Medical Policy Name	Transcranial Magnetic Stimulation for Treatment of Major Depression
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Issued By	Chief Medical Officer
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Purpose

To provide practice parameters for Transcranial Magnetic Stimulation (TMS) so that benefits are applied in a consistent and relevant fashion.
This document applies to the use of TMS in Treatment Resistant Depression (TRD), which is the only indication for this device in psychiatric disorders. TMS is not a first line treatment of depression, even for those with severe depression.
This document addresses only TMS treatment requests for depression. This document is not meant to serve as a standard of care.

Definitions

Transcranial Magnetic Stimulation (TMS) was developed in 1985 and was initially a research tool used to non-invasively probe neurologic function in the cortex. The procedure consists of placing an electromagnetic coil on the scalp. A powerful AC current is passed through the coil. This results in a rapidly fluctuating intense magnetic field, which changes ionic flow in neural tissue located below the coil. The frequency of the fluctuation can also be manipulated. “Fast” TMS is delivered at frequencies of 3 to 20 Hz. By contrast, “slow” TMS is defined as a frequency of less than 1 Hz.

- In late 2008, the Food and Drug Administration (FDA) approved the NeoPulse device, now known as NeuroStar® TMS, marketed by Neuronetics. Since that time, other machines have also been approved for safety. The original FDA device approval indication is for treatment of depression in adult patients who have failed one 6-week course of an antidepressant. This approval was done under a 501K submission, demonstrating safety, but not substantial equivalence in efficacy. According to FDA documents, both the BrainsWay Deep TMS systems and the NeuroStar TMS Therapy System are currently indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current depressive episode. Since then, the FDA has approved a deep TMS (dTMS) unit for treatment of Obsessive-Compulsive Disorder. At this time there are multiple device approvals made by the FDA for TMs devices.

- TMS has been explored in migraine, spinal cord injury, tinnitus, mania, anxiety, movement disorders, pain, OCD, auditory hallucinations in schizophrenia and multiple other disorders.

- The side effects of TMS are local discomfort at the site of the magnetic field, muscle twitching and headaches. If the frequency is too great, seizures may develop. Magnetic Seizure Therapy (MST), which is using TMS to stimulate the induction of seizures, has been tried as an alternative to the electrical induction of seizures in electroconvulsive therapy (ECT). MST is currently in research and considered experimental/investigational.

Navigated Transcranial Magnetic Stimulation (nTMS) is being studied as a diagnostic tool to stimulate functional cortical areas at precise anatomical locations to induce measurable responses. This technology is being investigated to map functionally essential motor areas for diagnostic purposes and for treatment planning. nTMS is considered experimental and investigational.

Policy

A. Requests for TMS
    1. Requests for TMS are submitted on Lucet's TMS Treatment Request Form. The information submitted on the form will provide pertinent clinical information about the patient's past and current treatment history and response. Timelines for receiving information, making determinations, and peer review if needed will follow Lucet's standard benefit determination timeframes.
    2. Training and Requirements
        a. The attending physician is a board-certified psychiatrist with training in the use of TMS in Major Depression.
        b. Lucet will register any clinics or practitioners via documentation of certification, prior to allowing use of this benefit.

B. Treatment and Authorization Codes
    1. TMS is considered medically necessary when one (1) treatment session per day is given for five (5) consecutive days per week for six (6) consecutive weeks. Immediately following the six (6) (week treatment period, the treatment frequency is tapered, as follows:
        a. Week One (after six-week initial treatment): 3 treatment sessions
        b. Week Two (after six-week initial treatment): 2 treatment sessions
        c. Week Three (after six-week initial treatment): 1 treatment session
    2. These Current Procedural Terminology (CPT) codes will be used in following manner:
        a. 90867: Therapeutic transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, treatment delivery and management. (Report only once per course of treatment). (Do not report 90867 in conjunction with 90868, 90869, 95860-95870, 95928, 95929, 95939)
        b. 90868: Subsequent treatment delivery and management, per session
        c. 90869: Subsequent motor threshold re-determination with delivery and management (Do not report 90869 in conjunction with 90867, 90868, 95860-95870, 95928, 95929, 95939)
    3. The attending physician is required to personally perform codes 90867 and 90869

4. Code 90868 may be administered by a technician, but this individual is required to have certification in administering TMS
5. If TMS is found to be medically necessary, authorization will be for one unit of 90867, 36 units of 90868, and one unit of 90869
6. Requests for additional units of 90869 should be submitted with detailed clinical rationale

C. TMS Treatment Certification Guideline
Must meet both (1) and (2):

1. Transcranial magnetic stimulation of the brain administered with an FDA-approved device meets the definition of medical necessity as a treatment of resistant major depressive disorder when ALL of the following criteria (sections a-d) have been met.
    a. Confirmed diagnosis of severe Major Depressive Disorder WITHOUT Psychosis (International Classification of Disease: ICD-9 codes 296.2x and 296.3X, and ICD -10 codes F32.x and F33.x) with severity documented by one (1) clinically accepted depression rating scale from the following list. One (1) test should be chosen and employed during the entire treatment course.

Table 1

Name of test	Number of items	Minimum score for initial Authorization
Beck Depression Inventory (BDI)	21	>29
Inventory of Depressive Symptomatology Clinician-rated (IDS-C)	30	>36
Quick Inventory of Depressive Symptomatology Self-reported (QIDS-SR)	16	>15
Montgomery-Asberg Depression Rating Scale (MADRS)	10	>34
Patient Health Questionnaire (PHQ9)	9	>19

    b. The request is for a member between the ages of 18 and 70.
    c. The member is not actively abusing substances (UDS confirmation may be required).
    d. The member has any one of the following:
        i. Failure of four (4) trials of psychopharmacologic agents approved by the FDA for treating Major Depressive Disorder and at least two (2) of these trials should use augmentation of the currently prescribed antidepressant. These must include:
            - Medicine trials from at least two (2) different antidepressant classes (for example SSRI, SNRI, TCA, MAI-O, etc.)
            - Two (2) augmentation trials along with a primary antidepressant. Medications for this purpose are limited to FDA approved selected second generation antipsychotics with this indication, and the

clinical literature has established other medications: lithium, buspirone, psychostimulants (amphetamines and derivatives) and thyroid supplementation.

ii. Inability to tolerate a therapeutic dose of medications as evidenced by four (4) trials of psychopharmacologic agents (consistent with C. 1. d. i. above) with documented distinct intolerable side effects.

iii. Is a candidate for electroconvulsive therapy (ECT), and ECT outcome would not be overall superior to TMS (e.g., in cases with psychosis, acute suicidal risk, catatonia, or life-threating dysfunction in basic life needs, TMS should not be utilized).

2. Standardized depression rating scales should be performed during TMS treatment to monitor progress at a minimal frequency of an initial pre-treatment test which is to occur prior to the six (6) week initial treatment period, followed by testing every two (2) weeks during the six (6) week treatment period and a final test at the last treatment visit. If the rating scales document a lack of meaningful change or worsening of symptom intensity, review by a physician advisor may be indicated.

D. Retreatment Requests for TMS:
Must meet both (1) and (2):

1. Meets all requirements for initial TMS treatment (above)
2. Repeat acute treatment for relapse of depressive symptoms is considered medically necessary when both (a) and (b) are met:
    a. There is documentation submitted that the member responded to prior treatments, specifically with a 50% or greater improvement in a standard rating scale for depressive symptoms (e.g., PHQ-9, BDI, MADRS, QIDS-SR or IDS-C score).
    b. A minimum of ninety (90) days has elapsed since the termination of the prior TMS treatment course.
        i. If member meets the above relapse criteria, a five (5) days per week treatment course of left dorsolateral prefrontal cortex TMS treatment that lasts for six (6) weeks (total of thirty (30) sessions), followed by a three (3) week taper of three (3) TMS treatment sessions in week 1, two (2) TMS treatment sessions the next week, and one (1) TMS treatment session in the third and final week. Treatment frequency of less than five (5) days per week will be reviewed for medical necessity.
        ii. If TMS is found to be medically necessary, authorization will be for one (1) unit of 90867, thirty-six (36) units of 90868, and one (1) unit of 90869.
        iii. Requests for additional units of 90869 should be submitted with detailed clinical rationale.
        iv. If the member does not meet the criteria for 50% reduction in rating scale scoring, the request will not be considered medically necessary.

DI. Exclusions
Lucet considers the following to be exceptions to authorizing benefits. However, the member's health plan policy contract dictates whether a service is eligible to be covered for benefit payments.

1. The member has non-removable metallic objects or implants in his/her head or neck regions.
2. The member has an active neurologic disorder, including but not limited to encephalopathy, dementia from any cause, Parkinson's Disease, post-stroke syndromes, increased intracranial pressure or bleeding, cerebral aneurysm, A-V malformations, CSF shunts, implants in the CNS or head/neck, etc.
3. There is evidence of active psychotic symptoms.
4. The request is for Maintenance TMS Treatment.
5. The request is for treatment of OCD. In 2018, the FDA approved TMS as a safe medical device for treatment of Obsessive-Compulsive Disorder (OCD). The current peer reviewed literature was reviewed and does not support expanding the medical policy to cover this diagnosis as an indication for TMS.
6. The request is for Intermittent Theta Burst Stimulation (ITBS). In 2018, the FDA also approved ITBS as a safe medical device for treatment resistant depression. The current peer reviewed literature was reviewed does not support expanding the medical policy to cover ITBS.
7. TMS treatment for all other psychiatric diagnoses found in the DSM-5

Exceptions

Exceptions to this policy must be approved by the Chief Medical Officer or their designee.

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