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# *LEVEL OF CARE GUIDELINES*

***Effective Date:*** January, 2015

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## Transcranial Magnetic Stimulation

**Transcranial Magnetic Stimulation (TMS) is a non-invasive technique used to apply brief magnetic pulses to the brain by an FDA approved device in the treatment of Major Depressive Disorder for members 22 years and older. The pulses are administered by passing high currents through an electromagnetic coil placed adjacent to the patient's scalp. The pulses induce an electrical field in the brain tissue activating neurons in the targeted brain structure. By stimulating areas of the brain, the goal is to lessen the duration or severity of depressive episodes.**

**The course of TMS is focused on addressing the "why now" factors that precipitated admission (e.g., changes in the member's signs and symptoms, psychosocial and environmental factors, or level of functioning) to the point that the "why now" factors that precipitated admission no longer require treatment.**

### 1. Admission Criteria

1.1. (See Common Criteria for All Levels of Care)

AND

1.1.1. The member is age > 22 with diagnosed Major Depressive Disorder (MDD)

AND

1.1.2. The member's condition has not responded to at least (4) prior antidepressant medication trials at or above the minimal effective dose and duration in the **current episode** following algorithm driven treatment as defined by either Sequenced Treatment Alternatives to Relieve Depression (STAR*D) or the Texas Medication Algorithms Project (TMAP)

OR

1.1.3. The member has a documented inability to tolerate psychopharmacologic agents as evidenced by trials of four such agents, from at least two different agent classes, with distinct side effects

OR

1.1.4. The member has a documented history of response to TMS in a previous depressive episode, as evidenced by a greater than 50% improvement on a standardized rating scale for depression symptoms, such as the BDI, HAM-D, MADRS, PHQ-9, etc.

AND

1.1.5. The member's current baseline depression measurement score has been documented according to one of the following validated rating scales:

1.1.5.1. Beck Depression Scale (BDI),

1.1.5.2. Hamilton Depression Rating Scale (HDRS),

1.1.5.3. Montgomery-Asberg Depression Rating Scale (MADRS) or

1.1.5.4. Patient Health Questionnaire (PHQ-9)

AND

1.1.1. A trial of evidence-based psychotherapy known to be effective in the treatment of MDD of an adequate frequency and duration has been attempted without significant improvement in depressive symptoms as documented by standardized rating scales that reliably measure depressive symptoms.

AND

1.1.2. TMS treatment is provided using a device that is approved by the FDA for the treatment of Major Depressive Disorder.

AND

1.1.3. The order for TMS treatment 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 direct supervision of this psychiatrist (present in the area and immediately available, but not necessarily personally providing the treatment).

## 2. Continued Treatment Criteria

2.1. (See Common Criteria for All Levels of Care)

AND

2.2. After the initial treatment sessions have been completed, a concurrent review will be conducted to review the member's response to treatment.

2.2.1. Adequate treatment response after 10-15 sessions is typically considered at least 50% improvement from the member's baseline depression score (Avery, 2008).

AND

2.3. Providers should document weekly measurement scores of the member's depressive symptoms as evidence of the member's response at the beginning of each treatment week, with no more than 5 business days between measurement periods.

AND

2.4. If there has been a less than 50% improvement of symptoms after the initial 10-15 sessions have been completed, the following may be indicated:

2.4.1. A reevaluation of the member's treatment plan and whether changes to the member's course of treatment or level of care are required.

2.4.2. A reassessment of the member's motor threshold;

2.4.2.1. If the motor threshold is modified, 5 additional sessions may be authorized to determine response with a concurrent review at the end of the 5 sessions.

AND

2.5. If there has been at least 50% improvement, up to 15 remaining sessions may be authorized for Neurostar and up to 5 additional sessions for Brainsway, with weekly measurement of the member's symptoms and updates to the treatment plan as appropriate.

2.5.1. The initial course of treatment for NeuroStar includes:

2.5.1.1. Administration of a total of 3,000 individual magnetic pulses delivered over a 37 minute period.

2.5.1.2. 5 treatment sessions per week for 4 to 6 weeks, depending upon the patient's treatment response.

2.5.2. The initial course of treatment for Brainsway includes:

2.5.2.1. Administration of a total of 1,980 individual magnetic pulses delivered over a 20 minute period.

2.5.2.2. 5 treatment sessions per week for 4 weeks.

**3. Discharge Criteria**

3.1. After completion of the initial TMS course, it should be determined if remission has been achieved. Remission is typically defined by the following measurement scores (O'Reardon, 2007; McDonald, 2011):

3.1.1. Beck Depression Scale (BDI) score of <9

3.1.2. Hamilton Depression Rating Scale (HAM-D) score of <8 on the HAM-D-17 and <11 on the HAM-D-24

3.1.3. Montgomery-Asberg Depression Rating Scale (MADRS) score of < 10

3.1.4. Patient Health Questionnaire (PHQ-9) score of < 5

3.2. If remission has been achieved, the provider should initiate up to 6 taper sessions on a twice weekly basis.

**4. TMS is considered unproven and not medically necessary in the following circumstances:**

4.1. Patients that do not meet the proven coverage criteria

4.2. TMS treatment of behavioral disorders other than Major Depressive Disorder

4.3. Patients with Major Depressive Disorder who were able to tolerate, but failed to receive clinical benefit from previous electroconvulsive therapy (ECT); ECT remains the treatment of best established efficacy against which other stimulation treatments should be compared (APA, 2010)

4.4. Maintenance therapy (i.e., additional, less frequent TMS after completing course of treatment to maintain clinical response)

**5. TMS is contraindicated in the following populations (contraindicated use of TMS could result in serious injury or death):**

5.1. Patients who have conductive, ferromagnetic, or other magnetic-sensitive metals implanted in their head within 30 cm of the treatment coil. Examples include metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices, and stents.

5.2. Patients who have active or inactive implants (including device leads), including deep brain stimulators, cochlear implants, and vagus nerve stimulators.

5.3. Patients with psychoses or with psychiatric emergencies where a rapid clinical response is needed, such as marked physical deterioration, catatonia, or immediate suicide risk.

**6. The safety and effectiveness of TMS therapy has not been established in the following patient populations or clinical conditions through a controlled clinical trial. The use of TMS in these patients is therefore unproven:**

6.1. Patients who have a suicide plan or who have recently attempted suicide

6.2. Patients younger than 22 years of age or older than 70 years of age; the FDA defines persons aged 21 years or younger at the time of their diagnosis or treatment to be pediatric patients (U.S. Food and Drug Administration, 2016)

6.3. Patients with a lifetime history of obsessive compulsive disorder, bipolar disorder, or psychotic disorder including schizoaffective disorder and major depression with psychotic features

6.4. Patients with a history of substance abuse, eating disorder or post-traumatic stress disorder, if present in the past year

6.5. Patients with a history of or risk factors for seizures

6.6. Patients with other neurological conditions, such as cerebrovascular disease, dementia, movement disorders, increased intracranial pressure, a history of repetitive or severe head trauma, or primary/secondary tumors in the central nervous system

6.7. Patients with vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers, and implantable cardioverter defibrillators

6.8. Patients who are pregnant or nursing

## 2. Clinical Best Practices

2.1. Evaluation & Treatment Planning

2.1.1. (See Common Clinical Best Practices for All Levels of Care)

2.1.2. An evaluation is conducted to identify the events which triggered the request for service at this particular point (i.e., the “Why Now”) (Optum Level of Care Guidelines, 2014). All of the following should be evaluated as part of the standard evaluation of Major Depressive Disorder (American Psychiatric Association, Clinical Practice Guideline, Major Depressive Disorder, 2010):

2.1.2.1. The events leading up to the current episode of care

2.1.2.2. Baseline measurement of depressive symptoms with the use of one of the following validated rating scales (O'Reardon, 2007):

2.1.2.2.1. Beck Depression Scale (BDI),

2.1.2.2.2. Hamilton Depression Rating Scale (HDRS),

2.1.2.2.3. Montgomery-Asberg Depression Rating Scale (MADRS) or

2.1.2.2.4. Patient Health Questionnaire (PHQ-9)

2.1.2.3. Current level of functioning

2.1.2.4. The identification of any co-occurring conditions

2.1.2.5. Current and historic substance use

2.1.2.6. History of medication treatment trials and response

2.1.2.7. The history of interventions including psychosocial interventions, use of community resources, and response to previous interventions

2.1.2.8. Side effects experienced from prescribed and over-the-counter medications

2.1.2.9. Results of laboratory tests when indicated

2.1.2.10. The history of the onset and progression of symptoms

2.1.2.11. The member's ability to make informed treatment decisions

2.1.2.12. The ability of the member's family/caregiver to participate in the member's treatment

2.1.2.13. The optimal treatment setting and the member's ability to benefit from a different level of care

2.1.3. Suicide risk should be evaluated. Assessment of suicide risk should include the following (American Psychiatric Association, Clinical Practice Guideline, Suicidal Behaviors, 2003):

2.1.3.1. The member's most current diagnoses

2.1.3.2. Current suicidal ideation, plan and means

2.1.3.3. The history of suicidal behavior

2.1.3.4. The nature of the current crisis or other unique issues that may have precipitated suicidal behavior

2.1.3.5. Relevant familial factors such as the history of attempts, completion of suicide, and mental illness

2.1.3.6. If there is active suicidality, additional review may be warranted to evaluate whether TMS is the most appropriate treatment, or whether a more intensive treatment is indicated.

2.1.3.7. In addition to the elements of a standard evaluation, members being considered for TMS should also be evaluated for the specific indications, and safety and effectiveness considerations.

## 3. Treatment

3.1. Prior to initiating treatment, the member's motor threshold (MT) is determined in order to provide an estimate of the magnetic field intensity, and to provide a head surface landmark to permit navigation to the treatment location.

3.2. (MT) should be reestablished each week to ensure the most accurate treatment location.

3.3. At the start of each treatment week a severity of depression measurement with one of the below validated rating scales should be repeated with at least 5 business days between each measurement period.

3.3.1. Beck Depression Scale (BDI)

3.3.2. Hamilton Depression Rating Scale (HDRS-17 or 21)

3.3.3. Montgomery-Asberg Depression Rating Scale (MADRS)

3.3.4. Patient Health Questionnaire (PHQ-9)

3.4. At the completion of the standard TMS course, a remission measurement should be administered. Remission is indicated by the following scores (O'Reardon, 2007; McDonald, 2011):

3.4.1. Beck Depression Scale (BDI) score of <9

3.4.2. Hamilton Depression Rating Scale (HAM-D) score of <8 on the HAM-D-17 and <11 on the HAM-D-24

3.4.3. Montgomery-Asberg Depression Rating Scale (MADRS) score of < 10

3.4.4. Patient Health Questionnaire (PHQ-9) score of < 5

3.5. If remission has been achieved, up to 6 taper sessions, twice weekly should be initiated.

3.6. Current evidence does not recommend any maintenance or booster/repeat TMS treatment outside of the standard treatment parameters once a full course of TMS has been completed (TMS Technology Assessment, 2015).

## References


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## History

| Revision Date | Name | Revision Notes |
|---|---|---|
| 1/2015 | L. Urban | Version 1 |
| 1/2016 | L. Urban | Version 2 |

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| 10/2016 | L. Urban | Version 2-Revised |