

# Clinical Policy: Transcranial Magnetic Stimulation for the Treatment of Major Depressive Disorder

Reference Number: MO.CP.BH.202

Date of Last Revision: 01/25

Coding Implications
Revision Log

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

#### Description

The Home State Health Plan Transcranial Magnetic Stimulation (TMS) for Major Depressive Disorder (MDD) Clinical Policy is based on the Missouri Department of Social Services Behavioral Health Services Manual, revised December 20, 2024.

Transcranial magnetic stimulation (TMS) is a noninvasive method of brain stimulation. The technique involves placement of a small coil over the scalp and passing a rapidly alternating. current through the coil wire, which produces a magnetic field that passes unimpeded through. the brain. Repetitive transcranial magnetic stimulation (rTMS) is delivered as a series of pulses called a train and is used to treat major depression and other illnesses by modulating activity in cortical regions and associated neural circuits. Depending on stimulation parameters (frequency, intensity, pulse duration, stimulation site), rTMS can either increase or decrease the excitability of the affected brain structures. 1,2

#### Policy/Criteria

- I. It is the policy of Home State Health and Centene Advanced Behavioral Health that repetitive transcranial magnetic stimulation (rTMS) is considered medically necessary when meeting all of the following:
  - A. Member/enrollee is  $\geq 18$  years old;
  - B. Member/enrollee has a confirmed diagnosis of major depressive disorder (MDD), severe (either recurrent or single episode), per the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision criteria;
  - C. One or more of the following:
    - 1. Resistance to treatment with psychopharmacologic agents as evidenced by both of the following:
      - Lack of clinically significant response to one trial of psychopharmacologic agents in the current depressive episode from at least two different agent classes;
      - b. Each agent in the treatment trial was administered as an adequate course of mono- or poly-drug therapy;
    - 2. Inability to tolerate psychopharmacologic agents as evidenced by at least two total trials of psychopharmacologic agents from within two different agent classes, with distinct side effects;
    - 3. History of good response to TMS in a previous depressive episode as evidenced by a greater than 50% improvement in a standardized rating scale for depressive symptom severity including but not limited to the following:
      - a. Patient Health Questionnaire-9 (PHQ-9);



#### Transcranial Magnetic Stimulation for the Treatment of Major Depressive Disorder

- b. Beck Depression Inventory (BDI);
- c. Hamilton Depression Rating Scale (HAM-D);
- d. Montgomery Asberg Depression Rating Scale (MADRS);
- e. Quick Inventory of Depressive Symptomatology (QIDS);
- f. Inventory for Depressive Symptomatology Systems Review (IDS-SR);
- 4. Member/enrollee is a candidate for and has declined electroconvulsive therapy (ECT), and TMS is considered a less invasive treatment option;
- D. Planned use of a depression severity standardized rating scale, by the TMS provider to monitor response during treatment, with a documented pre-TMS score;
- E. Physician's Health Questionnaire-9 (PHQ-9) score of ≥ 15 throughout the current course of treatment, or its equivalent in one of the other standardized rating scales for depressive symptoms noted in I.C.3.;
- F. The member/enrollee has participated in an adequate trial of evidence-based psychotherapy (such as cognitive behavioral therapy and/or interpersonal therapy) during the current episode of illness, without significant improvement. Note: this therapy should overlap with the psychopharmacologic trials;
- G. One of the following:
  - For TMS administered in any setting, a psychiatrist who has experience in administering TMS therapy examined the member/enrollee, reviewed their records, and wrote the order for treatment;
  - 2. For TMS administered in any setting, an advanced practice psychiatric nurse (P-APRN) who has experience in administering TMS therapy examined the member/enrollee, reviewed their records, wrote the order for treatment and will directly supervise the treatment (must be present in area but does not necessarily personally provide the treatment);
  - 3. For TMS administered in a community mental health center, a physician with experience administering TMS wrote the order for treatment and will directly supervise the treatment (must be present in area but does not necessarily provide the treatment);
- H. The provider will administer TMS with a US Food and Drug Administration (FDA) cleared device for the treatment of MDD in a safe and effective manner according to the manufacturer's user manual and specified stimulation parameters;
- I. None of the following conditions or contraindications to TMS are present:
  - 1. Seizure disorder or any history of seizures (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence);
  - 2. Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode;
  - 3. Neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, or primary or secondary tumors in the central nervous system;
  - 4. Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 cm from the TMS magnetic coil or other implanted metal items including, but not limited to:
    - a. Cochlear implant;
    - b. Implanted cardiac defibrillator (ICD);
    - c. Pacemaker;
    - d. Vagus nerve stimulator (VNS);
    - e. Metal aneurysm clips or coils, staples, or stents. Note: Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with TMS;
  - J. Requested treatment is for one treatment per day (up to 23 treatments per month and no more



# Transcranial Magnetic Stimulation for the Treatment of Major Depressive Disorder than 36 in one year);

- II. It is the policy of Home State Health and Centene Advanced Behavioral Health that maintenance treatment with Repetitive transcranial stimulation (rTMS) is not medically necessary, as there is insufficient evidence in the published peer reviewed literature to support it.
- III. It is the policy of Home State Health and Centene Advanced Behavioral Health that a medical director will consider requests for *retreatment* of Repetitive transcranial magnetic stimulation (rTMS), to treat Major Depressive Disorder (MDD) if all of the following are met:
  - A. Criteria for initial rTMS treatment guidelines noted in I.A through I, continues to be met;
  - B. The member/enrollee has subsequently developed a relapse of depressive symptoms after responding to the initial TMS treatments, as evidenced by a greater than 50% improvement, using a standardized rating scale, as noted in I.C.3.

#### **Background**

Major depressive disorder (MDD), also known as depression, is a debilitating mental health disorder characterized by  $\geq 1$  depressive episode lasting  $\geq 2$  weeks and involving depressed mood, loss of interests/pleasure, fatigue, change in weight, sleep disturbances, cognitive impairments, and/or feelings of worthlessness.<sup>2</sup> According to the National Institute of Mental Health (NIMH), in 2021, an estimated 14.5 million adults (5.7%) aged 18 or older and an estimate of 5.0 million adolescents aged 12 to 17 (20.1%) in the United States has had at least one major depressive episode with severe impairment.<sup>3</sup>

Evidence supporting the use of repetitive TMS includes a network meta-analysis of 31 randomized trials of pharmacologic and somatic interventions in patients with treatment-resistant depression (sample size not reported), including 11 trials that studied TMS. Six weeks after baseline, response (improvement of symptoms ≥50 percent) was more than eight times as likely with TMS than placebo pill/sham stimulation (odds ratio 8.6, 95% CI 1.2-112.6). However, discontinuation of treatment due to adverse effects was four times more likely with TMS than placebo pill/sham.²

### TMS Society<sup>4</sup>

In October 2008, conventional repetitive TMS (TMS) was FDA cleared for the treatment of adults with major depressive disorder (MDD) who had one failed medication trial. TMS has since been established as a treatment with an excellent safety profile. TMS is minimally invasive and does not require anesthesia, has no cognitive side effects, and is conducted in outpatient clinics. TMS can be administered with different coils and different protocols. In 2013 deep and conventional repetitive TMS (dTMS) were cleared for treatment resistant MDD, defined as having failed to respond to antidepressant medication, without a specific number of medication trials. In 2018 theta burst stimulation (iTBS) was cleared for MDD.

#### **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



Transcranial Magnetic Stimulation for the Treatment of Major Depressive Disorder the submission of claims for reimbursement of covered services.

CPT <sup>(R)*</sup>	Description
Codes	
90867	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial,
	including cortical mapping, motor threshold determination, delivery, and management
	(once per course of treatment)
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

Reviews, Revisions, and Approvals		Approval Date
Initial approval incorporating the state specific requirements from Provider Bulletin, Volume 44, Number 23, effective 11/1/21	Date 11/1/21	11/30/21
Annual review. Policy restructured and reformatted. Reordered Criteria for clarity to align with the MO state regulation. Replaced all instances of "member" with "member/enrollee." Replaced all instances of commas with semicolons. Removed all instances of the word "or" and replaced with semicolons. Replaced criteria section I. (H) as section II to address "retreatment of TMS." Added standard therapeutic doses for at least 6 weeks duration to I.E.,1.c References reviewed, updated, and reformatted. Replaced all instances of "dashes (-)" in page numbers with the word "to"	11/22	12/22
Annual Review. Updated description to reflect change in identification number "Missouri Department of Social Services Provider Bulletin, Volume 44, Number 48", revised June 1, 2022. Additional updates to description and background with no clinical significance. In criteria point I. added "a confirmed diagnosis of MDD). In I.G.1. added "advanced psychiatric nurse" and I.G.5 added "Community Mental Health Centers (identified with provider type 56 enrollment) may utilize a physician with experience administering TMS to order and directly supervise TMS treatment (must be present in area but does not necessarily personally provide the treatment)". Updated description and background with no clinical significance. References reviewed and updated.	11/23	11/23
Annual Review. Updates made to align with changes made to the Missouri Department of Social Services Behavioral Health Services Manual, updated on December 20, 2024. Minor policy restructuring and formatting changes. Change in the number of trials of psychopharmacologic agents from "two" to "one" applied to, I.C.,1. a: "the lack of clinically significant response to "one" trial of psychopharmacologic agents in a depressive episode from at least two different agent classes". Added I.F. "The member/enrollee has participated in an adequate trial of evidence-based psychotherapy (such as cognitive behavioral therapy and/or interpersonal therapy) during the current episode of illness, without significant improvement. Note: this therapy should overlap with the psychopharmacologic trials". Added I.G. 1 through 3. indicating the type of setting TMS can be administered.	01/25	

# home state health

#### **CLINICAL POLICY**

Transcranial Magnetic Stimulation for the Treatment of Major Depressive Disorder

Added I.H. "The provider will administer TMS with a US Food and Drug		
Administration (FDA) cleared device for the treatment of MDD in a safe		
and effective manner according to the manufacturer's user manual and		
specified stimulation parameters". Background updated. References		
reviewed and updated.		

#### References

- Missouri Department of Social Services. Behavioral Health Service Manual. <a href="https://mydss.mo.gov/media/pdf/behavioral-health-services-manual">https://mydss.mo.gov/media/pdf/behavioral-health-services-manual</a>. Published December 20, 2024. Accessed January 13, 2025.
- 2. Holtzheimer, P. Unipolar depression in adults: Indications, efficacy, and safety of transcranial magnetic stimulation (TMS). UpToDate. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated February 15, 2023. Accessed January 13, 2025.
- 3. National Institute of Mental Health. Major Depression. <a href="https://www.nimh.nih.gov/health/statistics/major-depression">https://www.nimh.nih.gov/health/statistics/major-depression</a>. Updated July 2023. Accessed January 13,2025.
- 4. Clinical TMS Society (CTMSS). About TMS Therapy. Website. https://www.clinicaltmssociety.org. Accessed January 13, 2025.
- 5. Local Coverage Determination: Transcranial Magnetic Stimulation (TMS) (L34641). Centers for Medicare and Medicaid Services Website. <a href="https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34641">https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34641</a>. Revised April 25, 2024. Accessed January 13, 2025.
- 6. Holtzheimer, P. Unipolar Major Depression: Administering transcranial magnetic stimulation (TMS). UpToDate. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated February 02, 2023. Accessed January 13, 2025.
- 7. Health Technology Assessment. Maintenance Repetitive Transcranial Magnetic Stimulation for Prevention of Recurrent Depression in Adults. Hayes. <a href="https://www.hayesinc.com">https://www.hayesinc.com</a>... Published April 24, 2024. Accessed January 13, 2025.
- 8. Thase, M., Connolly, R. Unipolar depression in adults: Choosing treatment for resistant depression. UpToDate. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated November 2, 2023. Accessed January 13,2025.

#### **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,



Transcranial Magnetic Stimulation for the Treatment of Major Depressive Disorder 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. Members/enrollees 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/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 <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <a href="http://www.cms.gov">http://www.cms.gov</a> for additional information.

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