Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Medical Benefit

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<th>Effective Date: 08/15/14</th>
<th>Next Review Date: 09/15</th>
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Preauthorization

| Yes | Review Dates: 05/09, 03/10, 03/11, 03/12, 03/13, 03/14, 07/14, 09/14 |

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

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. Repetitive TMS (rTMS) is being evaluated as a treatment of depression and other psychiatric/neurologic brain disorders.

Background

Transcranial magnetic stimulation (TMS) was first introduced in 1985 as a new method of noninvasive stimulation of the brain. The technique involves placement of a small coil over the scalp; passing a rapidly alternating current through the coil wire, which produces a magnetic field that passes unimpeded through the scalp and bone, resulting in electrical stimulation of the cortex. TMS was initially used to investigate nerve conduction; for example, TMS over the motor cortex will produce a contralateral muscular-evoked potential. The motor threshold, which is the minimum intensity of stimulation required to induce a motor response, is empirically determined for each individual by localizing the site on the scalp for optimal stimulation of a hand muscle, then gradually increasing the intensity of stimulation. The stimulation site for treatment of depression is usually 5 cm anterior to the motor stimulation site.

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 does not require anesthesia and does not induce a convulsion.

rTMS is also being tested as a treatment for a variety of other disorders including alcohol dependence, Alzheimer’s disease, neuropathic pain, obsessive-compulsive disorder (OCD), post-partum depression, Parkinson disease, stroke, posttraumatic stress disorder, panic disorder, epilepsy, dysphagia, Tourette’s syndrome, schizophrenia, migraine, spinal cord injury, fibromyalgia, and tinnitus. In addition to the potential for altering interhemispheric imbalance, it has been proposed that high frequency rTMS may facilitate neuroplasticity.

Regulatory Status

Devices for transcranial stimulation have received clearance by the U.S. Food and Drug Administration (FDA) for diagnostic uses. One device, NeoPulse (Neuronetics, Atlanta, GA), received approval in Canada, Israel, and the
United States as a therapy for depression. Initially examined by the FDA under a traditional 510(k) application, the NeoPulse, now known as NeuroStar® TMS, received clearance for marketing as a “De Novo” device in 2008. NeuroStar® TMS is indicated for the treatment of patients with depression who have failed one six-week course of antidepressant medication. The Brainsway™ H-Coil Deep TMS device (Brainsway Ltd.) received FDA clearance in 2013. This device is indicated for the treatment of depression in patients who have failed to respond to antidepressant medications in their current episode of depression and is a broader indication than that of the NeuroStar® TMS, which specifies the failure of one course of antidepressant medication. (FDA product code: OBP)

Note: An FDA advisory panel met in January 2007 to determine if the risk-to-benefit profile for the NeoPulse was comparable to the risk-to-benefit profile of predicate electroconvulsive therapy (ECT) devices. The panel was not asked for a recommendation regarding the regulatory determination of substantial equivalence for this 510(k) submission. Materials presented at the Neurological Devices Panel meeting are posted online at: www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4273b1_00-index.htm.

In 2013 the Cerena™ TMS device (Eneura Therapeutics) received De Novo marketing clearance for the acute treatment of pain associated with migraine headache with aura. Warnings, precautions, and contraindications include the following:

- The device is only intended for use by patients experiencing the onset of pain associated with a migraine headache with aura.
- The device should not be used on headaches due to underlying pathology or trauma.
- The device should not be used for medication overuse headaches.
- The device has not been demonstrated as safe or effective when treating cluster headache or chronic migraine headache.
- The device has not been shown to be effective when treating during the aura phase.
- The device has not been demonstrated as effective in relieving the associated symptoms of migraine (photophobia, phonophobia, and nausea).
- Safety and effectiveness have not been established in pregnant women, children under the age of 18, and adults over the age of 65.

The De Novo 510(k) review process allows novel products with moderate or low risk profiles and without predicates which would ordinarily require premarket approval as a class III device to be down-classified in an expedited manner and brought to market with a special control as a class II device.

Related Protocols

Vagus Nerve Stimulation

Treatment of Tinnitus

Policy (Formerly Corporate Medical Guideline)

Repetitive transcranial magnetic stimulation (rTMS) of the brain may be considered medically necessary as a treatment of major depressive disorder when all of the following conditions (1-3) have been met:

1. Confirmed diagnosis of severe major depressive disorder (single or recurrent) documented by standardized rating scales that reliably measure depressive symptoms; AND
2. Any one of the following (a, b, c, or d):
a. Failure of four trials of psychopharmacologic agents including two different agent classes and two augmentation trials; OR
b. Inability to tolerate a therapeutic dose of medications as evidenced by four trials of psychopharmacologic agents with distinct side effects; OR
c. History of response to rTMS in a previous depressive episode (at least three months since the prior episode); OR
d. Is a candidate for electroconvulsive therapy (ECT) and ECT would not be clinically superior to rTMS (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition rTMS should NOT be utilized); AND
3. Failure of a trial of a psychotherapy known to be effective in the treatment of major depressive disorder of an adequate frequency and duration, without significant improvement in depressive symptoms as documented by standardized rating scales that reliably measure depressive symptoms.

rTMS for major depressive disorder that does not meet the criteria listed above is considered investigational.

Continued treatment with rTMS of the brain as maintenance therapy is considered investigational.

Transcranial magnetic stimulation of the brain is considered investigational as a treatment of all other psychiatric/neurologic disorders, including but not limited to bi-polar disorder, schizophrenia, obsessive-compulsive disorder, or migraine headaches.

Policy Guidelines

Repetitive transcranial magnetic stimulation should be performed using an FDA cleared device in appropriately selected patients, by physicians who are adequately trained and experienced in the specific techniques used. A treatment course should not exceed five days a week for six weeks (total of 30 sessions), followed by a three-week taper of three TMS treatments in week one, two TMS treatments the next week, and one TMS treatment in the last week.

Contraindications to rTMS include:

a. Seizure disorder or any history of seizure with increased risk of future seizure; OR
b. Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; OR
c. Neurological 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 (CNS); OR
d. Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 centimeters from the TMS magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator (ICD), pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents.

The following should be present for the administration of rTMS:

a. An attendant trained in basic cardiac life support and the management of complications such as seizures, as well as the use of the equipment must be present at all times; AND
b. Adequate resuscitation equipment including, for example, suction and oxygen; AND
c. The facility must maintain awareness of response times of emergency services (either fire/ambulance or “code team”), which should be available within five minutes. These relationships are reviewed on at least a one year basis and include mock drills.
Medicare Advantage

For Medicare Advantage transcranial magnetic stimulation (TMS) is considered medically necessary in adults who have a confirmed diagnosis of major depressive disorder (MDD), single or recurrent episode, is delivered by a device that is FDA-approved or –cleared for the treatment of MDD and meets the following criteria:

- Resistance to treatment as evidenced by a lack of a clinically significant response to four (4) trials of psychopharmacologic agents in the current depressive episode;
- Two different agent classes, at or above the minimum effective dose and duration and includes trials of at least two (2) evidence-based augmentation therapies; or
- Inability to tolerate psychopharmacologic agents as evidenced by four (4) trials of psychopharmacologic agents with distinct side effects; or
- History of response to TMS in a previous depressive episode; or
- History of response to electroconvulsive therapy (ECT) in a previous or current MDD episode, or inability to tolerate ECT, and TMS is considered a less invasive treatment option; and
- A trial of an evidence-based psychotherapy known to be effective in the treatment of MDD of an adequate frequency and duration without significant improvement in depressive symptoms as documented by standardized rating scales that reliably measure depressive symptoms; and
- The order for treatment (or retreatment) is written by a physician (MD or DO) who has examined the patient and reviewed the record. The physician must have experience in administering TMS therapy and the treatment must be given under direct supervision of this physician, i.e., he or she must be in the area and be immediately available.

Limitations

The benefits of TMS use must be carefully considered against the risk of potential side effect in patients with any of the following:

- Seizure disorder or any history of seizure (except those induced by ECT or isolated febrile seizures in infancy or childhood without subsequent treatment or recurrence). Additional consideration should be given for individuals on medications which may lower the seizure threshold or with conditions rendering the patient more prone to seizures, such as alcoholism;
- Presence of vagus nerve stimulators leads in the carotid sheath;
- Presence of an implanted medical device located < 30 cm from the TMS magnetic coil, including but not limited to pacemakers, implanted defibrillators, vagus nerve simulators, cochlear implants, aneurysm clips or coils stents, and bullet fragments. (Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with TMS.)
- The attending physician must monitor and document the patient’s clinical progress during treatment. The attending physician must use evidence-based validated depression monitoring scales such as the Geriatric Depression Scale (GDS), the Personal Health Questionnaire Depression Scale (PHQ-9), the Beck Depression Scale (BDI) Hamilton Rating Scale for Depression (HAM-D), the Montgomery Asberg Depression Rating Scale (MADRS), the Quick Inventory of Depressive Symptomatology (QIDS) or the Inventory for Depressive Symptomatology Systems Review (IDS-SR) to monitor treatment response and the achievement of remission of symptoms.

TMS is considered not medically necessary for any of the following:

- Presence of psychotic symptoms in the current depressive episode;
• Acute or chronic psychotic disorder such as schizophrenia, schizophreniform disorder, or schizoaffective disorder;
• 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;
• Maintenance therapy; and
• All other conditions not included in the above list of “Indications.”

Retreatment may be considered medically necessary for patients who met the guidelines for initial treatment and subsequently developed relapse of depressive symptoms if the patient responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms or if there were a relapse after remission [e.g., (GDS), PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR score]. A repeat treatment program is allowed as above.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References
We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transcranial magnetic stimulation for depression. TEC Assessments 2009; Volume 24, Tab 5.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transcranial magnetic stimulation for depression. TEC Assessments 2011; Volume 26, Tab 3.


46. Yang YR, Tseng CY, Chiou SY et al. Combination of rTMS and Treadmill Training Modulates Corticomotor Inhibition and Improves Walking in Parkinson Disease: A Randomized Trial. Neurorehabil Neural Repair 2012.


65. National Government Services Local Coverage Determination (LCD): Transcranial Magnetic Stimulation (L32038), Revision Effective Date for services performed on or after 09/01/2014.