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

Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 12/11/2019

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 repetitive transcranial magnetic stimulation (rTMS) of the brain as a treatment of major depressive disorder to be eligible for coverage.**

Patient Selection Criteria
Coverage eligibility will be considered for repetitive transcranial magnetic stimulation (rTMS) 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 repetitive transcranial magnetic stimulation (rTMS) 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 repetitive transcranial magnetic stimulation (rTMS) (e.g., in cases with psychosis, acute suicidal risk, catatonia or

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- Life-threatening inanition repetitive transcranial magnetic stimulation (rTMS) should NOT be utilized;

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 repetitive transcranial magnetic stimulation (rTMS) 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 repetitive transcranial magnetic stimulation (rTMS) of the brain as maintenance therapy to be investigational.*

Based on review of available data, the Company considers repetitive transcranial magnetic stimulation (rTMS) 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
Repetitive transcranial magnetic stimulation (TMS) should be performed using a U.S. Food and Drug Administration-cleared device in appropriately selected patients, 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 TMS treatments in week 1, 2 TMS treatments the next week, and 1 TMS treatment in the last week.
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, schizophréniform 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. 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. TMS 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. The stimulation site for the treatment of depression is usually 5 cm anterior to the motor stimulation site.
Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 12/11/2019

In contrast to electroconvulsive therapy, TMS does not require general anesthesia and does not generally induce a convulsion. 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 (e.g., 5-10 Hz) TMS of the left dorsolateral prefrontal cortex had antidepressant effects. Low-frequency (1-2 Hz) stimulation of the right dorsolateral prefrontal cortex has also been investigated. The rationale for low-frequency TMS is inhibition of right frontal cortical activity to correct the interhemispheric imbalance. A combination approach (bilateral stimulation), or deep stimulation with an H1 coil, is also being explored, as is theta burst stimulation.

Repetitive TMS is also being tested as a treatment for a variety of other disorders. In addition to the potential for altering interhemispheric imbalance, it has been proposed that high-frequency repetitive TMS may facilitate neuroplasticity.

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

In 2008, The NeoPulse, now known as NeuroStar® TMS, was granted a de novo 510(k) classification by the FDA. 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.
Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 12/11/2019

In 2013, 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 a 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.

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.

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

Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 12/11/2019

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Indication</th>
<th>FDA Clearance No.</th>
<th>FDA Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurostar</td>
<td>Neuronetics</td>
<td>Major Depressive Disorder</td>
<td>K083538</td>
<td>12/16/2008</td>
</tr>
<tr>
<td>Brainsway Deep TMS System</td>
<td>Brainsway</td>
<td>Major Depressive Disorder</td>
<td>K122288</td>
<td>01/07/2013</td>
</tr>
<tr>
<td>Springtms Total Migraine</td>
<td>Eneura</td>
<td>Migraine headache with aura</td>
<td>K140094</td>
<td>05/21/2014</td>
</tr>
<tr>
<td>System</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rapid Therapy System</td>
<td>Magstim</td>
<td>Major Depressive Disorder</td>
<td>K143531</td>
<td>05/08/2015</td>
</tr>
<tr>
<td>Magvita</td>
<td>Tonica Elektronik</td>
<td>Major Depressive Disorder</td>
<td>K150641</td>
<td>07/31/2015</td>
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</tbody>
</table>

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Policy # 00121
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Current Effective Date: 12/11/2019

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Diagnosis</th>
<th>Code</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurosoft</td>
<td>TeleEMG</td>
<td>Major Depressive Disorder</td>
<td>K160309</td>
<td>12/22/2016</td>
</tr>
<tr>
<td>Horizon</td>
<td>Magstim</td>
<td>Major Depressive Disorder</td>
<td>K171051</td>
<td>09/13/2017</td>
</tr>
<tr>
<td>Nexstim</td>
<td>Nexstim</td>
<td>Major Depressive Disorder</td>
<td>K171902</td>
<td>11/10/2017</td>
</tr>
<tr>
<td>Apollo</td>
<td>Mag &amp; More</td>
<td>Major Depressive Disorder</td>
<td>K180313</td>
<td>05/04/2018</td>
</tr>
<tr>
<td>Brainsway Deep TMS System</td>
<td>Brainsway</td>
<td>Obsessive-Compulsive Disorder</td>
<td>K183303</td>
<td>03/08/2019</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration; TMS: transcranial magnetic stimulation.
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.
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**Rationale/Source**

Transcranial magnetic stimulation (TMS) is a noninvasive method of delivering electrical stimulation to the brain. TMS 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 that stimulate neuronal function. Repetitive TMS (rTMS) is being evaluated for the treatment of treatment-resistant depression (TRD) and other psychiatric and neurologic disorders.
Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Policy #  00121
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For individuals who have TRD who receive rTMS, the evidence includes a large number of sham-controlled randomized trials and meta-analyses of these trials. The relevant outcomes are symptoms, functional outcomes, and quality of life. The meta-analyses found a clinical benefit associated with rTMS for TRD with improved response rates and rates of remission compared with sham. The most recent meta-analyses have concluded that the effect of rTMS, on average depression scores, is smaller than the effect of electroconvulsive therapy (ECT) on TRD and that the mean improvement in depression scores with rTMS 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 rTMS is in accelerating or enhancing the response to antidepressant medications, and there is some evidence that rTMS, when given in conjunction with the initiation of pharmacologic therapy, improves the response rate compared with pharmacologic therapy alone. The effect of rTMS 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 rTMS decreases with longer follow-up, though some studies have reported persistent response up to six months in some patients. There is limited evidence to compare the effects of these treatments on cognition, although the adverse events of rTMS appear to be minimal. While the most recent meta-analyses have reported that the effect of rTMS is smaller than the effect of ECT on TRD, because rTMS does not require general anesthesia or induce seizures, some individuals may decline ECT so the balance of incremental benefits and harms associated with rTMS may be reasonable compared with ECT. Based on the short-term benefit observed in randomized controlled trials (RCTs) and the lack of alternative treatments, aside from ECT in patients with TRD, rTMS may be considered a treatment option in patients with TRD who meet specific criteria. The evidence for thetaburst stimulation includes a large randomized trial showing noninferiority with another method of rTMS; no significant differences were noted in the number of adverse events. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have migraine headaches who receive rTMS, the evidence includes a sham-controlled RCT of 201 patients conducted for submission to the Food and Drug Administration for clearance in 2013. 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 the effects of the technology on health outcomes.
Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 12/11/2019

For individuals who have obsessive-compulsive disorder who receive rTMS, the evidence includes a number of small-to-moderate sized sham-controlled RCTs and a meta-analysis of these studies. The meta-analysis of 15 RCTs (total n=483 patients, range 18-65 patients) found a benefit of rTMS on patient-reported obsessive-compulsive disorder 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 more recent RCT compared deep rTMS to sham in 99 patients for 6 weeks, with an additional 4 weeks of follow-up as a secondary outcome. Using a modified ITT analysis (n=94), there was a larger mean change from baseline on the primary efficacy outcome; Yale-Brown Obsessive Compulsive Scale score 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=0.003), as measured by a 30% or greater decrease in the Yale-Brown Obsessive Compulsive Scale. 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 rTMS 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 the effect of the technology on health outcomes.

For individuals who have psychiatric or neurological disorders other than depression, migraine, or obsessive-compulsive disorder (e.g., amyotrophic lateral sclerosis, chronic pain, epilepsy, fibromyalgia, panic disorder, Parkinson disease, posttraumatic stress disorder, schizophrenia, stroke, substance use disorder and craving) who receive rTMS, the evidence includes numerous small RCTs and meta-analyses of these randomized trials. The 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 the effects of the technology on health outcomes.
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Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 12/11/2019

**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.

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 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**

**American Psychiatric Association**
The American Psychiatric Association (2018) published consensus recommendations on repetitive transcranial magnetic stimulation (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 four published trials of repetitive TMS (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.”
Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Policy #  00121
Original Effective Date:  06/05/2002
Current Effective Date:  12/11/2019

American Academy of Child and Adolescent Psychiatry
The American Academy of Child and Adolescent Psychiatry (2013) 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.

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (2015) 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.

The Institute (2014) 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.

American Academy of Neurology
The American Academy of Neurology (2006) issued practice guidelines on the evaluation and treatment of depression, psychosis, and dementia in Parkinson disease. The guidelines found the evidence insufficient to support or refute the efficacy of TMS or electroconvulsive therapy in the treatment of depression associated with Parkinson disease (level U; data inadequate or conflicting given current knowledge, treatment is unproven).

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

Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 12/11/2019

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Unpublished</strong></td>
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<tr>
<td>NCT02376491</td>
<td>Efficacy of Intermittent Theta Burst Stimulation Compared to 10 Hz Stimulation on Dorsolateral Prefrontal Cortex in Treatment-Resistant Major Depressive Disorder: a Double-blind Randomized Study</td>
<td>60</td>
<td>Mar 2019</td>
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<tr>
<td>NCT03762746</td>
<td>TMS for Treatment-Resistant Auditory Verbal Hallucination in Schizophrenia</td>
<td>40</td>
<td>Feb 2019</td>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>NCT02977299</td>
<td>Augmentation Versus Switch: Comparative Effectiveness Research Trial for Antidepressant Incomplete and Non-responders</td>
<td>639</td>
<td>Jan 2022</td>
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</table>
Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 12/11/2019

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Description</th>
<th>Participants</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT03289923</td>
<td>Concurrent fMRI-guided rTMS and Cognitive Therapy for the Treatment of Major Depressive Episodes</td>
<td>50</td>
<td>Jan 2020</td>
</tr>
<tr>
<td>NCT02910024</td>
<td>Theta-Burst-Stimulation in Early Rehabilitation of Stroke (TheSiReS)</td>
<td>150</td>
<td>Feb 2021</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

References
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Page 15 of 23
Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

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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.
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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
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
11/08/2018 Medical Policy Committee review
12/05/2019 Medical Policy Committee review

Next Scheduled Review Date: 12/2020
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Coding

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

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>90867, 90868, 90869</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

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

Policy # 00121
Original Effective Date: 06/05/2002
Current Effective Date: 12/11/2019

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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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