Clinical Policy: Transcranial Magnetic Stimulation for Treatment Resistant Major Depression

Reference Number: CP.BH.200 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

Transcranial Magnetic Stimulation (TMS) is a non-invasive treatment that uses pulsed magnetic fields to induce an electric current in a localized region of the cerebral cortex. An electromagnetic coil placed on the scalp induces focal, patterned current in the brain that temporarily modulates cerebral cortical functioning. Stimulation parameters may be adjusted to alter the excitability of the targeted structures in specific cortical regions. TMS parameters include cranial location, stimulation frequency, pattern, duration, intensity, and the state of the brain under the coil.[1]

Policy/Criteria

I. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation® that requests for initial treatment with repetitive transcranial magnetic stimulation (rTMS), deep TMS (dTMS), or Theta Burst Stimulation (iTBS) are considered medically necessary for ***adults ≥ 18 years of age*** when meeting all the following criteria:

A. The member/enrollee has a confirmed diagnosis of major depressive disorder (MDD), severe (single episode or recurrent), per most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM);
B. The member/enrollee does not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder;
C. The member/enrollee has failed a trial of (or has an intolerance to) psychopharmacologic therapy, as evident by a Physician's Health Questionnaire-9 (PHQ-9) score of ≥ 15 throughout the current course of treatment (or other equivalent standardized scale score), indicating moderately severe to severe depression, which is documented by one of the following:
    1. Failure of two trials of antidepressants from at least two different antidepressant classes administered as an adequate course with a recognized standard therapeutic dose of at least six weeks duration within the last 24 months;
    2. Inability to tolerate (i.e., documentation of major adverse interactions with medically necessary medications or intolerable side effects) four trials of antidepressants from at least two different antidepressant classes;
D. 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 antidepressant trials;
E. The member/enrollee has failed a trial of electroconvulsive therapy (ECT); or its use is contraindicated or there is documentation by a psychiatrist indicating why TMS is clinically preferable;

F. The member enrollee is referred for TMS treatment by the provider treating the member/enrollee's MDD;
G. A comprehensive psychiatric evaluation to determine the necessity for TMS has been completed by a qualified licensed provider, such as one of the following:
   1. Psychiatrist (MD, DO, or MBBS [Bachelor of Medicine, Bachelor of Surgery]);
   2. Psychiatric Nurse Practitioner;
H. Direct supervision of treatment is provided by a licensed psychiatrist, trained in TMS therapy, except where state scope of practice acts allows for other provider types to supervise;
I. Request is for up to 36 sessions. *Note*: Recommended schedule is five days a week for six weeks, with an optional six sessions for tapering);
J. 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 the following:
   1. NeuroStar® Advanced TMS Therapy System;
   2. Apollo TMS Therapy System;
   3. BrainsWay Deep TMS;
   4. Horizon TMS Therapy System;
   5. MagVita TMS Therapy with MagPro R20;
   6. MagVita TMS Therapy System w/Theta Burst Stimulation;
   7. Neurosoft TMA (Cloud TMS);
   8. Nexstim Brain Therapy;
   9. Magstim Horizon 3.0 TMS Therapy System Range;
K. The member/enrollee does not have any of the following contraindications:
   1. 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;
   2. Vagus nerve stimulator leads in the carotid sheath;
   3. Less than three months of substantiated remission from substance use disorder;
   4. Concomitant esketamine intranasal, ketamine infusion or other infusion therapies;
L. Documentation of rTMS, iTBS or dTMS protocol used;
M. Planned use of an evidenced based standardized depression rating scale (including severity), documenting the score prior to treatment, and monitored throughout the course of treatment.

II. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that requests for *initial treatment* with repetitive transcranial magnetic stimulation (rTMS) will be reviewed on a case-by-case basis by a medical director for ***adolescents ages 15 through 17 years old,*** informed by all the following criteria:

A. The treatment is administered using the NeuroStar® TMS Therapy System, as an adjunct for the treatment of major depressive disorder (MDD), in accordance with the specific Food and Drug Administration (FDA)-labeled indication;
B. The member/enrollee has a confirmed diagnosis of MDD, severe (single episode or recurrent), per most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM);
C. The member/enrollee does not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder;
D. The member/enrollee has failed a trial of (or has an intolerance to) psychopharmacologic therapy, as evident by a PHQ-9: Modified for Teens (PHQ-A) score of ≥ 15 throughout the current course of treatment (or other equivalent standardized scale score), indicating moderately severe to severe depression, evidenced by one of the following:
    1. Documentation of failure of two trials of antidepressants from at least two different antidepressant classes administered as an adequate course with a recognized standard therapeutic dose of at least six weeks duration within the last 24 months;
    2. Inability to tolerate (i.e., documentation of major adverse interactions with medically necessary medications or intolerable side effects) two trials of antidepressants from at least two different antidepressant classes within the last 24 months;
E. 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 antidepressant trials;
F. The member/enrollee has failed a trial of electroconvulsive therapy (ECT); or its use is contraindicated or there is documentation by a psychiatrist indicating why TMS is clinically preferable;
G. The member/enrollee is referred for TMS treatment by the provider treating the member/enrollee's MDD;
H. A comprehensive psychiatric evaluation to determine the necessity for TMS has been completed by a qualified licensed provider, such as one of the following:
    1. Psychiatrist (MD, DO, or MBBS [Bachelor of Medicine, Bachelor of Surgery]);
    2. Psychiatric Nurse Practitioner;
I. Direct supervision of treatment is provided by a licensed psychiatrist, trained in TMS therapy, except where state scope of practice acts allows for other provider types to supervise;
J. Request is for up to 36 sessions (Note: recommended schedule is five days a week for six weeks, with an optional six sessions for tapering);
K. The member/enrollee does not have any of the following contraindications:
    1. 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;

2. Vagus nerve stimulator leads in the carotid sheath;
3. Less than three months of substantiated remission from substance use disorder;
4. Concomitant esketamine intranasal, ketamine infusion or other infusion therapies;

L. Documentation of rTMS protocol used;
M. Planned use of an adolescent, evidence-based, standardized depression rating scale (including severity), documenting the score prior to treatment, and monitored throughout the course of treatment.

III. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that requests for ***retreatment*** with rTMS, dTMS or iTBS ***for adults ≥ 18 years of age*** will be reviewed on a case-by-case basis by a medical director, informed by all the following:

A. The member/enrollee has a confirmed diagnosis of major depressive disorder (MDD), severe (single episode or recurrent), per most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM);
B. The member/enrollee does not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder;
C. Current depressive symptoms have worsened to a PHQ-9 severity score ≥ 15 (or equivalent in other standardized depression severity scale);
D. Prior treatment response demonstrated at least a 50% improvement in baseline standardized depression rating scores, (with a documented 6-month duration of response);
E. The member/enrollee is referred for TMS treatment by the provider treating the member/enrollee's MDD;
F. A comprehensive psychiatric evaluation to determine the necessity for TMS retreatment has been completed by a qualified licensed provider, such as one of the following:
   1. Psychiatrist (MD, DO, or MBBS [Bachelor of Medicine, Bachelor of Surgery]);
   2. Psychiatric Nurse Practitioner;
G. 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;
H. Direct supervision of treatment is provided by a licensed psychiatrist, trained in TMS therapy, except where state scope of practice acts allows for other provider types to supervise;
I. Request is for up to 36 sessions (Note: recommended schedule is five days a week for six weeks, with an optional six sessions for tapering);
J. 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 the following:
   1. NeuroStar® Advanced TMS Therapy System;
   2. Apollo TMS Therapy System;
   3. BrainsWay Deep TMS;
   4. Horizon TMS Therapy System;
   5. MagVita TMS Therapy with MagPro R20;
   6. MagVita TMS Therapy System w/Theta Burst Stimulation;

7. Neurosoft TMA (Cloud TMS);
8. Nexstim Brain Therapy;
9. Magstim Horizon 3.0 TMS Therapy System Range;

K. The member/enrollee does not have any of the following contraindications:
   1. 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;
   2. Vagus nerve stimulator leads in the carotid sheath;
   3. Less than three months of substantiated remission from substance use disorder;
   4. Concomitant esketamine intranasal, ketamine infusion or other infusion therapies;
L. Documentation of rTMS, iTBS or dTMS protocol used;
M. Planned use of an evidence-based standardized depression rating scale (including severity), documenting the score prior to treatment, and monitored throughout the course of treatment;
N. If the member/enrollee is not achieving remission, consideration of treatment augmentation or potential alternative treatment such as ECT.

IV. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that requests for ***retreatment*** with rTMS for ***adolescents ages 15 through 17 years*** will be reviewed on a case-by-case basis by a medical director, informed by all the following:

A. The requested treatment is with the NeuroStar® TMS Therapy System, as an adjunct for the treatment of MDD, in accordance with the specific Food and Drug Administration (FDA)-labeled indication;
B. The member/enrollee has a confirmed diagnosis of major depressive disorder (MDD), severe (single episode or recurrent), per most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM);
C. The member/enrollee does not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder;
D. Current depressive symptoms have worsened to a PHQ-A severity score ≥ 15 (or equivalent in other standardized depression severity scale);
E. Prior treatment response demonstrated at least a 50% improvement in baseline standardized depression rating scores, (with a documented 6-month duration of response);
F. The member/enroll is referred for TMS treatment by the provider treating the member/enrollee's MDD;
G. A comprehensive psychiatric evaluation to determine the necessity for TMS retreatment has been completed by a qualified licensed provider, such as one of the following:
   1. Psychiatrist (MD, DO, or MBBS [Bachelor of Medicine, Bachelor of Surgery]);
   2. Psychiatric Nurse Practitioner;

H. 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;
I. Direct supervision of treatment is provided by a licensed psychiatrist, trained in TMS therapy, except where state scope of practice acts allows for other provider types to supervise;
J. Request is for up to 36 sessions. Note: Recommended schedule is five days a week for six weeks, with an optional six sessions for tapering;
K. The member/enrollee does not have any of the following contraindications:
    1. 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;
    2. Vagus nerve stimulator leads in the carotid sheath;
    3. Less than three months of substantiated remission from substance use disorder;
    4. Concomitant esketamine intranasal, ketamine infusion or other infusion therapies;
L. Documentation of rTMS protocol used;
M. Planned use of an evidence-based standardized depression rating scale (including severity), documenting the score prior to treatment, and monitored throughout the course of treatment;
N. If the member/enrollee is not achieving remission, consideration of treatment augmentation or potential alternative treatment such as ECT.

V. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that **maintenance treatment** with repetitive transcranial magnetic stimulation (rTMS), Theta Burst Stimulation (iTBS) or deep transcranial magnetic stimulation(dTMS) is considered not medically necessary, as there is insufficient evidence in the published, peer-reviewed literature to support it.

VI. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that there is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of *MRI guided theta burst stimulation,* including but not limited to, *Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT),* beyond established TMS/TBS techniques.

Background

Major depressive disorder (MDD), also known as depression, is a debilitating mental health disorder characterized by ≥ 1 depressive episode lasting ≥ 2 weeks and involving depressed mood, loss of interests/pleasure, fatigue, change in weight, sleep disturbances, cognitive impairments, and/or feelings of worthlessness.[2] 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.[3]

Psychotherapy and pharmacology are often the standard treatment for MDD. Patients who do not respond to this treatment are candidates for alternative treatments such as repetitive transcranial magnetic stimulation (TMS) and electroconvulsive therapy (ECT). In contrast to electroconvulsive therapy, TMS does not require general anesthesia and does not induce convulsion. The effects of TMS depend on the parameters of waveform, frequency, intensity, and duration of stimulation.[4]

Types of TMS:
Repetitive TMS (rTMS)[5]:
rTMS is currently the most widespread form of TMS for clinical applications. In rTMS, magnetic pulses are delivered in a rapid series or "train." When rTMS is used, multiple single-pulse stimuli are presented at a specific frequency, intensity, and time duration. In the context of MDD treatment, rTMS is often delivered at a frequency ≥ 10 Hertz (Hz) and targets the dorsolateral prefrontal cortex, a region important for high order executive function.

Deep TMS (dTMS)[5]:
Deep TMS is administered by commercially available rTMS devices that theoretically stimulate brain structures beneath the superficial prefrontal cortex using magnetic coils (H coils); these H coils can induce a magnetic field with a deeper and wider distribution than the standard (figure eight) coils used for surface cortical TMS. The depth of stimulation beneath with H coils is approximately 4 cm; H coils also stimulate surface cortical structures.

Theta burst TMS (iTBS)[5]:
iTBS is a form of rTMS wherein short bursts of three to five pulses per second are administered at a higher frequency (50 Hz) but with a specific interburst interval that generates an overall lower stimulation frequency (5 Hz).

Literature Review
Repetitive Transcranial Magnetic Stimulation(rTMS)[4,5]
An evidence review of rTMS 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.7 The results indicated that six weeks after baseline, the overall 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).

Deep Transcranial Magnetic Stimulation (dTMS)[6]
In 2019, Filipčić, et.al, conducted a randomized trial to the clinical outcome between TMS protocols delivered by H1-coil and the figure 8 coil. Based upon network meta-analyses of randomized trials, the efficacy and acceptability of deep TMS appears to be comparable to that of surface cortical TMS and theta burst TMS. A four-week randomized trial compared add-on deep TMS (20 sessions) with surface cortical TMS in patients with treatment-resistant depression (n = 147) who continued to receive stable, ongoing pharmacotherapy. Although remission in the two groups was comparable, response occurred in more patients who were treated with

adjunctive deep TMS than surface cortical TMS (67 versus 44 percent). In addition, all-cause discontinuation occurred more than twice as often with deep TMS than surface cortical TMS (10 and 4 percent of patients).

Theta burst Stimulation(iTBS)[7]
In 2021, a systematic review conducted by Voigt et al, focused on theta burst stimulation of TRD. The reviewers included 8 RCTs comparing theta burst stimulation to sham treatment, and 1 comparing theta burst stimulation to conventional rTMS. As measured by the HAM-D, Theta burst stimulation was superior to sham on response (RR 2.4; 95% CI: 1.27 to 4.55; p=.007; I2 = 40%). There was no statistically significant difference between theta burst stimulation and conventional rTMS (RR 1.02; 95% CI: 0.85 to 1.23; p=.80; I2 = 0%). There was There is no difference between theta burst stimulation and rTMS in the incidence of adverse events.[7]

TMS for adolescents[8,]
In 2021, Croarkin, et. al, conducted a double blind, randomized, sham controlled trial across 13 sites to examine the safety and efficacy of 10-Hz TMS for adolescents with TRD. The participants included adolescents with TRD (aged 12-21 years). Treatment resistance was defined as an antidepressant treatment record level of 1 to 4 in a current episode of depression. Intention-to-treat patients (n = 103) included those randomly assigned to active NeuroStar TMS monotherapy (n = 48) or sham TMS (n = 55) for 30 daily treatments over 6 weeks. The primary outcome measure was change in the Hamilton Depression Rating Scale (HAM-D-24) score. After 6 weeks of blinded treatment, improvement in the least-squares mean (SE) HAM-D-24 scores were similar between the active (-11.1 [2.03]) and sham groups (-10.6 [2.00]; P = 0.8; difference [95% CI], - 0.5 [-4.2 to 3.3]). Response rates were 41.7% in the active group and 36.4% in the sham group (P = 0.6). Remission rates were 29.2% in the active group and 29.0% in the sham group (P = 0.95). There were no new tolerability or safety signals in adolescents. Although TMS treatment produced a clinically meaningful change in depressive symptom severity, this did not differ from sham treatment. The authors concluded that future studies should focus on strategies to reduce the placebo response and examine the optimal dosing of TMS for adolescents with TRD.[8]

On January 25, 2024, Hayes published a medical code brief for 0889T-0892T. These codes were added to describe the delivery and management of accelerated, repetitive high-dose functional connectivity magnetic resonance imaging (MRI)-guided theta-burst stimulation. Based on a review of full-text clinical practice guidelines and position statements, Hayes determined that there was weak support for the use of intermittent theta burst stimulation (iTBS) and for use of MRI guidance for transcranial magnetic stimulation (TMS) coil positioning for treatment of major depressive disorder (MDD). At the time of the report, there were no published guidelines for accelerated magnetic resonance imaging (MRI)-guided theta burst stimulation (TBS).[9]

On April 24, 2024, Hayes published its annual review of maintenance rTMS for prevention of recurrent depression in adults. The review concluded that there was a very low-quality body of evidence to draw conclusions regarding the effectiveness and safety of rTMS as a maintenance

treatment. There are currently no clinical practice guidelines or position statements that propose definitive patient selection criteria for maintenance rTMS for treatment of MDD.[10]

Food and Drug Administration (FDA)[11]:
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. In 2013, deep and conventional repetitive TMS (dTMS) was cleared for treatment resistant MDD. In August 2018, Intermittent Theta Burst Stimulation (iTBS) was first approved by the FDA. In 2024, the FDA approved NeuroStar Advanced Therapy as an adjunct to an existing therapy for the treatment of MDD in adolescent patients aged 15-21 years.

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

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Policy reviewed, updated, and adopted as Centene Corporate policy.	12/18	12/18
Restructured (with no wording changes) section regarding failure of or intolerance to psychopharmacologic agents.	02/19	
Added contraindications to retreatment section III.	03/19	03/19
References reviewed and updated. Specialist review.	11/19	11/19
Policy reviewed, updated, and adopted as a Centene Behavioral Health Corporate Policy. Naming convention was changed from CP.MP.172	11/19	02/20

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Transcranial Magnetic Stimulation to CP. BH.200 Transcranial Magnetic Stimulation.		
Policy/Criteria section updated to clarify that Section I. refers to initial approval of TMS sessions. Updated item I.B. to reflect "Oversight of treatment is provided by a licensed psychiatrist." Updated I.C. to include "Other standardized scale indicating moderately severe to severe depression." Added Section I.I., "The initial request can be reviewed for up to 20 TMS sessions." Added Section II. to include criteria for authorization of additional TMS sessions.	5/20	5/20
Annual review included a full literature review. No updates made to the references. Policy did require edits to the content. The following edits were made to the Policy/Criteria section I, specified quantity of "20 sessions" in the section; removed "Failure of psychopharmacologic agents, both of the following" Removed mono-or poly-drug therapy with antidepressants involving: added c. "at least two recognized augmentation treatments have been attempted such as Lithium, Thyroid Hormone, Second generation Antipsychotic augmentation, dual antidepressant approaches, etc." Removed "this initial request can be reviewed for up to 20 TMS sessions in Section 1. Item 9. Included new Section III. "Requests for TMS taper: For patients who demonstrated after 30 TMS sessions >50% reduction in baseline severity scores who are approaching PHQ-9 scores of 9 or for those who have a history of good response to TMS followed by relapse into depression within a 6-month period, authorization of up to 6 taper TMS additional sessions over a period 3 weeks will be considered." Removed from Section II. For patients who demonstrated less than or equal to 50% reduction in baseline severity scores who are approaching PHQ-9 scores of 9 or for those who have a history of good responses to TMS followed by relapse into depression over a 6-month period, authorization of up to 6 taper TMS sessions over a period 3 weeks will be considered. Included "Stanford Accelerated Intelligent Neuromodulation Therapy or SAINT, an accelerated, high-dose, iTBS protocol with fcMRI-guided targeting, was well tolerated and safe in a sample size of 21 patients with TRD who received fifty iTBS sessions (1,800 pulses per session, 50-minute intersession interval) delivered as 10 daily sessions over 5 consecutive days at 90% resting motor threshold (adjusted for cortical depth) (Eleanor J. Cole et al., 2020). Nineteen of 21 participants (90.5%) met remission criteria (defined as a score <11 on the MADRS). In the intent-to-treat analysis, 19 of 22 participants (86.4%) met the remission criteria. Neuropsychological testing demonstrated no negative cognitive side effects to the background section.	2/21	02/21
Changed medical necessity statements to require review by a medical director. Minor edits made for clarity of review process.	2/21	2/21
Review of recent research and annual review of policy by the CABH CPSC. Revisions included Policy/Criteria, initial sessions revised from 30 to 20;	2/22	2/22

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Section II, additional sessions revised from 20 to 10; and a statement was added to the background section in reference to a randomized clinical trial published by J.A. Yesavage et al (2018), Effect of Repetitive Transcranial Magnetic Stimulation on Treatment-Resistant Major Depression in US Veterans to reflect the reference supports CABH exclusion criteria related to treatment of ongoing SUD, PTSD, and comorbidity disorders. Added to refences: • Eleanor J. Cole et al., Stanford Neuromodulation Therapy (SNT): A Double-Blind Randomized Controlled Trial. American Journal of Psychiatry, vol 179, pp. 132 to 141, October 21, 2021. https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2021.20101429 • Jerome A, Yesavage, MD, et al.; Effect of Repetitive Transcranial Magnetic Stimulation on Treatment-Resistant Major Depression in US Veterans, A Randomized Clinical Trial. JAMA Psychiatry. 2018;75(9): 884-893/jamapsychiatry.2018.1483. Published online June 27, 2018.		
Revised Policy/Criteria Section I.B. to reflect that oversight of treatment is provided by a licensed psychiatrist except where state scope of practice acts allows otherwise.	4/22	4/22
Annual Review. Revisions made to Policy/Criteria Section I. E to reflect the elimination of point 1 completely. The former point 2 and 3 will now be combined as the new point 1. The original point 4 has now changed to become the new point 2. Replaced terminology in Policy/Criteria I: H.5, II: B.5, III: V.5 from "Substance abuse at time of treatment" to "a minimum month substantiated early remission from substance use disorder"	5/22	6/22
In Policy/Criteria Section I, changed the initial number of sessions from 20 to 30 authorizations reviewed on a case-by-case basis; and Section II.A was changed from an additional 10 to additional 6 sessions of TMS reviewed on a case-by-case basis. Changed "Last Review Date" in the policy header to "Date of Last Revision," and changed "Date" in the revision log table header to "Revision Date." Changed all instances of "member" to "member/enrollee."	8/22	8/22
Ad hoc Review. Policy restructured. Added additional information to the description section with no impact on the policy. Replaced all instances of the statement "It is the policy of health plans affiliated with Centene Corporation®" with "It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation." Deleted criteria point I.D as the information was redundant to I.B. In criteria subsection I.I. (5), clarified that three months or less of remission constitutes a contraindication. Added the statement "requests for six tapered final sessions of TMS (over a 3-week period)" to the revised criteria point II. Added criteria point II.A to indicate that "all initial criteria must be met prior to request for additional sessions." Deleted what was criteria III as the information was redundant to criteria II. In criteria section III, replaced	11/22	12/22

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"maintenance treatment with TMS is not medically necessary, as there is insufficient evidence in the published peer reviewed literature to support it" with "It is the policy of health plans affiliated with Centene Corporation that maintenance treatment with TMS is not medically necessary, as there is insufficient evidence in the published peer reviewed literature to support it". Added criteria point IV.A to indicate that "criteria for initial TMS treatment guidelines continues to be met." Added semicolons throughout the criteria section. References reformatted. Replaced all instances of "dashes (-) in page numbers to the word "to."		
Annual Review. In criteria statement I, added the frequency of sessions to (5 days a week, for six weeks)". In policy statement I. replaced "transcranial magnetic stimulation TMS" with "repetitive transcranial magnetic stimulation (rTMS)." In policy statement I: added the statement: "and up to a total of 30 sessions of Theta Burst Stimulation (TBS)". Added to criteria point I.B. the statement regarding FDA cleared devices and included examples of current FDA approved devices. Added criteria point I.D: "Planned use of standardized rating scale by TMS provider to monitor response during treatment." Removed the statement regarding augmentation from I.H.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 (and within the last 24 months if the current episode exceeds 24 months of duration)". Added the statement to criteria point I.H.2.b. "… (and discontinuation)." Added contraindication to criteria point I.K.10: "Not experiencing acute active suicidal ideation with intent." Added a new policy statement II: It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that there is insufficient evidence to support the safety and efficacy of more than 30 sessions of TBS". Background section updated. References reviewed, revised, and updated. Coding reviewed. Policy submitted for internal review. Policy submitted to AMR for external review.	02/23	03/23
Annual Review. Updated description with no clinical significance. Minor rewording throughout the policy for clarity with no clinical significance. Criteria point I.D. added that the pre-TMS score should documented to measure progress more effectively "Planned use of a depression severity standardized rating scale by the TMS provider to monitor response during treatment, "with pre-TMS score documented." Removed prior criterion I.G. and reworded criteria regarding trial and failure of psychopharmacologic therapy and psychotherapy in new I.G and I.H. to include the requirement for a standardized scale to indicate moderate to severe depression throughout treatment. In I.G., clarified that the member/enrollee must present with the "failure or intolerance to two trials of psychopharmacologic agents from at least two different agent classes." In I.G.2, required that both criteria a and b be met for intolerance. In G.2.b, specified that "at least 4	03/24	03/24

Reviews, Revisions, and Approvals	Revision Date	Approval Date
antidepressants representing at least 2 different drug classes" must have been attempted. In I.H., added a note that the therapy should overlap with medication trials. In I.J., added contraindication "concomitant esketamine intranasal, ketamine infusion or other infusion therapies." Removed HCPCS coding table including G0295. Background section updated. References reviewed and updated.		
Annual review. Policy restructured and reformatted for clarity. Description updated. Criteria restructuring in policy statements I and III which apply to adults ≥ 18 years of age only. Added new policy statements II and IV, which apply to adolescents 15-17 years of age only. In policy statements I and III, added deep TMS (dTMS) as a form of TMS for adults ≥ 18 years of age. In I.A. removed the psychosis exclusion from the diagnosis criteria. In I.B. removed criteria statement "the major depressive disorder diagnosis is not part of a presentation with multiple psychiatric comorbidities and there is no evidence of psychosis or substance use" and replaced it with "The member/enrollee does not have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder. In I.C.1. replaced the term "psychopharmacologic agents" with "antidepressants" and removed the statement "during the current depressive episode (and within if the current episode exceeds 24 months of duration)". In I.C.2. combined subpoints for clarity. In I.D. removed requirement for PHQ-9 scores to be documented throughout treatment and added a broader statement referencing evidenced based treatment " 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"; in the note associated, replaced "medication trials" with "antidepressant trials". In. I.F. added criteria statement "The member/enrollee is referred for TMS treatment by the provider treating the member/enrollee's MDD". In I.G. added criteria indicating that a comprehensive psychiatric evaluation has been completed by a qualified licensed provider (MD, DO or MBBS). In I.I added frequency of services "up to 36 sessions" and added a note indicating a schedule recommendation "Recommended schedule is for five days a week for six weeks, with an optional six sessions for tapering". In I.K. removed the following relative contraindications: "history of seizures, severe cardiovascular disease," acute psychotic disorders in the current depressive episode, dementia, and active suicidal ideation with intent. In I.L. added new criteria statement "Documentation of rTMS, iTBS or dTMS protocol used" In III. D. added the statement "with a documented 6-month duration of response". Added policy statement VI. which states that MRI guided theta burst is considered experimental and investigational. Background and references reviewed and updated.	02/25	02/25

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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. 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.

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.