Transcranial Magnetic Stimulation

POLICY

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.\(^1\) 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.

GEHA considers navigational transcranial magnetic stimulation (nTMS) investigational and experimental. This technique uses “frameless stereotactic” neuronavigation systems, in which patients’ head MRIs allow TMS to be applied to precise underlying cortical targets.

GEHA considers repetitive transcranial magnetic stimulation (rTMS) in a healthcare provider’s office medically necessary when the following criteria are met for up to 30 treatments over 6 weeks:

- Administered by an FDA cleared device and utilized in accordance with the FDA labeled indications; and
- The member meets one of the following criteria:
  - 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
  - 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
  - The member is age 18 years or older; and
- 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

• 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

• 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

• The member has no contraindications to rTMS (refer to contraindications below); and

• Treatment consists of a maximum of 30 sessions (five days a week for six weeks). Note: Treatments beyond 30 sessions may be reviewed for medical necessity.

GEHA considers rTMS contraindicated and experimental and investigational in persons with any of the following contraindications to rTMS because the safety and effectiveness in person with these contraindications has not been established:

• Persons with high alcohol or illicit drug consumption; or

• The member is suicidal; or

• The member has a metal implant in or around the head (e.g., aneurysm coil or clip, metal plate, ocular implant, stent); or

• 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

• There is presence of implanted devices, (e.g., cardiac pacemaker or defibrillator, cochlear implant, deep brain stimulator, implantable infusion pump, spinal cord stimulator, vagus nerve stimulator, etc.); or

• The member has a seizure disorder/epilepsy; or

• If the member has severe cardiovascular disease, he has been evaluated and cleared for rTMS treatment by a cardiologist

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):

• Alzheimer's disease

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- Amyotrophic lateral sclerosis
- ADHD
- Anxiety disorders
- Auditory verbal hallucinations
- Autism
- Blepharospasm
- Bulimia nervosa
- Chronic pain including neuropathic pain (e.g., orofacial pain, and central post-stroke pain)
- Communication and swallowing disorders (e.g., aphasia (including post-stroke aphasia), dysarthria, dysphagia (including post-stroke dysphagia), and linguistic deficits)
- Epilepsy (including status epilepticus)
- Congenital hemiparesis
- Dystonia
- Fibromyalgia
- Levodopa-induced dyskinesia
- Migraine
- Mood disorders
- Obsessive-compulsive disorder
- Panic disorder


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• Parkinson disease
• Phantom pain associated with spinal cord injury
• Post-traumatic stress disorder
• Schizophrenia
• Smell and taste dysfunction (e.g., phantosmia and phantageusia)
• Spasticity
• Stroke treatment (e.g., motor impairment, and post-stroke hemiplegia)
• Substance addiction
• Tourette syndrome
• Tinnitus
• Traumatic brain injury

RATIONALE

Transcranial magnetic stimulation has been investigated in the treatment of various psychiatric disorders, especially depression. This procedure is usually carried out in an outpatient setting. In contrast to electroconvulsive therapy, TMS does not require anesthesia or analgesia. Furthermore, it does not affect memory and usually does not cause seizures.

The evidence for rTMS in patients who have TRD includes numerous double-blind, randomized sham controlled short-term trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. Results of these trials show small mean improvements across groups as a whole. The percentage of subjects who show a clinically significant response is reported at approximately 2 to 3 times that of sham controls, with approximately 15% to 25% of patients meeting the definition of clinical response. Based on the short-term benefit observed in randomized controlled trials and the lack of alternative treatments, aside from electroconvulsive therapy in patients with TRD, rTMS may be considered a treatment option in patients with TRD who meet specific criteria. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

However, the available peer-reviewed medical literature has not established the effectiveness of rTMS in the treatment of psychiatric disorders. The literature regarding its effectiveness in the treatment of a major depressive disorder (MDD) has both been supportive and non-supportive of the procedure. More

research is clearly needed to ascertain the roles of various stimulation parameters of rTMS for its optimal outcome as well as its long-term effectiveness in the treatment of psychiatric disorders.

The evidence for rTMS in patients who have other psychiatric or neurologic conditions includes numerous small randomized trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. These other conditions include Alzheimer disease, attention-deficit/hyperactivity disorder, amyotrophic lateral sclerosis, bulimia nervosa, chronic pain, epilepsy, fibromyalgia, migraine headache, obsessive compulsive disorder, panic disorder, Parkinson disease, postpartum depression, posttraumatic stress disorder, schizophrenia, stroke, and substance abuse and craving. The available clinical trials are small and report mixed results. There are no large, high-quality trials for any of these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.