Medical Coverage Policy

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Transcranial Magnetic Stimulation

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Coverage Policy

An initial regimen of transcranial magnetic stimulation (TMS) using an FDA approved device is considered medically necessary when an individual meets ALL of the following criteria:

- age 18 years or older
- diagnosis of major depressive disorder (unipolar), moderate-to-severe, single or recurrent episode or acute relapse, without psychosis, as defined by the most recent edition of Diagnostic and Statistical Manual of Mental Disorders
- during the index or current episode of depression ALL of the following criteria are met:
  - a total of at least three trials of antidepressant medications, at adequate therapeutic doses, from at least two different classes of antidepressant medications for at least four weeks and/or documentation that the individual has been unable to complete an adequate medication trial due to intolerance of or medical contraindication to a particular medication or class of medication.
  - no significant reduction in depressive symptoms following pharmacotherapy as documented by validated depression monitoring scales
  - had an adequate trial of an evidence-based psychotherapy known to be effective in the treatment of major depressive disorder, without significant improvement in depressive symptoms, as documented by validated depression monitoring scales

Repeat transcranial magnetic stimulation (TMS) for a recurrence or an acute relapse of major depressive disorder is considered ~~as~~ medically necessary when BOTH of the following criteria are met:

- all of the above criteria for initial TMS therapy were met prior to the initial course of TMS
- individual had more than a 50% improvement in prior TMS treatments as evidenced by standard rating scale for depressive symptoms

Transcranial magnetic stimulation (TMS) for any other indication, including but not limited to migraine headaches or as a maintenance therapy, it is considered experimental, investigational or unproven.

Overview

This Coverage Policy addresses transcranial magnetic stimulation (TMS) for the treatment of major depressive disorder and other conditions.

General Background

Transcranial Magnetic Stimulation (TMS) for Depression

Standard treatments for major depressive disorder (MDD) include psychotherapy, pharmacotherapy, and/or electroconvulsive therapy (ECT). Although the majority of individuals respond to standard treatments for depression, some do not benefit, or cannot tolerate these interventions. Therefore, alternate treatment options are being investigated, including transcranial magnetic stimulation (TMS), vagal nerve stimulation, cranial electrical stimulation and herbal/homeopathic remedies (Miniussi, et al., 2005).

TMS uses brief magnetic field pulses to stimulate nerve cells in the brain. Standard TMS is typically applied with an electromagnetic coil called a figure-of-eight coil (8-coil). Deep TMS can be applied with different types of coils: the H-coil, the C-core coil and the circular crown coil. The only deep TMS coil whose safety and effectiveness has been tested in clinical trials is the H-coil. During the TMS procedure, clinicians place a large electromagnetic coil on the patient's scalp near the forehead. The electromagnetic current repeatedly switches on and off for up to 10 times per second to produce the pulses. To determine the therapeutic magnetic strength, the amount of magnetic energy is adjusted until the motor threshold is reached (i.e., the patient's fingers or hands start to twitch). It has been proposed that the stimulation is intended to alter brain activity in areas responsible for mood. TMS is less invasive than vagal nerve stimulation and is not intended to induce seizures like electroconvulsive therapy (ECT). TMS may cause some short-term side effects such as headache, tingling of facial muscles, scalp discomfort, lightheadedness, or discomfort from the noise that the device makes. Hearing loss and seizures have been reported as uncommon side effects. Symptom relief may not take place for several weeks (Bersani, et al., 2013).

Although the evidence investigating transcranial magnetic stimulation (TMS) for the treatment of major depressive disorder (MDD) primarily consists of small patient populations and short-term follow-ups, some randomized controlled trials have reported that TMS had better outcomes than sham therapy and in some studies outcomes were reported as good as electroconvulsive therapy (ECT) with fewer side effects. As a result, TMS has become an established treatment option for a carefully selected subset of patients with MDD.

Initial TMS is a treatment option for a patient who is age 18 years or older and has a diagnosis of unipolar, depressive disorder, moderate-to-severe, single or recurrent episode or acute relapse, without psychosis, as defined by the most recent edition of the Diagnostic and Statistical Manual (DSM) of Mental Disorders. Potential TMS candidates are those patients who have failed at least three trials of antidepressant medications, at adequate therapeutic doses, including at least two different classes for a period of at least four weeks. The regimen should have included one or more anti-depressant medications. Antidepressant classes include: selective serotonin reuptake inhibitors (SSRIs; e.g., sertraline, fluoxetine), serotonin-norepinephrine reuptake inhibitors (SNRIs; e.g., desvenlafaxine, duloxetine), tricyclic antidepressants (TCAs; e.g., amitriptyline, nortriptyline, desipramine) and monoamine oxidase inhibitors (MAOIs; e.g., isocarboxazid, phenelzine) and may be given in combination regimens. Following pharmacotherapy, TMS candidates are those who demonstrate no significant reduction in depressive symptoms which is documented by results of validated depression monitoring scales (e.g., Patient Health Questionnaire [PHQ-9], Beck Depression Inventory [BDI], Hamilton Depression

Rating Scale [HAM-D], Montgomery-Asberg Depression Rating Scale [MADRS], Quick Inventory of Depressive Symptomatology Self-reported [QIDS], Inventory of Depressive Symptomatology Clinician-rated [IDS-SR score]). Adherence to the medication should be documented or it should be documented if the patient has intolerance to the medication or could not take the medication due to medical contraindications (Rachid, 2017; Lyness, 2015; Trivedi, 2015; FDA, 2014).

A major depressive episode as defined in the DSM-5 implies a prominent and relatively persistent (e.g., nearly every day for at least two weeks) depressed or dysphoric mood that represents a change from previous functioning, and includes at least five of the following nine symptoms, one of which is either of the first two symptoms (Institute for Clinical Systems Improvement [ICSI], 2016; Neuronetics, Inc., 2015):

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

TMS should also be preceded by evidenced-based psychotherapy (e.g., cognitive behavioral psychotherapy, interpersonal psychotherapy, psychodynamic therapy) known to be effective for the treatment of depression. TMS candidates are those who do not show significant improvement on depression monitoring scales following psychotherapy. Adequate therapy may include at least one weekly session for at least 12 weeks. A face-to-face psychiatric evaluation that establishes that the diagnostic criteria are met for major depressive disorder should be performed and documented. An assessment of currently prescribed medications and a medical assessment to evaluate for any medical conditions that might increase the risks associated with TMS and/or the presence of contraindications to TMS are indicated. The patient should be educated regarding potential risks and benefits of the procedure. Because TMS may be associated with an increased risk of a seizure, the benefits of TMS use must be carefully considered against the risk in individuals taking medications which may lower the seizure threshold (Holtzheimer, 2015; Hayes, 2014; reviewed 2017).

A history of a favorable response to TMS in a previous episode of depression with more than a 50% improvement is predictive of a favorable TMS outcome (Holtzheimer, 2015; Lebow, et al., 2015; Hayes, 2014; FDA, 2014; O'Reardon, et al., 2007).

The initial course of TMS typically includes up to 30 visits over a 4–6 week period and may be followed by six tapered treatments over a three week period. Treatment will last for 30–60 minutes, and the entire session may take up to two hours. TMS is administered in an outpatient setting by a Board-certified or Board-eligible psychiatrist who has completed specialized training that results in certification for TMS administration. The procedure does not require anesthesia.

Repeat treatments may be appropriate for acute relapse or recurrence when the patient experienced more than a 50% improvement in the initial TMS regimen as noted by standard rating scales used to measure depressive symptoms (e.g. Patient Health Questionnaire [PHQ-9], Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HAM-D], Montgomery-Asberg Depression Rating Scale [MADRS], Quick Inventory of Depressive Symptomatology Self-reported [QIDS], Inventory of Depressive Symptomatology Clinician-rated [IDS-SR score]) (Holtzheimer, 2015; Fitzgerald, et al., 2013; Mantovan, et al., 2012a; Jacicak, et al., 2010).

Maintenance TMS has been proposed, but maintenance regimens have not been established and reported outcomes are conflicting. One study suggested that clustered TMS maintenance (five sessions over two days, done once a month) prevented relapse better than no maintenance. Another study reported that a single, monthly TMS session showed no advantage over observation only. There is a lack of evidence supporting the long-term, maintenance effects of TMS. Studies are primarily in the form of case series and retrospective

reviews with small patient populations (Philip, et al., 2016; Hayes, 2016; Health Quality Ontario, 2016; Holtzheimer, 2015; Fitzgerald, et al., 2013).

Several variations of administering repetitive TMS to patients with major depression have been studied including: accelerated repetitive TMS, high-dose repetitive TMS, theta-burst repetitive TMS, deep-repetitive TMS, low frequency rTMS (LFrTMS) (1 Hz) and bilateral repetitive TMS (Holtzheimer, 2015). A recent review of the evidence for TMS treatment of depression states that studies are being conducted to test a weak oscillating TMS device that is proposed to not cause seizures and therefore might enable home delivery of TMS for the treatment of schizophrenia and depression (George, et al., 2013). Currently, TMS is not recommended for use in the home nor are the devices FDA approved for in-home use.

While the majority of clinical trials on TMS have evaluated its use in depression, numerous other conditions have also been studied, including, but not limited to: Parkinson's disease, post-traumatic stress disorder, acute ischemic stroke, obsessive-compulsive disorders, schizophrenia, alcohol dependence, tinnitus, migraines, chronic neuropathic pain, and spinal cord injury. There is insufficient published evidence to support the effectiveness of TMS for these other conditions nor are the devices FDA approved for these indications.

U.S. Food and Drug Administration (FDA)
Transcranial Magnetic Stimulation (TMS) systems are FDA 510(k) approved as Class II devices. In July 2011, the FDA issued a Class II TMS guidance detailing special controls that should be combined with general controls to ensure safety and effectiveness of rTMS systems for treatment of patients with MDD.

The Neurostar TMS Therapy® System (Neuronetics, Inc., Malvern, PA) was one of the first systems to be approved by the FDA. The System was originally FDA approved in 2008. Labeling was updated and approved in 2013 to comply with the FDA 2011 TMS guidance. In 2014, based upon the outcomes of a randomized controlled trial (n=197) (George, et al., 2010), a new 510(k) approval was issued to "expand the indicated population in major depression to adult patients who have failed to benefit from one or more prior antidepressant medications in the current episode". The 2016 indications for use state that the "NeuroStar TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. The FDA's Neurological Devices Panel reviewed Neuronetics' research comparing the NeuroStar TMS Therapy System device with electroconvulsive therapy (ECT) and concluded that the research did not establish a risk-to-benefit profile that was comparable to the risk to benefit profile of the predicate device, ECT, because effectiveness had not been demonstrated. The Panel agreed that the safety profile of the device was better than that of ECT devices, but concluded that additional study was necessary to establish the device's effectiveness (FDA, 2008-2016).

Examples of other approved devices include:

- Brainsway Deep TMS System (Brainsway LTD., Jerusalem, Israel) - intended for the treatment of depressive episodes in adult patients suffering from MDD who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode
- Rapid Therapy System (Magstim Company, LTD., Philadelphia, PA) - indicated for the treatment of major depressive disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode
- MagVita TMS Therapy System (Tonica, Elektroni A/S, Farnum, Denmark) - indicated for the treatment of major depressive disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode

Literature Review–Depression
Systematic reviews and randomized controlled trials evaluating the safety and efficacy of TMS for treatment-resistant, major depressive disorder in adults have been reported. Studies have compared TMS to electroconvulsive therapy (ECT) (Ren, et al., 2014; Berlim et al., 2013b; Minichino, et al., 2012; Keshtkar, et al., 2011; Hansen, et al., 2011; Mcloughlin, et al., 2007; Eranti, et al., 2007; Rosa, et al., 2006) and TMS to sham (Liu, et al., 2014; Gaynes, et al., 2014; Allan, et al., 2011; Ray, et al., 2011; Pallanti, et al., 2010; Triggs, et al., 2010; Schutter, et al., 2009; Lam, et al., 2008; Mogg, et al., 2008; O'Reardon, et al., 2007; Herwig et al., 2007; Hermann, et al., 2006; Fitzgerald, et al., 2006a; Machii, et al., 2006). Prospective case series have also

investigated TMS as a therapeutic option for treatment-resistant depression (Dunner, et al., 2014; Carpenter, et al., 2012; Mantovani, et al., 2012a; Janicak, et al., 2010; Avery et al., 2008).

Outcome measures varied and included the Clinical Global Impressions-Severity of Illness scale (CGSI), patient reported inventory of Depressive Symptoms Self Report (IDS-SR), 9-Item Patient Health Questionnaire (PHQ-9), Clinical Global Impressions-Severity of Illness Scale (CGI-S), Hamilton Depression Rating Scale (HDRS), Beck Depression Inventory-II, visual analogue mood scales (VAMS), and Brief Psychiatric Rating Scale. Reduction in depressive symptoms, suicide ideation and remission of depression were reported.

Although there are conflicting results, overall improvement or remission of symptoms of depression and/or suicidal tendencies following TMS were reported, especially when TMS was compared to sham. Other studies reported better outcomes with ECT. However, some studies reported that response and remission rates following TMS were as good as ECT with fewer side effects. TMS adverse events, which were typically mild and transient, included headache and localized discomfort/pain of the scalp during stimulation. In rare cases seizures and psychotic symptoms were reported following TMS. Studies were limited by small patient populations, short-term follow-ups and heterogeneity of treatment regimens. Additional research is needed to define optimal TMS treatment protocols. Peer-reviewed, published studies supporting TMS as a maintenance therapy and as a treatment option for young people less than age 18 years are lacking.

Kedzior et al. (2015) conducted a systematic review and meta-analysis of sixteen randomized controlled trials (RCTs) to investigate the durability of the antidepressant effect of high frequency rTMS (n=253) compared to sham (n=242). Included studies had a follow-up period during which maintenance rTMS was not administered and all subjects were on anti-depressant medications. Durability was defined as the long-term effect of rTMS (tested during follow-up phases in the absence of maintenance treatment). The aim was to assess a continuous outcome (mean depression ratings on standardized scales) instead of response rates. The antidepressant effect of rTMS during follow-up decreased over time and tended to be lower in RCTs with follow-up phases of 8–16 weeks compared to 1–4 weeks. A higher reduction in depression scores was associated with shorter duration of depression, outpatient status and unipolar, nonpsychotic depression. Author-noted limitations of the meta-analysis included: there were too few RCTs with unmedicated patients to disentangle the role of antidepressants from that of rTMS in reducing depression; lack of blinding of patients and reasons that patients dropped out of studies; most RCTs did not report whether any changes in medication occurred after the acute phases; and the data did not allow comparison of the rates of response, remission, and acceptability of rTMS. The results showed that once achieved, rTMS had acute and longer term antidepressant properties in the absence of maintenance treatment.

Leggett et al. (2015) conducted a systematic review of the literature to evaluate rTMS for treatment-resistant depression in young people, ages 13–25 years. Three prospective cohort studies with small patient populations (n=7–9) met inclusion criteria. Follow-ups ranged from one month to three years. Anxiety levels based on the Screen for Child Anxiety-Related Disorders Questionnaire were significantly lower but no significant difference was reported in the Suicide Ideation Questionnaire. The three-year study was a follow-up of an earlier study and suggested that the subjects did not experience worsening or improvement in depression severity over time without repeat rTMS. The third study reported a decrease in the mean Children's Depression Rating Scale. Meta-analysis was not possible due to the limited data. The limited number and the low quality of the studies restrict the ability to draw generalized conclusions about the use of rTMS in this age group. The rTMS protocols were heterogeneous. Currently, FDA approved TMS devices are only approved for use in adult patients, age 18 years and older.

Agency for Healthcare Research and Quality (AHRQ): The 2011 comparative effectiveness review on nonpharmacological interventions for treatment-resistant depression (TRD) in adults concluded that comparative clinical research on nonpharmacologic interventions in a TRD population is early in its infancy, and many clinical questions about efficacy and effectiveness remain unanswered. Interpretation of the data was hindered by varying definitions of TRD and the paucity of relevant studies. The greatest volume of evidence was for ECT and rTMS. However, the strength of the evidence was low for beneficial outcomes. ECT and rTMS did not produce different clinical outcomes in TRD, and ECT produced better outcomes than pharmacotherapy. No trials directly compared the likelihood of maintaining remission for nonpharmacologic interventions. The few trials addressing

adverse events, subpopulations, subtypes, and health-related outcomes provided low or insufficient evidence of differences between nonpharmacologic interventions (Gaynes, et al., 2011).

Technology Assessments
In a 2016 (reviewed 2017) Directory Report on left repetitive high-frequency left transcranial magnetic stimulation (HFL-rTMS) for treatment-resistant depression, Hayes concluded that HFL-rTMS has a modest positive benefit, reducing the symptoms of depression, as a monotherapy and as an add-on therapy. According to Hayes, the quality of the large body of evidence was moderate, including 15 randomized, sham controlled trials (n=30–301). The evidence was insufficient to support HFL-rTMS for maintenance therapy to prevent relapse.

A 2016 (reviewed 2017) Hayes technology brief on low frequency rTMS (LFrTMS) (1 Hz) included seven randomized controlled trials (n=26–170). The studies reported that LFrTMS, in addition to pharmacotherapy, produced antidepressant effects. However, results were mixed suggesting no difference between LFrTMS and sham therapy as an adjuvant therapy to antidepressant treatment. Results also suggested that there was no difference between LFrTMS and HFrTMS as an add-on therapy. The low-quality evidence did not allow definitive conclusions regarding the efficacy of LFrTMS as a monotherapy. The therapies appeared safe with mild adverse events (e.g., scalp discomfort, transitory headaches).

In a 2016 (reviewed 2017), directory report on comparative effectiveness of HFL-rTMS, Hayes reported that there was insufficient evidence to support the use of HFL-rTMS combined with ECT compared to ECT alone for treatment-resistant major depressive disorder. The conclusion was based on ten randomized controlled trials with small patient populations (n=32–121). Various outcome criteria and treatment regimens for rTMS and ECT were used.

Professional Societies/Organizations
The 2010 American Psychiatric Association (APA) Practice Guideline for the Treatment of Patients with Major Depressive Disorder stated that evidence for TMS is currently insufficient to support its use in the initial treatment of major depressive disorder. Electroconvulsive therapy (ECT) remains the treatment of best established efficacy against which other stimulation treatments (e.g., VNS, deep brain stimulation, TMS, other electromagnetic stimulation therapies) should be compared. A substantial number of studies of TMS have been conducted, but most have had small sample sizes, and the studies overall have yielded heterogeneous results. Further complicating the interpretation of the TMS literature is the variability in stimulation intensities (relative to the motor threshold), stimulus parameters (e.g., pulses/second, pulses/session), anatomical localization of stimulation, and number of TMS sessions in the treatment course. As an initial treatment in the acute phase of major depression the guideline reported that the goal of treatment in the acute phase should be aimed at remission of the major depressive episode and achieving a full return to the patient's baseline level of functioning. Acute phase treatment may include pharmacotherapy, depression-focused psychotherapy, combination therapies (e.g., medications and psychotherapy, or other somatic therapies such as ECT, TMS, or light therapy) (Gelenberg, et al., 2010). There has been no update to this guideline since 2010.

<u>Transcranial Magnetic Stimulation - Other Psychiatric or Neurological Disorders</u>

Literature Review
There have been a number of studies and meta-analyses conducted that explored the efficacy of TMS for a selection of neuropsychiatric-related disorders. Some of the methodological limitations of these studies include small patient populations; short-term follow-ups; variability in technique and outcome measures; and varied diagnostic groups on and off pharmacotherapy. Therefore, the clinical utility and improvement in health outcomes of TMS in the treatment of other psychiatric or neurological disorders have not been clearly established. TMS has not been proven effective in the peer-reviewed published scientific literature for the following indications nor are the devices FDA approved for these conditions.

- addictions (Maiti et al., 2017; Grall-Bronnec and Sauvaget, 2014)
- alcohol dependence (Mishra, et al., 2010)
- Alzheimer disease (Liao, et al., 2015; Ahmed, et al., 2012; Cotelli, et al., 2010)
- amyotrophic lateral sclerosis (ALS) (Fang, et al., 2013; Guo, et al., 2011; Di Lazzaro, et al., 2010)
- anorexia nervosa (McClelland, et al., 2016)

- anxiety disorder (Diefenback, et al., 2016)
- attention deficit hyperactivity disorder (ADHD) (Bloch, et al., 2010)
- auditory hallucinations in schizophrenia (Freitas, et al., 2012; Slotema, et al., 2011; Cordes, et al., 2010; Loo, et al., 2010; Dlabac-de Lange, et al., 2010; Freitas, et al., 2009; Fitzgerald, et al., 2005, Shonefldt-Lecuona, et al., 2004; Hoffman, et al., 2003; Aleman, et al., 2007)
- autism (Sokhadze, et al., 2010)
- blepharospasm (Kranz, et al., 2010; Kahn, et al., 2010)
- bulimic disorders (Van den Eynde, et al., 2010)
- chronic pain (Jin, et al., 2015; Galhardoni, et al., 2015; O'Connell, et al., 2014; Boldt, et al., 2014; Taylor, et al., 2012; O'Connell, et al., 2011; Sampson, et al., 2011; 2010)
- chronic tinnitus (Folmer, et al., 2015; Meng, et al., 2011; Anders, et al., 2010; Lorenz, et al., 2010; Frank, et al., 2010; Marcondes, et al., 2010; Langrebe, et al., 2008; Khedr, et al., 2008; Rossi, et al., 2007; Kleinjung, et al., 2005; De Ridder, et al., 2005; Plewnia, et al. 2003)
- children (Allen, et al., 2017)
- epilepsy (Pereira, et al., 2016; Chen, et al., 2016; Brodbeck, et al., 2010)
- facial pain (Hodaj, et al., 2015)
- fibromyalgia (Saltychev and Laimi, 2017; Knijnik, et al., 2016; Marlow, et al., 2012, 2013)
- focal dystonia (Schneider, et al., 2010)
- Huntington's disease (Medina, et al., 2010)
- obsessive-compulsive disorder (Zhou, et al., 2017; Trevizol, et al., 2016; Berlim, et al., 2013c; Mansur, et al., 2011; Mantovani, et al., 2010; Rodriguez-Martin, et al., 2003; Alonso, et al., 2001)
- panic disorder (Li, et al., 2014: Mantovani, et al., 2012b)
- Parkinson's disease (Chung and Mak, 2016: Wagle, et al., 2016; Chou, et al., 2015; Shirota, et al., 2013; Benninger, et al., 2011; Arias, et al., 2010; Hartelius, et al., 2010; Pal, et al., 2010; Filipović, et al., 2010; Fregni, et al., 2004)
- postherpetic neuralgia (Ma, et al., 2015)
- post-operative pain (Borckardt, et al., 2006; Khedr, et al., 2005)
- post-stroke aphagia (Li, et al., 2015)
- post-stroke dysphagia (Du, et al., 2016)
- post-traumatic stress disorder (Yan, et al., 2017; Trevizon, et al., 2016; Berlim and Eynde, 2014; Karsen, et al., 2014; Boggio, et al, 2010; Cohen, et al., 2004)
- schizophrenia (He, et al., 2017; Wobrock, et al., 2015; Dougall, et al., 2015; Quan, et al., 2015; Bais, et al., 2014: Blumberger, et al., 2010; Matheson, et al., 2010; McNamara, et al., 2001)
- smell and taste dysfunction (Henkin, et al., 2011)
- spinal cord injury (Nardone, et al., 2015; Awad, et al., 2013; Soler, et al., 2010; Kumru, et al., 2010)
- stroke (Graef, et al., 2016; Zheng, et al., 2015; Avenanti, et al., 2012; Corti, et al., 2012; Weiduschat, et al., 2011; Emara, et al., 2010; Takeuchi, et al., 2010; Chang, et al., 2010; Kim, et al., 2010; Khaleel, et al., 2010; Lim, et al., 2010; Khedr, et al., 2009, 2010; Fregni, et al., 2006)
- tic disorders (Wu, et al., 2014; Steeves, et al., 2012; Kwon, et al., 2011)
- tinnitus (Soleimani, et al., 2016)
- Tourette syndrome (Landeros-Weisenberger, et al., 2015)

In a meta-analysis, Slotema et al. (2010) examined if rTMS is effective for various psychiatric disorders. Data were obtained from randomized, sham-controlled studies of rTMS treatment for depression (34 studies, n=751 rTMS and n=632 sham), auditory verbal hallucinations (AVH, seven studies), negative symptoms in schizophrenia (seven studies), and obsessive-compulsive disorder (OCD, three studies). Studies included a comparison of rTMS versus electro-convulsive therapy (ECT, six studies) for depression. Standardized mean effect sizes of rTMS versus sham were computed based on pre-treatment versus post-treatment comparisons. The mean weighted effect size of rTMS versus sham for depression was 0.55 ($p<0.001$). Monotherapy with rTMS was more effective than rTMS as adjunctive to antidepressant medication. ECT was superior to rTMS in the treatment of depression (mean weighted effect size -0.47, $p=0.004$). In the treatment of AVH, rTMS was superior to sham treatment, with a mean weighted effect size of 0.54 ($p<0.001$). The mean weighted effect size for rTMS versus sham in the treatment of negative symptoms in schizophrenia was 0.39 ($p=0.11$) and for OCD, 0.15 ($p=0.52$). Side effects were mild, yet more prevalent with high-frequency rTMS at frontal locations. The

authors stated that although the efficacy of rTMS in the treatment of depression and AVH may be considered proven, the duration of the effect is as yet unknown. Effect sizes were measured immediately after the cessation of rTMS treatment. There are indications that the effects of rTMS may last for several weeks to months. The authors reported that although rTMS cannot replace ECT in depressive patients, there may be subgroups in which rTMS can replace antidepressant medication.

In evidence-based guidelines for the treatment of tinnitus, the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) recommended against the use of TMS for the routine treatment of persistent, bothersome tinnitus. The recommendation was based on inconclusive data from randomized controlled trials (Tunkel, et al., 2014).

Transcranial Magnetic Stimulation for Migraine

The Cerena Transcranial Magnetic Stimulator (TMS) (eNeura Therapeutics, Sunnyvale, CA) device is the same device as the Spring TMS™ Total Migraine System marketed by eNeura Therapeutics in Europe. The device is small enough to be placed inside a large purse and can be used in the home or office where a comfortable chair or couch is available to the individual during use. The individual activates the subscriber information module (SIM) chip inside his or her prescription card for the device. The chip works only with the individual's device, and the prescription must be renewed regularly. When the individual experiences the onset of a migraine attack, the individual places the device on a flat surface in the "on" mode, presses the power button, and places the device behind the head at the base of the skull. The device has folding handles, which the individual can hold during treatment. When in place, the individual slides the treatment delivery switches housed in the handles to administer a pulse; a second pulse completes the treatment in less than a minute. The system automatically records the treatment history and is used with a headache diary program on a personal computer. Both the treatment history and headache diary can be uploaded to an online journal on the eNeura Therapeutics website. The device uses single-pulse transcranial magnetic stimulation (sTMS).

U.S. Food and Drug Administration (FDA)
The Cerena Transcranial Magnetic Stimulator (TMS) (eNeura Therapeutics, Sunnyvale, CA) received FDA 510(k) approval via the de novo premarket review pathway. This is the first approved device proposed to relieve pain caused by migraine headaches that are preceded by an aura: a visual, sensory or motor disturbance immediately preceding the onset of a migraine attack (FDA, 2013). In 2016, eNeura received a Class II FDA 510(k) approval for the sTMS mini device. Per the FDA approval, "the sTMS mini is indicated for the acute treatment of pain associated with migraine headache with aura. The device is designed for patient use where treatments are self-administered and can be delivered in a variety of settings including the home or office". The device is available by prescription only.

Literature Review
There have been limited studies in the peer-reviewed literature exploring the efficacy of TMS for the treatment of pain associated with migraine headache with aura. Some of the methodological limitations of these studies include small sample size, limited follow-up intervals and high dropout rates. Additional randomized controlled trials are needed to determine optimal treatment parameters, including the range of doses and timing of treatment, to confirm the effectiveness and durability of TMS for the treatment of pain associated with migraine headache with aura (Misra, et al., 2012; Brighina, et al., 2004: Teepker, et al., 2010; Clarke, et al., 2006, Brighina, et al., 2004).

The FDA clearance of the Cerena TMS device was based on a single multi-center randomized, double-blind, parallel-group, two-phase, sham-controlled study (Lipton, et al., 2010). Adults aged 18-70 years who met the International Classification Headache Disorders criteria for migraine headache with aura. Phase one of the trial enrolled 267 adults who experienced visual aura preceding at least 30% of migraines followed by moderate or severe headache in more than 90% of those attacks. Participants in phase one were trained to use an electronic diary to verify prospectively the diagnosis of migraine with aura; 66 participants (25%) dropped out after phase one of the trial. In phase two, 201 individuals randomized to either sham stimulation (n=99) or sTMS (n=102) self-applied the device to the back of the head, pressing a button to administer two pulses, each approximately 0.9 Tesla and lasting less than a millisecond, 30 seconds apart. Participants were instructed to treat up to three attacks over three months while experiencing aura. The primary outcome measure was pain-free response two

hours after the first attack. Thirty-seven participants did not treat a migraine attack and were excluded from the outcome analyses. A total of 164 participants treated for at least one attack of migraine with aura with sTMS (n=82) or with sham stimulation (n=82) reported that pain-free response rates two hours after stimulation were significantly higher with sTMS (39%, 32 of 82) than with sham stimulation (22%, 18 of 82; p=0.018). Sustained pain-free response rates with no recurrence and no rescue drug use significantly favored sTMS at 24 hours (29%, [24 of 82] versus 16% [13 of 82]; p=0.0405) and 48 hours (27% [22 of 82] versus 13% [11 of 82]; p=0.0327) after treatment. There were no significant differences in secondary outcomes (headache response at two hours, use of rescue drugs, Migraine Disability Assessment [MIDAS] score and consistency of pain relief response) between groups. The study did not demonstrate that sTMS was effective in relieving the associated symptoms of migraine, including nausea, photophobia, and phonophobia. No device-related serious adverse events were reported. Limitations of this study include the high dropout rate during phase one of the trial (25%, 66 of 267), the potential for unblinding of the device after administration of treatment, and variations in the time intervals from the onset of aura to treatment and pain intensity at the time of treatment. Additional randomized controlled trials are needed to determine optimal treatment parameters, including the range of doses and timing of treatment, to confirm the safety and durability of sTMS for the treatment of pain associated with migraine headache with aura.

In a Prognosis Overview on Cerna, Hayes (2014) concluded that there was insufficient published evidence to draw conclusions regarding the efficacy of this device for the treatment of migraine headaches. The best available study was the Lipton et al, (2010) study discussed above.

Professional Societies/Organizations
The American Academy of Neurology evidence-based practice parameter for the evaluation and treatment of depression, psychosis, and dementia in Parkinson disease (2006) concludes that there is insufficient evidence to support or refute the efficacy of TMS or ECT in the treatment of depression associated with Parkinson disease (Miyasaki, et al., 2006). There has been no update to this practice parameter since 2006.

Diagnostic Navigated Transcranial Magnetic Stimulation (nTMS)

Navigated transcranial magnetic stimulation (nTMS) is being investigated as a noninvasive modality to map essential functional motor cortex areas for diagnostic indications and for preoperative treatment planning. It uses electromagnetic pulses to stimulate points of the patient's brain and then records the motor output (if any) on a standard electromyogram. Direct electrical stimulation (DES) is the gold standard for brain mapping and is used intraoperatively but is not used preoperatively. DES cannot be replaced by a noninvasive method due to its unique capability to stimulate subcortical structures accurately and to monitor function during surgery. Preoperative functional brain imaging is used widely in the context of rolandic (the motor area of the cerebral cortex lying just anterior to the central sulcus and comprising part of the precentral gyru) brain tumor surgeries. The most widely adopted method is functional magnetic resonance imaging (fMRI), but magnetoencephalography (MEG), PET, and electroencephalography have also been used for preoperative mapping (Takahashi, et al., 2013; Pitch, et al., 2012).

U.S. Food and Drug Administration (FDA)
In 2009, the Nexstim eXimia Navigated Brain Stimulation System (NexStim, North Attelboro, MA) received 510(k) FDA approval. The 510(k) summary indications for use state, "The Nexstim eXimia Navigated Brain Stimulation System (NBS System) is indicated for non-invasive mapping of the primary motor cortex of the brain to its cortical gyrus. The NBS System provides information that may be used in the assessment of the primary motor cortex for pre-procedural planning. The NBS System is not intended to be used during a surgical procedure. The NBS System is intended to be used by trained clinical professionals" (FDA, 2009).

Literature Review-navigated transcranial magnetic stimulation (nTMS)
There is limited evidence at this time to permit conclusions regarding the impact of nTMS testing on health outcomes. Several comparative studies with small sample sizes suggest that nTMS may be useful as a mapping modality of the motor cortex. Studies are primarily in the form of case series with small patient populations and lack a comparator. Additional well-designed clinical studies with larger patient populations are required (Krieg, et al., 2014; Krieg, et al., 2013; Coburger, et al., 2013; Tarapore, et al., 2012; Forster, et al., 2012; Krieg, et al., 2012; Picht, et al,. 2012, Frey, et al., 2012; Makela, et al., 2012; Picht, et al., 2011).

Hayes (2017) conducted a systematic review of the literature to evaluate nTMS for mapping of the primary motor cortex to provide information that may be used for preprocedural planning. Eight studies met inclusion criteria including one retrospective review. Although the overall body of evidence suggested that nTMS may be beneficial, a definitive conclusion could not be made due to the poor quality of the evidence. Limitations of the studies included: small, heterogeneous patient populations; retrospective study design; lack of power analysis; difference in sample sizes between groups; short- term follow-ups; various follow-up durations; and limited statistical analyses.

In a systematic review of observational studies, Takahashi et al. (2013) studied the spatial accuracy and clinical utility of nTMS in rolandic brain tumor surgery in or near the motor cortex. Eleven reports in which adult patients were examined with nTMS prior to surgery met the inclusion criteria. For mapping of the motor cortex, most studies used a biphasic TMS pulse (250–280 µsec pulse length) from a figure-eight coil with an outer diameter of 70 mm applied at 110% of the resting motor threshold and a maximum frequency of 0.25 Hz.2–5,7–9,12,14–17,20,21. For lower-extremity stimulation the intensity was adapted on an individual basis. Quality criteria consisted of documentation of the influence of nTMS brain mapping on clinical decision making in a standardized prospective manner and/or performance of intraoperative direct electrical stimulation (DES) and comparison with nTMS results. Cross-observational assessment of nTMS accuracy was established by calculating a weighted mean distance between nTMS and DES. All studies reviewed concluded that nTMS correlated well with the “gold standard” of DES. The mean distance between motor cortex identified on nTMS and DES by using the mean distance in 81 patients described in six quantitatively evaluated studies was 6.18 mm. The nTMS results changed the surgical strategy based on anatomical imaging alone in 25.3% of all patients, based on the data obtained in 87 patients in two studies. The nTMS technique spatially correlates well with the gold standard of DES. Its functional information benefits surgical decision making and changes the treatment strategy in one-fourth of cases. The studies included in the review were limited by small sample sizes. The impact of nTMS on the operation was not reported in the majority of the studies.

In a 2016 search and summary report on nTMS, Hayes reported that although there was a moderate amount of published evidence, well-designed, large randomized controlled trials are lacking. A review of the abstracts showed conflicting findings. There was considerable overlap of authorship in the retrieved abstracts, and the majority of the published studies consisted of small patient populations with various diagnosis.

Professional Societies/Organizations
Professional society opinion on this technology is lacking.

Use Outside of the US
Galician Agency for Health Technology Assessment: In the 2014 revised clinical practice guideline on the management of depression, the HTA Working Group stated that TMS is not currently recommended for the treatment of depression due to the uncertainly about its clinical efficacy.

Health Quality Ontario: The Ontario Health Technology Advisory Committee (OHTAC) (2016) conducted a technology assessment on rTMS for treatment-resistant depression. Twenty-three randomized controlled trials comparing rTMS with sham and six comparing rTMS with electroconvulsive therapy (ECT) met inclusion criteria. Repetitive TMS versus sham studies showed a statistically significant improvement in depression scores following rTMS, but follow-ups did not show that the effect continued for long periods of time. Trials comparing rTMS to ECT showed statistically and clinically significant improvements in favor of ECT.

National Institute for Health and Clinical Excellence (NICE): In the 2015 update of the interventional procedural guidance document on repetitive TMS for depression, NICE (United Kingdom) reported that there were no major safety concerns regarding TMS. The evidence on its efficacy in the short-term is adequate, although the clinical response is variable. According to NICE, clinicians should, in particular, inform patients about available treatment options, and make sure patients understand the procedure may not give them benefit. Further evidence on patient selection, details of the precise type and stimulation regime used, long-term outcomes and the use of maintenance treatment is needed.

In January 2014, NICE issued an interventional procedural guidance document on TMS for treating and preventing migraine. The authors reported that the evidence on the efficacy of TMS for the treatment of migraine and prevention of migraine is limited. Evidence on its safety in the short and medium term is adequate but there is uncertainty about the safety of long-term or frequent use of TMS. Nice concluded that the procedure should only be used with special arrangements for clinical governance, consent and audit or research.

The 2016 update of the Canadian Network for Mood and Anxiety Treatments (CANMAT) clinical guidelines for the management of major depressive disorder in adults recommends rTMS as a first-line therapy for patients with MDD who have failed at least one antidepressant. Both high-frequency and low-frequency rTMS have demonstrated efficacy. A limited number of studies have suggested that long-term outcomes appear more favorable with maintenance rTMS, but maintenance schedules have not been established (Milev, et al., 2016).

The 2013 Royal Australian and New Zealand College of Psychiatrists position statement on repetitive transcranial magnetic stimulation stated the following under the clinical indications**:**

- Major depression: rTMS should be offered in psychiatric clinical settings with appropriate protocols, training and equipment to appropriately selected patients with major depression.
- Refractory hallucinations in schizophrenia: rTMS may be offered on a restricted basis to carefully selected patients with schizophrenia who have auditory hallucinations that have not improved with adequate trials of antipsychotic medications. This should only be performed in tertiary referral centers with appropriate expertise.
- Other psychiatric disorders: Until further data are available, rTMS should only be used for the treatment of other psychiatric disorders within a research protocol which has had formal ethical review and approval.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	**Description**
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management

Considered Experimental/Investigational/Unproven when used to report transcranial magnetic stimulation for any other indication, including presurgical mapping:

CPT®* Codes	**Description**
64999	Unlisted procedure, nervous system
0310T	Motor function mapping using non-invasive navigated transcranial magnetic stimulation (nTMS) for therapeutic treatment planning, upper and lower extremity (Code deleted 12/31/2017)

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