

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

Reference Number: CP.BH.201

Date of Last Revision: 02/23

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## 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 using a coil to pass electrical energy. <sup>1</sup> Obsessive Compulsive Disorder (OCD) treatment with TMS delivers magnetic stimulation to the frontal brain structures and networks, targeting previously unreachable areas of the brain. <sup>2</sup>

## Policy/Criteria

- I. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation<sup>®</sup> that a medical director will review initial requests for up to 30 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), per DSM-5-TR Criteria;
  - 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:
    1. Brainsway Deep Transcranial Magnetic Stimulation System;
    2. MagVenture TMS Therapy System;
    3. Horizon 3.0 (with or without StimGuide+) and E-z Cool Coil;
  - C. Oversight of treatment is provided by a licensed psychiatrist;
  - D. OCD is not part of a presentation with multiple psychiatric comorbidities;
  - E. 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:
      - 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, SNRI, clomipramine, or atypical antipsychotics due to one of the following:
        - i. Drug interactions with medically necessary medications;

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- ii. Inability to tolerate psychopharmacologic agents, as evidenced by trials of four such agents with distinct side effects in the current episode;
  - F. 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 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. Deep brain stimulators;
      - h. Vagus nerve stimulators;
      - i. Other implanted electrodes or stimulators);
    3. Vagus nerve stimulator leads in the carotid sheath;
    4. 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;
    5. Substance abuse at time of treatment and/or substance use disorder;
    6. Severe dementia;
    7. Severe cardiovascular disease;
    8. Known non-adherence with previous treatment for OCD;
    9. Neurological disease or head injury;
    10. Pregnancy;
    11. Any mental health disorder other than OCD (e.g. mood disorders, psychotic disorders, other anxiety disorders, etc.);
    12. No active suicidal ideation with intent.
- II.** It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that requests for taper of six final sessions of dTMS will be reviewed by a medical director on a case-by-case basis, informed by the following:
- A. Criteria for initial dTMS treatment guidelines continues to be met;
  - B. There has been a positive treatment response, evidenced by a  $\geq 30\%$  reduction of OCD symptom severity, as measured by the YBOCS score (or other standardized OCD scale);
  - C. For members/enrollees who demonstrated a  $>30\%$  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 six month period, authorization of an additional six tapered dTMS sessions over a period of three weeks will be considered.

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- 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 factors:
- A. Criteria for initial dTMS treatment guidelines 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;

### Background

Obsessive Compulsive Disorder (OCD) is a mental health disorder which includes obsessional thoughts and/or compulsions that are time consuming (more than one hour a day), cause significant distress, and impair work or social functioning. Obsessions are defined as recurrent and persistent thoughts, impulses, or images that cause distressing emotions such as anxiety, fear or disgust. Compulsions are repetitive behaviors or mental acts that a person feels driven to perform in response to an obsession. According to the American Psychological Association (APA) 2-3% of individuals in the United States are impacted by OCD.<sup>3</sup>

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. It is estimated that 40% of patients are resistant to medication, 26% fail to initiate CBT, and 31% drop out before completing therapy.<sup>4</sup>

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 is administered by commercially available repetitive TMS devices that theoretically stimulate brain structures beneath the superficial prefrontal cortex using magnetic coils (H coils). H coils can induce a magnetic field with a deeper and wider distribution than the standard coils used for surface cortical TMS.<sup>3</sup> The depth of stimulation treated with H coils is up to approximately 4 cm deep. H coils also stimulate surface cortical structures.<sup>1</sup>

In 2018, The U.S. Food and Drug Administration (FDA) permitted the marketing of the Brainsway Deep transcranial Magnetic Stimulation System for treatment of obsessive compulsive disorder.<sup>5</sup> The decision was based upon a multicenter double-blind sham-controlled study in which patients randomly received treatment with the Brainsway device using high frequency (20HZ) or sham dTMS.<sup>6</sup> Daily treatments (medical management) were maintained at their current dosages throughout the study, for six weeks. The study evaluated the reduction in patients' Yale-Brown Obsessive Compulsive Scale (YBOCS) score, a common metric for measuring the severity of a patient's OCD.<sup>5</sup> The primary efficacy end point was the change in score from baseline to posttreatment assessment. In addition, the study measured response rates (defined as a reduction of >30% in YBOS score) at the post treatment assessment and after an additional month of follow up. The results indicated that 38 percent of patients responded to the

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Brainsway device (i.e., greater than 30 percent reduction in YBOCS score), whereas 11 percent of patients responded when using the sham device.<sup>5</sup> At the 1 month follow up, the response rates were 45.2% in the active treatment group and 17.8% in the sham treatment group.<sup>6</sup>

In 2020, the FDA cleared MagVenture TMS Therapy<sup>®</sup> for adjunct treatment of obsessive-compulsive disorder (OCD). MagVenture TMS Therapy is an adjunct treatment to existing OCD therapies which may involve pharmaceutical and behavioral therapy. It is an outpatient procedure with no systemic side effects. The treatment specifically targets the networks in the brain which are known to be particularly affected by OCD, including the deeper-lying structures.<sup>7</sup>

#### *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.<sup>8</sup>

The Centers for Medicare & Medicaid Services (CMS) has published indications and limitations for Deep TMS (d-TMS).<sup>9</sup> A literature review was conducted to examine the use of rTMS for OCD as a reconsideration of the prior stance. The conclusions of the analysis indicated that "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."<sup>9</sup>

#### **Coding Implications**

This clinical policy references Current Procedural Terminology (CPT<sup>®</sup>). CPT<sup>®</sup> is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2022, 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.

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Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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	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. 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

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
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 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
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 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 specialist. Policy reviewed by external specialist.	02/23	03/23

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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.

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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.

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