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

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

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.


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

Resources: (cont.)


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

Resources: (cont.)


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

Resources: (cont.)


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

**Resources:** (cont.)


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

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

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.

Navajo: Díí kwée’ átah níllígíí Blue Cross Blue Shield of Arizona haada yít’éego bííhídííkíído éí doócágí Háída bíjá aniyeedíígí táádoó le’é yíí a’dlíi kíído beeheaz’àáníí hóló dáí táí t’áí hazaadk’ehí háká a’dooowolgo bee haz’a doo bágíh ilínígíí. Ata’ halné’ígíí kojí bích’í’h hólíilíí 877-475-4799.

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 thợ ngôn ngữ, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعدهم أسرة بفحص Blue Cross Blue Shield of Arizona السورسيبريك، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أي تكلفة. للتحدث مع مترجم أتصل ب 877-475-4799.
MULTI-LANGUAGE INTERPRETER SERVICES: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 도와드리는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관심이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Diomscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問があれば、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi: اگر شما، یا کسی که شما به آن کمک می‌کنید، سوال‌های مربوط به Blue Cross Blue Shield of Arizona دارد، می‌توانید به مدرک مربوط به آن سوال نظر داشته باشید و به صورت رایگان در تلفن 877-475-4799 تماس حاصل نمایید.

Assyrian: Blue Cross Blue Shield of Arizona می‌توانید به آن کمک می‌کنید، سوال‌های مربوط به نظر داشته باشید و به صورت رایگان در تلفن 877-475-4799 تماس حاصل نمایید.

Serbo-Croatian: Ukoliko vi ili neko kome vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodocem, nazovite 877-475-4799.

Thai: หากคุณหรือบุคคลที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณจะได้รับความช่วยเหลือและข้อมูลภาษาของคุณได้โดยไม่เสียค่าใช้จ่าย ติดต่อที่ 877-475-4799