Transcranial Magnetic Stimulation (TMS)

Guideline Number: BHCDG852016

Effective Date: October, 2014

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Product:

2001 Generic UnitedHealthcare COC/SPD

2007 Generic UnitedHealthcare COC/SPD

2009 Generic UnitedHealthcare COC/SPD

2011 Generic UnitedHealthcare COC/SPD

Related Coverage Determination Guidelines:

Treatment of Depressive Disorders

Related Medical Policies:

INSTRUCTIONS FOR USE

This Coverage Determination Guideline provides assistance in interpreting behavioral health benefit plans that are managed by Optum. This Coverage Determination Guideline is also applicable to behavioral health benefit plans managed by Pacificare Behavioral Health and U.S. Behavioral Health Plan, California (doing business as Optum California ("Optum-CA").

When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificates of Coverage (COCs), Schedules of Benefits (SOBs), or Summary Plan Descriptions (SPDs) may differ greatly from the standard benefit plans upon which this guideline is based.

In the event that the requested service or procedure is limited or excluded from the benefit, is defined differently, or there is otherwise a conflict between this document and the COC/SPD, the enrollee's specific benefit document supersedes these guidelines.

All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements that supersede the COC/SPD and the plan benefit coverage prior to use of this guideline. Other coverage determination guidelines and clinical guideline may apply.

Optum reserves the right, in its sole discretion, to modify its coverage determination guidelines and clinical guidelines as necessary.

While this Coverage Determination Guideline does reflect Optum's understanding of current best practices in care, it does not constitute medical advice.

Key Points

- 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.
- Services should be consistent with evidence-based practice as described in Part III, and should be of sufficient intensity to address the member's needs (UnitedHealthcare, Certificate of Coverage, 2007, 2009 & 2011).
- TMS is not considered a first-line intervention for the treatment of Major Depressive Disorder. First-line interventions should be consistent with evidenced-based practices as outlined in the Coverage Determination Guideline for the Treatment of Depressive Disorders.

PART I: BENEFITS

Before using this guideline, please check enrollee's specific plan document and any federal or state mandates, if applicable.

Benefits

Benefits include the following services:

- Diagnostic evaluation and assessment
- Treatment planning
- Referral services
- Medication management
- Member, family, therapeutic group and provider-based case management services
- Crisis intervention

Covered Services

Covered Health Service(s) – 2001

Those health services provided for the purpose of preventing, diagnosing or treating a sickness, injury, mental illness, substance abuse, or their symptoms.

A Covered Health Service is a health care service or supply described in Section 1: What's Covered--Benefits as a Covered Health Service, which is not excluded under Section 2: What's Not Covered--Exclusions.

Covered Health Service(s) – 2007, 2009 and 2011

Those health services, including services, supplies, or Pharmaceutical Products, which we determine to be all of the following:

- Provided for the purpose of preventing, diagnosing or treating a sickness, injury, mental illness, substance abuse, or their symptoms.
- Consistent with nationally recognized scientific evidence as available, and prevailing medical standards and clinical guidelines as described below.
- Not provided for the convenience of the Covered Person, Physician, facility or any other person.
- Described in this Certificate of Coverage under Section 1: Covered Health Services and in the Schedule of Benefits.
- Not otherwise excluded in this Certificate of Coverage under Section 2: Exclusions and Limitations.

In applying the above definition, "scientific evidence" and "prevailing medical standards" shall have the following meanings:

- "Scientific evidence" means the results of controlled clinical trials or other studies published in peer-reviewed, medical literature generally recognized by the relevant medical specialty community.
- "Prevailing medical standards and clinical guidelines" means nationally recognized professional standards of care including, but not limited to, national consensus statements, nationally recognized clinical guidelines, and national specialty society guidelines.

Limitations and Exclusions

The requested service or procedure for the treatment of a mental health condition must be reviewed against the language in the enrollee's benefit document. When the requested service or procedure is limited or excluded from the enrollee's benefit document, or is otherwise defined differently, it is the terms of the enrollee's benefit document that prevails.

Inconsistent or Inappropriate Services or Supplies – 2001, 2007, 2009 & 2011

Services or supplies for the diagnosis or treatment of Mental Illness that, in the reasonable judgment of the Mental Health/Substance Use Disorder Designee, are any of the following:

- Not consistent with nationally recognized scientific evidence as available, and prevailing medical standards and clinical guidelines as described below.
- Not consistent with generally accepted standards of medical practice for the treatment of such conditions.

- Not consistent with services backed by credible research soundly demonstrating that the services or supplies will have a measurable and beneficial health outcome, and are therefore considered Unproven.
- Not consistent with the level of care guidelines or best practice guidelines as modified from time to time.
- Not clinically appropriate for the member's Mental Illness or condition based on generally accepted standards of medical practice and benchmarks.

Additional Information

This Coverage Determination Guideline is applicable to benefit plans that provide coverage for TMS. TMS is not considered a first-line intervention for the treatment of Major Depressive Disorder. First-line interventions should be consistent with evidenced-based practices as outlined in the Coverage Determination Guideline for the Treatment of Depressive Disorders.

The lack of a specific exclusion for a service does not imply that the service is covered.

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

1. Patients that do not meet the proven coverage criteria
2. TMS treatment of behavioral disorders other than Major Depressive Disorder
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. Maintenance therapy (i.e., additional, less frequent TMS after completing course of treatment to maintain clinical response)

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

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

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.

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:

1. Patients who have a suicide plan or who have recently attempted suicide
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)
3. Patients with a lifetime history of obsessive compulsive disorder, bipolar disorder, or psychotic disorder including schizoaffective disorder and major depression with psychotic features
4. Patients with a history of substance abuse, eating disorder or post-traumatic stress disorder, if present in the past year
5. Patients with a history of or risk factors for seizures
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
7. Patients with vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers, and implantable cardioverter defibrillators
8. Patients who are pregnant or nursing

PART II: COVERAGE CRITERIA

1. Criteria for Initial TMS Treatment

1.1. TMS may be indicated when one of the following three criteria is met:

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

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

1.2.1. Beck Depression Scale (BDI),

1.2.2. Hamilton Depression Rating Scale (HDRS),

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

1.2.4. Patient Health Questionnaire (PHQ-9)

AND

1.3. 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

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

AND

1.5. 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. Criteria for Continued Treatment

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

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

2.2. Providers 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.

2.3. 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:

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

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

2.3.2.1. 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.

2.3.3. If there has been at least 50% improvement, up to 15 remaining sessions may be authorized.

2.3.3.1. The initial course of treatment for Neurostar includes:

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

2.3.3.1.2. 5 treatment sessions per week for 4 to 6 weeks, depending upon the patient's treatment response.

2.3.3.2. The initial course of treatment for Brainsway includes:

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

2.3.3.2.2. 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.

PART III: CLINICAL BEST PRACTICE

1. Evaluation

1.1. 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, 2016). 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):

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

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

1.1.2.1. Beck Depression Scale (BDI),

1.1.2.2. Hamilton Depression Rating Scale (HDRS),

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

1.1.2.4. Patient Health Questionnaire (PHQ-9)

1.1.3. Current level of functioning

1.1.4. The identification of any co-occurring conditions

1.1.5. Current and historic substance use

1.1.6. History of medication treatment trials and response

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

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

1.1.9. Results of laboratory tests when indicated

1.1.10. The history of the onset and progression of symptoms

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

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

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

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

1.2.1. The member's most current diagnoses

1.2.2. Current suicidal ideation, plan and means

1.2.3. The history of suicidal behavior

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

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

1.2.6. 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.

1.2.7. 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 outlined in Part II.

2. **Treatment**

2.1. 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.

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

2.3. At the start of each treatment week a severity of depression measurement with one of the below validated rating scales should be repeated with no more than 5 business days between each measurement period.

2.3.1. Beck Depression Scale (BDI)

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

2.3.3. Montgomery-Asberg Depression Rating Scale (MADRS)

2.3.4. Patient Health Questionnaire (PHQ-9)

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

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

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

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

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

2.5. If remission has been achieved taper sessions should be initiated as indicated by the member's treatment plan (O'Reardon, 2007).

2.6. If the member has not adequately responded to treatment, further review and reassessment are required.

2.7. 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.

PART IV: ADDITIONAL RESOURCES

Clinical Protocols

Optum maintains clinical protocols that include the Level of Care Guidelines and Best Practice Guidelines which describe the scientific evidence, prevailing medical standards and clinical guidelines supporting our determinations regarding treatment. These clinical protocols are available to Covered Persons upon request, and to Physicians and other behavioral health care professionals on ubhonline.

Peer Review

Optum will offer a peer review to the provider when services do not appear to conform to this guideline. The purpose of a peer review is to allow the provider the opportunity to share additional or new information about the case to assist the Peer Reviewer in making a determination including, when necessary, to clarify a diagnosis.

Second Opinion Evaluations

Optum facilitates obtaining a second opinion evaluation when requested by a member, provider, of when Optum otherwise determines that a second opinion is necessary to make a determination, clarify a diagnosis or improve treatment planning and care for the member.

Referral Assistance

Optum provides assistance with accessing care when the provider and/or member determine that there is not an appropriate match with the member's clinical needs and goals, or if additional providers should be involved in delivering treatment.

PART V: DEFINTIONS

Booster/Repeat Treatment Any reintroduction of TMS in the current depressive episode for any change in clinical presentation after a full course of TMS per the standard treatment parameters has been completed.

Diagnostic and Statistical Manual of the American Psychiatric Association (DSM) A manual produced by the American Psychiatric Association which provides the diagnostic criteria for mental health and substance use disorders, and other problems that may be the focus of clinical attention. Unless otherwise noted, the current edition of the DSM applies.

Maintenance Treatment Any additional, less frequent TMS sessions after a full course of TMS treatment per the standard treatment parameters has been completed to maintain clinical response.

Major Depressive Disorder According to the DSM, Major Depressive Disorder is a form of Mood Disorder whose essential feature is the presence of a Major Depressive episode of at least two weeks duration during which there is either depressed mood or the loss of interest or pleasure in nearly all activities.

Motor Threshold The MT is the minimum intensity required to evoke a response in the target area. The TMS intensity usually will need periodic adjustment according to the subject's MT

Outpatient Visits provided in an ambulatory setting.

Prevailing Medical Standards and Clinical Guidelines Nationally recognized professional standards of care including, but not limited to, national consensus statements, nationally recognized clinical guidelines, and national specialty society guidelines.

Unproven Services are services including medications that are not consistent with prevailing medical research that has determined the services to not be effective for treatment of the condition and/or not to have the beneficial effect on behavioral health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed literature (COC, 2001, 2007, 2009, 2011).

PART VI: REFERENCES

1. American Psychiatric Association, Practice Guideline for the Treatment of Patients with Major Depressive Disorder, 2010. Retrieved from http://www.psychiatryonline.com/pracGuide/pracGuidehome.aspx
2. American Psychiatric Association, Practice Guideline for the Treatment of Patients with Suicidal Behaviors, 2003. Retrieved from http://www.psychiatryonline.com/pracGuide/pracGuidehome.aspx
3. Avery, D.H., Isenberg, K.E., Sampson, S.M., Janicak, P.G., Lisanby, S.H., Maixner, D.F., George, M.S. (2008). Transcranial magnetic stimulation in the acute treatment of major depressive disorder: Clinical response in an open-label extension trial. Journal of Clinical Psychiatry, 69(3), 441-451.

4. Centers for Medicare and Medicaid Services, Local Coverage Determinations for Transcranial Magnetic Stimulation (2016). Retrieved from www.cms.gov.
5. George, M.S., Lisanby, S.H., Avery, D., McDonald, W.M., Durkalski, V., Pavlicova, M., Sackeim, H.A. (2010). Daily left prefrontal transcranial magnetic stimulation therapy for major depressive disorder. Archives of General Psychiatry, 67(5), 507-516.
6. McDonald, W.M., Durkalski, V., Ball, E.R., Holtzheimer, P.E., Pavlicova, M., Lisanby, S.H., George, M.S. (2011). Improving the antidepressant efficacy of transcranial magnetic stimulation: Maximizing the number of stimulations and treatment location in treatment-resistant depression. Depression and Anxiety, 28(11), 973-980.
7. National Institute of Mental Health (2010). Sequenced Treatment Alternatives to Relieve Depression. Retrieved from http://www.nimh.nih.gov/trials/practical/stard/stard-treatment-flowchart.pdf
8. Optum Level of Care Guidelines, 2016. Retrieved from https://providerexpress.com/html/clinResources.html
9. Optum Technology Assessment (2015). Transcranial Magnetic Stimulation (TMS) Therapy for Major Depression.
10. O'Reardon, J.P., Solvason, H.B., Janicak, P.G., Sampson, S., Isenberg, K.E., Nahas, Z., Sacheim, H.A. (2007). Efficacy and safety of transcranial magnetic stimulation in the acute treatment of major depression: A multisite randomized controlled trial. Biological Psychiatry, 62, 1208-1216.
11. Sequenced Treatment Alternatives for the Treatment of Depression: STAR*D Algorithm retrieved from: http://www.ccjm.org/content/75/1/57.full.pdf
12. Texas Department of State Health Services (2010). Texas Medication Algorithm Project Procedural Manual. Retrieved from http://www.pbhcare.org/pubdocs/upload/documents/TMAP%20Depression%202010.pdf
13. UnitedHealthcare Generic Certificate of Coverage, 2001.
14. UnitedHealthcare Generic Certificate of Coverage, 2007.
15. UnitedHealthcare Generic Certificate of Coverage, 2009.
16. UnitedHealthcare Generic Certificate of Coverage, 2011.

PART VII: CODING

The Current Procedural Terminology (CPT) codes and HCPCS codes listed in this guideline are for reference purposes only. Listing of a service code in this guideline does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document.

Limited to specific CPT and HCPCS codes?	**X Yes ☐ No**
90867	Therapeutic repetitive transcranial magnetic

	stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management

DSM-5 Codes	ICD-10 Codes	Applicable Diagnoses
296.23	F32.2	Major Depressive Disorder, Single, Severe without Psychotic Features
296.33	F33.2	Major Depressive Disorder, Recurrent, Severe without Psychotic Features

Limited to specific place of service (POS)?	**X Yes ☐ No**
Outpatient	
Limited to specific provider type?	**X Yes ☐ No**
Physician	Psychiatrist who has examined the patient and supervises the treatment

Limited to specific revenue codes?	**☐ Yes X No**

PART VIII: HISTORY

Revision Date	Name	Revision Notes
10/2014	L. Urban	Version 1-Final
9/2015	L. Urban	Version 2-Final
10/2015	L. Urban	Version 2-Final Revised
2/2016	L. Urban	Version 3-Final
7/2016	L. Urban	Version 3-Final Revised
9/2016	L. Urban	Version 3-Final Revised

The enrollee's specific benefit documents supersede these guidelines and are used to make coverage determinations. These Coverage Determination Guidelines are believed to be current as of the date noted.