



# Louisiana

## Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Policy # 00121

Original Effective Date: 06/05/2002

Current Effective Date: 01/10/2022

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider transcranial magnetic stimulation (TMS) of the brain using an FDA-cleared device and modality, which can include but is not limited to, conventional TMS, deep TMS, and theta burst stimulation (see Policy Guidelines) as a treatment of major depressive disorder to be **eligible for coverage**.\*\*

#### Patient Selection Criteria

Coverage eligibility will be considered for transcranial magnetic stimulation (TMS) of the brain as a treatment of major depressive disorder when **ALL** of the following criteria have been met:

- Confirmed diagnosis of severe major depressive disorder (single or recurrent) documented by standardized rating scales that reliably measure depressive symptoms; **AND**
- Any **ONE** of the following:
  - Failure of 4 trials of psychopharmacologic agents including 2 different agent classes and 2 augmentation trials; **OR**
  - Inability to tolerate a therapeutic dose of medications as evidenced by 4 trials of psychopharmacologic agents with distinct side effects; **OR**
  - History of response to transcranial magnetic stimulation (TMS) in a previous depressive episode (at least 3 months since the prior episode); **OR**
  - Is a candidate for electroconvulsive therapy (ECT); further, electroconvulsive therapy (ECT) would not be clinically superior to transcranial magnetic stimulation (TMS) (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition transcranial magnetic stimulation (TMS) should NOT be utilized);

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### AND

- 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.

## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of transcranial magnetic stimulation (TMS) for major depressive disorder when patient selection criteria are not met is considered to be **investigational**.\*

Based on review of available data, the Company considers continued treatment with transcranial magnetic stimulation (TMS) of the brain as maintenance therapy to be **investigational**.\*

Based on review of available data, the Company considers transcranial magnetic stimulation (TMS) of the brain as a treatment of all other psychiatric/neurologic disorders, including but not limited to bipolar disorder, schizophrenia, obsessive-compulsive disorder (OCD), or migraine headaches to be **investigational**.\*

## Policy Guidelines

Transcranial magnetic stimulation (TMS) should be performed using a U.S. Food and Drug Administration cleared device in appropriately selected patients over age 18 years, by physicians who are adequately trained and experienced in the specific techniques used.

A variety of TMS modalities have been developed, which differ on parameters including stimulation intensity, frequency, pattern, and site of the brain stimulation.

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In conventional TMS, high frequency stimulation is delivered over the left dorsolateral prefrontal cortex (DLPFC) or low frequency stimulation over the right DLPFC. In bilateral TMS, both procedures are performed in the same session.

Theta burst stimulation is administered at lower intensities and at shorter intervals than conventional TMS.

Deep TMS employs an H-coil helmet designed to encompass a broader surface area and stimulate deeper brain structures than conventional TMS.

A treatment course of conventional TMS should not exceed 5 days a week for 6 weeks (total of 30 sessions), followed by a 3-week taper of 3 TMS treatments in week 1, 2 TMS treatments the next week, and 1 TMS treatment in the last week.

Theta burst stimulation may be administered using an accelerated protocol. One example of an accelerated theta burst protocol is the Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) protocol, consisting of 10 daily sessions over 5 consecutive days.

Contraindications to repetitive TMS include:

- Seizure disorder or any history of seizure with increased risk of future seizure; or
- Presence of acute or chronic psychotic symptoms or disorders (eg, schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; or
- Neurologic conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system; or
- Presence of an implanted magnetic-sensitive medical device located 30 centimeters or less from the TMS magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator, pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents.

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The following should be present for the administration of repetitive TMS:

- An attendant trained in basic cardiac life support and the management of complications such as seizures, as well as the use of the equipment must be present at all times; and
- Adequate resuscitation equipment including, eg, suction and oxygen; and
- The facility must maintain awareness of response times of emergency services (either fire/ambulance or “code team”), which should be available within 5 minutes. These relationships are reviewed on at least a 1-year basis and include mock drills.

## **Background/Overview**

### **Transcranial Magnetic Stimulation**

Transcranial magnetic stimulation (TMS), introduced in 1985 as a new method of noninvasive stimulation of the brain, involves placement of a small coil over the scalp, passing a rapidly alternating current through the coil wire, which produces a magnetic field that passes unimpeded through the scalp and bone, resulting in electrical stimulation of the cortex. Transcranial magnetic stimulation was initially used to investigate nerve conduction (eg, TMS over the motor cortex will produce a contralateral muscular-evoked potential). The motor threshold, which is the minimum intensity of stimulation required to induce a motor response, is empirically determined for each person by localizing the site on the scalp for optimal stimulation of a hand muscle, then gradually increasing the intensity of stimulation. Interest in the use of TMS as a treatment for depression was augmented by the development of a device that could deliver rapid, repetitive stimulation. Imaging studies had shown a decrease in the activity of the left dorsolateral prefrontal cortex in depressed patients, and early studies suggested that high-frequency (eg, 5 to 10 Hz) TMS of the left dorsolateral prefrontal cortex had antidepressant effects. In contrast to electroconvulsive therapy (ECT), TMS does not require general anesthesia and does not generally induce a convulsion. Repetitive TMS (rTMS) is also being tested as a treatment for a variety of other psychiatric and neurologic disorders.

Conventional TMS delivers repeated electromagnetic pulses to induce prolonged modulation of neural activity, typically applied over the dorsolateral prefrontal cortex. High-frequency rTMS (usually  $\geq 10$  Hz) induces an increase in neural activity whereas low-frequency TMS (usually  $\leq 1$  Hz) has the opposite effect. If both procedures are performed in the same session, the intervention is described as bilateral rTMS.

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A variety of TMS modalities have been developed, which differ on parameters including stimulation intensity, frequency, pattern, and site of the brain stimulation. Deep TMS employs an H-coil helmet design to encompass a broader surface area and stimulate deeper brain structures than conventional TMS. Theta burst stimulation is administered at lower intensities and shorter intervals than conventional rTMS.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

Devices for transcranial stimulation have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for diagnostic uses (FDA Product Code: GWF). A number of devices subsequently received FDA clearance for the treatment of major depressive disorder in adults who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Some of these devices use deep TMS or theta burst protocols. For example, the Brainsway Deep TMS system was FDA cleared for treatment resistant depression in 2013 based on substantial equivalence to the Neurostar TMS Therapy System, and the Horizon (Magstim) and MagVita (Tonica Elektronik) have FDA clearance for their theta burst protocols.

Indications were expanded to include treating pain associated with certain migraine headaches in 2013, and obsessive-compulsive disorder in 2018.

In 2014, eNeura Therapeutics received 510(k) marketing clearance for the SpringTMS<sup>®</sup>‡ for the treatment of migraine headaches. The device differs from the predicate Cerena<sup>TM</sup>‡ TMS device with the addition of an LCD screen, a use authorization feature, a lithium battery pack, and a smaller size. The stimulation parameters are unchanged. The sTMS Mini (eNeura Therapeutics) received marketing clearance by the FDA in 2016. FDA product code: OKP.

In August 2018, the Deep TMS System (Brainsway) was granted a de novo 510(k) classification by the FDA as an adjunct for the treatment of adult patients with obsessive-compulsive disorder. The new classification applies to this device and substantially equivalent devices of this generic type.

The NeoPulse, now known as NeuroStar<sup>®</sup>‡ TMS, was granted a de novo 510(k) classification by the FDA in 2008. The de novo 510(k) review process allows novel products with moderate or low-risk

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profiles and without predicates, which would ordinarily require premarket approval as a class III device, to be down-classified in an expedited manner and brought to market with a special control as a class II device.

In 2014, the Cerena™‡ TMS device (eNeura Therapeutics) was granted a de novo 510(k) classification by the FDA for the acute treatment of pain associated with migraine headache with aura. Warnings, precautions, and contraindications include the following:

- The device is only intended for patients experiencing the onset of pain associated with a migraine headache with aura.
- The device should not be used:
  - on headaches due to underlying pathology or trauma.
  - for medication overuse headaches.
- The device has not been demonstrated as safe and/or effective:
  - when treating cluster headache or a chronic migraine headache.
  - when treating during the aura phase.
  - in relieving the associated symptoms of a migraine (photophobia, phonophobia, and nausea).
  - in pregnant women, children under the age of 18, and adults over the age of 65.

Table 1 lists some devices that are FDA cleared for major depressive disorder (Product Code: OBP), migraine headache pain (Product Code: OKP), and obsessive-compulsive disorder (Product Code: QCI).

Table 1. Repetitive TMS Devices Cleared by FDA for Major Depression, Migraine, or Obsessive-Compulsive Disorder

Device	Manufacturer	Indication	FDA Clearance No.	FDA Clearance Date
Neurostar	Neuronetics	Major Depressive Disorder	K083538	12/16/2008

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Brainsway Deep TMS System	Brainsway	Major Depressive Disorder	K122288	01/07/2013
		Obsessive-Compulsive Disorder	K183303	03/08/2019
Springtms Total Migraine System	Eneura	Migraine headache with aura	K140094	05/21/2014
Rapid Therapy System	Magstim	Major Depressive Disorder	K143531	05/08/2015
Magvita	Tonica Elektronik	Major Depressive Disorder	K150641	07/31/2015
Mag Vita TMS Therapy System w/Theta Burst Stimulation	Tonica Elektronik	Major Depressive Disorder	K173620	8/14/2018
Neurosoft	TeleEMG	Major Depressive Disorder	K160309	12/22/2016
Horizon	Magstim	Major Depressive Disorder	K171051	09/13/2017
Horizon TMS Therapy System (Theta Burst Protocol)	Magstim	Major Depressive Disorder	K182853	03/15/2019
Nexstim	Nexstim	Major Depressive Disorder	K171902	11/10/2017
Apollo	Mag & More	Major Depressive Disorder	K180313	05/04/2018

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FDA: U.S. Food and Drug Administration; TMS: transcranial magnetic stimulation.

### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Transcranial magnetic stimulation (TMS) is a noninvasive method of delivering electrical stimulation to the brain. The technique involves the placement of a small coil over the scalp and passing a rapidly alternating current through the coil wire. The electrical current produces a magnetic field that passes unimpeded through the scalp and bone and stimulates neuronal function. Repetitive TMS is being evaluated for the treatment of treatment-resistant depression (TRD) and other psychiatric and neurologic disorders. A variety of TMS modalities have been developed, which differ on parameters including stimulation intensity, frequency, pattern, and site of the brain stimulation. In conventional TMS, high frequency stimulation is delivered over the left dorsolateral prefrontal cortex (DLPFC) or low frequency stimulation over the right DLPFC. In bilateral TMS, both procedures are performed in the same session. Deep TMS employs an H-coil helmet designed to encompass a broader surface area and stimulate deeper brain structures than conventional TMS. Theta burst stimulation is administered at lower intensities and shorter intervals than conventional TMS.

### **Summary of Evidence**

For individuals who have TRD who receive TMS, the evidence includes a large number of sham-controlled randomized controlled trials (RCTs) and meta-analyses of these trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. Meta-analyses found improved response rates and rates of remission for conventional TMS and theta burst stimulation compared with sham TMS. Additionally, a head-to-head trial showed noninferiority of theta burst stimulation to conventional TMS, with no difference in the incidence of adverse events. Meta-analyses have concluded that the effect of TMS on average depression scores is smaller than the effect of electroconvulsive therapy (ECT) on TRD and that the mean improvement in depression scores with

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TMS did not reach the minimal clinically important difference; however, clinically meaningful improvements were noted in a subgroup of studies using higher frequency pulses. One potential area of benefit for TMS is in accelerating or enhancing the response to antidepressant medications, and there is some evidence that TMS, when given in conjunction with the initiation of pharmacologic therapy, improves the response rate compared with pharmacologic therapy alone. The effect of TMS appears to be less robust when it is given in combination with a stable dose of antidepressant medication. Meta-analyses have also found that the efficacy of TMS decreases with longer follow-up, though some studies have reported a persistent response up to 6 months in some patients. There is limited evidence to compare the effects of these treatments on cognition, although the adverse events of TMS appear to be minimal. While meta-analyses have reported that the effect of TMS is smaller than the effect of ECT on TRD, because TMS does not require general anesthesia or induce seizures, some individuals may decline ECT so the balance of incremental benefits and harms associated with TMS may be reasonable compared with ECT. Based on the short-term benefit observed in RCTs and the lack of alternative treatments aside from ECT in patients with TRD, TMS may be considered a treatment option in patients with TRD who meet specific criteria. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have migraine headaches who receive TMS, the evidence includes a sham-controlled RCT of 201 patients conducted for submission to the U.S. Food and Drug Administration for clearance in 2013. Relevant outcomes are symptoms, functional outcomes, and quality of life. The trial results were limited by the 46% dropout rate and the use of a post hoc analysis. No recent studies have been identified with these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obsessive-compulsive disorder (OCD) who receive TMS, the evidence includes a number of small-to-moderate sized, sham-controlled, double-blind RCTs and meta-analyses of these studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. A meta-analysis of 15 RCTs (N=483 patients, range 18-65 patients) conducted in 2016 found a benefit of TMS on patient-reported OCD symptom severity at time points ranging from 2 to 6 weeks, but there was substantial variability in the stimulation parameters, including the cortical region that was stimulated and the frequency of stimulation. A meta-analysis conducted in 2021 included 22 RCTs. Three of 5 TMS protocols assessed were significantly more efficacious than sham TMS, and all treatment strategies were similar to sham TMS regarding tolerability. Deep TMS was not more

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effective than sham TMS, but there was direct evidence from only 1 RCT for this comparison. The overall quality of the evidence was rated very low for efficacy and low for tolerability, and the reviewers concluded that high quality RCTs with low selection and performance bias are needed to further verify the efficacy of specific TMS strategies for OCD treatment. The RCT that was the basis of FDA clearance of deep TMS for treatment of OCD compared deep TMS to sham in 99 patients for 6 weeks, with an additional 4 weeks of follow-up as a secondary outcome. Using a modified intention-to-treat (ITT) analysis (n=94), there was a larger mean decrease from baseline (improvement) on the Yale-Brown Obsessive Compulsive Scale (YBOCS) score (the primary efficacy outcome) in the active treatment group (-6.0 points) than the sham group (-2.8 points), translating to a moderate effect size of 0.69. At 6 weeks, the response rate was 38.1% in the active treatment group compared to 11.1% in the sham group (p=.003), as measured by a 30% or greater increase in the YBOCS. The difference in the primary outcome measure between active and sham groups was not statistically significant in the ITT analysis. There was a benefit for TMS on clinician-reported measures of improvement, but no significant difference between groups on patient-reported disability and impairment. Additional trials with sufficient sample size and follow-up duration are needed to confirm these results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have psychiatric or neurological disorders other than depression, migraine, or OCD (eg, amyotrophic lateral sclerosis, chronic pain, epilepsy, fibromyalgia, panic disorder, Parkinson disease, posttraumatic stress disorder, schizophrenia, stroke, substance use disorder, and craving) who receive TMS, the evidence includes numerous small RCTs and meta-analyses of these randomized trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. The trials included in the meta-analyses are typically small and of low methodologic quality. In addition, stimulation parameters have not been established, and trial results are heterogeneous. There are no large, high-quality trials for any of these conditions demonstrating efficacy or the durability of any treatment effects. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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## **Supplemental Information**

### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### **2014 Input**

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2014. Reviewers considered repetitive transcranial magnetic stimulation (rTMS) to be medically necessary for treatment-resistant depression. Input agreed with the proposed criteria for treatment of treatment-resistant depression with repetitive transcranial magnetic stimulation, as included in the policy statement.

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **American Academy of Child and Adolescent Psychiatry**

In 2013, the American Academy of Child and Adolescent Psychiatry published practice parameters on the assessment and treatment of children and adolescents with tic disorders. The Academy did not recommend rTMS, citing the limited evidence on the safety, ethics, and long-term impact on development.

### **American Psychiatric Association**

The American Psychiatric Association (2018) published consensus recommendations on rTMS for the treatment of depression. The guidelines state, "Multiple randomized controlled trials and published literature have supported the safety and efficacy of rTMS antidepressant therapy." The recommendations include information on the following variables: clinical environment, operator

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requirements, documentation, coils, cortical targets, coil positioning methods, determination of motor threshold, number of treatment sessions for acute treatment, and allowable psychotropic medications during TMS treatment.

The American Psychiatric Association's (2007, reaffirmed in 2012) guidelines on the treatment of patients with obsessive-compulsive disorder have indicated that "findings of the 4 published trials of rTMS are inconsistent, perhaps because the studies differed in design, stimulation sites, duration, and stimulation parameters. The available results and the technique's non-invasiveness and good tolerability should encourage future research, but the need for daily treatment may limit the use of TMS in practice."

### **National Institute for Health and Care Excellence**

In 2015, the National Institute for Health and Care Excellence (NICE) provided revised guidance, stating that evidence on the short-term efficacy of rTMS for depression is adequate, although the clinical response is variable and some patients may not benefit.

In 2014, the NICE provided guidance on the use of rTMS for treating and preventing migraine. The guidance stated that evidence on the efficacy of TMS for the treatment of migraine was limited in quantity and for the prevention of migraine was limited in both quality and quantity. Evidence on its safety in the short- and medium-term was adequate, but there was uncertainty about the safety of long-term or frequent use of TMS.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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### Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 2.

**Table 2. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<i>Ongoing</i>			
NCT02977299	Augmentation Versus Switch: Comparative Effectiveness Research Trial for Antidepressant Incomplete and Non-responders With Treatment-Resistant Depression (ASCERTAIN-TRD)	639	Jan 2022
NCT02910024	Theta-Burst-Stimulation in Early Rehabilitation of Stroke (TheSiReS)	150	Feb 2024
NCT02927236	Neuroplasticity Following Theta-Burst Stimulation in Cocaine Use Disorder	170	Dec 2022
NCT03556722	Effectiveness and Tolerability of Repetitive Transcranial Magnetic Stimulation For Preventive Treatment Of Episodic Migraine: A Single Centre, Randomised, Double-Blind, Sham-Controlled Phase 2 Trial	76	Dec 2021

NCT: national clinical trial.

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### **Policy History**

Original Effective Date: 06/05/2002

Current Effective Date: 01/10/2022

- 05/16/2002 Medical Policy Committee review
- 06/05/2002 Managed Care Advisory Council approval
- 06/24/2002 Format revision. No substance change to policy.
- 06/01/2004 Medical Director review
- 06/15/2004 Medical Policy Committee review
- 06/28/2004 Managed Care Advisory Council approval
- 06/07/2006 Medical Director review
- 06/21/2006 Medical Policy Committee approval. Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
- 06/04/2008 Medical Director review
- 06/18/2008 Medical Policy Committee approval. No change to coverage eligibility.

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06/04/2009	Medical Director review
06/17/2009	Medical Policy Committee approval. No change to coverage eligibility.
06/03/2010	Medical Policy Committee review
06/16/2010	Medical Policy Implementation Committee approval. No change to coverage eligibility.
12/31/2010	Coding updated.
06/02/2011	Medical Policy Committee review
06/15/2011	Medical Policy Implementation Committee approval. No change to coverage eligibility.
06/06/2012	Coding updated.
06/14/2012	Medical Policy Committee review
06/20/2012	Medical Policy Implementation Committee approval. No change to coverage eligibility. Added the word “neurologic” to the investigational statement.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage changed from investigational to eligible for coverage with criteria for transcranial magnetic stimulation of the brain for treatment-resistant depression. Continued treatment with transcranial magnetic stimulation of the brain as maintenance therapy and for all other psychiatric/neurologic disorders is investigational.
06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/30/2016	Medical Policy Committee review
07/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis codes
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/02/2017	Medical Policy Committee review

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- 11/15/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Policy Guidelines added to the end of the coverage section.
- 11/08/2018 Medical Policy Committee review
- 11/21/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 12/05/2019 Medical Policy Committee review
- 12/11/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 12/03/2020 Medical Policy Committee review
- 12/09/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 12/02/2021 Medical Policy Committee review
- 12/08/2021 Medical Policy Implementation Committee approval. Removed “repetitive” from transcranial magnetic stimulation in the coverage sections. Eligible for coverage statement on transcranial magnetic stimulation (TMS) for treatment resistant depression revised to specify "using an FDA-cleared device and modality, which can include but is not limited to, conventional TMS, deep TMS, and theta burst stimulation." Information on different modalities including theta burst stimulation added to the Policy Guidelines. Coverage intent unchanged.

Next Scheduled Review Date: 12/2022

### **Coding**

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	90867, 90868, 90869
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with technology evaluation center(s);

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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