Clinical Policy: Transcranial Magnetic Stimulation for Treatment Resistant Major Depression

Reference Number: IA.CP.BH.200 Coding Implications
Date of Last Revision: 06/24 Revision Log

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

Description
Transcranial magnetic stimulation (TMS) is a noninvasive brain stimulation technique that uses magnetic fields to stimulate nerve cells in the brain. The objective of the technique is to stimulate areas of the brain involved in mood regulation to lessen the duration or severity of depressive episodes. Repetitive TMS (rTMS) is rapidly administered pulses of the TMS and is often used interchangeably with the term TMS. The intervention uses a large alternating electrical current passed through a metal coil placed against the scalp to generate rapidly alternating magnetic fields, which pass through the skull nearly unrestricted and induce electric currents that alter neurons in a focal area of the surface cortex. Theta burst stimulation (TBS), a subtype of repetitive transcranial magnetic stimulation (rTMS).[1]

Policy/Criteria
I. It is the policy of Iowa Total Care and Centene Advanced Behavioral Health that a medical director will review requests for up to 36 sessions of repetitive transcranial magnetic stimulation (rTMS) or up to 36 sessions of theta burst stimulation (TBS), on a case-by-case basis, when meeting all the following criteria:
   A. Member/enrollee is 18 years of age or older;
   B. Member/enrollee has a confirmed diagnosis of major depressive disorder (MDD) or persistent depressive disorder (PDD), per most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM);
   C. The treatment is administered using a Food and Drug Administration (FDA) cleared device and utilized in accordance with the FDA labeled indications such as but not limited to one of the following:
      1. BrainsWay Deep TMS;
      2. MagVita TMS Therapy with MagPro R20;
      3. MagVita TMS Therapy System w/Theta Burst Stimulation;
      4. Neurosoft TMA (Cloud TMS);
      5. Magstim Rapid^2 Therapy System;
      6. Magstim Horizon Performance System;
      7. Apollo TMS Therapy System;
      8. Nexstim Brain Therapy;
      9. Magstim Horizon TMS Therapy System Range;
      10. NeuroStar TMS Therapy System.
   D. Planned use of a depression severity standardized rating scale by the TMS provider to monitor response during treatment, with pre-TMS score documented;
   E. Oversight of treatment is provided by a licensed psychiatrist except where state scope of practice acts allows otherwise;
   F. Failure of or intolerance to psychopharmacologic agents meeting one of the following:

1. At least two different trials of pharmacological classes were administered as an adequate course of antidepressants with a recognized standard therapeutic dose of at least six weeks duration during the current depressive episode;
2. Member/enrollee is unable to take antidepressants due to documentation of both of the following:
   a. Major adverse drug interactions with medically necessary medications;
   b. Inability to tolerate antidepressant agents as evidenced by trials (and discontinuation) of at least four such agents that were clearly causative of intolerable side effects in the current episode;

G. Does not have any of the following contraindications:
1. History of seizures;
2. Presence of conductive or ferromagnetic or other magnetic-sensitive metals implanted or embedded in head or neck within 30 cm of TMS coil placement other than dental fillings to include but not limited to the following:
   a. Cochlear implant;
   b. Implanted electrodes/stimulators;
   c. Aneurysm clips or coils;
   d. Stents;
   e. Bullet fragments;
   f. Metallic dyes in tattoos;
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. Less than three months of substantiated remission from substance use disorder;
6. Concomitant esketamine intranasal, ketamine infusion or other infusion therapies;
7. Severe dementia;
8. Severe cardiovascular disease;
9. Known non-adherence with previous treatment for depression;
10. No acute psychotic disorders in the current depressive episode;
11. No active suicidal ideation with intent.

II. It is the policy of Iowa Total Care and Centene Advanced Behavioral Health that that maintenance treatment with rTMS or TBS is not medically necessary, as there is insufficient evidence in the published peer-reviewed literature to support it.

III. It is the policy of Iowa Total Care and Centene Advanced Behavioral Health that requests for retreatment with rTMS, or TBS will be reviewed on a case-by-case basis by a Medical Director, informed by all of the following:

A. Criteria for initial treatment in section I. continues to be met;

B. Current major depressive symptoms have worsened by 50% from the prior best response of the PHQ-9 score;

C. Prior treatment response was at least a 50% or greater reduction from baseline depression scores.

IV. It is the policy of Iowa Total Care and Centene Advanced Behavioral Health that there is insufficient evidence in the published peer-reviewed literature to support the use of TMS in the following:

A. Treatment of all or other psychiatric or neurological disorders, including but not limited to the following:
   1. Bipolar disorder;
   2. Obsessive Compulsive Disorder (OCD);
   3. Dementia;
   4. Substance abuse;
   5. Chronic pain syndrome;
   6. Eating disorders;
   7. Post Traumatic Stress Disorder (PTSD);
   8. Schizophrenia;

B. In the pediatric population younger than 18 years of age.

Background

According to the National Institute of Mental Health (NIMH), major depression is one of the most common mental disorders in the United States. The results from the 2021 national survey on drug use and health, indicated that an estimated 14.5 million adults in the United States have had at least one major depressive episode with severe impairment.[2] Globally, it is estimated that more than 246 million people have a MDD diagnosis, and this prevalence increased during the COVID-19 pandemic.[2]

It is estimated that 30% of people with MDD have experienced treatment resistant depression (TRD), which indicates they have failed to respond adequately to an evidence based, standard treatment, such as psychotherapy or pharmacotherapy. Electroconvulsive therapy (ECT) and repetitive transcranial magnetic stimulation (rTMS) are typically considered to be the most effective interventions to treat TRD. Recent studies suggest the short-term efficacy and safety of Theta burst stimulation (TBS), which is a subtype of repetitive transcranial magnetic stimulation (rTMS).[3]

Repetitive magnetic stimulation (rTMS) is often delivered at a frequency ≥ 10 Hertz (Hz) and targets the dorsolateral prefrontal cortex, a region important for high order executive functions. Theta burst stimulation (TBS) is delivered in short bursts of three to five pulses per second (sec) are administered at a higher frequency (50 Hz) but with a specific interburst interval that generates an overall lower stimulation frequency (5 Hz).[3]

In 2023, Holzheimer, P, et.al., reviewed the indications, efficacy, and safety of TMS. Their review provided evidence supporting the use of repetitive TMS, which included 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, it is noted that discontinuation of treatment due to adverse effects was four times more likely with TMS than placebo pill/sham.[1]

In 2023, Vida, R et.al, conducted a meta-analysis of randomized sham-controlled trials on the efficacy of repetitive transcranial magnetic stimulation(rTMS) adjunctive therapy for major depressive disorder (MDD). They included 19 randomized double-blinded sham-controlled studies for quantitative analysis for response (n = 854 patients) and 9 studies for remission (n = 551 patients). The risk ratio (RR) for response and remission were 2.25 and 2.78, respectively for patients after two treatment failures using rTMS as add-on treatment compared to standard pharmacotherapy. The authors concluded that rTMS is significantly more effective than sham rTMS in TRD in response and remission outcomes and may be beneficial as an adjunctive treatment in patients with MDD after two treatment failures.[4]

In 2024, Hayes published its annual review to evaluate the effectiveness and safety of theta burst stimulation (TBS), alone and compared with repetitive transcranial magnetic stimulation (rTMS) and/or with sham TBS, for the management of treatment-resistant major depressive disorder (MDD). The evidence suggests that the short-term efficacy and safety of TBS are comparable with rTMS. The literature search identified 9 relevant clinical studies (reported on in 11 articles). Six studies used intermittent TBS (iTBS) delivered to the left dorsolateral prefrontal cortex (DLPFC), 2 studies used bilateral TBS (blTBS) (continuous TBS to the right DLPFC and iTBS to the left DLPFC), and 1 study delivered iTBS bilaterally to the dorsomedial prefrontal cortex (DMPFC). The body of evidence suggests that TBS is potentially effective for reducing the symptoms of depression, including suicidality, and improving health-related quality of life (HRQOL) among adult patients with treatment-resistant MDD; however, questions remain regarding rates of response and remission and the durability of treatment effect is uncertain. Most of the studies found that rates of clinical response and remission at the end of TBS treatment ranged from 35% to 55% and 18% to 30%, respectively. Rates of response and remission during posttreatment follow-up were inconsistent across studies. The evidence showed that TBS led to significant improvement of depression symptoms when compared with pretreatment values or with sham therapy.[3]

On April 24, 2024, Hayes published its annual review for repetitive transcranial magnetic stimulation (rTMS) as a maintenance treatment to prevent the recurrence of symptoms in adult patients with major depressive disorder (MDD). The conclusion of the focus report indicated that there is an overall very low-quality body of evidence that is insufficient to attest to the efficacy and safety of maintenance rTMS for MDD.[5]

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 2023, 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

HCPCS ®* Codes	Description
G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	6.23.22	
Updated the number of sessions to be approved from 30, then 6 to 36 per committee meeting on 6/29/22.	6.30.22	
Annual Review. Policy restructured and reformatted. Added Centene Advanced Behavioral Health to policy statements. Changed "Last Review Date" and "Effective Date" in the policy header to "Date of Last Revision," Added statement to me. "It is the policy of Iowa Total Care® that a medical director will review requests for up to 36 sessions of repetitive transcranial magnetic stimulation (rTMS) or up to 36 sessions of Theta Burst Stimulation (TBS), on a case-by-case basis, when meeting all of the following criteria". Deleted the original policy statement II. added to I.D: "1. At least two different trials of pharmacological classes were administered as an adequate course of antidepressants with a recognized standard therapeutic dose of at least six weeks duration during the current depressive episode; 2. The member/enrollee is unable to take antidepressants due to documentation of one of the following…" Added the contraindication list to I.E. Added the following statement to III. "It is the policy of Iowa Total Care that maintenance treatment with rTMS or TBS is not medically necessary, as there is insufficient evidence in the published peer reviewed literature to support it." to replace "It is the policy of Iowa Total Care that TMS maintenance therapy is considered not medically necessary as there is insufficient evidence to support this treatment at the present time." Added IV. A-C." It is the policy of Iowa Total Care that request for retreatment with rTMS or TBS will be	06/23	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
reviewed on a case-by-case basis by a Medical Director, informed by all of the following…." Updated the background section. Added Coding Implication Section. Added 3 CPT codes to the list: 97104, 97032 and G0295. Removed ICD 10 code chart. Updated references. Added Important Reminder section.		
Clarified policy statement III.B to align with the language noted in the IME policy: removed "Current depressive symptoms have worsened to a PHQ-9 severity score > 15 (or other standardized depression severity scale)" and replaced with "Current major depressive symptoms have worsened by 50 percent from the prior best response of the PHQ-9 score"	07/23	07/23
Annual review. Description updated. Added member/enrollee to criteria points I.A and B. Added I.C. to include the accepted FDA approved devices in order to align with the corporate policy. Background updated. References reviewed and updated	06/24	06/24

References

1. Holtzheimer PE. Unipolar depression in adults: Indications, efficacy, and safety of transcranial magnetic stimulus (TMS). UpToDate. https://www.uptodate.com/contents/search. Updated February 15,2023. Accessed May 29, 2024.
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5. Health Technology Assessment. Maintenance Repetitive Transcranial Magnetic Stimulation for Prevention of Recurrent Depression in Adults. Hayes. https://www.hayesinc.com/. Published April 4, 2023. Annual Review April 24, 2024. Accessed May 29, 2024.
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8. Miron JP, Jodoin VD, Lespérance P, Blumberger DM. Repetitive transcranial magnetic stimulation for major depressive disorder: basic principles and future directions. Ther Adv Psychopharmacol. 2021; 11:20451253211042696. Published 2021 Sep 23.

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9. Richter K, Kellner S, Licht C. rTMS in mental health disorders. Front Netw Physiol. 2023; 3:943223. Published 2023 Jul 28. doi:10.3389/fnetp.2023.943223

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. 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.

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.