

TMS has been investigated in the treatment of various disorders, primarily depression, that can be tried when other depression treatments have not worked. rTMS does not induce seizures or involve complete sedation with anesthesia, like what is involved with ECT. Studies have shown successful course of TMS to last 1-4 weeks. There is no empirical evidence for successful maintenance.

TMS treatment must be delivered by a device that is FDA-approved or cleared for the treatment of Major Depressive Disorder in a safe and effective manner. Treatment should generally follow the protocol and parameters specified in the manufacturer's user manual, with modifications only as supported by the published scientific evidence base. The order for treatment must be written by a physician who has examined the patient and reviewed the record. The physician must have experience in administering TMS therapy and the treatment must be given under the supervision of this physician.
.

All of the following must be met:	**All of the following must be met:**	**Any of the following must be met:**
1. Patient has a confirmed diagnosis of major depressive disorder, single or recurrent episode 2. The patient must exhibit resistance to treatment as evidenced by: a) At least 4 trials of psychopharmacologic agents in the	1. The patient continues to meet all admission criteria 2. The patient is demonstrating a response to treatments.	1. Patient no longer meets admission criteria and/or meets criteria for another LOC, either more or less intensive 2. Patient is unable or unwilling to participate

current depressive episode of treatment at or above the minimum effective dose b) At least 2 evidence-based augmentation therapies c) A trial of evidence-based psychotherapy known to be effective in the treatment of MDD of an adequate frequency and duration without significant improvement documented by standardized rating scales. 3. History of response to TMS in a previous depressive episode 4. History of response to electroconvulsive therapy (ECT) in a previous or current MDD episode or inability to tolerate ECT **Exclusions:** ***Any*** *of the following criteria are sufficient for exclusion from this level of care:* 1) Patient has a history of seizures (not ECT induced or isolated febrile seizure in infancy or childhood) or conditions that make the patient more prone to seizures, such as alcoholism 2) TMS is contraindicated due to medications that lower the seizure threshold 3) Presence of vague nerve stimulator leads in the carotid sheath 4) Presence of an implanted medical device located < 30 cm from the TMS magnetic coil including but not limited to	3. Treatment is not being completed for maintenance therapy	3. Patient or legal guardian has withdrawn consent for treatment 4. Active Treatment is no longer occurring 5. Patient's individual treatment plan and goals have been met.

pacemakers, implanted defibrillators, or vagus nerve stimulators. 5) Presence of psychotic symptoms in the current depressive episode 6) Acute or chronic psychotic disorder such as schizophrenia, schizophreniform disorder, or schizoaffective disorder 7) Neurologic conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system 8) Persons with conductive, ferromagnetic or other magnetic sensitive metals implanted in their head which are nonremovable and within 30 cm of the TMS magnetic coil. 9) Maintenance therapy		