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Subject: Transcranial Magnetic Stimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Transcranial magnetic stimulation (TMS) is a noninvasive method of delivering electrical stimulation to the brain. A magnetic field is delivered through the skull where it induces electric currents that affect neuronal function. Navigating transcranial magnetic stimulation (nTMS) is being evaluated as a treatment for neurological disorders.

TMS was initially used to investigate nerve conduction; for example, TMS over the motor cortex will produce a contralateral muscular-evoked potential.The technique involves placement of a small coil over the scalp; a rapidly alternating current is passed through the coil wire, which produces a magnetic field that passes unimpeded through the scalp and bone, resulting in electrical stimulation of the cortex.

Interest in the use of TMS as a treatment for depression was augmented by the development of a device that could deliver rapid, repetitive stimulation. Imaging studies had shown a decrease in activity of the left dorsolateral prefrontal cortex (DLPFC) in depressed patients, and early studies suggested that high frequency (e.g., 5–10 Hz) TMS of the left DLPFC had antidepressant effects. Low frequency (1–2 Hz) stimulation of the right DLPFC has also been investigated. The rationale for low frequency TMS is inhibition of right frontal cortical activity to correct the interhemispheric imbalance. A combination approach (bilateral stimulation), or deep stimulation with an H1 coil, are also being explored. In contrast to electroconvulsive therapy, TMS can be performed in an office setting as it does not require anesthesia and does not induce a convulsion.

The Food and Drug Administration (FDA) has approved several transcranial magnetic stimulation (TMS) systems and devices (e.g., NeuroStar® TMS Therapy System (Neuronetics, Inc.), Brainsway Deep TMS System (Brainsway Ltd.), Magstim Rapid^2 Therapy System (Magstim Company Limited), MagVita TMS Therapy System (Tonica Elektronik A/S)).

For exclusions and training and other requirements for TMS, see the **OTHER section** of this guideline.

Navigated Transcranial Magnetic Stimulation (nTMS)

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. There is some evidence in the medical literature for nTMS as an evolving technique for mapping of brain function.

POSITION STATEMENT:

Initial Transcranial Magnetic Stimulation (TMS) Treatment

Transcranial magnetic stimulation (TMS) of the brain administered with an FDA approved device **meets the definition of medical necessity** as a treatment of major depressive disorder in adults when **ALL** of the following criteria (1-3) have been met:

1. Confirmed diagnosis of severe major depressive disorder without psychosis with severity documented by one *clinically accepted depression rating scale (Table 1) that reliably measure depressive symptoms (e.g., Beck Depression Inventory (BDI), Inventory of Depressive Symptomatology Clinician-rated (IDS-C), Quick Inventory of Depressive Symptomatology Self-reported (QIDS-SR), Montgomery-Asberg Depression Rating Scale (MADRS), Patient Health Questionnaire (PHQ9)). One test should be chosen and employed during the entire treatment course; **AND**

2. The member is between the age of 18 and 70 and is not actively abusing substances (urine drug screening (UDS) confirmation may be required) and has any one of the following (a, b, or c):

    a. Failure of 4 trials of psychopharmacologic agents approved by the FDA for treating major depressive disorder. The trials must include:

        I. Medicine trials from at least two different antidepressant classes (e.g., SSRI, SNRI, TCA, MAI-O).

        II. Two augmentation trials along with the primary antidepressant. Medication for this purpose are limted to FDA approved selected second generation antipsychotics with this indication, and the clinical literature has established other medications: lithium, buspirone, trazodone, mirtazapine, psychostimulants (amphetamines and derivatives) and thyroid supplementation.

    b. Inability to tolerate a therapeutic dose of medications as evidenced by 4 trials of psychopharmacologic agents (consistent with the above criteria (2 a. 1 and 2 above) with documented distinct intolerable side effects; **OR**

    c. 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)

3. Standardized depression rating scale (Table 1) 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 6 week initial treatment period, followed by testing every 2 weeks during the 6 week treatment period, followed by testing every 2 weeks during the 6 week treatment period and a final test at

the last treatment visit. The scores will be required for concurrent authorization. If the rating scales document a lack of meaningful change or worsening of symptom intensity, review by a physician advisor may be indicated.

Abbreviations: SSRI= selective serotonin reuptake inhibitors; SNRI= serotonin and norinephrine reuptake inhibitors; TCA= tricyclic antidepressants; MAI-O= monoamine oxidase inhibitor.

Treatment

TMS **meets the definition of medical necessity** when 1 treatment session per day is given for 5 consecutive days per session for 6 consecutive weeks. Immediately following the 6 week treatment period, the treatment frequency is tapered, as follows:

- Week 1 (after 6-week initial treatment): 3 treatment sessions
- Week 2 (after 6-week initial treatment): 2 treatment sessions
- Week 3 (after 6-week initial treatment): 1 treatment session

Retreatment Requests for Transcranial Magnetic Stimulation (TMS)

Retreatment request for transcranial magnetic stimulation (TMS) of the brain administered with an FDA approved device **meets the definition of medical necessity** when the following criteria (1 and 2) have been met:

1. Meets all requirements for initial TMS treatment (above)
2. Repeat acute treatment for relapse of depressive symptoms is considered medically necessary when both i and ii 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 90 days has elapsed since the termination of the prior TMS treatment course.
        I. If member meets the above relapse criteria, a 5-day a week treatment course of left dorsolateral prefrontal cortex TMS treatment that lasts for six weeks (total of 30 sessions), followed by a three-week taper of three TMS treatment sessions in week 1, two TMS treatment sessions the next week, and one TMS treatment session in the third and final week. Treatment frequency of less than five days/week will be reviewed for medical necessity.
        II. If the member does not meet the criteria for 50% reduction in rating scale scoring, the request will not be considered medically necessary.

Table 1

Depression Rating Scale	Number 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 Symptomology Self-reported (QIDS-SR)	16	>15
Montgomery-Asberg Depression Rating Scale (MADRS)	10	>34
Patient Health Questionnaire (PHQ9)	9	>19

For required documentation, refer to the **REIMBURSEMENT INFORMATION** section of this guideline.

For exclusions and training and other requirements for TMS, see **OTHER** section of this guideline.

Transcranial magnetic stimulation (TMS) of the brain is considered **experimental or investigational** as a treatment for **ALL** other indications, including but not limited to other psychiatric/neurologic disorders (e.g., bipolar disorder, schizophrenia, obsessive compulsive disorder (OCD), migraine headaches, stroke, epilepsy, memory (working)). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transcranial magnetic stimulation (TMS) (including high frequency deep transcranial magnetic stimulation (HF DTMS/HF dTMS)) utilizing the Brainsway device (helmet) as a treatment for obsessive compulsive disorder (OCD) and **ALL** other indications is considered **experimental or investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Navigated transcranial magnetic stimulation (nTMS) is considered **experimental or investigational** for all indications, including but not limited to brain mapping. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

BILLING/CODING INFORMATION:

CPT Coding:

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

If TMS is found to be medically necessary, authorization will be for 1 unit of 90867, 36 units of 90868, and 1 unit of 90869.

Requests for additional units of 90869 should be submitted with detailed clinical rationale.

Refer to section entitled **POSITION STATEMENT**.

REIMBURSEMENT INFORMATION:

The primary treating physician may be required to submit documentation for the member, which supports the criteria for TMS in the position statement of this guideline.

Refer to section entitled **POSITION STATEMENT**.

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment and reason for transcranial magnetic stimulation (TMS).

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Laboratory studies	26436-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Current, discharge, or administered medications	34483-8	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

PROGRAM EXCEPTIONS:

Coverage for transcranial magnetic stimulation (TMS) referenced in this guideline performed and billed in an outpatient or office location will be handled through New Directions Behavioral Health® for select products. New Directions Behavioral Health will determine coverage for these services for select products. Refer to member's contract benefits.

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: The following Local Coverage Determination (LCD) Transcranial Magnetic Stimulation for Major Depressive Disorder (L34522) is located at fcso.com.

DEFINITIONS:

Major depression: a combination of symptoms (e.g., persistent sad, anxious, or "empty feelings, hopelessness or pessimism, difficulty concentrating, remembering details, and making decisions) that are disabling and prevents an individual from functioning normally.

RELATED GUIDELINES:

None applicable.

OTHER:

NOTE: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Other names used to report transcranial magnetic stimulation of the brain:

- Brain stimulation therapy
- Navigated transcranial magnetic stimulation (nTMS)
- NeoPulse Transcranial Magnetic Stimulation

Exclusions:

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 (e.g., encephalopathy, dementia form 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).
3. There is evidence of active psychotic symptoms.
4. The request is for maintenance TMS treatment.

Training and Other Requirements:

1. The attending physician is a board certified psychiatrist with training in the use of TMS in Major Depression.
2. The attending physician is required to perform TMS treatment (code 90867 and 90869).
3. A technician may perform TMS treatment (code 90868) (under direct supervision of the attending physician); the technician performing TMS treatment (code 90868) is required to have certification in performing TMS treatment (code 90868).
4. New Directions Behavioral Health will register clinics or practitioners via documentation of certification, prior to determining coverage for TMS.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/27/22.

GUIDELINE UPDATE INFORMATION:

06/15/02	New Medical Coverage Guideline.
06/15/03	Reviewed; no change in coverage.
06/15/04	Review and revision to guideline; consisting of updated references and various changes.
07/15/05	Review and revision of guideline; consisting of updated references.
06/15/06	Review and revision of guideline; consisting of updated references.
07/01/06	HCPCS coding update; consisting of the addition of 0160T and 0161T and the deletion of 0018T.
07/15/07	Review and revision of guideline; consisting of updated references and reformatted guideline.
04/15/08	Review and revision of guideline; consisting of updated references.
05/15/09	Updated description section. No change in position statement. Updated references.
01/01/11	Annual HCPCS coding update: deleted 0160T and 0161T. Added 90867 and 90868.
05/15/11	Scheduled review; no change in position statement. Updated references.
01/01/12	Annual HCPCS coding update; added 90869 and revised 90867 and 90868 code descriptor.
10/15/12	Added program exception for Medicare Advantage products; CPT code 90867, 90868 and 90869 is considered not medically reasonable and necessary; considered a non-covered service.
06/15/13	Scheduled review. Revised position statement; added “including repetitive TMS (rTMS) and “for all indications to TMS position statement. Revised experimental or investigational rationale, added “there is insufficient published evidence in the published peer-reviewed literature regarding the long-term effect of TMS on health outcomes”. Added position statement for navigated transcranial magnetic stimulation (nTMS) (experimental or investigational). Updated description and references.
10/15/13	Updated program exception for Medicare Advantage products; added LCD title Transcranial Magnetic Stimulation for Major Depressive Disorder.
10/15/14	Scheduled review. Revised position statement; added indication and criteria for TMS. Added definition for major depression. Updated references.
11/15/14	Revised; treatment course, depression rating scale table, documentation, training and other requirements. Updated references.
09/15/15	Annual review; deleted “and/or BPAD depressed” from failure of trial of an evidenced based psychotherapy statement and updated references.
11/01/15	Revision: ICD-9 Codes deleted.
12/15/16	Annual review; no change to position statement. Updated description and references.
01/01/18	Annual review; revised position statement. Updated references.
12/15/18	Review; added position statement for all other indications including but not limited to other psychiatric/neurologic disorders. Updated references.

05/15/19	Review; added memory (working) to experimental or investigational position statement. Added TMS (including high frequency deep transcranial magnetic stimulation (HF DTMS/HF dTMS) utilizing the Brainsway device (helmet) for the treatment of obsessive compulsive disorder (OCD) and all other indications. Updated references.
01/01/20	Revision; deleted "repetitive TMS (rTMS)" from guideline. Added statement regarding FDA approved selected second generation antipsychotics. Updated references.
01/01/21	Review and revision. Added heading "Initial Transcranial Magnetic Stimulation (TMS) Treatment" to position statement. Deleted history of response to TMS in a previous depressive episode. Added retreatment request for TMS and criteria. Updated references.
01/01/23	Review and revision; revised and expanded criteria. Updated references.