Protocol

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

(20150)

Medical Benefit		**Effective Date**: 01/01/16	**Next Review Date**: 09/19
Preauthorization	Yes	**Review Dates**: 05/09, 03/10, 03/11, 03/12, 03/13, 03/14, 07/14, 09/14, 09/15, 09/16, 09/17, 09/18	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With treatment-resistant depression	Interventions of interest are: • Repetitive transcranial magnetic stimulation	Comparators of interest are: • Pharmacotherapy • Psychological and behavioral therapy • Electroconvulsive therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With other psychiatric or neurologic disorders other than depression	Interventions of interest are: • Repetitive transcranial magnetic stimulation	Comparators of interest are: • Pharmacotherapy • Therapy as appropriate including either physical and occupational therapy or psychological and behavioral therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

DESCRIPTION

Transcranial magnetic stimulation (TMS) is a noninvasive method of delivering electrical stimulation to the brain. TMS involves placement of a small coil over the scalp and passing a rapidly alternating current through the coil wire. The electrical current produces a magnetic field that passes unimpeded through the scalp and bone, that stimulates neuronal function. Repetitive transcranial magnetic stimulation (rTMS) is being evaluated for the treatment of treatment-resistant depression (TRD) and other psychiatric and neurologic disorders.

SUMMARY OF EVIDENCE

For individuals who have TRD who receive rTMS, the evidence includes a large number of sham-controlled randomized controlled trials (RCTs) and meta-analyses of these trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. The meta-analyses found a clinical benefit associated with rTMS for TRD with improved response rates and rates of remission compared with sham. The most recent meta-analyses have concluded that the effect of rTMS, on average depression scores, is smaller than the effect of electroconvulsive therapy (ECT) on TRD and that the mean improvement in depression scores with rTMS did not reach the minimal clinically important difference; however, clinically meaningful improvements were noted in a subgroup of stud-

ies using higher frequency pulses. One potential area of benefit for rTMS is in accelerating or enhancing the response to antidepressant medications, and there is some evidence that rTMS, when given in conjunction with the initiation of pharmacologic therapy, improves the response rate compared with pharmacologic therapy alone. The effect of rTMS appears to be less robust when it is given in combination with a stable dose of antidepressant medication. Meta-analyses have also found that the efficacy of rTMS decreases with longer follow-up, though some studies have reported persistent response up to six months in some patients. There is limited evidence to compare the effects of these treatments on cognition, although the adverse events of rTMS appear to be minimal. While the most recent meta-analyses have reported that the effect of rTMS is smaller than the effect of ECT on TRD, because rTMS does not require general anesthesia or induce seizures, some individuals may decline ECT as the balance of incremental benefits and harms associated with rTMS may be reasonable compared with ECT. Based on the short-term benefit observed in RCTs and the lack of alternative treatments, aside from ECT in patients with TRD, rTMS may be considered a treatment option in patients with TRD who meet specific criteria. The evidence for theta burst stimulation includes a large randomized trial showing noninferiority with another method of rTMS; no significant differences were noted in the number of adverse events. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have psychiatric or neurologic disorders other than depression (e.g., amyotrophic lateral sclerosis, chronic pain, epilepsy, fibromyalgia, migraine headache, obsessive-compulsive disorder, panic disorder, Parkinson disease, posttraumatic stress disorder, schizophrenia, stroke, substance abuse and craving) who receive rTMS, the evidence includes numerous small RCTs and meta-analyses of these RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. The trials included in the meta-analyses are typically small and of low methodologic quality. In addition, stimulation parameters have not been established, and trial results are heterogeneous. There are no large, high-quality trials for any of these conditions demonstrating efficacy. A demonstration of the durability of any treatment effects. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

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); further 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 used);

    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.

Repetitive TMS 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**.

Repetitive TMS 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 a U.S. Food and Drug Administration (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 (e.g., schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; OR

c. 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 (CNS); OR

d. Presence of an implanted magnetic-sensitive medical device located 30 centimeters or less from the TMS magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator, pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents.

The following should be present for the administration of repetitive TMS:

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, e.g., 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, and meet the following criteria (see Medicare Advantage Policy Guidelines):

- 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 TMS treatment is delivered by a device that is FDA-approved or –cleared for the treatment of MDD in a safe and effective manner. TMS treatment should generally follow the protocol and parameters specified in the manufacturer's user manual, with modifications only as supported by the published scientific evidence base; **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.

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;
- Persons with conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head which are non-removable and within 30 cm of the TMS magnetic coil. Examples include cochlear implants, implanted electrodes/stimulators, 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.)
- 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].

MEDICARE ADVANTAGE POLICY GUIDELINES

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 less than 30 cm from the TMS magnetic coil, including but not limited to pacemakers, implanted defibrillators, vagus nerve simulators.

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.

BACKGROUND

TRANSCRANIAL MAGNETIC STIMULATION

Transcranial magnetic stimulation (TMS), introduced in 1985 as a new method of noninvasive stimulation of the brain, 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; e.g., 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 person 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 five cm anterior to the motor stimulation site.

In contrast to electroconvulsive therapy, TMS does not require general anesthesia and does not generally induce a convulsion. 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., five to ten Hz) TMS of the left DLPFC had antidepressant effects. Low-frequency (one to two 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, as is theta burst stimulation.

Repetitive TMS (rTMS) is also being tested as a treatment for a variety of other disorders including alcohol dependence, Alzheimer disease, neuropathic pain, obsessive-compulsive disorder, postpartum depression, Parkinson disease, stroke, posttraumatic stress disorder, panic disorder, epilepsy, dysphagia, Tourette syndrome, schizophrenia, migraine, spinal cord injury, fibromyalgia, and tinnitus. (See the Treatment of Tinnitus on Protocol for rTMS for 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 been cleared for marketing by the U.S. Food and Drug Administration (FDA) for diagnostic uses. The NeoPulse, now known as NeuroStar® TMS, was granted a de novo 510(k) classification by FDA in 2008. A number of devices subsequently received FDA clearance for the treatment of major depressive disorders in adults who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Some devices are listed in Table 1. FDA product code: OBP.

Table 1. rTMS Devices Cleared by FDA for the Treatment of Major Depressive Disorder

Device	Manufacturer	FDA Clearance No.	FDA Clearance
NeuroStar® TMS	Neuronetics	DEN070003	2008
Brainsway™ H-Coil Deep TMS	Brainsway	K122288	2013
Rapid^2 Therapy System	Magstim	K162935	2015
MagVita TMS Therapy System	Tonica Elektronik	K150641	2015
Neurosoft TMS	TeleEMG	K160309	2016
Mag Vita TMS Therapy System with Theta Burst Stimulation	Tonica Elektronik	K173620	2018

FDA: Food and Drug Administration; rTMS: repetitive transcranial magnetic stimulation.

In 2013, the Cerena™ TMS device (eNeura Therapeutics) was granted a de novo 510(k) classification by FDA for the acute treatment of pain associated with a migraine headache with aura. Warnings, precautions, and contraindications include the following:

- The device is only intended for 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.
  - for medication overuse headaches.
- The device has not been demonstrated as safe and/or effective:
  - when treating cluster headache or a chronic migraine headache.
  - when treating during the aura phase.
  - in relieving the associated symptoms of a migraine (photophobia, phonophobia, and nausea).
  - 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.

In 2014, eNeura Therapeutics received 510(k) marketing clearance for the SpringTMS® for the treatment of migraine headache. The device differs from the predicate Cerena™ TMS device with the addition of an LCD screen, a use authorization feature, lithium battery pack, and smaller size. The stimulation parameters are unchanged. The sTMS Mini (eNeura Therapeutics) received marketing clearance by the FDA in 2016. FDA product code: OKP

RELATED PROTOCOLS

Treatment of Tinnitus

Vagus Nerve Stimulation

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.

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