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

Reference Number: CP.BH.201 Coding Implications
Date of Last Revision: 02/25 Revision Log

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

Description
This clinical policy describes the medical necessity criteria for Deep Transcranial Magnetic Stimulation(dTMS) for the treatment of obsessive-compulsive disorder (OCD).

Obsessive Compulsive Disorder (OCD) is a mental health disorder which includes obsessions, which are recurring, persistent and intrusive. Individuals who experience such obsessive thoughts feel the need to do something in a repetitive, compulsive manner which can be time consuming (more than one hour a day), and often and contributes to emotional distress, or significantly interferes with daily activities such as social interactions.[1]

Deep Transcranial Magnetic Stimulation (dTMS) utilizes magnetic fields to safely regulate the neural activity of brain structures associated with OCD. It utilizes a non-invasive tool using an H-7 coil that stimulates deep regions of the brain, regulating the anterior cingulate cortex (ACC) and the medial prefrontal cortex (mPFC).[2]

Policy/Criteria
I. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation® that *initial treatment* of obsessive-compulsive disorder with deep transcranial magnetic stimulation is considered medically necessary when meeting all of the following criteria:
- A. The member/enrollee is ≥ 18 years old;
- B. The member/enrollee has a confirmed diagnosis of obsessive-compulsive disorder (OCD), per the current Diagnostic and Statistical Manual of Mental Disorders (DSM);
- C. Obsessive Compulsive Disorder (OCD) is not part of a presentation with multiple psychiatric comorbidities;
- D. The member/enrollee failed 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 representing at least two different agent classes, and one of the following:
     a. 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 member/enrollee 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. Request is for up to 36 sessions. **Note**: Recommended schedule is for five days a week for six weeks, with an optional six sessions for tapering;
F. Treatment is administered using a Food and Drug Administration (FDA) cleared device utilized in accordance with the FDA labeled indications such as but not limited to one of the following:
   1. Brainsway Deep Transcranial Magnetic Stimulation System (dTMS H7coil);
   2. MagVenture TMS Therapy System (cool DB8o coil);
   3. Magstim Horizon 3.0 (with or without StimGuide+) and E-z Cool Coil;
   4. NeuroStar Advanced Therapy System;
G. Direct supervision of treatment is provided by a licensed psychiatrist except where state scope of practice acts allows for other provider types to supervise;
H. The member/enrollee does not have any of the following contraindications:
   1. Conductive or ferromagnetic or other magnetic-sensitive metals implanted or embedded in head or neck within 30 cm of dTMS H7 coil placement other than dental fillings including but not limited to the following:
      a. Cochlear implants;
      b. Implanted electrodes/stimulators;
      c. Aneurysm clips or coils;
      d. Stents;
      e. Bullet fragments;
      f. Metallic dyes in tattoos;
      g. Vagus nerve stimulators;
   2. Other implanted stimulators controlled by or that use electrical or magnetic signals such as but not limited to the following:
      a. Deep brain stimulation;
      b. Cardiac pacemaker;
      c. Cardioverter defibrillator;
      d. Intracardiac lines;
      e. Medication pumps;
   3. Less than three months of substantiated remission from a substance use disorder;
   4. Known non-adherence with previous treatment for OCD;
   5. Any mental health disorder other than OCD (e.g., mood disorders, psychotic disorders, other anxiety disorders, etc.);

II. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that *maintenance treatment* with dTMS for obsessive-compulsive disorder is considered **not medically necessary,** as there is not sufficient peer-reviewed literature to support maintenance for dTMS at this time.

III. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that *retreatment* of obsessive-compulsive disorder with dTMS will be reviewed on a case-by-case basis by a medical director, informed by all of the following factors:

A. Criteria for initial dTMS treatment continues to be met;
B. Current OCD symptoms have worsened with YBOCS scores over 15;
C. Prior treatment response was at least a 30% drop from the baseline OCD scores (with a documented 6-month duration of response).

Background

According to the American Psychological Association (APA) 2-3% of individuals in the United States are impacted by obsessive compulsive disorder (OCD). Pharmacological treatment, such as selective serotonin reuptake inhibitors, combined with psychotherapy such as cognitive behavioral therapy (CBT) and exposure response prevention (ERP), are considered first line treatment for OCD.[1]

In 2019, Carmi et al. conducted a prospective multicenter randomized double-blind placebo-controlled trial which examined the therapeutic effect of dTMS. The research was conducted at 11 centers in which 99 OCD patients were randomly assigned to dTMS treatment with either high-frequency (20 Hz) or sham dTMS. The sessions were conducted daily following individualized symptom provocation for 6 weeks. The clinical responses were determined using YBOCS and the primary efficacy endpoint was the change in score from baseline to posttreatment assessment. The results indicated a reduction in YBOCS score among those who received active dTMS treatment. This was significantly greater than those who received sham treatment, with response rates of 38.1% and 11.1%, respectively. At the one-month follow-up, the response rates were 45.2% in the active treatment group and 17.8% in the sham treatment group. The study suggests that high frequency dTMS over the medial prefrontal cortex and anterior cingulate cortex significantly improved OCD symptoms and may be considered as a potential intervention for members/enrollees who do not respond adequately to pharmacological and psychological interventions."[4]

In 2021, Roth et al. conducted a review of the efficacy of dTMS for OCD in real world practices. This post marketing study entailed twenty-two clinical sites with H7-coils providing data on details of treatment and outcome (YBOCS) measures from a total of 219 patients. One hundred-sixty-seven patients who had at least one post-baseline YBOCS measure were included in the main analyses. Overall first and sustained response rates were 72.6% and 52.4%, respectively. The response rate was 57.9% of patients who had YBOCS scores after 29 dTMS sessions. The first response was achieved on average after 18.5 sessions (SD = 9.4) or 31.6 days (SD = 25.2). Onset of sustained one-month response was achieved in average after 20 sessions (SD = 9.8) or 32.1 days (SD = 20.5). Average YBOCS scores demonstrated continuous reduction with increasing numbers of dTMS sessions. The conclusion proposed that majority of OCD patients benefitted from dTMS, and the onset of improvement usually occurs within 20 sessions. Extending the treatment course beyond 29 sessions results in continued reduction of OCD symptoms, raising the prospect of value for extended treatment protocols in non-responders.[5]

Additional recent meta-analyses conclude that TMS of several brain targets represents a safe and effective treatment option for OCD, however, further research is needed to help clinicians individualize TMS protocols and targets for each member/enrollee.[6,7]

Clinical TMS Society[8]
Transcranial magnetic stimulation or TMS is a non-invasive, diagnostic, and therapeutic technique that uses small magnetic fields to stimulate or inhibit regions of the brain by electromagnetic induction through a small generator coil (Figure-8 or H-coil), placed over the patient's head. TMS delivers magnetic pulses to certain brain regions, producing changes in the activity of the brain cells. The frequency of pulse delivery influences whether brain activity is increased or decreased in the affected cells. This means that the effects of TMS treatment can be long lasting because it changes the patterns by which nerve cells and brain networks connect and communicate with each other.

International OCD Foundation[9]
TMS should be used as an add on treatment for those who have already tried first line treatment modalities such as ERP and/or medication.

Yale Brown Obsessive Compulsive Scale (Y-BOCS)[10]
The Y-BOCS was developed by Goodman, W.K., Price, L.H. Rassmussen, S.A., et al. in 1989. It is a standardized rating scale designed to rate the severity and type of symptoms in patients with obsessive compulsive disorder (OCD). measuring 10-items pertaining to obsessions and components on a five-point Likert scale. Scores range from 0 (no symptoms) to 4 (extreme symptoms) with the total score calculated by subtotaling the items which can range from 0 to 40.

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 2024, 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
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes

Reviews, Revisions, and Approvals	Revision Date	Approval Date
New Policy	8/20	11/20
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., 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 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.	3/22	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 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
Annual Review. Policy restructured and reformatted with no impact to meaning. Added the following statement to the description section: "obsessive compulsive disorder (OCD) treatment with TMS delivers magnetic stimulation to the frontal brain structures and networks, targeting previously unreachable areas of the brain." In policy statement I.: changed the initial request of sessions from "20" to "30" sessions. In criteria point I.A.: added the statement "per DSM-5-TR Criteria". Added criteria point I.B, "Administered using and Food and Drug Administration (FDA) cleared device and utilized in accordance with the FDA labeled indications such as but not limited to the following" and added a list of FDA approved devices. In criteria point I.F.4.: Added the following	02/23	03/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
statement "such as but not limited to the following". Removed the following statement from criteria point I.F.11.: "previously categorized as "Axis I" psychiatric disorders". Added the following contraindication to I.F.12.: "No active suicidal ideation with intent". In policy statement II. replaced "request for an additional 10 sessions" with "request for taper of six final sessions". Added to criteria point II.A. "Criteria for initial dTMS treatment guidelines continues to be met." In criteria point II.B. replaced "25% reduction of OCD symptom severity" with "30% reduction of OCD symptom severity". In criteria point II.C. replaced "25% reduction in baseline severity scores" with "30% reduction in baseline severity scores". Added to criteria point IV.A.: "Criteria for initial dTMS treatment guidelines continues to be met." In criteria point IV.C. changed the responses percentage baseline drop from "50% drop from the baseline OCD scores" to "30% drop from the baseline OCD scores". Deleted criteria point IV. D.1-9. as this information is captured in IV.A. Replaced all instances of "member" with "member/enrollee." Added semicolons throughout the criteria section. Coding reviewed. Background section updated. References reviewed, updated, and reformatted. Policy reviewed by internal specialists. Policy reviewed by external specialists.		
Annual Review. Updated description with no clinical significance. Minor rewording throughout the policy for clarity with no clinical significance. Separated former criteria point I. A into two sub points (A and B). Criteria point I. D. reworded for clarity "Direct supervision of treatment is provided by a licensed psychiatrist except where state scope of practice acts allows for other provider types to supervise." Removed I.H.3. "Vagus nerve stimulator leads in the carotid sheath" as this is captured in I.H.2.h. In criteria point I.H.4. Replaced "substance abuse at time of treatment" with "less than three months of substantiated remission from a substance use disorder." Removed "Neurological disease or head injury" and "pregnancy" from the contraindication list. Added new CPT/HCPCS codes: "97014: Application of a modality to 1 or more areas; electrical stimulation (unattended); 97032: Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes. Background section updated. References reviewed and updated.	03/24	03/24
Annual review. Updated description with no clinical significance. Minor rewording throughout the policy for clarity with no clinical significance. Removed verbiage indicating that the request must be reviewed by a medical director. In I.E., changed the frequency of services from 30 to 36 approved sessions "Request is for up to 36 sessions (Note: Recommended schedule is for five days a week for six weeks, with an optional six sessions for tapering)". In I.H. removed the following relative contraindications: history of seizures, severe dementia, severe cardiovascular disease, and active suicidal ideation with intent. Deleted what was policy statement II. referencing tapering criteria. In III. C. added statement indicating	02/25	02/25

Reviews, Revisions, and Approvals	Revision Date	Approval Date
documented 6-month duration of response. Background section updated. References reviewed and updated.		

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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/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Member/enrollee 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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, 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/enrollees, 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 prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.