

## Corporate Medical Policy

### Transcranial Magnetic Stimulation

#### Description of Procedure or Service

Transcranial magnetic stimulation (TMS) is a noninvasive technique that is being investigated as a modality for treatment resistant major depression (TRD). TMS was first introduced in 1985 as a new method of noninvasive stimulation of the brain. In October 2008, the NeuroStar® TMS received FDA marketing clearance as a de novo device for therapy of patients with TRD. Brief repetitive pulses of magnetic energy are applied to the scalp via a large electromagnetic coil to generate low levels of electrical current in the underlying brain tissue. These fields penetrate through nearby tissues, including the scalp, skull, meninges, and cerebrospinal fluid, to induce electric currents in underlying cortical neurons. The frequency of TMS pulses influences the effects on axons. Low frequencies of less than 5 Hz will hyperpolarize axons, transiently reducing their normal firing to inhibit their normal effects.

Depending on stimulation parameters (frequency, intensity, pulse duration, stimulation site), repetitive TMS (rTMS) to specific cortical regions can either increase or decrease the excitability of the affected brain structures. The goal of TMS is to stimulate areas of the brain involved in mood regulation to lessen the duration or severity of depressive episodes. TMS may be used to augment pharmacotherapy or in lieu of a new medication. Transcranial magnetic stimulation (TMS) is a non-invasive method of induction of a focal current in the brain and transient modulation of the function of the targeted cerebral cortex.

#### Background

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. 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.

Navigated transcranial magnetic stimulation (nTMS) is a noninvasive functional mapping technique that utilizes magnetic stimulation to generate electrical current in the brain cortex. Specific cortical mapping is conducted by stimulating different regions of the brain and measuring the impact via surface electrodes placed over desired muscles. Also, language and speech mapping maybe performed as the patient names objects displayed every few seconds on a computer monitor during magnetic stimulation. The surgeon uses the nTMS mapping results pre-surgically for treatment planning and intraoperatively, in conjunction with direct cortical stimulation, for surgical guidance.

### **Regulatory Status**

There are multiple FDA-approved devices currently used to deliver repetitive transcranial stimulation; examples may include, but not limited to:

Neurostar TMS, MagStim Rapid Therapy System and Magvita TMS Therapy System versions with and without MagProR20.

Guidance regarding requirements for these devices may be found at:

<https://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm265269.htm>

### **Policy Statement**

GEHA will provide coverage for TMS when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated.

### **Treatment with TMS is covered when:**

- 1) Administered by an FDA cleared device and utilized in accordance with the FDA labeled indications; and
- 2) The member is age 18 years or older; and
- 3) The member has a confirmed diagnosis of severe major depressive disorder (single or recurrent episode), documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.); and
- 4) There is documentation via legible medical records of 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 (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.); and
- 5) The member is currently receiving or is a candidate for electroconvulsive therapy (ECT) and rTMS is considered a less invasive equally effective treatment option (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition rTMS should not be utilized); and
- 6) The member has no contraindications to rTMS (refer to contraindications below); and
- 7) The member meets one of the following criteria:

- A) There is documentation via legible medical records of failure of four trials of psychopharmacologic agents, including two different agent classes, during the current depressive episode; or
- B) The member is unable to tolerate a therapeutic dose of medications as evidenced by documentation via legible medical records of four trials of psychopharmacologic agents with distinct side effects; and

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.

**When treatment with TMS is not covered:**

- 1) Persons with high alcohol or illicit drug consumption; or
- 2) The member is suicidal; or
- 3) The member has a metal implant in or around the head (e.g., aneurysm coil or clip, metal plate, ocular implant, stent); or
- 4) The member has neurological conditions (e.g., cerebrovascular disease, dementia, history of repetitive or severe head trauma, increased intracranial pressure or primary or secondary tumors in the central nervous system); or
- 5) The member has a seizure disorder/epilepsy; or
- 6) If the member has severe cardiovascular disease, unless the member has been evaluated and cleared for rTMS by a cardiologist.
- 7) For the purpose of maintenance therapy;
- 8) GEHA considers transcranial magnetic stimulation experimental and investigational for the following indications because its value and effectiveness has not been established (not an all-inclusive list):
  - A) Alzheimer's disease
  - B) Amyotrophic lateral sclerosis
  - C) ADHD
  - D) Anxiety disorders
  - E) Auditory verbal hallucinations
  - F) Autism
  - G) Blepharospasm
  - H) Bulimia nervosa
  - I) Chronic pain including neuropathic pain (e.g., orofacial pain, and central post-stroke pain)<sup>6</sup>
  - J) Communication and swallowing disorders (e.g., aphasia (including post-stroke aphasia), dysarthria,
  - K) Dysphagia (including post-stroke dysphagia), and linguistic deficits)
  - L) Epilepsy (including status epilepticus)
  - M) Congenital hemiparesis
  - N) Dystonia
  - O) Fibromyalgia
  - P) Levodopa-induced dyskinesia
  - Q) Migraine
  - R) Mood disorders

- S) Obsessive-compulsive disorder
  - T) Panic disorder
  - U) Parkinson disease
  - V) Phantom pain associated with spinal cord injury
  - W) Post-traumatic stress disorder
  - X) Schizophrenia
  - Y) Smell and taste dysfunction (e.g., phantosmia and phantageusia)
  - Z) Spasticity
  - AA) Stroke treatment (e.g., motor impairment, and post-stroke hemiplegia)
  - BB) Substance addiction
  - CC) Tourette syndrome
  - DD) Tinnitus
  - EE) Traumatic brain injury
- 9) Navigated Transcranial Magnetic Stimulation (nTMS) is considered experimental and investigational for motor function mapping and/or treatment planning of neurological disease/disorders (e.g. amyotrophic lateral sclerosis, epilepsy, and resection of brain tumors)
- 10) Single pulse TMS or Single-Pulse Transcranial Magnetic Stimulation (sTMS) (i.e. Cerena™ TMS; Spring TMS), dual pulse, high frequency, etc., as proposed treatment for a variety of disorders including alcohol dependence, Alzheimer disease, neuropathic pain, obsessive-compulsive disorder, postpartum depression, Parkinson disease, stroke, posttraumatic stress disorder, panic disorder, epilepsy, dysphagia, Tourette syndrome, schizophrenia, migraine headaches, spinal cord injury, fibromyalgia, obesity and tinnitus.

### **Policy Guidelines**

GEHA will provide coverage for TMS when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated. This guideline has been based on the FDA approval in 2008, in which for patients who have not found relief from antidepressant medication, rTMS as a treatment to alleviate symptoms of Major Depressive Disorder (MDD).

TMS should be performed by providers who are adequately trained and experienced to administer TMS therapy.

Guidance in this policy relates specifically to the determination of medical necessity. Please note that payment for specific services will always be dependent upon additional factors including, correct coding, contractual requirements, GEHA payment policy, etc. The fact that a service is determined to be clinically necessary does not dictate payment processes.

### **Physician documentation**

Clinical information required to determine medical necessity must be submitted along with the appropriate authorization request form. Authorization request form located at [www.geha.com](http://www.geha.com). This includes: patient history and evaluation, including tried and failed treatments; current presentation of symptoms; and treatment plan, including frequency and total number of sessions requested.

**Applicable codes include but are not limited to:**

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

**Scientific references**

Wasserman EM, Epstein CM, Ziemann U, Walsh V, Paus T, Lisanby SH, editors. The Oxford Handbook of Transcranial Stimulation. Oxford: Oxford University Press; 2008

Ahmed MA, Darwish ES, Khedr EM, et al. Effects of low versus high frequencies of repetitive transcranial magnetic stimulation on cognitive function and cortical excitability in Alzheimer's dementia. *J Neurol*. Jan 2012;259(1):83-92. PMID 21671144

Fang J, Zhou M, Yang M, et al. Repetitive transcranial magnetic stimulation for the treatment of amyotrophic lateral sclerosis or motor neuron disease. *Cochrane Database Syst Rev*. 2013;5:CD008554. PMID 23728676

Weaver L, Rostain AL, Mace W, et al. Transcranial magnetic stimulation (TMS) in the treatment of attention deficit/hyperactivity disorder in adolescents and young adults: a pilot study. *J ECT*. Jun 2012;28(2):98-103

Walpoth M, Hoertnagl C, Mangweth-Matzek B, et al. Repetitive transcranial magnetic stimulation in bulimia nervosa: preliminary results of a single-centre, randomized, double-blind, sham-controlled trial in female outpatients. *Psychother Psychosom*.

O'Connell NE, Wand BM, Marston L, et al. Non-invasive brain stimulation techniques for chronic pain. *Cochrane Database Syst Rev*. 2014;4:CD008208.

Sun W, Mao W, Meng X, et al. Low-frequency repetitive transcranial magnetic stimulation for the treatment of refractory partial epilepsy: a controlled clinical study. *Epilepsia*. Oct 2012;53(10):1782-1789. PMID 22950513

Marlow NM, Bonilha HS, Short EB. Efficacy of transcranial direct current stimulation and repetitive transcranial magnetic stimulation for treating fibromyalgia syndrome: a systematic review. *Pain Pract*. Feb 2013;13(2):131-145. PMID 22631436

National Institute for Health and Care Excellence. Transcranial magnetic stimulation for treating and preventing migraine. NICE interventional procedure guidance [IPG477]. 2014; <https://www.nice.org.uk/guidance/ipg477/chapter/1-recommendations>. Accessed November 17, 2015.

Berlim MT, Neufeld NH, Van den Eynde F. Repetitive transcranial magnetic stimulation (rTMS) for obsessive compulsive disorder (OCD): an exploratory meta-analysis of randomized and sham-controlled trials. *J Psychiatr Res*. Aug 2013;47(8):999-1006. PMID 23615189

Origination Date: Dec. 2016

Peer Reviewed: Dec. 2018

Next Review Date: Dec. 2019

Li H, Wang J, Li C, et al. Repetitive transcranial magnetic stimulation (rTMS) for panic disorder in adults. *Cochrane Database Syst Rev*. 2014;9:CD009083. PMID 25230088

Chou YH, Hickey PT, Sundman M, et al. Effects of repetitive transcranial magnetic stimulation on motor symptoms in Parkinson disease: a systematic review and meta-analysis. *JAMA Neurol*. Apr 2015;72(4):432-440. PMID 25686212

Isserles M, Shalev AY, Roth Y, et al. Effectiveness of deep transcranial magnetic stimulation combined with a brief exposure procedure in post-traumatic stress disorder--a pilot study. *Brain Stimul*. May 2013;6(3):377-383. PMID 22921765

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transcranial magnetic stimulation for the treatment of schizophrenia. *TEC Assessments*. 2011; Volume 26, Tab 6.

Hao Z, Wang D, Zeng Y, et al. Repetitive transcranial magnetic stimulation for improving function after stroke. *Cochrane Database Syst Rev*

Li Y, Qu Y, Yuan M, et al. Low-frequency repetitive transcranial magnetic stimulation for patients with aphasia after stroke: A meta-analysis. *J Rehabil Med*. Sep 3 2015;47(8):675-681

Liu S1, Sheng J1, Li B1, Zhang X1. Recent Advances in Non-invasive Brain Stimulation for Major Depressive Disorder. *Front Hum Neurosci*. 2017 Nov 6;11:526. doi: 10.3389/fnhum.2017.00526. eCollection 2017.

McGirr A1, Van den Eynde F2, Tovar-Perdomo S2, Fleck MP3, Berlim MT4. Effectiveness and acceptability of accelerated repetitive transcranial magnetic stimulation (rTMS) for treatment-resistant major depressive disorder: an open label trial. *J Affect Disord*. 2015 Mar 1;173:216-20. doi: 10.1016/j.jad.2014.10.068. Epub 2014 Nov 11.

Wang HN1, Wang XX1, Zhang RG1, Wang Y1, Cai M1, Zhang YH1, Sun RZ1, Guo L1, Qiao YT1, Liu JC1, He H1, Wang ZH1, Wan YC1, Tan QR2, Zhang ZJ3,4. Clustered repetitive transcranial magnetic stimulation for the prevention of depressive relapse/recurrence: a randomized controlled trial. *Transl Psychiatry*. 2017 Dec 18;7(12):1292. doi: 10.1038/s41398-017-0001-x.

Rachid F. Maintenance repetitive transcranial magnetic stimulation (rTMS) for relapse prevention in with depression: A review. *Psychiatry Res*. 2018 Apr;262:363-372.

Health Quality Ontario. Repetitive Transcranial Magnetic Stimulation for Treatment-Resistant Depression: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Ont Health Technol Assess Ser*. 2016 Mar

### **Policy implementation and updates**

Jan 2019      Update of references