

Clinical Policy: Deep Transcranial Magnetic Stimulation for the Treatment of Obsessive Compulsive Disorder

Reference Number: CP.BH.201 Date of Last Revision: 12/22 Coding Implications Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Description

Deep Transcranial Magnetic Stimulation (dTMS) is a non-invasive tool that stimulates deep regions of the brain, such as the anterior cingulate cortex (ACC) or ventral capsule/ventral striatum (VC/VS) region and is an FDA approved modality for obsessive compulsive disorder (OCD) treatment. dTMS alters neuron activity using a wire coil to stimulate with brief high currents.

Policy/Criteria

- I. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation[®] that a medical director will review initial requests for up to 20 sessions of deep transcranial magnetic stimulation on a case-by-case basis, informed by the following:
 - A. Age \geq 18 years with a diagnosis of Obsessive Compulsive Disorder (OCD);
 - B. Oversight of treatment is provided by a licensed psychiatrist;
 - C. Obsessive Compulsive Disorder (OCD) is not part of a presentation with multiple psychiatric comorbidities;
 - D. Failure to respond to a combination of multiple trials of medication combined with Cognitive Behavioral Therapy (CBT) and/or Exposure and Response Prevention (ERP) for at least 12 weeks during the current episode of illness, as demonstrated by both of the following:
 - 1. Less than 25% improvement in the Yale Brown Obsessive Compulsive Scale (Y-BOCS);
 - 2. Failure to respond to psychopharmacologic agents is defined as a lack of clinically significant response in the current OCD episode to four trials of agents from at least two different agent classes, and one of the following:
 - At least two of the treatment trials were administered as an adequate course of mono- or poly-drug therapy with Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs), clomipramine, or atypical antipsychotic augmentation involving standard therapeutic doses of at least 12 weeks duration;
 - b. The patient is unable to take SSRI, NSRI, clomipramine, or atypical antipsychotics due to one of the following:
 - i. Drug interactions with medically necessary medications;
 - ii. Inability to tolerate psychopharmacologic agents, as evidenced by trials of four such agents with distinct side effects in the current episode;
 - E. Does not have any of the following contraindications:
 - 1. History of seizures;
 - 2. Conductive or ferromagnetic or other magnetic-sensitive metals implanted or embedded in head or neck within 30 cm of dTMS coil placement other than dental fillings (e.g. cochlear implants, implanted electrodes/stimulators, aneurysm clips or



coils, stents, bullet fragments, metallic dyes in tattoos, deep brain stimulators, vagus nerve stimulators, other implanted electrodes or stimulators);

- 3. Vagus nerve stimulator leads in the carotid sheath;
- Other implanted stimulators controlled by or that use electrical or magnetic signals, (e.g. deep brain stimulation, cardiac pacemaker, cardioverter defibrillator, intracardiac lines and medication pumps);
- 5. Substance abuse at time of treatment;
- 6. Severe dementia;
- 7. Severe cardiovascular disease;
- 8. Known non-adherence with previous treatment for OCD;
- 9. Any mental health and substance use disorders (previously categorized as "Axis I" psychiatric disorders) other than OCD (e.g. including active alcohol or substance abuse, Mood Disorders, Psychotic Disorders, other Anxiety Disorders, etc.); neurological diseases or head injury; or pregnancy.
- **II.** It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that requests for an additional 10 sessions of dTMS will be reviewed by a medical director on a case-by-case basis, informed by the following:
 - A. There has been a positive treatment response, evidenced by a ≥25% reduction of OCD symptom severity, as measured by the YBOCS score (or other standardized OCD scale);
 - B. For patients who demonstrated a >25% reduction in baseline severity scores and are approaching a YBOCS score of 15 or for those who have a history of good response to dTMS followed by relapse into OCD over a 6 months period, authorization of an additional 6 taper dTMS sessions over a period of 3 weeks will be considered.
- III. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that maintenance treatment with dTMS is considered **not medically necessary**, as there is not sufficient peer reviewed literature to support maintenance for dTMS at this time.
- **IV.** It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that retreatment with dTMS will be reviewed on a case-by-case basis by a medical director, informed by all of the following:
 - A. Current OCD symptoms have worsened with YBOCS scores over 15;
 - B. Prior treatment response was at least a 50% drop from the baseline OCD scores;
 - C. Does not have any of the following contraindications:
 - 1. History of seizures
 - Conductive or ferromagnetic or other magnetic-sensitive metals implanted or embedded in head or neck within 30 cm of dTMS coil placement, other than dental fillings (e.g. cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils, stents, bullet fragments, metallic dyes in tattoos, deep brain stimulators, vagus nerve stimulators, other implanted electrodes or stimulators);
 - 3. Vagus nerve stimulator leads in the carotid sheath;
 - Other implanted stimulators controlled by or that use electrical or magnetic signals, (e.g. deep brain stimulation, cardiac pacemaker, cardioverter defibrillator, intracardiac lines and medication pumps);



- 5. Substance abuse at time of treatment;
- 6. Severe dementia;
- 7. Severe cardiovascular disease;
- 8. Known non-adherence with previous treatment for OCD;
- 9. Any mental health and substance use disorders (previously categorized as "Axis I" psychiatric disorders) other than OCD (e.g. including active alcohol or substance abuse, mood disorders, psychotic disorders, other anxiety disorders, etc.); neurological diseases or head injury; or pregnancy.

Background

Obsessive Compulsive Disorder (OCD) is a debilitating chronic condition with a lifetime prevalence in the United States of 2.3% and the disorder affects 1 to 3% of the population. The World Health Organization classifies OCD as one of the top ten debilitating medical conditions, as OCD is associated with a decreased quality of life and loss of income.^{1,3,5} Symptoms of OCD include obsessive thoughts, which are recurrent unwelcomed, intrusive, and distressing, accompanied by compulsive acts, which are repetitive and often time-consuming behaviors or rituals. Severe treatment resistant OCD can be chronic and disabling.^{5, 10}

Pharmacological treatment combined with psychotherapy is the standard initial treatment of OCD. Cognitive Behavioral Therapy (CBT) and/or Exposure and Response Prevention (ERP), combined with Selective Serotonin Reuptake Inhibitors (SSRIs) or Clomipramine are traditionally the first line of treatment for OCD, however the most severe patients do not respond to these methods and these treatments can have a slow treatment response. In patients with refractory or treatment resistant OCD, pharmacological treatment may include serotonin-noradrenaline re-uptake inhibitors (SNRIs), intravenous clomipramine, citalopram or atypical antipsychotic medication. Other treatments for resistant forms of OCD include repetitive transcranial magnetic stimulation, transcranial direct current stimulation (tDCS), invasive deep brain stimulation (DBS), vagal nerve stimulation (VNS), and electroconvulsive therapy (ECT).¹⁰

Over 40% of individuals diagnosed with OCD remain symptomatic and significantly disabled, even after initial evidence based treatment, therefore, an alternative treatment is non-invasive brain stimulation using deep Transcranial Magnetic Stimulation (dTMS).³ Deep Transcranial Magnetic Stimulation is a non-invasive tool, which stimulates deep areas of the brain, such as the anterior cingulate cortex (ACC) or ventral capsule/ventral striatum (VC/VS) region using a coil to pass electrical energy. Deep TMS alters neuron activity using a wire coil to stimulate with brief high currents. The FDA Approved the use of dTMS for OCD in 2018 due to data indicating dTMS can reduce YBOCS scores in individuals with OCD when compared to sham stimulation. However, currently only limited research exists regarding dTMS in the treatment of refractory OCD. Current research suggests that dTMS is an option for treatment of treatment resistant OCD when other evidence based pharmacological and psychotherapy combinations have failed.

Yale Brown Obsessive Compulsive Scale (Y-BOCS)

The Y-BOCS provides five rating dimensions for obsessions and compulsions: time spent or occupied; interference with functioning or relationships; degree of distress; resistance; and control (i.e., success in resistance). The 10 Y-BOCS items are each scored on a four-point scale from 0 = "no symptoms" to 4 = "extreme symptoms." The sum of the first five items is a severity





index for obsessions, and the sum of the last five an index for compulsions. A translation of total score into an approximate index of overall severity is:

- a. Subclinical <8
- b. Mild 8 to 15
- c. Moderate 16 to 23
- d. Severe 24 to 31
- e. Extreme 32 to 40

Generally, a reduction in Y-BOCS score of 25% or 35% with a final Y-BOCS is considered the criteria for response to treatment.

The Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD L33398, Transcranial Magnetic Stimulation, effective 10/1/20, published indications and limitations for Deep TMS (d-TMS), <u>LCD - Transcranial Magnetic Stimulation (L33398)</u> (cms.gov). The updated publication was based on a reconsideration request received April 2019 to allow coverage of dTMS for obsessive compulsive disorder (OCD). A literature review was conducted to examine the use of rTMS for OCD. The conclusions of the analysis based on the reconsideration request indicated "There is currently insufficient evidence to show use of rTMS or dTMS for OCD as reasonable and necessary for the treatment of illness or injury [SSA § 1862 (a)(1)(A)] in the Medicare population. Medical policies of commercial insurers also find the treatment not medically necessary. The rTMS studies have heterogenous populations, vary in frequency and site of stimulation, have mixed results, and short follow-ups. The dTMS investigations are in their infancy with one randomized double-blind controlled trial studying 99 patients, with a 12% drop-out rate, and a four-week follow-up. The ability of rTMS or dTMS to improve outcomes in patients with OCD is yet to be determined."

Coding Implications

This clinical policy references Current Procedural Terminology (CPT[®]). CPT[®] is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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



HCPCS	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD 10 CM	Description
F42 through F42.9	Obsessive-compulsive disorder

Reviews, Revisions, and Approvals		Approval Date
New Policy	Date 8/20	11/20
New Policy Additional language to Section I. Policy/Criteria, D. includes "score 16-23 for moderate symptoms and up to 31 for severe symptoms, minimum score being 24. A score indicating moderately severe to severe OCD throughout the current course of treatment (or other standardized scale indicating moderately severe to severe OCD); a. The Y-BOCS provides five rating dimensions for obsessions and compulsions: time spent or occupied; interference with functioning or relationships; degree of distress; resistance; and control (i.e., success in resistance). The 10 Y-BOCS items are each scored on a four-point scale from 0 = "no symptoms" to 4 = "extreme symptoms." The sum of the first five items is a severity index for obsessions, and the sum of the last five an index for compulsions. A translation of total score into an approximate index of overall severity is: Subclinical <8, Mild 8-15, Moderate 16-23, Severe 24-31 Extreme 32-40: a. Generally, a reduction in Y-BOCS score of 25% or 35% with a final Y- BOCS is considered the criteria for response to treatment. There is also a Children's YBOCS however, these procedures are currently only approved for adults.	2/21	2/21
Changed all medical necessity statements to require medical director review. Moved YBOC scale information in section I to the background. Minor edits made for clarity of review process.	3/21	4/21
Annual review of policy. Confirmed current CPT codes for TMS and ICD- 10 codes for OCD, and updated policy with grammar and format revisions.	2/22	2/22
Added CMS Local Coverage Determination (LCD L33398, Transcranial Magnetic Stimulation, effective 10/1/20, published indications and limitations for Deep TMS (d-TMS) to the background section and reference section.		4/22
Ad-hoc review. Changed "review date" in the header to "date of last revision: and "date" in the revision log header to "revision date". Edited policy statements I-IV to note that they apply to Centene Advanced Behavioral Health as well as plans affiliated with Centene Corporation. Replaced all instances of "dashes (-)" in page numbers with the word "to".	12/22	12/22



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 Local coverage determination: Transcranial Magnetic Stimulation (LCD L33398). Centers for Medicare and Medicaid Services. <u>https://www.cms.gov/medicare-coverage-database</u>. Published October 1, 2015 (Revised October 1, 2020). Accessed January 4, 2023.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.



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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <u>http://www.cms.gov</u> for additional information.

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