Local Coverage Determination (LCD)

Transcranial Magnetic Stimulation (TMS) in the Treatment of Adults with Major Depressive Disorder

L34522

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
First Coast Service Options, Inc.	A and B MAC	09101 - MAC A	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09102 - MAC B	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09201 - MAC A	J - N	Puerto Rico Virgin Islands
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LCD Information

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Issue

Issue Description

Transcranial Magnetic Stimulation (TMS) is a non-invasive treatment that uses pulsed magnetic fields to induce an electric current in a localized region of the cerebral cortex. When used as an antidepressant therapy, TMS produces a clinical benefit without the systemic side effects associated with standard oral medications. Currently First Coast Service Options, Inc. (FCSO) provides coverage for the use of TMS in patients with a confirmed diagnosis of severe major depressive disorder (MDD), who have failed four psychopharmacologic trials. FCSO has received a reconsideration request to expand the coverage of TMS to include moderate depression within the major depressive diagnosis, two reconsiderations to include treatment of patients who have failed at least one trial of psychopharmacologic agents, and a reconsideration to include treatment of patients suffering from obsessive-compulsive disorder (OCD). After review of the evidence submitted, it has been determined that there is insufficient evidence to support expanding TMS coverage to include moderate depression. Therefore, coverage will continue for severe major depressive disorder as defined by the current Diagnostic and Statistical Manual of Mental Disorders (DSM). Based on the review of substantial evidence and in alignment with company policy, the LCD has been modified to cover patients with at least one failed psychopharmacologic trial and/or demonstrates an intolerance to psychopharmacologic medications. On September 29, 2021, a multi-jurisdictional Contractor Advisory Committee (CAC) Meeting was held to discuss the evidence for TMS treatment in OCD. In addition to the evidence presented at the CAC Meeting, the evidence submitted to FCSO with the reconsideration requests for OCD was reviewed. Following the CAC meeting discussion and review of the evidence it has been determined that, at this time, there is insufficient evidence to support the use of TMS as a treatment for OCD.

CMS National Coverage Policy

This LCD supplements but does not replace, modify, or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for transcranial magnetic stimulation (TMS) in adults with severe major depressive disorder. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify, or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations, and rules for Medicare payment for TMS and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*,
  - Chapter 15, Section 60 Services and Supplies
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment may be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Section 1862(a)(1)(D) prohibits the payment for clinical care items and services for research and experimentation which are not reasonable and necessary.

Code of Federal Regulations (CFR) References:

- CFR, Title 21, Volume 8, Chapter I, Subpart H, Part 882, Subpart F, Section 882.5802 Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions.
- CFR, Title 21, Volume 8, Chapter I, Subpart H, Part 882, Subpart F, Section 882.5805 Repetitive transcranial magnetic stimulation system.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Transcranial Magnetic Stimulation (TMS) is FDA approved for the treatment of depression and obsessive-compulsive disorders.[1-3] It is a non-invasive procedure that uses pulsed magnetic fields to induce an electric current in a localized region of the cerebral cortex.[4-7] An electromagnetic coil is placed on the scalp inducing a focal current into the brain that temporarily modulates cerebral cortical function. A capacitor discharge provides electrical current in an alternating on/off pulse. Based on stimulation parameters this may be adjusted to alter the excitability of the targeted structures in specific cortical regions.[8] The electromagnetic current parameters include cranial location, frequency, strength, width, and volume dependent on the motor threshold that is individualized for each patient.[1,2]

TMS is delivered daily in an outpatient setting without anesthesia or analgesia for up to six weeks and there are no restrictions related to activities before or after treatment (e.g., driving, working, operating heavy machinery).[9]

Definitions

Major Depressive Disorder: The diagnosis based on the definition in the current Diagnostic and Statistical Manual of Mental Disorders (DSM). It is based on symptoms, characteristics, and requirements that are needed in order to be diagnosed with depression.

Major Depressive Disorder – Severe: A subcategory of major depressive disorder as differentiated within the DSM manual from mild, moderate, and severe. For example: “The number of symptoms is

substantially in excess of that required to make the diagnosis, the intensity of the symptoms is seriously distressing and unmanageable, and the symptoms markedly interfere with social and occupational functioning."[10]

Failure of a trial of a pharmacological agent: The failure of one or more psychopharmacological medications that are administered at both an adequate dose and adequate duration that are consistent with the FDA label and with a duration that would elicit a favorable response.[9,11-13]

Intolerance of a psychopharmacologic agent: Intolerable side effect(s) that are not expected to diminish or resolve with continued administration of the medication.[5,14,15]

Motor Threshold (MT) Intensity: The minimum stimulator setting that induces an observable motor response when applied to the patient.[1]

Frequency: The number of pulses delivered per second, measured in Hertz (Hz).[1]

Magnetic Field Strength: The measurement of voltage induced to the identified area.[1]

Pulse Width: The duration of time from the peak of a pulse to the peak of the next pulse.[1]

Stimulation Volume: The region of cortical tissue that is stimulated based on the Motor Threshold identified for the individual patient.[1]

Covered Indications

TMS of the brain for severe MDD, single or recurrent episode, is considered medically reasonable and necessary for up to six weeks[3,5,6,16-19] when the following criteria are met:

1. The patient has a confirmed diagnosis of severe MDD as defined by the current DSM.
   AND
2. The patient has demonstrated a failure of one or more trials of a pharmacological medication and/or demonstrates an intolerance to psychopharmacologic medications as defined in the definition section above.
   AND
3. The order for TMS procedure is written by a psychiatrist (MD or DO), who has examined the patient face to face and reviewed the record.[20]

Limitations

The following is considered an **ABSOLUTE CONTRAINDICATION:**

The presence of a medically implanted magnetic-sensitive device or other implanted metal items including, but not limited to, a cochlear implant, implanted cardiac defibrillator (ICD), pacemaker, vagus nerve stimulator (VNS), metal aneurysm clips/coils, staples, or stents, that are located less than or equal to 30 cm from the TMS magnetic coil.[1,6,15]

The following are considered **RELATIVE CONTRAINDICATIONS:**

1. The presence of a seizure disorder or any history of seizures (except those induced by Electroconvulsive therapy [ECT] or isolated febrile seizures in infancy without subsequent treatment or recurrence).
2. The presence of acute or chronic psychotic symptoms or disorders in the current depressive episode.
3. The presence of any neurological conditions including epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, or primary or secondary tumors in the central nervous system.

The following is considered not medically reasonable and necessary:

All other uses of TMS, including the use of TMS for OCD.[7,12,20-23]

Provider Qualifications

Services will be considered medically reasonable and necessary when all aspects of care are within the scope of practice of the provider's professional licensure, when performed according to the supervision requirements per state scope of practice laws, and when all procedures are performed by appropriately trained providers in the appropriate setting.

Notice: Services performed for any given diagnosis must meet all the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

Summary of Evidence

This summary of evidence focuses on the use of TMS in the treatment of MDD and TMS in the treatment of OCD and the use of TMS following one or more failed trials of pharmacological agents to determine whether the evidence is sufficient to draw conclusions about improved health outcomes for the Medicare population. In general, improved health outcomes of interest include patient quality of life and function.

In addition to reviewing evidence presented at a Multi-jurisdictional CAC Meeting and literature submitted with reconsiderations, a literature search was conducted using the following key words and phrases: TMS and OCD; TMS treatment for OCD; RCT of OCD TMS; OCD for deep transcranial magnetic stimulation (dTMS); Non-invasive/non-pharmacological OCD/depression treatment; and TMS as OCD treatment; scoring of Hamilton Rating Scale for Depression (HAMD); Montgomery-Asberg Depression Scale (MARDS) treatment parameters; DSM mild, moderate, severe depression. Along with various association guidelines. The highest level of evidence consisting of large randomized controlled trials (RCTs), multi-site RCTs, peer reviews and society endorsements were followed.

Clinical Trials

Rush et al[16] reviewed the protocol implemented by the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) that include a RCT that began with 3,671 patients who would receive the first of four levels of treatment beginning with medication. At any time during the protocol, if a patient achieved remission, they could then opt to be followed in a long-term naturalistic review that would

last 12 months. The study began with 41 clinical sites consisting of patients between 18-75 years of age, diagnosed with MDD, and not previously exposed to any treatment protocol in the first and second treatment steps.

Tools of depression measurement such as Hamilton Rating Scale of Depression (HRSD17) and Inventory of Depressive Symptomatology (IDS-C30), Quick Inventory of Depressive Symptomatology (QIDS-C16), Frequency, Intensity, and Burden of Side Effects Rating, among others were implemented as a baseline and used to gauge the effects of treatment throughout the study. Response was quantified as a 50% reduction from baseline on the QIDS-SR16. Remission was defined as QIDS-SR16 of ≤5 (HRSD17 ≤7) and relapse defined as QIDS-SR16 ≥11 (HRSD17≥ 14).

The treatment steps outlined in the review consisted of the following levels: Level one – involved administration of citalopram with the goal being a score of ≥14 on the HRSD17 scale. The study excluded 2,232 patients during and after the first level due to various reasons such as drop out and evaluation in patient scores. Level two and three - treatments were based on equipoised stratified random design. A choice of seven pharmacological or cognitive behavior therapies (CBT) were provided to the remaining 1,439 patients. Level three removed the option of CBT and continued with a pharmacological agent as an augmentation option or the ability to switch medication treatment plans for the 390 patients that continued to level four. Within level four - there were 123 patients that completed the final level. The overall results showed "QIDS-SR16 remission rates were 36.8%, 30.6%, 13.7%, and 13.0% for the first, second, third, and fourth acute treatment steps, respectively."[16(p1905)]

The results and conclusions of the trial also identified some key areas:

Patients that had prior treatment for MDD had a lower rate of remission (35.6%) in their current episode as compared to patients with no prior treatment (42.7%). Remission appeared to occur at 5.4-7.4 weeks at each level of treatment.

"Lower relapse rates were found among patients who were in remission at follow-up entry than for those who were not after the first three treatment steps."[16(p1905)]

Carpenter et al[18] conducted a clinical trial of 42 clinic based TMS treatment centers across the U.S. The trial consisted of 307 patients who underwent acute treatment with TMS for six weeks. The patients ranged in age from 18-90 years, with one or more failed pharmacological treatments, no prior treatments with TMS, and a confirmed diagnosis of major depression based on DSM-IV criteria. Patients were treated per protocol with TMS up to six weeks and had the opportunity to continue to a 52-week naturalistic continuation outcome study. The goal of this study was to determine the outcomes of TMS treatment for a large population of patients that were diagnosed with major depression.

The primary outcome measure was the amount of change from baseline to end-point on the Clinical Global Impressions-Severity of Illness Scale (CGI-S) with response being an end-point rating of three or less.

This study was initiated with 339 numerated patients, 307 met the criteria, and of those 307 patients, one patient dropped out before the second week and seven patients after two weeks of treatment

'completed' the study by establishing remission or responding to treatment. Nineteen patients dropped out and 280 continued treatments through the fourth week.

Within the fourth week,100 patients completed the study, 11 did not return and 169 continued through to the sixth week of treatment.

Within the sixth week, 91 patients completed the clinical trial and seven did not return for various reasons. Seventy-one patients remained and continued beyond the sixth week.

Beyond the sixth week, 67 patients completed the study while four remaining did not return. Only one adverse effect of a seizure was noted and reported during the study.

Acute phase treatment with continuous variables demonstrated a significant improvement in CGI-S total scores from baseline (-1.9 ± 1.4, $P < .0001$). Acute-phase treatment outcomes with categorical variables were consistent on all outcome measures with over half of the patients achieving responder status at the end of the acute treatment.

Since other research has suggested that there are several clinical variables that may influence a patient's response to treatment, secondary analyses were conducted in an effort to identify potential moderators of treatment outcome with TMS.

The response rate was determined by the change in baseline based on CGI testing tool. The authors, whom have a varied stake with Neuronetics, reported that, in weeks two and six a total of 58% of patients were considered responders while 37% were scored as in remission.

The study concluded that in the acute phase younger patients with lower pre-treatment baseline scores fared better by identifying greater remission. The authors note that "patients who had failed a minimum of one adequate antidepressant trial were as likely to be TMS responders as those who had failed two or more trials in the current episode" and that "more than half of patients achieved responder status at the end of acute treatment, and approximately one third of patients achieved remission."[18]

Fitzgerald et al[24] provided a meta-analysis of 11 clinical trials (nine published trials) over the course of 15 years. This analysis supported the determination of response to rTMS, the rate of response and remission, and touched on clinical and demographic predictors of responses. The compiled studies were comprised of 1,132 (62.8% female and 37.1% male) patients that were 18-89 years of age. Thirty-two percent of the patients were diagnosed with a single episode of MDD, 53% were diagnosed with recurrence of MDD, 13% were diagnosed with bipolar affective disorder and 1.7% were diagnosed with schizoaffective disorders.

Twenty-nine percent of the patients were treated with high-frequency left-sided rTMS; 45.4% of the patients received treatment with low-frequency right-sided rTMS; and 25% of the patients received sequential bilateral rTMS.

The scales used to determine response rates were the HAMD17 and MADRS and patients had to have an improved score(s) of 50% or better to be considered as a 'responder' to the treatment provided. The result of the analysis determined that there was a 57% reduction in depression rating

scale scores, 46% of patients achieved response criteria, and 31% completing rTMS treatment were in remission.

There were additional items reviewed such as the treatment response or the lower tolerance to biomedical interventions as it relates to patients that had failed at least two or more medication trials. Results of the review indicate a lower number of failed medication trials make patients more susceptible to rTMS.

There is a noted left and right sided treatment difference and unilateral versus bilateral treatment which may be related to 'priming stimulation' on the right side. "It is less clear why bilateral treatment is associated with a high response rate."[24(p752)]

In relation to age and improved response it was once thought that the distance between the scalp and cortex was larger in the elderly causing an 'underdosing' at the time of treatment. Improvements in care and treatment over the past 15 years seem to have corrected and compensated for the individual's size, shape, and treatment intensity.

This meta-analysis concluded that 44% responded to treatment and 56% were considered 'non-responders'. In addition, it was found that patients with a shorter episodic illness and lower number of failed medication trials had a better response to rTMS.

In summary "rTMS is an effective and useful clinical treatment for patients with depression although questions remain as to the most effective way to apply this intervention."[24(p752)]

Randomized Control Trials

Brakemeier et al[25] provided a logistic regression review for an acute TMS treatment phase of two weeks. The analysis was related to 70 patients with a DSM-IV criteria for bipolar II or MDD. Within the study the characteristics of the patients were as follows: 45% of patients had a single episode, 42% had recurrent depression and 11% had a diagnosis of recurrent bipolar disorder. Of those 70 patients, 55% were receiving antidepressants (four weeks prior to review and constantly during study) and 44% were pharmacologically free. The study determined that only 33% of the medication resistant patients responded to TMS and 83% of the medication resistant patients did not respond to treatment (non-responders).

Baseline scoring for HAMD17, CORE [elements of non-instructiveness], and Beck Depression Inventory (BDI) were completed. The patients were evaluated again after the first week of treatment and then again at the second week of rTMS treatment.

The study was meant to evaluate the 'physiopathology of depression' therefore patients were evaluated on a narrower response related to 'symptoms' to assist as predictors for treatment for responders and non-responders.

The following five factors were based on HAMD17 to detail: Psychic depression, Loss of motivation, Psychosis, Anxiety and Sleep disturbances. The patients had to show a 50% reduction in these HAMD17 identified factors to be considered a responder.

After two weeks of treatment 86% of the patients were responders and 14% were categorized as non-responders. It was noted by the authors that "statistically significant differences between responders and non-responders at baseline was observed for the variables 'duration of current episode', total number of antidepressant trials via the Antidepressant Treatment History Form (ATHF), medication resistance, and the two CORE criteria 'agitation' and 'retardation' [psychomotor slowing]."[25(p398)]

Regarding the five factors of the HAMD17 scoring there were notable improvements in responders in relation to psychic depression, sleep disturbances, and a loss of motivation. With this evidence, the authors conclude that "the main predictors of response to rTMS were duration of the Major Depressive Episode (MDE) less than five months."[25(p398)] It was also noted that the patients with low treatment resistance had a higher response rate than those with more than two medication trials.

Lisanby et al[19] provides a prediction of acute outcomes in relation to the degree of prior treatment in a multisite, randomized, double blinded, controlled clinical trial that incorporated 23 clinical sites to include multicultural nations such as the U.S., Australia, and Canada.

The trials were conducted between 2004-2005 and there were 301 patients that were resistant to pharmaceutical antidepressants. The trial placed patients into either an active or sham group with 155 patients in the active group and 146 patients in the sham group. Fifty-four percent of the 301 patients had received one antidepressant treatment trial of adequate dose and duration in the current episode, with the remainder of the patients (45.5%) receiving two to four adequate treatment trials. The baseline HAMD17, HAMD24 and MARDS scores averaged 22, 30 and 32 respectively, making patients moderately to severely ill.

Treatment was provided at the following requirements: TMS = MT 120%, 10 rep, 10Hz, trains of four seconds duration, 26 seconds intertrain interval (40 pulses per train) for a total of 75 pulse trains (300 pulses) over the Dorsolateral Prefrontal Cortex (DLPFC) for at least four weeks. Acute treatment was extended to six weeks if the patient did not exhibit a response or enter remission.

A total of 164 patients who failed to benefit from one adequate antidepressant treatment in the current episode showed significantly greater improvement in MADRS and HAMD24 total scores in comparison to patients who had failed two to four adequate antidepressant treatments.

The MARDS score for one adequate antidepressant was 0.0018 in the second week of treatment whereas the score for patients having more than one adequate antidepressant trials was 0.377. At the end of the fourth week the results were 0.0006 and 0.923 respectively and the evaluation at the end of the sixth week resulted in 0.0063 and 0.547 respectively. Therefore, less treatment resistance (TR) in the current episode and higher symptom severity at baseline was associated with greater clinical benefit for the patient. The limitation related to the study was related to only offering one TMS treatment protocol and TR was limited to four treatment failures in the current episode.

Levkovitz et al[5] conducted a review and additional research related to the use of rTMS in acute treatment periods ranging from three to six weeks. This study utilized the form of dTMS to investigate the efficacy and safety when applied in five-day sequence (five days per week) for four weeks, as monotherapy for patients with diagnosed MDD. In addition, these patients had either failed one to four antidepressant trials or did not tolerate at least two antidepressant treatments in the current

episode. This double-blind randomized placebo-controlled multicenter trial included patients that were 22-68 years of age from October 2009 to January 2012 in collaboration with independent data and a safety monitoring board.

This study focused on the subgenual cingulate gyrus which is a pathophysiological region in the brain associated with MDD. The idea was to "stimulate less focally and more deeply to reach connecting fiber tracts"[5(p65)] and study the effects of a 12-week treatment protocol. The H1-Coil was "developed for deeper and non-focal stimulation of dorsolateral and ventrolateral prefrontal areas that also project into other areas of brain reward system" and would be the type of device to deliver the dTMS protocol in patients in the study.

The study design included three phases: a 'wash-out' phase (one to two weeks), during which patients were tapered off all antidepressants, mood stabilizers and antipsychotics; a four-week acute treatment phase (daily treatment from Monday through Friday with dTMS or sham TMS), and a 12-week maintenance phase (two treatments per week of dTMS or sham TMS).

The study used the Hamilton Depression Rating Scale (HDRS21) and the CGI-S as scoring tools. The study resulted in 181 patients that were then divided into two groups. One group had 89 patients that would receive the dTMS treatment and 92 patients in the sham treatment group. At the end of the study (16 weeks) there were various dropouts or stages where the patients reached their primary endpoint, resulting in 43 dTMS patients and 28 sham patients.

Results were reported with the primary endpoint being the change in HDRS21 from baseline. There was a noted change from baseline of -6.39 in the dTMS group and -3.28 in the sham group. The secondary efficacy measures were related to response and remission rates. At the fifth week the rate of response for the dTMS group was 38.4% with the sham group reporting 21.4%, and remission rates of 32.6% and 14.6% respectively.[5]

At the conclusion of the study (16 weeks) the third efficacy measure was calculated resulting in the change in HDRS21 total scores from baseline. The response results were statistically significant with the dTMS group reporting 44.3% improvement versus a 25.6% improvement in the sham group. While the remission rates were 31.8% and 22.2% respectively.

There was also a subset analysis related to medication failures. The groups were divided into subjects that failed one or two medication trials and those who failed three or more. The results after the implementations of the Analysis of Variance (ANOVA) model resulted in the first stratum being 36.6% in the dTMS group and 16.7% in the sham group. The second stratum was 28.9% and 12.2% respectively, indicating that patients that have a greater medication failure rate are less likely to respond to dTMS.

As a result, this "randomized and placebo-controlled trial demonstrates that dTMS is an effective and tolerable treatment for patients with MDD who have not successfully responded to treatment with antidepressant medications in the current episode"[5(p72)] but not without adverse events that were reported such as nausea, vomiting, headache, site discomfort, insomnia, and muscle twitching.

Fregni et al[26] conducted an analysis of six randomized controlled trials that provided five double blind studies and one study with an open label trial to identify the predictors of antidepressant response to

TMS. There were 195 patients ranging from 18-91 years of age with DSM-V diagnosis of MDD scoring from 18-22 on the HAMD scoring tool. These studies used HAMD as a scoring mechanism and the requirement to determine a response to treatment was the reduction in base line score of ≥50% or remission as a post-treatment HAMD baseline of ≥7. Patients were given 10rTMS treatment sessions over a two-week period and re-evaluated.

The evidence was analyzed by applying various linear regressions, univariate analysis, logistic regression, and the removal of outliers. The evidence was provided in comparison tables and the results of treatment refractoriness was based on certain HAMD items (such as insomnia-early, work activities, fear, anxiety, systematic somatic symptoms, and diminished insight), one table was based on anxiety and work, and the third table in a linear regression model that removed an outlier study.

The actual adjusted predictors of antidepressant response in treatment refractoriness for scoring based on insomnia-early, work activities, fear, anxiety, systematic somatic symptoms and diminished insight (Model 1) was 24%-52%, for items related to evaluation of anxiety and work (Model 2) was 22%-48% and for the linear regression (Model 3) removing an outlier study resulted in refractoriness of 20%-46%.

The results provided a strong correlation to depression improvement after two weeks of rTMS treatment.

Carmi et al[27] studied 41 OCD patients who had failed two psychopharmacological trials plus CBT. The study provided baseline of clinical and electrophysiological measurements, a five-week treatment protocol, and a one-month follow-up for patients with OCD. Entrance criteria included an age range of 18-65 years old; a DSM-IV diagnosis of OCD; a score of ≥20 on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS); stable Selective Serotonin Reuptake Inhibitor (SSRI) medications for eight weeks prior to enrollment and unchanged during treatment; and CBT at maintenance phase (if conducted). Randomization of treatment was provided to the patients at a certain frequency protocol. One group received 1 Hz Low Frequency (LF), the second group received 20 Hz High Frequency (HF) and the third group being the sham group. Treatment occurred five times per week for five weeks. Primary and secondary outcomes were based on the Y-BOCS and CGI-S scoring tools which were obtained at: pre-treatment; prior to the second treatment session (weeks two to four); prior to the last treatment session; one week post treatment; and at a one-month follow-up evaluation.

The baseline characteristics of the three groups did not differ. Three of the 41 patients dropped out due to schedule conflicts and inconvenience. No adverse events occurred beyond headache and when asked to guess the group to which they were assigned, the vast majority of patients could not determine, of the three groups, which one they were assigned.

No trend was reported in the low frequency and two of the eight patients had a worsening Y-BOCS score; therefore, the low frequency group of the study was omitted. Sixteen patients completed the study for the HF group and 14 patients completed the study within the sham group. The percent change in Y-BOCS scores was significant at weeks four and five and a higher proportion of the HF group compared to the sham group (7/16 vs 1/14). Each remaining group reached the predefined response rate (30%) after five weeks. Using the more restrictive criterion of 35%, 5/16 HF and 1/14 sham individuals achieved the higher rate. Significant differences at one week occurred but not at

one-month follow-up. Similarly, the CGI-I results were significant after treatment and one week but not at four weeks.

Carmi[11] conducted research based on a prospective, randomized double-blind placebo-controlled trial to determine the benefits of dTMS to the medial prefrontal cortex and the anterior cingulate cortex of patients suffering from OCD.

The gage of improvement was based on YBOCS scored from baseline to post treatment evaluation and extended to a one month follow up. A full response was equivalent to a 30% reduction and a partial response was equivalent to a 20% reduction from the baseline scores. This study was conducted at 11 centers: nine in the U.S., one in Israel, and one in Canada. Each participant had a Y-BOCS score of >20 and they must have failed at least one pharmacological trial. Ninety-nine OCD patients were chosen for daily treatment sessions of five days a week, for a total of 25 sessions at high-frequency or sham dTMS for a period of six weeks (29 treatments).

The treatments provided the following results: post-treatment assessment at the sixth week, demonstrated that the Y-BOCS score decreased significantly from baseline in both the active (26.0 points, 95% CI=4.0, 8.1) and sham (23.3 points, 95% CI=1.2, 5.3) treatment groups (estimated slopes). The difference in slopes of change in Y-BOCS score between the two groups was statistically significant at the post-treatment assessment (2.8 points, p=0.01), for an effect size of 0.69. The effect was also present at the fourth week post-treatment follow-up assessment, at which point the mean Y-BOCS score had decreased by 6.5 points (95% CI=4.3, 8.7) in the active treatment group and by 4.1 points (95% CI=1.9, 6.2) in the sham treatment group. The rate of full response (a reduction >30% in Y-BOCS score) at the post-treatment assessment in the active treatment group was 38.1% (16/42), compared with 11.1% (5/45) in the sham treatment group (p=0.003).

Systematic Review/Meta-Analysis

Voigt et al's[28] systematic review of the literature was to assess the clinical efficacy for the use of rTMS in patients with MDD who have failed one or less pharmacologic trial versus two or more pharmacologic trials. The level and quality of evidence was assessed using the Center for Evidence-Based Medicine (CEBM) and the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria. In addition, they used a Systematic Reviews and Meta-Analyses (PRISMA) checklist to ensure the manuscript complied to minimum accepted guidelines for review.

The mean average age was 41 years, with 1,339 patients. Six studies were graded as ‘high quality’ by the GRADE and CEBM while the remaining four were low quality, but all demonstrated a positive effect for patients with less than one medication trial and the use of rTMS for treatments.

It has been noted within this analysis that the greater the medication resistance the greater the resistance to other therapeutic modalities. It was noted that 20-40% of patients cannot tolerate and do not benefit from repeated trials of antidepressants. The literature shows that “with medication the remission and response rates were: 30.6% and 28.5% after one failed medication therapy; 13.7% and 16.8% after two failed medication therapies and 13 and 16.3% after three failed medication therapies.”[28(p8)] The study also noted that the response and remission rates for rTMS were “95% response and 63% remission rate in treatment naïve patients; 43% response rate after one failed

medication trial; 36.6% remission after one to two failed medication therapies and; 28.9% remission after three to four failed medication therapies."[28(p9)] Additional evidence exists that if TMS is used by itself or in combination with an antidepressant for patients diagnosed with the first episode of MDD, it may be more effective and shorten the treatment period than if antidepressants were used alone.

Ma et al[12] reviewed nine RCTs with 290 patients diagnosed with OCD. Most of these patients were resistant to SSRI. Random assignments (not described within the review) were made using rTMS or sham rTMS. Y-BOCS scores were used as the primary outcome and response rate as the secondary outcome. The latter was determined by the RCT's definition. Drop-out rates were also evaluated. There were 154 active rTMS patients and 136 patients were in the sham rTMS group. Study size ranged from 18 to 65 years of age. The Y-BOCSs were reported to indicate improvement when rTMS was added to treatment with medication. There were nine patients in two studies that did not have SSRI-resistant OCD, but the improvement continued to be shown when these RCTs were excluded from the Y-BCOS analysis. Actual Y-BCOS scores were not provided. It was noted that the active rTMS patients had higher baseline Y-BOSC scores, and the response rates were available for eight of the nine trials. Fifty-five of 139 active patients (39.6%) and 27 of the 122 sham patients (22.1%) responded to rTMS. There was no difference in the drop-out rate between the active 8/207 (3.8%) and sham 7/94 (7.4%) subjects. Mean duration of rTMS treatment was 3.8 weeks with a range of two to six weeks. A sub-group analysis suggested treatment effects were greater at week two and week six, but the small number of studies with four weeks length may have precluded an accurate assessment. Stimulus parameters were not reported. No follow-up data were reported. The authors noted that future large-scale studies are needed to assess the long-term effect of rTMS as augmentation and monotherapy for OCD. No conflicts of interest were reported.

Rehn et al[23] conducted a systematic review and meta-analysis of rTMS used to treat OCD and focused on whether certain TMS parameters were associated with higher treatment effectiveness. Eighteen RCTs were included, six of which were also included in the Ma et al (2014) study. Selected studies had patients aged 18-75 years with DSM-IV diagnosis of OCD; had randomized rTMS or sham treatment with either single- or double-blinding or parallel or cross-over design; more than five OCD subjects per arm; LF (</= 1 Hz) or HF-rTMS (>/=5 Hz) for >/= 5 sessions either as mono- or augmentation strategy; and pre- and post-reporting of Y-BOCS scores. Studies were excluded if patients were starting a new medication at the same time as rTMS. The total number of patients was 484 with 262 receiving active rTMS and 222 receiving sham rTMS. Patients ranged in age from 18 to 46 years of age. All trials used rTMS as an augmentation therapy with most of the patients having some degree of treatment resistance. The last Y-BOCS measurement obtained was used as the post-treatment score. Pre-and post-treatment Y-BOCS were available from each of the 18 studies, but the actual scores were not provided. Overall, active rTMS was significantly superior to sham rTMS. Cortical targets over the Bilateral Dorsolateral Prefrontal Cortex (B-DLPFC), Right Dorsolateral Prefrontal Cortex (R-DLPFC)and the supplementary motor area (SMA) yielded significantly superior Y-BOCS scores over sham treatments. Active rTMS directed at the Left Dorsolateral Prefrontal Cortex (L-DLPFC) was not significant in relation to the sham rTMS group. Six trials had Y-BOCS scores at four weeks or less post-treatment and three had scores 12 weeks post-treatment. Improvements in scores were maintained. The authors stated that the clinical utility of rTMS in the treatment of OCD requires further investigation to discern the most optimal stimulation parameters.

Lusicic et al[21] performed a systematic review on the effect of rTMS and dTMS on different brain targets in OCD. Twenty studies met inclusion criteria with 19 using rTMS and one dTMS. All but one of the rTMS trials are included in the meta-analyses described above. The brain areas included in the review were DLPFC, SMA, orbitofrontal/medial prefrontal cortex (OFC), and anterior cingulate cortex (ACC). Frequency stimulation was low (1 Hz) or high (>/=5 Hz). Treatment duration varied from two to six weeks with follow-up ranging from none to three months. Three tables listed 16 of the studies. Nine had Y-BOCS score reductions with rTMS versus sham; eight showed no significant difference. Summaries of dTMS showed that the authors concluded treatment of OCD with neurostimulation shows promise, but it is yet to be determined how best to optimize the approach using rTMS or dTMS to achieve clinically relevant results.

Societal Consensus

Perera et al[7] provides a peer and consensus review related to the effect of rTMS on patients that are in an acute phase of clinical depression and followed for six months to evaluate the durability of TMS. Within the systematic review the authors included over 100 publications and used five major levels of evidence to determine the greater emphasis of studies which resulted in RCT and systematic reviews. The authors also requested additional information such as scientific publication, manufactures' product manuals and manufactures' Medical Technology Dossiers. One additional piece was a survey conducted by the Clinical TMS Society.

The review detailed the first randomized, sham controlled multicenter trial reported by O'Reardon et al (2007). This was a global 23 site study that consisted of numerous phases such as one week, no treatment lead in, a four-to-six-week acute monotherapy of TMS treatment, and then a four to six week open-label trial for non-responders. This study concluded that in the patients that failed one prior medication trial there was a robust effect from TMS versus the sham group ($p<0.001$). The second sham controlled, randomized multicenter trial was conducted by the National Institutes of Mental Health as researched by George (2010). This eight-week study detailed a two-week lead-in phase, three-week fixed TMS treatment protocol phase and a three-week treatment extension phase. The results were summarized as "TMS as monotherapy produced significant and clinically meaningful antidepressant therapeutic effects greater than sham."[7(p340)] The third review consisted of the Brainsway trial that involved 20 locations between the U.S., Canada, Europe, and Israel as researched by Levkovitz (2015). This fully blinded, randomized-active sham trial studied patients with MDD who had failed one to four pharmacological trials. The patients were given TMS in the acute four-week phase and followed with treatment for an additional 12 weeks. The total sample size was 703 patients. The results of this study demonstrated that 64%-90% of patients showed acute TMS durability benefits, and most of the patients relapsing had responded to more TMS treatments.

Additional reviews related to durability and maintenance studies were reviewed and collected. The 'index/acute' course was defined as "the initial series of treatment given to relieve acute symptoms."[7(p340)]. Five meta-analyses were referenced in the consensus information along with society endorsements such as American Psychiatric Association and the World Federation of Societies for Biological Psychiatry to name a few.

As a result of this review and research the following five recommendations emerged: 1) TMS therapy is recommended as an acute treatment for symptomatic relief of depression in the indicated patient

population. 2) TMS therapy is recommended for use as a subsequent option in patients who previously benefited from an acute treatment course and are experiencing a recurrence of their illness (continuation or maintenance). 3) TMS therapy can be administered with or without the concomitant administration of antidepressant or other psychotropic medications. 4) TMS therapy can be used as a continuation or maintenance treatment for patients who benefit from an acute course. 5) TMS therapy can be reintroduced in patients who are relapsing into depression after initially responding to TMS treatment.

McClintock et al[17] provided a consensus statement concluding that "Repetitive transcranial magnetic stimulation (rTMS) is a safe, noninvasive neuromodulation therapy for major depressive disorder (MDD)."[17(p2)] Furthermore, the expert opinion of the National Network of Depression Centers (NNDC) in association with members from the American Psychiatric Association (APA) determined that "rTMS is appropriate as a treatment in patients with MDD even if the patient is medication resistant or has significant comorbid anxiety as long as it is provided within treatment parameters."[17(p5)] The FDA approved the use of rTMS in 2008 for MDD but limited treatment to adults versus adolescents, females with perinatal depression or other neuropsychiatric disorders.

The consensus statement was provided after the review and analysis of three large RCTs, the meta-analyses of 29 RCTs, and review of 118 publications all related to the use of rTMS for MDD as defined by DSM.

The three multicenter industry-sponsored studies in the treatment of MDD resulted in a response rate of 24% and remission rate of 17% with active rTMS, compared with 15% response and 8% remission with sham rTMS.

The meta-analysis of 29 RCTs resulted in 1,371 patients with a response rate of 95%, and remission rate of 95%. The consensus provided a few examples of the RCTs such as:

A systematic review and meta-analysis of 16 double-masked, parallel-design resulted in a response rate of 95%.

The National Institute of Mental Health (NIMH) sponsored a study resulting in a 15% response rate and 14% remission rate in comparison with a 5% response and remission rates in the sham group.

Another industry-sponsored study resulted in a response rate of 37% and remission rate of 30% compared to a 28% response rate and 16% remission rate with sham group.

In conclusion "Practitioners are encouraged to implement rTMS based on available evidence-guided recommendations and to employ systematic measurement for documenting safety and efficacy".[17(p16)] It was also recommended that six weeks of standard acute TMS treatment will "very likely be needed to achieve results consistent with published regulatory rituals."[17 (p8)]

The National Institute for Health and Care Excellence (NICE)[29] provided guidelines for 'Repetitive transcranial magnetic stimulation for depression' Interventional procedure guidelines:

- Support use of TMS as there are no major safety concerns when used for depression.
- Efficacy is short-term with variable clinical responses.

- Further evidence is needed based on regime type, stimulation used, long-term outcomes and maintenance treatment.

U.S. Food and Drug Administration (FDA)

The FDA provides information related to the marketing and Class II Special Controls for Repetitive Transcranial Magnetic Stimulation (rTMS) in the treatment of Major Depressive Disorders in 2008 and the treatment relates to obsessive-compulsive disorders in 2011.[1-3]

The following is a summary of the evidence submitted with a reconsideration request to extend coverage to include 'moderate' in addition to severe major depressive disorder diagnosis:

Müller et al[30] conducted a study to assess the depression severity of patients with major depression as diagnosed by DSM-IV, by utilizing HAMD17, MARDS and CGI scores. The study attempted to establish the cut off scores for moderate and severe depression in MADRS by using cross-validation to a previous study and by using CGI to correspond with MADRS and HAMD17. It was determined that the correlation between mean MADRS, HAMD17, and CGI scores that were $r>0.85$; $P<0.0001$. The author identified that "No empirically based MADRS cut-off scores to separate 'moderate' from 'severe' depression were available so far."[30(p256)]

Eighty-five hospitalized patients with a diagnosis of major depression were evaluated by five psychiatrists that were trained and reviewed using the interrater reliability coefficients that were >0.85. Patients were interviewed and scored within one week of admission and before or the same day of discharge. The Pearson's correlation coefficient and receiver operating characteristic curves were calculated, and the level of statistical significance was set at $X=0.05$.

MARDS and HAMD17 were based on a mean with confidence intervals of 95%. 'Moderate' was defined as 13.9 on MARDS versus 12.3 on HAMD17 for 15 patients. 'Severe' was defined as 35.9 on the MARDS versus 26.5 on the HAMD17 for 25 patients. This would conclude that a difference of ≥ 22 points on the MARDS would separate 'moderate' from 'severe'. A difference of ≥ 13.5 points on the HAMD17 would separate 'moderate' from 'severe'.

There were two noted limitations 1) the scoring psychiatrist was also the patient's treating physician and 2) the role various antidepressants play in the scoring for each patient. It was noted by the author that further studies to validate groupings should include DSM-IV or ICD-10 CM diagnostic severity categories.

Zimmerman et al[31] concluded a severity classification based on the use and derivatives of the HAMD17, CGI and correlates with the Schedule for Affective Disorders and Schizophrenia (SAD) for 627 outpatients with current major depression. The majority of the outpatients in the study were white females that had health insurance. Additionally, 64% were females between the ages of 18 to 78 years of age. Sixty-two percent were college educated with 31% completing a four-year college.

The data collected during the study was compared to the CGI severity scoring and placed in the receiver operating curve (ROC) to determine the cutoff scores for HAMD17. The results where then referenced as the mean scores with HAMD mean being 18.8 (SD = 5.6) and a one-way analysis comparing HAMD17 to CGI. The results on the HAMD17 were lower with mild depression than for

patients with moderate depression. The scores were as follows: 15.3 +4.9 vs.18.1+5.1, t= −3.7, p<.001 for mild and 18.1 +5.1 vs.23.0+5.7, t= −9.0, p<.001 respectively. Resulting in the following depression severity HAMD17 range None = 0-7, mild 8-16, moderate 17-23 and severe ≥24.

It was noted that there are no "well-demarcated lines separating the severity subtypes"[31] and that the cutoffs are to be used to define severity categories for interpreting studies of efficacy of antidepressants and the effect of treatment selection.

The following is a summary of the evidence submitted with two reconsideration requests to provide coverage for the failure of one or more psychopharmacological medications for MDD.

Brakemeier et al[32] conducted a study related to the review and proof of prior studies as it relates to drug free patients. Within the study they chose 79 patients, 48 from Munich and 31 from Berlin all with MDD or Bipolar II that were naïve to rTMS and 35% were drug resistant with one to five treatment trials.

The treatment trials of rTMS varied between location and was not uniform in the protocol. The result demonstrated that 79 patients completed the treatment session and after two weeks 34% showed an antidepressant response from baseline HAMD scores. The mean reduction in the HAMD21 scores was 69% in responders and 4% in non- responders. Additional models such as the logistic regression, linear regression and statistical methods were applied to determine response with all pointing back to "non-treatment resistant patients with a short duration of episode were more likely to respond to rTMS than medication resistant (43% vs. 18%) (P = 0.023)."[28]

Yang et al[33] conducted a RTC that incorporated one clinical site. The trial was conducted between 2016-2017 and there were initially 82 participants who had the first episode of depression with no administration of any antidepressant or antipsychotic medication. Forty-one patients were within the active group and 41 patients were placed in the sham group. Four patients dropped out with the remaining 78 patients having an average baseline HAMD17 score of 24 within the active group and a score of 25 for the patients in the sham group making participants moderately to severely ill.

TMS treatment was provided at the following dose/time: exercise threshold 100%, ten repetitions, 1Hz, 1,200 total stimulations with a 20-minute session over ten sessions. Patients were also treated with 10mg of Escitalopram (Lexapro) during the acute treatment phase.

The HAMD17 scores at the end of two weeks drastically improved to an average of 15 (compared to a baseline score of 24) on the HAMD scoring tool. The sham group reported a mean scoring of 20 compared to 25 on the HAMD tool. At the end of four weeks of treatment the active group's mean HAMD scoring was nine in comparison to the patients in the sham groups that averaged 13 on the HAMD tool. At the end of four weeks of acute treatment it was determined that 36 (87%) patients in the active group and 17 (41%) patients in the sham group noted improvement in clinical symptoms.

Consultation Summary

Contractor Advisory Committee (CAC) Evidentiary Summary – 09/29/2021

Wisconsin Physicians Service Insurance Corporation (WPS) hosted a multi-jurisdictional CAC meeting to review the evidence for reconsideration requests to determine if coverage for OCD is warranted when a treatment plan has included TMS as an option. Additionally, the CAC was tasked to determine if TMS treatment should be reserved for treatment resistant patients if there is a standard of managing severity and if the evidence supported a significant portion of the Medicare population.

Subject matter experts (SMEs) from Psychiatry, Neurology, Emergency Psychiatric Services, Geriatric Psychiatry, TMS Clinics, OCD/Neuromodulation Programs, and Neuropsychopharmacology were represented. All literature submitted by the SMEs to supplement the reference list was also reviewed.

The panel of SMEs determined that while confidence in coverage of TMS in OCD was noted it did not support treatment within the Medicare population and the studies suffered from small sample sizes, bias, poor design, limited follow-up, and inconsistent results. Many questions remain in terms of the efficacy, location of device application, frequency and duration of use, and the clinical presentation of the patient at the time TMS treatment is initiated.

Analysis of Evidence (Rationale for Determination)

Coverage of items and services in the Medicare program is provided based on what is reasonable and necessary for the Medicare population. This concept is operationalized by the application of evidentiary standards, clinical validity, and clinical utility. Through the process of review and reconsideration the focus remains on patient outcomes that demonstrate reduced mortality and morbidity, and that will improve patient quality of life and function. The evidence thresholds for coverage are a careful balance of benefits and harms in the consideration of net health outcomes.

The level of treatment resistance related to the failure of medication trials and intolerance to psychopharmacologic medications shows direct correlation with the level of treatment resistance and aids in the success of TMS treatment, for patients with MDD. The clear and reported treatment success was identified in studies related to the failure of at least one pharmacological trial and/or an intolerance of a psychopharmacologic medication. Two consensuses' statements from the neurological societies indicate an improved status and follow up for the patients that received TMS treatment with only having failed one or more trials.

The FDA provided special controls and guidance in 2008 for the use of TMS in MDD. Within the clinical manifestations of MDD there are varying degrees of depression (mild, moderate, and severe). There are various clinical evaluation and rating tools such as Quick Inventory of Depressive Symptomatology – Self Rating (QIDS-SR)16, Inventory of Depressive Symptomatology – Self Rating (IDS-SR30), HAMD17, HAMD21 and HAMD24, available to assist the provider in diagnosing major depressive disorders per the DSM.

The evaluations and rating tools can provide guidance to severity, but there is no defined standard of measurement or classification to determine mild, moderate, or severe. This hinders any standardized treatment protocols, expected outcomes or benefits to the patient but aids the healthcare professional in diagnosing MDD.

The clinical trials, RCTs, Meta-analyses, societal recommendations, and literature provided in this LCD demonstrated different standards for entry into the studies, different rating/evaluation tools, different outcome standards and differences in post treatment follow up. With the varied protocol standards,

clinical validity, and clinical utility there is no existing evidence that meets the requirement of reasonable and necessary to expand the criteria of MDD to other than 'severe' as defined by the most current DSM criteria when diagnosed by the psychiatrist that examined the patient face to face.

In 2018, the FDA expanded the use of TMS in OCD based on a RCT multi-center study with 100 patients and reviewed the 'Brainsway' device through the de nova premarket pathway. Even though TMS was determined to be safe in the treatment of OCD, the current evidence has not been standardized or replicated to the standard and quality needed in providing a balance of benefits and harm when considering net health outcomes for the beneficiary.

Within the literature available, limitations include a lack of standardized protocol and a lack of high-quality studies. Current studies have small sample sizes, bias, poor design, limited follow-up, and inconsistent results. The authors agree there is a low risk associated with treatment, but the literature suggests safety and long-term data has not been obtained. There is a trend towards a benefit, as noted in the meta-analysis and randomized control trials, that suggest there may be a role in refractory OCD. However, many questions remain in terms of the efficacy, location of the device application, and the frequency/duration of the treatment. Several systematic reviews/meta-analyses conclude that TMS demonstrated a range from no-response to modest effect on the reduction of OCD symptoms. Further research is required to determine optimal frequency, total pulses per session, and duration of treatment. This will be closely monitored for any future research. At this time, TMS treatment for OCD has been determined to be not medically reasonable and necessary.

Following extensive literature review, discussions with CAC members, and SMEs it has been determined that TMS treatment will be considered medically reasonable and necessary for patients with a confirmed diagnosis of severe major depressive disorder and that have demonstrated a failure of one or more pharmacological medications and/or intolerance to psychopharmacologic medications. At this time TMS treatment for OCD has been determined to be not medically reasonable and necessary.

General Information

Associated Information

Please refer to the related Local Coverage Article: Billing and Coding: Transcranial Magnetic Stimulation (TMS) in the Treatment of Adults with Major Depressive Disorder (A57647) for documentation requirements, utilization parameters and all coding information as applicable.

Sources of Information

N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
12/11/2022	R6	LCD posted for notice on 10/27/2022 to become effective 12/11/2022. 06/09/2022 - Proposed LCD posted for comment.	• Creation of Uniform LCDs With Other MAC Jurisdiction
11/28/2019	R5	Revision Number: 4 Publication: November 2019 Connection LCR A/B2019-075 Explanation of Revision: Based on Change Request (CR) 10901, the LCD was revised to remove all billing and coding and all language not related to reasonable and necessary provisions ("Bill Type Codes," "Revenue Codes," "CPT/HCPCS Codes," "ICD-10 Codes that Support Medical Necessity," "Documentation Requirements" and "Utilization Guidelines" sections of the LCD) and place them into a newly created billing and coding article. Also, other formatting was updated regarding the "Limitations" and "Provider Qualifications" sections. The effective date of this revision is for claims processed on or after January 8, 2019, for dates of service on or after October 3, 2018. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this LCD.	• Other (Revision based on CR10901)

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/22/2019	R4	Revision Number: 3 Publication: February 2019 Connection LCR A/B2019-004 Explanation of Revision: Based on review of the LCD, grammatical errors were corrected and the “Sources of Information” section of the LCD was revised to alphabetize the references. The effective date of this revision is based on process date. In addition, based on CR 10901, the “Coverage Indications, Limitations, and/or Medical Necessity” section of the LCD was revised to update the section number for Pub. 100-08, Chapter 13 from 13.5.1 to 13.5.4. Also, “Pub. 100-08, Chapter 13, Section 13.5.4” was added to the “CMS National Coverage Policy” section of the LCD. The effective date of this revision is for claims processed on or after 01/08/2019, for dates of service on or after 09/26/2018. 01/22/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this LCD.	• Other (Revisions based on review)
06/26/2018	R3	Revision Number: 2 Publication: July 2018 Connection LCR A/B2018-055 Explanation of Revision: The “Sources of Information” section of the LCD was	• Reconsideration Request

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		updated to include multiple published sources from reconsideration requests. The content of the LCD has not been changed in response to the reconsideration requests. The effective date of this revision is based on date of service. 06/26/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.	
01/09/2018	R2	Revision Number: 1 Publication: January 2018 Connection LCR A/B2018-010 **Explanation of Revision:** Based on an annual review of the LCD, it was determined that some of the italicized language in the “Indications and Limitations of Coverage and/or Medical Necessity” section of the LCD does not represent direct quotation from the CMS sources listed in the LCD; therefore, this LCD is being revised to assure consistency with the CMS sources. The effective date of this revision is based on date of service. 01/09/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the	• Other (Annual Review completed on 10/30/2017.)

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.	
10/01/2015	R1	ICD-10 LCD UPDATED.	• Other

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A57647 - Billing and Coding: Transcranial Magnetic Stimulation (TMS) in the Treatment of Adults with Major Depressive Disorder

A59263 - Response to Comments: Transcranial Magnetic Stimulation (TMS) in the Treatment of Adults with Major Depressive Disorder (MCD Archive Site)

LCDs

DL34522 - Transcranial Magnetic Stimulation (TMS) in the Treatment of Adults with Major Depressive Disorder (MCD Archive Site)

Related National Coverage Documents

NCDs

N/A

Public Versions

Updated On	Effective Dates	Status	
10/21/2022	12/11/2022 - N/A	Currently in Effect	You are here

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A