

## 2020-2021 Magellan Healthcare Guidelines

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**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:** July 1, 2020

**Last Review Date:** May 28, 2020

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### Background

Transcranial magnetic stimulation (TMS) may be considered for treatment of major depressive disorder 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. Resistance to treatment is defined in this guideline as a failure to achieve a fifty percent (50%) reduction in depressive symptoms after adequate trials of antidepressant therapy and evidence-based psychotherapy.

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

### I. Indications for Treatment

ALL of the following must be met:

- A. The patient has a confirmed DSM-5 diagnosis of major depressive disorder, severe (single or recurrent episode) documented by standardized rating scales that reliably measure depressive symptoms.
- 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 depressive 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;<sup>1</sup> *or*

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<sup>1</sup>Resistance to treatment is defined by a failure to achieve a 50% reduction in symptoms, in accordance with objective measures... from a pharmacologic trial where the medication is administered at both an adequate dose and for an adequate period of time consistent with accepted standard of care. A dose will be considered adequate when the medication is administered consistent with the FDA label. Where starting dosage is lower than maximum recommended dosage, the dose of any medication will be considered adequate when an initial response failure is followed by titrating the dosage upwards towards the maximum recommended dosage. Where such titration does not occur, the record must document the rationale for the decision not to increase the dose. Duration of therapy will be considered adequate, when a particular medication is administered for a length of time consistent with expectations for

- 2) The patient has demonstrated an inability to tolerate psychopharmacologic agents as evidenced by two (2) trials of psychopharmacologic agents from at least two (2) different agent classes, with distinct side effects;<sup>2</sup> *or*
  - 3) The patient has a history of good response to TMS during an earlier episode of the treatment-resistant major depressive disorder as evidenced by a greater than 50% improvement in a standard rating scale for depressive 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 three (3) months since the last TMS session; *or*
  - 4) Is a candidate for electroconvulsive therapy (ECT); however, there is a clinical contraindication for ECT or the patient refuses ECT.
- D. An evidence-based psychotherapy of an adequate frequency and duration addressing the current depressive 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 not 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 depressive episode;
  - 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.

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expected response times for that medication or class of medications as defined in the medical literature supporting the efficacy of that medication or medication class and by the standard of care. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Repetitive Transcranial Magnetic Stimulation (rTMS) for Adults with Treatment Resistant Major Depressive Disorder (L34998))

<sup>2</sup> Psychopharmacologic agent side effects will be considered intolerable, when those side effects are of a nature where they are not expected to diminish or resolve with continued administration of the drug. (Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Repetitive Transcranial Magnetic Stimulation (rTMS) for Adults with Treatment Resistant Major Depressive Disorder (L34998))

- 5) Concomitant esketamine intranasal, ketamine infusion or other infusion therapies for major depressive disorder.
- 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, obsessive-compulsive disorder; schizophrenia.

## **II. Treatment Guidelines**

- A. TMS is reasonable and necessary for up to thirty (30) visits over a seven (7) week period, followed by six (6) tapered treatments. The number of treatments is evaluated against patient response and the published evidence-based literature. If medically necessary and appropriate for a member, additional sessions will be authorized.
- 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 by use of a device approved or cleared by the FDA for the purpose of supplying TMS for these indications.
- 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:<sup>3</sup>
  - 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).

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<sup>3</sup> See "Appendix: Depression Monitoring Scales"

### **III. 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 depressive symptoms;
- B. Patient responded to prior TMS treatments as evidenced by a greater than fifty percent (50%) improvement in standard rating scale measurements for depressive 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 three (3) months since the last TMS session.
- D. If the patient meets the relapse criteria, up to thirty (30) visits for treatment followed by an additional six (6) visits for tapering is considered reasonable and necessary. The number of treatments is evaluated against patient response and the published evidence-based literature. If medically necessary and appropriate for a member, additional sessions will be authorized.

#### 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. 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.
- 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 and 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: Depression 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<br>30 Questions                    | <b>GDS</b>     | 0 -30       | 0-9              | 10-19 | NA       | NA              | 20-30  | NA          |
| The Personal Health Questionnaire Depression Scale | NA  | <b>PHQ-9</b>   | 0 - 27      | 0-4              | 5-9   | 10-14    | 15-19           | 20-27  | NA          |
| The Beck Depression Inventory                      | Original Version                                | <b>BDI</b>     | 0-63        | 0-9<br>(minimal) | 10-18 | 19-29    | NA              | 30-63  | NA          |
| The Hamilton Rating Scale for Depression           | 17 Questions                                    | <b>HAM-D</b>   | 0 - 52      | 0-7              | 8-16  | 17-23    | NA              | ≥24    | NA          |
| The Hamilton Rating Scale for Depression           | 24 Questions                                    | <b>HAM-D</b>   | 0-15        | 0-4              | 5-8   | 8-11     | NA              | 12-15  | ≥23         |
| The Inventory for Depressive Symptomatology        | Self Reported Version<br>30 Questions           | <b>IDS-SR</b>  | 0-84        | 0-13             | 4-25  | 26-38    | NA              | 39-48  | 49-84       |
| The Montgomery-Asberg Depression Rating Scale      | NA  | <b>MADRS</b>   | 0-60        | 0-6              | 7-19  | 20-34    | NA              | NA     | 35-60       |
| The Quick Inventory of Depressive Symptomatology   | Clinician Administered Version-<br>16 Questions | <b>QIDS-16</b> | 0-27        | 0-5              | 6-10  | 11-15    | NA              | 16-20  | 21-27       |