

Corporate Medical Policy

Transcranial Magnetic Stimulation

File Name:	transcranial_magnetic_stimulation
Origination:	1/2009
Last CAP Review:	7/2011
Next CAP Review:	7/2012
Last Review:	7/2011

Description of Procedure or Service

Transcranial magnetic stimulation (TMS) is a non-invasive 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; 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; 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 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 showed 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) is also being explored. TMS is also being tested as a treatment for other disorders including schizophrenia, migraine, spinal cord injury, tinnitus, and fibromyalgia. In contrast to electroconvulsive therapy, TMS does not require anesthesia and does not induce a convulsion.

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 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 6-week course of antidepressant medication.

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 at www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4273b1_00-index.htm.

A summary of the meeting is available at <http://www.fda.gov/cdrh/panel/summary/neuro-012607.html>.

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*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Transcranial Magnetic Stimulation is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When transcranial magnetic stimulation is covered

Not applicable.

When transcranial magnetic stimulation is not covered

Transcranial Magnetic Stimulation is considered **investigational** for all indications, including but not limited to treatment of depression and other psychiatric/neurologic disorders such as schizophrenia or migraine headaches.

Policy Guidelines

A 2009 BCBSA TEC Assessment evaluated rTMS for depression. The Assessment concluded that the available evidence does not permit conclusions regarding the effect of TMS on health outcomes.

Limitations of the evidence included:

- Equivocal efficacy in the largest sham-controlled trial of TMS,
- Uncertain clinical significance of the short-term anti-depressant effects found in meta-analyses,
- A lack of information beyond the acute period of treatment, and
- Lack of comparison with standard therapy (a second course of antidepressant therapy) in the population for whom TMS is indicated (patients who have failed one 6 week course of antidepressant medication).

The literature on rTMS for treatment-resistant depression (variably defined) includes a number of double-blind randomized sham-controlled short-term trials. Results of these trials show mean improvements of uncertain clinical significance across groups as a whole. The percentage of subjects who show a clinically significant response is reported at about 2 to 3 times that of sham controls, with around 15% to 25% of patients responding. The treatment protocols are time intensive, and the patients most likely to benefit from treatment are not currently known. Importantly, a number of open issues need to be addressed before this procedure is widely implemented. In addition to determining which of the locations and treatment parameters examined to date are most effective, further research is needed to guide the number of sessions needed to elicit a clinically significant response, to determine whether the response is durable with or without anti-depressant medications, and to provide some information about whether, and what types of, maintenance treatments are needed.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

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Applicable service codes: 90867, 90868, 90869

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.50, 12/13/07

U.S. Food and Drug Administration, (FDA). Brief summary from the Neurological Devices Panel Meeting - January 26, 2007. Retrieved 10/30/08 from <http://www.fda.gov/cdrh/panel/summary/neuro-012607.htm>.

Senior Medical Director Review 12/10/2008

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.50, 12/11/08

Specialty Matched Consultant Advisory Panel - 5/2009

BCBSA Technology Evaluation Center (TEC). Transcranial magnetic stimulation for depression. TEC Assessments 2009, Volume 24, Tab 5

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.50, 12/10/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.50, 1/13/2011

Policy Implementation/Update Information

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| 2/2/09 | New policy implemented. Reviewed with Senior Medical Director 12/10/08. Transcranial Magnetic Stimulation is considered investigational for all indications including but not limited to treatment of depression and other psychiatric/neurologic disorders. Notification given 2/2/09. Effective date 5/11/2009. |
| 7/6/09 | Specialty Matched Consultant Advisory Panel Review 5/28/09. "Description" revised. No changes to policy statement. References added. (btw) |
| 6/22/10 | Policy Number(s) removed (amw) |
| 10/26/10 | Description section revised. Specialty Matched Consultant Advisory Panel review 9/30/10. Policy accepted as written. (adn) |
| 1/4/2011 | CPT codes 90867 and 90868 added to the Billing/Coding section. CPT codes 0160T and 0161T deleted. (adn) |
| 8/16/11 | Specialty Matched Consultant Advisory Panel Review 7/27/11. No changes to policy. (adn) |
| 1/1/12 | CPT code 90869 added to Billing/Coding section. (adn) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.