

Repetitive Transcranial Magnetic Stimulation for Treatment Refractory Depression

Policy Number:

MM.12.015

Line(s) of Business:

PPO; HMO; QUEST Integration

Section:

Other/Miscellaneous

Place(s) of Service:

Outpatient

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I. Description

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. A rapidly alternating current is passed through the coil wire, producing 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. 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 showed a decrease in activity of the left dorsolateral prefrontal cortex (DLPFC) in depressed patients, and early studies suggested that high frequency TMS of the left DLPFC had antidepressant effects.

The studies of repetitive transcranial magnetic stimulation (rTMS) in the peer-reviewed medical literature show a short-term benefit for individuals with treatment refractory major depressive disorder (MDD) who received active versus sham rTMS. Treatment benefit has been defined by response or remission rates using depression rating scales. Studies also demonstrate that rTMS is well tolerated and without adverse effects. Most studies have short treatment periods, varying from one to six weeks and few studies have included long-term outcomes. Durability at this time is unclear and the optimal approach to sustaining any benefit achieved is unknown. In addition, the use of rTMS as a maintenance therapy is not supported by a controlled clinical trial.

Questions still need to be answered about rTMS, including optimal stimulation parameters, optimal length of treatment, and duration of response. Most studies have short treatment periods, varying from one to six weeks and few studies have included long-term outcomes. Durability at this time is unclear and the optimal approach to sustaining any benefit achieved is unknown. In addition, the use of rTMS as a maintenance therapy is not supported by a controlled clinical trial. Antidepressant medication remains the biological treatment of first choice for MDD.

Electroconvulsive therapy (ECT) continues to be effective treatment for treatment refractory depression, but adverse cognitive effects renders ECT undesirable in many cases. For the cohort of

patients who have failed or cannot tolerate antidepressant medications and/or ECT and have failed to respond to evidence-based psychotherapy, rTMS is an option.

II. Criteria/Guidelines

- A. Repetitive TMS is covered (subject to Limitations Exclusions and Administrative Guidelines) for use in adults with a confirmed diagnosis of severe MDD, when all of the following criteria are met:
1. One or more of the following is met:
 - a. The patient is refractory to treatment as evidenced by a lack of a clinically significant response to a minimum of four trials of therapy in the current depressive episode which must include:
 - i. Four antidepressant medications from at least two different agent classes, used for at least eight weeks at the maximum dose as approved by the FDA or documentation supports that higher doses were not tolerated when the dose is less than the FDA-approved maximum. **AND**
 - ii. At least two evidence-based augmentation therapies. Augmentation therapy is defined as a medication regimen consisting of an antidepressant and one or more medications, which are not antidepressants that are added to increase the efficacy of the antidepressant.
 - b. Inability to tolerate antidepressant medications as evidenced by four trials of such medications from at least two different classes, with distinct side effects.
 - c. History of refractoriness or intolerance to treatment as noted above and response to rTMS in a previous depressive episode.
 2. The patient has had a trial of evidence-based psychotherapy known to be effective in the treatment of MDD of an adequate frequency and duration without significant improvement in depressive symptoms.
 3. The patient has declined ECT.
 4. Repetitive TMS is administered by a U.S. Food and Drug Administration (FDA) cleared device for the treatment of MDD under the supervision of a licensed psychiatrist according to specified stimulation parameters.
- B. Continuation of repetitive TMS beyond four weeks is covered when documentation supports that the patient is responding to treatment.

III. Limitations/Exclusions

- A. Repetitive TMS is contraindicated in patients with the following:
1. Seizure disorder or any history of seizure (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence).
 2. Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode.
 3. 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, pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents.

- B. Repetitive TMS is not covered for all other behavioral health indications and neuropsychiatric disorders (e.g., anxiety disorders, mood disorders, schizophrenia) as it is not known to be effective in improving health outcomes.
- C. Repetitive TMS is not covered when used as maintenance therapy for MDD as it is not known to be effective in improving health outcomes.
- D. Treatments are limited to 30 treatments within the first six weeks, followed by three treatments in the seventh week, two treatments in the eighth week and one treatment in the ninth week.

IV. Administrative Guidelines

- A. Precertification is required for the initial four weeks of treatment with rTMS. Complete HMSA's Precertification request and fax or mail the form as indicated. The following documentation from the patient's medical record must be submitted:
 - 1. Names, doses and dates of use of at least four antidepressant medications from at least two different classes and at least two augmentation therapies that were tried and found to be ineffective.
 - 2. If applicable, names, doses and dates of use of at least four antidepressant medications from at least two different classes that were tried and not tolerated.
 - 3. Documentation supporting trial and ineffectiveness of evidence-based psychotherapy.
 - 4. If applicable, documentation supporting that the patient was refractory to treatment and has had a response to rTMS during a previous depressive episode.
 - 5. Documentation supporting that the patient has declined ECT.
- B. Precertification is required for continuation of treatment beyond four weeks. Documentation from the medical record supporting that the patient is responding to treatment must be submitted.
- C. Applicable Codes

CPT	Description
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

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References

1. New England Comparative Effectiveness Public Advisory Council (CEPAC). Coverage Policy Analysis: Repetitive Transcranial Magnetic Stimulation (rTMS). Completed by the Institute for Clinical and Economic Review (ICER). June 2012.
2. Institute for Clinical Systems Improvement (ICSI). Health care guideline: Major depression in adults in primary care. 15th Edition. (May 2012).
3. Gelenberg AJ, Freeman MP, Markowitz JC, et al. American Psychiatric Association (APA). Practice guideline for the treatment of patients with major depressive disorder. 3rd Edition. (October 2010).
4. George M, Post R. Daily Left Prefrontal Repetitive Transcranial Magnetic Stimulation for Acute Treatment of Medication-Resistant Depression. *Am J Psychiatry* 168:4. April 2011.
5. The National Alliance on Mental Illness. Transcranial Magnetic Stimulation Fact Sheet. August 2012.
6. Janicak, P. G., Z. Nahas, et al. (2010). "Durability of clinical benefit with transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant major depression: assessment of relapse during a 6-month, multisite, open-label study." *Brain Stimulation* 3(4): 187-199.
7. O'Reardon, J. P., H. B. Solvason, et al. (2007). "Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression: A Multisite Randomized Controlled Trial." *Biol Psychiatry* 62(11): 1208-1216.
8. Avery, D. H., K. E. Isenberg, et al. (2008). "Transcranial Magnetic Stimulation in the Acute Treatment of Major Depressive Disorder: Clinical Response in an Open-Label Extension Trial." *J Clin Psychiatry* 69(3): 441-451.
9. Connolly K, Helmer A et. al, Effectiveness of Transcranial Magnetic Stimulation in Clinical Practice Post-FDA Approval in the United States: Results Observed with the First 100 Consecutive Cases of Depression at an Academic Medical Center. *J Clin Psychiatry* 2012;73(4):e567-e573.
10. Keitner GI, Mansfield AK. Management of treatment-resistant depression. *Psychiatr Clin North Am* 2012; 35:249.