Corporate Medical Policy
Transcranial Magnetic Stimulation

Description of Procedure or Service

Transcranial magnetic stimulation (TMS) is a treatment option for major depression. 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, transently 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.

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. The member is age 18 years or older; and
2. 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
3. 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
4. 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
5. The member has no contraindications to rTMS (refer to contraindications below); and
6. 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)
   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) Pregnancy
X) Post-traumatic stress disorder
Y) Schizophrenia
Z) Smell and taste dysfunction (e.g., phantosmia and phantogeusia)
AA) Spasticity
BB) Stroke treatment (e.g., motor impairment, and post-stroke hemiplegia)
CC) Substance addiction
DD) Tourette syndrome
EE) Tinnitus
FF) 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.

**Physician Documentation**

A. Clinical information required to determine medical necessity must be submitted
C. Patient history and evaluation, including tried and failed treatments; current presentation of symptoms; and treatment plan, including frequency and total number of sessions requested.

**Policy Guidelines**

GEHA will provide coverage for TMS when it is determined to 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 whom 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.

The American Psychiatric Association practice guideline recommends TMC as a secondary method of treatment for major depression after medication, psychotherapy or other somatic therapies such as Electroconvulsive therapy (ECT) or light therapy.
Background
A major depressive episode as defined in the DSM-5 (APA, 2013) implies a prominent and relatively persistent (e.g., nearly every day for at least two weeks) depressed or dysphoric mood that represents a change from previous functioning, and includes at least five of the following nine symptoms, one of which is either of the first two symptoms:

- Depressed mood
- Markedly diminished interest or pleasure in usual activities
- Significant change in weight and/or appetite
- Insomnia or hypersomnia
- Psychomotor agitation or retardation
- Fatigue or loss of energy
- Feelings of worthlessness or excessive or inappropriate guilt
- Slowed thinking or impaired concentration
- Recurrent thoughts of death or suicidal ideation or a suicide attempt.

Standard treatments for major depressive disorder (MDD) include psychotherapy, pharmacotherapy, and/or electroconvulsive therapy (ECT). Although the majority of individuals respond to standard treatments for depression, some do not benefit, or cannot tolerate these interventions. Therefore, alternate treatment options are being investigated, including transcranial magnetic stimulation (TMS), vagal nerve stimulation, cranial electrical stimulation and herbal/homeopathic remedies.

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 (APA, 2010).

The response to TMS in depression can be predicted. Understanding the predictors of response to TMS treatment in depression will help the clinicians in appropriate selection of patients for TMS treatment and likely to improve to the treatment outcome (Kar, 2019).

The clinical utility and improvement in health outcomes of rTMS in the treatment of other psychiatric or neurological disorders outside of major depression, have not been clearly established. rTMS has not been proven effective in the peer-reviewed published scientific literature for the following indications nor are there devices FDA approved for these conditions.

- addictions (Maiti et al., 2017; Grall-Bronnec and Sauvaget, 2014)
- alcohol dependence (Mishra, et al., 2010)
- Alzheimer disease (Hayes, 2018; Liao, et al., 2015; Ahmed, et al., 2012; Cotelli, et al., 2010)
• amyotrophic lateral sclerosis (ALS) (Fang, et al., 2013; Guo, et al., 2011; Di Lazzaro, et al., 2010)
• anorexia nervosa (McClelland, et al., 2016)
• anxiety disorder (Diefenback, et al., 2016)
• attention deficit hyperactivity disorder (ADHD) (Bloch, et al., 2010)
• auditory hallucinations in schizophrenia (Freitas, et al., 2012; Slotema, et al., 2011; Cordes, et al., 2010)
• autism (Sokhadze, et al., 2010)
• blepharospasm (Kranz, et al., 2010)
• bulimic disorders (Van den Eynde, et al., 2010)
• chronic pain (O’Connell, et al., 2018; Jin, et al., 2015; Galhardoni, et al., 2015)
• chronic tinnitus (Folmer, et al., 2015; Meng, et al., 2011)
• children (Allen, et al., 2017)
• epilepsy (Pereira, et al., 2016; Chen, et al., 2016)
• facial pain (Hodaj, et al., 2015)
• fibromyalgia (Saltychev and Laimi, 2017; Knijnik, et al., 2016)
• focal dystonia (Schneider, et al., 2010)
• Huntington’s disease (Medina, et al., 2010)
• panic disorder (Li, et al., 2014)
• Parkinson’s disease (Chung and Mak, 2016; Wagle, et al., 2016; Chou, et al., 2015)
• postherpetic neuralgia (Ma, et al., 2015)
• post-operative pain (Borckardt, et al., 2006)
• post-stroke aphagia (Li, et al., 2015)
• post-stroke dysphagia (Du, et al., 2016)
• post-traumatic stress disorder (Yan, et al., 2017; Trevizon, et al., 2016)
• schizophrenia (He, et al., 2017; Wobrock, et al., 2015; Dougall, et al., 2015)
• smell and taste dysfunction (Henkin, et al., 2011)
• spinal cord injury (Nardone, et al., 2015; Awad, et al., 2013)
• stroke (Dionísio, et al., 2018; Zhang, et al., 2017; Graef, et al., 2016)
• tic disorders (Wu, et al., 2014; Steeves, et al., 2012)
• tinnitus (Soleimani, et al., 2016)
• Tourette syndrome (Landeros-Weisenberger, et al., 2015)

Regulatory Status

Repetitive transcranial magnetic stimulation (rTMS) is a procedure and therefore falls outside the regulatory authority of the FDA. However, the FDA is responsible for regulating medical devices sold in the United States. The FDA has classified devices used in rTMS as class II devices under product code GWF (Stimulator, Electrical, Evoked Response) or OBP (Transcranial Magnetic Stimulator), subject to special controls, i.e., 510(k) Premarket Notification.

The following codes are for reference purposes only and do not imply that the service is covered or non-covered under the member's benefit policy. Applicable codes may include but are not limited to:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<td>90867</td>
<td>Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management</td>
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<tr>
<td>90868</td>
<td>Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session</td>
</tr>
<tr>
<td>90869</td>
<td>Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management</td>
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Scientific References


Policy implementation and updates

Jan 2019  Update of references
Dec 2019  Background info added, supporting references added. No change in policy coverage