LOUISIANA BLUE

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

Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 03/01/2026

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 in individuals aged 15 and older to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility may be considered for TMS of the brain as a treatment of major depressive disorder in individuals aged 15 and older when **ALL** of the following criteria have been met (see Policy Guidelines section for treatment protocols and contraindications):

- 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:
    - Individual has tried and had an inadequate response to 2 antidepressant agents from 2 different antidepressant classes (i.e., selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, tricyclic antidepressants, bupropion, or mirtazapine). An adequate trial of an antidepressant is defined by **BOTH** of the following:
        - The trial length was at least 6 weeks at generally accepted doses or of sufficient duration as determined by the treating physician at the generally accepted doses; **AND**
        - Individual was ≥80% adherent to the agent during the trial; or
    - Inability to tolerate a therapeutic dose of medications due to distinct side effects; or
    - History of response to TMS in a previous depressive episode (at least 3 months since the prior episode) demonstrated by at least 50% improvement in symptoms as documented by standardized rating scale; or

- Is a candidate for electroconvulsive therapy; further, electroconvulsive therapy would not be clinically superior to TMS (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition TMS should NOT be used);

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 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 or booster treatments to be **investigational.***

Based on review of available data, the Company considers subsequent treatment with transcranial magnetic stimulation (TMS) of the brain for any of the following situations to be **investigational*:**

- Lack of response to a prior episode of repetitive TMS or deep TMS treatments as defined by not achieving at least a 50% reduction in severity of scores for depression on a standardized rating scale by the end of acute phase treatment; OR
- For novel delivery mechanisms (i.e., multiple TMS sessions per day).

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

PHQ-9 is a widely used, validated, and standardized rating scale for assessing depression severity. It consists of 9 items based on DSM criteria for major depressive disorder. Each item is scored 0-3, giving a total score of 0-27. Interpretation of total score:

- 0-4: Minimal depression
- 5-9: Mild depression

- 10-14: Moderate depression
- 15-19: Moderately severe depression
- 20-27: Severe depression

Transcranial magnetic stimulation (TMS) should be performed using a U.S. Food and Drug Administration cleared device in appropriately selected individuals over age 15 years, by health care professionals 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.

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 usually does not exceed 5 days a week for 6 weeks (total of 30 sessions), however the treatment plan can be individualized depending on the type of device used, safety and side effect considerations and response to treatment.

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:

a. Seizure disorder or any history of seizure with increased risk of future seizure; or
b. Presence of acute or chronic psychotic symptoms or disorders (eg, schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; or
c. 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
d. Excessive use of alcohol or illicit substances withing the last 30 days may increase seizure risk during TMS; or
e. 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.

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

a. 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
b. Adequate resuscitation equipment including, eg, suction and oxygen; and
c. 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 ≥10 Hz) induces an increase in neural activity whereas low-frequency TMS (usually ≤1 Hz) has the opposite effect. If both procedures are performed in the same session, the intervention is described as bilateral rTMS.

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.

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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®‡ for the treatment of migraine headaches. The device differs from the predicate Cerena™‡ 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®‡ 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 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.

The FDA has cleared multiple rTMS systems for adjunctive treatment of major depressive disorder in adolescents aged 15 to 21, including the NeuroStar Advanced Therapy System (K231926), the Magstim Horizon (K243869), and the MagVenture (K251125) stimulators.

In 2022, the Magnus Neuromodulation System (NMS) with Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) Technology (Magnus Medical, Inc.) received approval to treat major depressive disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

In 2024, NeuroStar (Neuronetics, Inc) received approval to treat major depressive disorder in adolescents. This is the first and only device approved for adolescents, and it must be used as an augmentation agent in connection with antidepressant medications.

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 Transcranial Magnetic Stimulation Devices Cleared by the U.S. Food and Drug Administration for Major Depression, Migraine, or Obsessive-Compulsive Disorder

Device	Manufacturer	Indication	FDA Clearance No.	FDA Clearance Date
MagVenture TMS Therapy System	Tonica Elektronik	Major depressive disorder and obsessive-compulsive disorder	K193006	08/09/2020
Ultimate rTMS for OCD (M-series)	Brain Ultimate, Inc.	Major depressive disorder and obsessive-compulsive disorder	K230735	09/13/2023
CloudTMS Edge for OCD	TeleEMG, LLC	Obsessive-Compulsive Disorder	K233742	12/22/2023

Savi Dual™‡ Migraine Therapy	ENeura	Migraine (acute and prophylactic treatment in individuals ≥12 years of age)	K230358	05/16/2023
Horizon 3.0 TMS Therapy System	Magstim	Major depressive disorder and obsessive-compulsive disorder	K222171	01/13/2023
ALTMS Magnetic Stimulation Therapy System	REMED Co., Ltd	Major depressive disorder	K220625	04/06/2022
Neurostar	Neuronetics	Major Depressive Disorder	K083538	12/16/2008
		Obsessive-Compulsive Disorder	K212289	05/06/2022
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

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 regulations, other plan medical policies, and accredited national guidelines.

Description

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 the passing of 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 treatment-resistant depression (TRD) who receive transcranial magnetic stimulation (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 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 systematic review (n=8 trials) and a sham-controlled RCT of 201 patients conducted for submission to the Food and Drug Administration (FDA) for clearance in 2013. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review found that repetitive TMS (rTMS) reduced migraine pain intensity and frequency compared to sham; it was unclear whether patients were receiving background pharmacotherapy. 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 to 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 26 RCTs. The primary analysis found a significant effect of rTMS compared to sham on OCD symptoms, but the effect seemed to last only until 4 weeks after the last 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, bipolar disorder, generalized anxiety disorder, panic disorder, posttraumatic stress disorder, schizophrenia, substance use disorder and craving, amyotrophic lateral sclerosis, chronic pain, epilepsy, fibromyalgia, Parkinson disease, stroke recovery) 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.

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 rTMS, 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 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."

Veteran's Affairs/Department of Defense
The 2022 Veteran's Affairs/Department of Defense (VA/DoD) guideline for management of major depressive disorder recommends offering rTMS to patients who have experienced partial response or no response to an adequate trial of 2 or more pharmacologic treatments (strength of recommendation: weak). Recommended options for the second treatment attempt after the initial therapy tried include switching to another antidepressant or adding augmentation therapy with a second-generation antipsychotic. The recommendation for rTMS was graded as weak due to limitations of the available literature including small study effects, high rates of discontinuation, lack of allocation concealment, and the practical limitations of the need for daily treatment and lack of widespread access to facilities that offer this therapy. The guideline also concluded that there is limited evidence to recommend for or against theta-burst stimulation for treatment of depression.

The 2023 VA/DoD guideline for management of bipolar disorder states "for individuals with bipolar disorder who have demonstrated partial or no response to pharmacologic treatment for depressive symptoms, we suggest offering repetitive transcranial magnetic stimulation [rTMS] as an adjunctive treatment." However, the recommendation was rated as "weak" and the confidence in the evidence was very low. For the management of PTSD, the 2023 guideline found insufficient evidence for or against rTMS.

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.

In 2020, the NICE stated that rTMS has not demonstrated any major safety concerns for management of obsessive-compulsive disorder or auditory hallucinations, but evidence for both uses is lacking; therefore, NICE recommends that rTMS be used in patients with these conditions only in the context of research.

International Neuromodulation Society/North American Neuromodulation Society
In 2020, an expert consensus panel from the International Neuromodulation Society-North American Neuromodulation Society performed a literature review and published recommendations for transcranial magnetic stimulation in the treatment of pain and headache. For neuropathic pain, the panel recommended transcranial magnetic stimulation to the primary motor cortex (high level evidence) or the left dorsolateral prefrontal cortex (F3 location) (at least moderate level evidence). For postoperative pain, the panel recommended that transcranial magnetic stimulation to the F3 location be only selectively offered due to at least moderate certainty that the net benefit is small. For primary headache, the panel only based 2 recommendations on moderate certainty evidence: single transcranial magnetic stimulation for acute migraine and high-frequency rTMS to the primary motor cortex for migraine prevention. For posttraumatic brain injury, high level evidence supported a recommendation for high-frequency transcranial magnetic stimulation to the primary motor cortex or the F3 location.

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.

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT02910024	Theta-Burst-Stimulation in Early Rehabilitation of Stroke (TheSiReS)	150	Sep 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	Apr 2022
Ongoing			
NCT06545474	Repetitive Transcranial Magnetic Stimulation (rTMS) as an Early Intervention in Major Depression (MD) Compared to Antidepressant Selective Serotonin Reuptake Inhibitor (SSRI) Medication (Early-TMS)	106	Dec 2026
NCT06370988	Theta-Burst Stimulation for Bipolar Depression	124	May 2029
NCT06524505	Efficacy, Tolerability, and Cognitive Effects of Deep Transcranial Magnetic Stimulation for Bipolar Depression: a Double-blind, Randomized Controlled Trial	100	Oct 2024
NCT05389670	Theta-burst Repetitive Transcranial Magnetic Stimulation (TBS) of the Right Inferior Frontal Gyrus for Treatment of Nicotine Dependence	60	Apr 2026
NCT05331937	Transcranial Magnetic Stimulation (TMS) for Patients With Exposure Therapy-resistant Obsessive-compulsive Disorder (OCD): TETRO - a Multicenter Randomized Controlled Trial	250	Sep 2027
NCT05100888	Theta-burst rTMS in Schizophrenia to Ameliorate Negative and Cognitive Symptoms: a Double-blind, Randomized Clinical Trial	90	Dec 2025

NCT: national clinical trial.

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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.
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
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.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. Minor editorial refinements to policy statements. Coverage eligibility unchanged.
10/05/2023	Medical Policy Committee review
10/11/2023	Medical Policy Implementation Committee approval. Specified adults as a treatment of major depressive disorder in the When Services May Be Eligible for Coverage section. Reference to Policy Guidelines in the coverage section. Revised coverage criteria.
06/14/2024	Coding update
10/03/2024	Medical Policy Committee review

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10/08/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/04/2025	Medical Policy Committee review
12/10/2025	Medical Policy Implementation Committee approval. Added a requirement for demonstrated improvement of least 50% or more in symptoms as documented by standardized rating scale to the criteria bullet for history of response to transcranial magnetic stimulation in a previous depressive episode. Added booster treatments to the investigational statement for continued treatment with transcranial magnetic stimulation of the brain as maintenance therapy. Added subsequent treatment with transcranial magnetic stimulation of the brain with criteria as investigational. Added the PHQ-9 standardized rating scale to the Policy Guidelines section. Lowered the age requirement from 18 to 15 years for transcranial magnetic stimulation with a U.S. FDA cleared device in the coverage with criteria and Policy Guidelines sections. Added a contraindication to repetitive transcranial magnetic stimulation for excessive alcohol use or illicit substances.

Next Scheduled Review Date: 12/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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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	0889T, 0890T, 0891T, 0892T, 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);
    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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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.