2021-2022 Magellan Healthcare Guidelines

Guideline: Transcranial Magnetic Stimulation Treatment – for non-Medicare Blue Cross and Blue Shield of Texas (under Health Care Service Corporation) plans that cover TMS
Effective Date: Feb. 21, 2022
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Background

Transcranial magnetic stimulation (TMS) may be considered for treatment of major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) for adults who, by accepted medical standards, can be expected to improve significantly through medically necessary and appropriate TMS treatment.

The treating psychiatrist must demonstrate that the patient's symptoms are treatment-resistant to both a course of medication management and a course of psychotherapy.

Standardized rating scales that reliably measure depressive or obsessive-compulsive disorder symptoms must be used to document severity of illness and response to treatment.

This guideline relates to both rTMS and dTMS devices that have been approved or cleared by the FDA for the treatment of the approved indications below.

I. Indications for Treatment

ALL of the following must be met:

A. The patient has a confirmed Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis of:

1) Major depressive disorder (MDD), severe (single or recurrent episode) documented by standardized rating scales that reliably measure depressive symptoms; *or*

2) Obsessive-compulsive disorder (OCD).

B. Is used only for adults 18 years or older who are not pregnant.

C. One or more of the following:

1) The patient has demonstrated medication treatment resistance during the current disorder episode as evidenced by lack of a clinically significant response to at least two (2) failed trials of psychopharmacologic agents including at least two (2) different agent classes.

2) The patient has a history of good response to TMS during an earlier episode of the treatment-resistant major depressive disorder (MDD) or OCD as evidenced by a greater than 50% improvement in a standard rating scale for depressive or OCD symptoms. The time between treatment episodes should allow for assessment clinically and by one of the rating scales to clearly document that the patient responded and then relapsed, is typically at least six (6) months since the last TMS session; *or*

D. An evidence-based psychotherapy of an adequate frequency and duration addressing the current disorder episode was attempted without significant improvement in depressive symptoms as documented by standardized rating scales that reliably measure depressive symptoms.

E. The use of TMS in patients with any of the following is considered <u>not</u> reasonable and necessary (ALL of the following are absent):

1) Seizure disorder or any history of seizures (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence or any condition or treatment that may lower the seizure threshold); or

2) Presence of acute or chronic psychotic symptoms or disorders, such as schizophrenia, schizophreniform disorder, or schizoaffective disorder, in the current disorder episode or within the last six (6) months (whichever is longer);

3) 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.

4) Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 cm from the TMS magnetic coil or other implanted metal items including, but not limited to a cochlear implant, implanted cardiac defibrillator (ICD), pacemaker, vagus nerve stimulator (VNS), or metal aneurysm clips or coils, staples or stents.

5) Concomitant esketamine intranasal, ketamine infusion or other infusion therapies for these disorders.

6) Used for maintenance therapy, continuous therapy, rescue therapy or extended active therapy as these are not supported by controlled clinical trials and are therefore considered not reasonable and necessary.

7) TMS is considered investigational as a treatment of all other psychiatric and neurologic disorders, including but not limited to any of the following: bipolar disorder; migraine headaches, and schizophrenia.

8) Excessive use of alcohol or illicit substances within the last thirty (30) days.

II. Retreatment

Repeat treatment (retreatment) may be considered for patients who meet ALL of the following:

A. Patient met guidelines for initial treatment and subsequently developed relapse of symptoms;

B. Patient responded to prior TMS treatments as evidenced by a greater than fifty percent (50%) improvement in standard rating scale measurements for symptoms;

C. Retreatment is not requested as maintenance therapy or continuous therapy. The time between treatment episodes should allow for assessment clinically and by one of the aforementioned rating scales to clearly document that the patient responded and then relapsed, typically six (6) months since the last TMS session.

III. Treatment Guidelines

A. TMS is reasonable and necessary for treatment of MDD for up to thirty (30) visits over a seven (7) week period, followed by six (6) tapered treatments for MDD. Deep TMS (dTMS) is reasonable and necessary for treatment of OCD for up to twenty-nine (29) sessions. The number of treatments is evaluated against patient response and the published evidence-based literature. .

B. The order for treatment (or retreatment) is written by a psychiatrist who has examined the patient and reviewed the record. The psychiatrist will have experience in administering TMS therapy. The treatment shall be given under the direct supervision of this psychiatrist, i.e., the physician must be present in the area, but does not necessarily personally provide the treatment

C. Physician and non-physician treating personnel must meet all provider qualifications, trainings, expectations and documentation requirements.

D. Treatment must be provided using a rTMS or dTMS device approved or cleared by the FDA for the treatment of the approved indications in this guideline.

E. Standardized rating scales that reliably measure depressive symptoms must be used to document severity of illness and response to treatment. These rating scales include:

1) The Personal Health Questionnaire Depression Scale (PHQ-9)
2) The Beck Depression Inventory (BDI)
3) The Montgomery-Asberg Depression Rating Scale (MADRS)
4) Geriatric Depression Scale (GDS)
5) The Quick Inventory of Depressive Symptomatology (QIDS)
6) The Hamilton Rating Scale for Depression (HAM-D)
7) The Inventory for Depressive Symptomatology Systems Review (IDS-SR).

F. Standardized rating scales that reliably measure obsessive-compulsive symptoms must be used to document severity of illness and response to treatment. These rating scales include:

   1) Yale-Brown Obsessive-Compulsive Scale (Y-BOCS)

IV. Provider Qualifications and Other Requirements

A. There is documentation of a clinical evaluation performed by a physician who is appropriately trained to provide TMS, to include:

   1) A psychiatric history, including past response to antidepressant medication(s) and/or TMS and/or ECT, mental status and current functioning; *and*

   2) A medical history and examination when clinically indicated.

B. The order for treatment or retreatment is written by a physician (MD or DO) who has examined the patient and reviewed the medical record. The treatment shall be given under direct supervision of this physician, i.e., he or she must be in the area and immediately available. The physician will assess the patient at each treatment, and be present in the area, but not necessarily provide the treatment. The attending physician must monitor and document the patient's clinical progress during treatment. The attending physician must use evidence-based, validated depression monitoring to monitor treatment response and the achievement of remission of symptoms.

C. Provider education and training:

   1) Physicians: The physician utilizing this technique must have completed a psychiatric residency program accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or the Royal College of Physicians and Surgeons of Canada (RCPSC); Board certification in psychiatry by the American Board of Psychiatry and Neurology is preferred. The physician must have completed a university-based course in TMS, or the course approved by the device manufacturer. The training must be specific to the device in use at the authorization request.

D. An attendant/individual trained in basic life support, the management of complications such as seizures, in addition to training in the application of the TMS apparatus, must be present at all times with the patient while the treatment is applied.

E. The attending physician provides personal supervision for the initial motor threshold determinations, treatment parameter definition and TMS treatment course planning and documentation supportive of the level of supervision. The patient has either the attending physician or the attendant physically present at all times during the TMS session.

F. During subsequent delivery and management of TMS sessions, the attending physician must meet face to face with the patient when there is a change in the patient's mental status and/ or other significant change in clinical status.

G. Access to emergency equipment, including cardiac defibrillator suction, is readily available while the patient is receiving TMS.

H. The treatment must be provided by use of a device approved or cleared by the FDA for the purpose of supplying transcranial magnetic stimulation for this indication.

I. When clinically indicated, the patient is released in the care of a responsible adult who can monitor and provide supportive care as needed.

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APPENDIX: Symptom Monitoring Scales

Standardized Rating Scale Name	Note	Acronym	Scale Range	None OR Normal	Mild	Moderate	Moderate Severe	Severe	Very Severe
Geriatric Depression Scale	Long Version 30 Questions	**GDS**	0 -30	0-9	10-19	NA	NA	20-30	NA
The Personal Health Questionnaire Depression Scale	NA	**PHQ-9**	0 - 27	0-4	5-9	10-14	15-19	20-27	NA
The Beck Depression Inventory	Original Version	**BDI**	0-63	0-9 (minimal)	10-18	19-29	NA	30-63	NA
The Hamilton Rating Scale for Depression	17 Questions	**HAM-D**	0 - 52	0-7	8-16	17-23	NA	≥24	NA
The Hamilton Rating Scale for Depression	24 Questions	**HAM-D**	0-15	0-4	5-8	8-11	NA	12-15	≥23
The Inventory for Depressive Symptomatology	Self Reported Version 30 Questions	**IDS-SR**	0-84	0-13	4-25	26-38	NA	39-48	49-84
The Montgomery-Asberg Depression Rating Scale	NA	**MADRS**	0-60	0-6	7-19	20-34	NA	NA	35-60
The Quick Inventory of Depressive Symptomatology	Clinician Administered Version- 16 Questions	**QIDS-16**	0-27	0-5	6-10	11-15	NA	16-20	21-27
Yale-Brown Obsessive Compulsive Scale	**Clinician Administered 10 items**	**Y-BOCS**	**0-40**	**0-7**	**8-15**	**16-23**	**--**	**24-31**	**32-40**