Clinical Policy: Transcranial Magnetic Stimulation for Treatment Resistant Major Depression

Reference Number: IA.CP.BH.200
Date of Last Revison: 07/23

Coding Implications
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 used for the treatment of psychiatric and neurological disorders, including MDD. TMS works by passing electrical energy through a coil to generate an electromagnetic field. The objective is to stimulate areas of the brain involved in mood regulation to lessen the duration or severity of depressive episodes.

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 of the following criteria:

A. Adult 18 years of age or older;
B. Confirmed diagnosis of major depressive disorder (MDD) or persistent depressive disorder (PDD), per the most current Diagnostic and Statistical Manual of Mental Health Disorders (DSM);
C. Planned use of a standardized rating scale by the TMS provider to monitor response during treatment;
D. Oversight of treatment is provided by a licensed psychiatrist except where state scope of practice acts allows otherwise;
E. Failure of a full course of evidence-based psychotherapy, such as cognitive behavioral therapy for the current depressive episode;
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. The member/enrollee is unable to take antidepressants due to documentation of one 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 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. Severe dementia;
7. Severe cardiovascular disease;
8. Known non-adherence with previous treatment for depression;
9. No acute psychotic disorders in the current depressive episode;
10. No active suicidal ideation with intent.

II. It is the policy of Iowa Total Care and Centene Advanced Behavioral Health 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

Transcranial magnetic stimulation (TMS)

TMS is a noninvasive brain stimulation technique used for the treatment of psychiatric and neurological disorders, including MDD. Using the principles of electromagnetic induction, TMS works by passing electrical energy through a coil to generate an electromagnetic field. When placed over the scalp, the stimulation coil focuses a pulse of electrical current that penetrates the cortical surface two centimeters (cm) to four cm and directly alters local superficial neuronal activity.[1]

Repetitive transcranial magnetic stimulation (rTMS)
TMS is typically delivered in a train of pulses, also known as rTMS. It is often delivered at a frequency ≥ 10 Hertz (Hz) and generally targets the dorsolateral prefrontal cortex, a region important for high order executive functions. The procedure typically takes 40 minute to complete, five times per week for four to six weeks for a total of 20 to 30 sessions.[1]

Theta burst Stimulation (TBS)
Theta burst stimulation (TBS) is a form of rTMS wherein 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). A session can be completed in three minutes and can be delivered using a variety of regimens.[1]

In January 2023, Hayes published a health technology assessment which assessed the effectiveness and safety of TBS, alone and compared with repetitive transcranial magnetic stimulation (rTMS), and/ or sham TBS, for the management of treatment resistant major depressive disorder in adults. The conclusion from the focus report indicated that an overall low-quality body of evidence suggests that TBS is a safe and potentially effective intervention for improving acute depressive symptoms and quality of life (QOL) among adult patients with unipolar TRD. However, the short-term efficacy and safety of TBS appears to be largely comparable with rTMS. A typical session of standard rTMS takes approximately 40 minutes to complete, whereas a single session of standard TBS can be completed in approximately 3 minutes. The TBS therapy can be delivered in intermittent bursts (similar to high-frequency rTMS) or continuous bursts (similar to low-frequency rTMS) and has different effects based on coil placement. In addition, TBS can be delivered using a variety of regimens. The evidence suggests that the short-term efficacy and safety of TBS appears to be largely comparable with rTMS. The findings of a positive effect of TBS vs. sham, and noninferiority of TBS vs. standard HFL rTMS support the continued development of TBS to treat depression.[1]

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 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. 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 I. "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	06/23	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
rTMS or TBS will be 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

References

1. Health Technology Assessment. Theta Burst Stimulation for Treatment- resistant Unipolar Depression in Adults. Hayes. www.hayesinc.com. Published January 12, 2023. Accessed May16, 2023.
2. National Institute of Mental Health. Major Depression. https://www.nimh.nih.gov/health/statistics/major-depression. Updated January 2022. Accessed May 16, 2023.
3. 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 16, 2023.
4. Holtzheimer PE. Unipolar major depression in adults: Administering transcranial magnetic stimulus (TMS). UpToDate. https://www.uptodate.com/contents/search. Updated February 02, 2023. Accessed May 16, 2023.
5. Health Technology Assessment. Maintenance Repetitive Transcranial Magnetic Stimulation for Prevention of Recurrent Depression in Adults. Hayes. www.hayesinc.com. Published April 4, 2023. Accessed May 16, 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/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.

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.