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

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

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 patients, 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, “Sensory Evoked Potentials”.

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

- 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)
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 (cont.)

  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.

- 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:**

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

Resources:

Literature reviewed 01/05/16. 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 one prior antidepressant medication at or above the minimal effective dose and duration in the current episode. (Classified in class II with establishment of special controls.)