



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 01/22/16
LAST REVIEW DATE: 08/21/18
LAST CRITERIA REVISION DATE: 01/17/17
ARCHIVE DATE:

TRANSCRANIAL MAGNETIC STIMULATION OF THE BRAIN AS TREATMENT FOR DEPRESSION AND OTHER PSYCHIATRIC/NEUROLOGIC DISORDERS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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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. In contrast to electroconvulsive therapy, TMS does not require anesthesia and does not induce a convulsion.



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Description: (cont.)

Repetitive TMS (rTMS) has been utilized as a treatment of depression. TMS (rTMS) has been investigated as a treatment 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 syndrome, schizophrenia, migraine, spinal cord injury, fibromyalgia and tinnitus.

Repetitive transcranial magnetic stimulation should be performed using a U.S. Food and Drug Administration (FDA)-cleared device in appropriately selected individuals, by physicians who are adequately trained and experienced in the specific techniques used. A treatment course should not exceed 5 days a week for 6 weeks (total of 30 sessions), followed by a 3-week taper of 3 transcranial magnetic stimulation (TMS) treatments in week 1, 2 TMS treatments the next week, and 1 TMS treatment in the last week.

Criteria:

For transcranial magnetic stimulation used in intraoperative monitoring of motor evoked potentials, see BCBSAZ Medical Coverage Guideline #O450, "*Sensory Evoked Potentials*".

For navigated transcranial magnetic stimulation for presurgical evaluation of eloquent brain areas, see BCBSAZ Medical Coverage Guideline #O872, "*Navigated Transcranial Magnetic Stimulation for Presurgical Evaluation of Eloquent Brain Areas*".

For transcranial magnetic stimulation used in treatment of tinnitus, see BCBSAZ Medical Coverage Guideline #O784, "*Treatment of Tinnitus*".



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Criteria: (cont.)

- Transcranial magnetic stimulation (TMS) or repetitive transcranial magnetic stimulation (rTMS) of the brain is considered **medically necessary** as a treatment of major depressive disorder with documentation of **ALL** of the following:
 1. Confirmed diagnosis of severe major depressive disorder (single or recurrent) documented by standardized rating scales that reliably measure depressive symptoms
 2. **ONE** of the following:
 - Failure of 4 trials of psychopharmacologic agents, including 2 different agent classes and 2 augmentation trials
 - Inability to tolerate a therapeutic dose of medications as evidenced by 4 trials of psychopharmacologic agents with distinct side effects
 - History of response to rTMS in a previous depressive episode (at least 3 months since the prior episode)
 - 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)
 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.
 4. Absence of **ALL** of the following contraindications:
 - No vagus nerve stimulator leads in the carotid sheath
 - No other implanted stimulators controlled by or that use electrical or magnetic signals
 - No conductive or ferromagnetic or other magnetic-sensitive metals implanted or embedded in head or neck within 11.81 inches (30cm) of TMS coil placement other than dental fillings
 - No acute or chronic psychotic disorder
 - No seizure disorder or history of seizure disorder
 - No substance abuse at the time of treatments
 - No severe dementia
 - No known non-adherence with previous treatment for depression

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Criteria: (cont.)

- Transcranial magnetic stimulation (TMS) or repetitive transcranial magnetic stimulation (rTMS) of the brain as a treatment of all other indications or if above criteria not met is considered **experimental or investigational** based upon:
1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

These indications include, *but are not limited to:*

- Maintenance therapy
- Alcohol dependence
- Alzheimer's disease
- Bi-polar disorder
- Fibromyalgia
- Migraine headache
- Neuropathic pain
- Obsessive-compulsive disorder (OCD)
- Postpartum depression
- Spinal cord injury
- Schizophrenia
- Tinnitus
- Tourette's syndrome
- Parkinson disease
- Stroke
- Posttraumatic stress disorder
- Panic disorder
- Epilepsy
- Dysphagia



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Resources:

Literature reviewed 08/29/17. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 2.01.50 BCBS Association Medical Policy Reference Manual. Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders. Re-issue date 07/13/2017, issue date 11/20/2001.
2. Anderson IM, Delvai NA, Ashim B, et al. Adjunctive fast repetitive transcranial magnetic stimulation in depression. *Br J Psychiatry*. 2007 Jun 2007;190:533-534.
3. Andre-Obadia N, Mertens P, Gueguen A, Peyron R, Garcia-Larrea L. Pain relief by rTMS: differential effect of current flow but no specific action on pain subtypes. *Neurology*. 2008 Sep 9 2008;71(11):833-840.
4. Anninos P, Adamopoulos A, Kotini A, Tsagas N, Tamiolakis D, Prassopoulos P. MEG evaluation of Parkinson's diseased patients after external magnetic stimulation. *Acta Neurol Belg*. 2007 Mar 2007;107(1):5-10.
5. Avery DH, Isenberg KE, Sampson SM, et al. Transcranial magnetic stimulation in the acute treatment of major depressive disorder: clinical response in an open-label extension trial. *J Clin Psychiatry*. 2008 Mar 2008;69(3):441-451.
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7. Berlim MT, Van den Eynde F, Daskalakis ZJ. High-frequency repetitive transcranial magnetic stimulation accelerates and enhances the clinical response to antidepressants in major depression: a meta-analysis of randomized, double-blind, and sham-controlled trials. *J Clin Psychiatry*. Feb 2013;74(2):e122-129.
8. Berlim MT, Van den Eynde F, Daskalakis ZJ. Efficacy and acceptability of high frequency repetitive transcranial magnetic stimulation (rTMS) versus electroconvulsive therapy (ECT) for major depression: a systematic review and meta-analysis of randomized trials. *Depress Anxiety*. Jul 2013;30(7):614-623.

TRANSCRANIAL MAGNETIC STIMULATION OF THE BRAIN AS TREATMENT FOR DEPRESSION AND OTHER PSYCHIATRIC/NEUROLOGIC DISORDERS (cont.)

Resources: (cont.)

9. Berlim MT, van den Eynde F, Tovar-Perdomo S, Daskalakis ZJ. Response, remission and drop-out rates following high-frequency repetitive transcranial magnetic stimulation (rTMS) for treating major depression: a systematic review and meta-analysis of randomized, double-blind and sham-controlled trials. *Psychol Med.* Jan 2014;44(2):225-239.
10. Borckardt JJ, Smith AR, Reeves ST, et al. Fifteen minutes of left prefrontal repetitive transcranial magnetic stimulation acutely increases thermal pain thresholds in healthy adults. *Pain Res Manag.* 2007 Winter 2007;12(4):287-290.
11. Bortolomasi M, Minelli A, Fuggetta G, et al. Long-lasting effects of high frequency repetitive transcranial magnetic stimulation in major depressed patients. *Psychiatry Res.* 2007 Mar 30 2007;150(2):181-186.
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13. Bystritsky A, Kaplan JT, Feusner JD, et al. A preliminary study of fMRI-guided rTMS in the treatment of generalized anxiety disorder. *J Clin Psychiatry.* 2008 Jul 2008;69(7):1092-1098.
14. California Technology Assessment Forum. Controversies in Migraine Management. 08/19/2014.
15. Cardoso EF, Fregni F, Martins Maia F, et al. rTMS treatment for depression in Parkinson's disease increases BOLD responses in the left prefrontal cortex. *Int J Neuropsychopharmacol.* 2008 Mar 2008;11(2):173-183.
16. Carpenter LL, Janicak PG, Aaronson ST, et al. Transcranial magnetic stimulation (TMS) for major depression: a multisite, naturalistic, observational study of acute treatment outcomes in clinical practice. *Depress Anxiety.* Jul 2012;29(7):587-596.
17. Centonze D, Koch G, Versace V, et al. Repetitive transcranial magnetic stimulation of the motor cortex ameliorates spasticity in multiple sclerosis. *Neurology.* 2007 Mar 27 2007;68(13):1045-1050.
18. Charnsil C, Suttajit S, Boonyanaruthee V, Leelarphat S. An open-label study of adjunctive repetitive transcranial magnetic stimulation (rTMS) for partial remission in major depressive disorder. *Int J Psychiatry Clin Pract.* Jun 2012;16(2):98-102.

TRANSCRANIAL MAGNETIC STIMULATION OF THE BRAIN AS TREATMENT FOR DEPRESSION AND OTHER PSYCHIATRIC/NEUROLOGIC DISORDERS (cont.)

Resources: (cont.)

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TRANSCRANIAL MAGNETIC STIMULATION OF THE BRAIN AS TREATMENT FOR DEPRESSION AND OTHER PSYCHIATRIC/NEUROLOGIC DISORDERS (cont.)

Resources: (cont.)

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Resources: (cont.)

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FDA 510K Summary for NeuroStar TMS®:

- FDA-approved indication: Treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. (Classified in class II with establishment of special controls.)



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Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

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Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

