Coverage Guidance for TMS for OCD

COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY

Introduction: Transcranial Magnetic Stimulation (TMS) is a non-invasive treatment that uses pulsed magnetic fields to induce an electric current in a localized region of the cerebral cortex. An electromagnetic coil placed on the scalp induces focal, patterned current in the brain that temporarily modulates cerebral cortical function. Capacitor discharge provides electrical current in alternating on/off pulses. Stimulation parameters may be adjusted to alter the excitability of the targeted structures in specific cortical regions. TMS parameters include cranial location, stimulation frequency, pattern, duration, intensity and the state of the brain under the coil.

History/Regulatory: In October 2008, conventional rTMS with a figure-8 coil was FDA cleared for the treatment of adults with major depressive disorder (MDD) who had one failed medication trial. TMS has since been established as a treatment with an excellent safety profile. rTMS with the H1 coil was cleared in January of 2013 for adults with MDD who failed any number of treatments. rTMS (dTMS) with the H7 coil was cleared in August of 2018 as an adjunctive treatment for adults with Obsessive Compulsive Disorder (OCD). In its approval, The FDA noted 38% of patients receiving dTMS had at least a 30% reduction in the Yale-Brown Obsessive-Compulsive Scale (YBOCS) score, compared with 11% of patients who received sham treatment.[1] Post marketing analysis of 219 patients from 22 community sites demonstrated a response rate of 57.9% after 29 sessions, with improving response rates and response magnitudes with longer treatment durations, 50% at 31 days and 78% after 60 days.[25] Clinical sub analysis and electrophysiological studies suggest that the mechanism of action of dTMS for OCD is different from medications and CBT, and non-response to either is not a predictor of response to TMS.[9,26,27] Additionally, patients with comorbid OCD and MDD generally only needed treatment with H7/OCD protocol to treat both conditions.[28] In August 2020, the Cool D-B80 coil was also FDA cleared for adjunct treatment of OCD.[24]

Obsessive Compulsive Disorder (OCD): Unlike major depressive disorder (MDD), which tends to be an episodic illness, OCD is a chronic lifelong disorder that typically begins in adolescence.[2,3] It is the fourth most common mental illness and can cause significant distress and disability. Patients exhibit obsessions, compulsions and avoidance symptoms, which are correlated to abnormal activity in the cortico-striato-thalamic-cortical circuit.[4] Severe refractory cases are referred for neurosurgery (lesional or with an implanted brain stimulator).[5-8] There is now a non-invasive approach using TMS to target the abnormal circuitry of OCD. In this approach, a coil is placed over the anterior cingulate cortex, which is 4 cm anterior to the foot motor cortex and beneath the dorsomedial prefrontal cortex.[1,9] TMS for OCD is performed 5 days per week for 6 weeks for a total of 29 sessions. Prior to each treatment, patients undergo individually tailored provocations to activate the abnormal OCD circuitry (for instance, asking a person with germ-related obsessions and compulsions to touch the floor and then not use hand sanitizer). There is no need for anesthesia or analgesia and there are no activity restrictions before or after treatment (e.g., driving, working, operating heavy machinery).
Other non-invasive treatments for OCD include cognitive behavioral therapy (CBT) and pharmacotherapy. CBT specific to OCD is known as exposure and response prevention (ERP), utilizing a trained cognitive behavioral therapist to guide the treatment.[10,11] Pharmacotherapy options include serotonin reuptake inhibitors (SRIs), such as fluoxetine, paroxetine, sertraline and fluvoxamine, and the predominantly serotonergic tricyclic antidepressant clomipramine.[12-17]

INDICATIONS FOR COVERAGE

TMS for OCD will be covered if it is prescribed by a licensed psychiatrist who is trained in the use of TMS, and if the patient meets the below criteria.

Initial Treatment: TMS for OCD is considered medically necessary for use in an adult who meets #1 and #2 of the following criteria:

1. Has a confirmed diagnosis of Obsessive-Compulsive Disorder (OCD) as per DSM-5 criteria

AND

2. One or more of the following:

Resistance to treatment as evidenced by persistent OCD symptoms after two indicated therapies (two medications or one medication plus psychotherapy) were tried each for a minimum of eight weeks; CBT psychotherapy, while a treatment option, is not required as a pre-requisite to TMS OCD treatment; or

Inability to tolerate psychopharmacologic agents as evidenced by trials with two distinct psychopharmacologic agents; or

History of response to TMS for OCD in the past was clinically meaningful; or

Resistance to treatment with CBT as evidenced by persistent OCD symptoms despite 8 weeks of ERP with a CBT therapist; or

If the patient is currently receiving antipsychotics, opioids, benzodiazepines, glutamatergic agents or other agents which could be considered investigational or relatively risky treatments, TMS may be considered reasonable and necessary and a safer alternative than additional treatment trials.[18-20]

The order for treatment (or retreatment) must be written by a psychiatrist (MD or DO) who has examined the patient, reviewed the record, and is prescribing an evidence-based OCD TMS protocol. This physician shall oversee the treatment, but does not have to personally administer the sessions or be in the area. The physician must be reachable and interruptible in case of problems.

COVERAGE LIMITATIONS

The benefits of TMS use must be carefully considered against the risk of potential side effects in patients with any of the following:

Seizure disorders or medical conditions may increase the risk of seizure. There is always an extremely small chance for TMS to cause a seizure during the TMS session in non-epileptics.[21-22]

The seizure risk with TMS is somewhat higher in patients with known seizure risk factors, however it remains a very low risk.[23] TMS may be indicated in patients with known seizure risk factors if the potential benefit outweighs the risk.

Repetitive TMS is contraindicated in the presence of an implanted magnetic-sensitive medical device located less than or equal to 10 cm from the TMS coil, such as a cochlear implant. MRI safe and MRI-conditional aneurysm clips or coils,

staples or stents are not a contraindication for TMS. Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with TMS. Similarly, cervical fusion and fixation devices, and hypoglossal and vagal nerve stimulators, are not contraindications for TMS treatment.

UTILIZATION GUIDELINES

The treatment must be provided by the use of a device cleared by the FDA for the purpose of TMS. It is expected that the services will be performed as indicated by current medical literature and standards of practice.

TMS for adolescents with OCD may be appropriate if there is a higher level of treatment resistance. These cases should be reviewed individually for medical necessity and considered a compassionate use.

TMS is reasonable and necessary for a minimum of 29 visits over a 6-week period. Extensions in 2 to 4-week increments will be cleared based on clinical need with evidence of response from the first 29 sessions.

If patients cannot come in five days a week, treatments may be administered three days a week over a longer period of time.

Retreatment may be considered for patients who met the guidelines for initial treatment and experienced at least a 30% reduction in the YBOCS score, as long as the improvement persisted for at least one month after the prior treatments ended.

There are currently two FDA cleared TMS devices for the treatment of OCD, however as other devices are approved, these criteria can be interpreted to apply to those devices as well.

CODING

CPT/HCPCS Codes Group 1 Paragraph:

Group 1 Codes: CODE	DESCRIPTION
90867 x 1	THERAPEUTIC REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (TMS) TREATMENT; INITIAL, INCLUDING CORTICAL MAPPING, MOTOR THRESHOLD DETERMINATION, DELIVERY AND MANAGEMENT
90868 (all other days)	THERAPEUTIC REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (TMS) TREATMENT; SUBSEQUENT DELIVERY AND MANAGEMENT, PER SESSION
90869 (once a week)	THERAPEUTIC REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (TMS) TREATMENT; SUBSEQUENT MOTOR THRESHOLD RE-DETERMINATION WITH DELIVERY AND MANAGEMENT

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