Clinical Policy: Transcranial Magnetic Stimulation for Treatment Resistant Major Depression

Reference Number: CP.BH.200
Date of Last Revision: 02/23

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. 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. The objective is to stimulate areas of the brain involved in mood regulation to lessen the duration or severity of depressive episodes. TMS is typically delivered in a train of pulses, also known as repetitive TMS (rTMS), at a frequency ≥ 10 Hertz (Hz) and generally targets the dorsolateral prefrontal cortex, a region important for high order executive function. An alternative to conventional rTMS, is Theta Burst Stimulation (TBS), which 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).[1]

Policy/Criteria

I. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation® that a medical director will review requests for an initial course of up to 30 sessions (five days a week, for six weeks) of repetitive transcranial magnetic stimulation (rTMS) or an initial course of up to 30 sessions of Theta Burst Stimulation (TBS), on a case-by-case basis, when meeting all of the following criteria:
   A. Age ≥ 18 years;
   B. 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. 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.
   C. Member/enrollee has a confirmed diagnosis of major depressive disorder (MDD), severe (either recurrent or single episode) without psychosis, per DSM-5-TR criteria;
   D. Planned use of a standardized rating scale by the TMS provider to monitor response during treatment;

E. The major depressive disorder diagnosis is not part of a presentation with multiple psychiatric comorbidities and there is no evidence of psychosis;
F. Oversight of treatment is provided by a licensed psychiatrist except where state scope of practice acts allows otherwise;
G. Failure to respond to a combination of multiple trials of medication and evidence-based psychotherapy treatment during the current episode of illness, with the Physician's Health Questionnaire-9 (PHQ-9) score of > 15 throughout the current course of treatment (or other standardized scale indicating moderately severe to severe depression);
H. 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 (and within the last 24 months if the current episode exceeds 24 months of duration);
    2. The patient 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;
I. Failure of an evidence-based psychotherapy such as a formal trial of cognitive behavioral therapy and/or interpersonal therapy during the current episode;
J. Failure of an adequate trial of electroconvulsive therapy (ECT) unless its use is contraindicated or physician documentation states why TMS is clinically preferable;
K. 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 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.

III. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that a medical director will review requests for six tapered final sessions of rTMS (over a three-week period) on a case-by-case basis, informed by the following factors:

A. Criteria for initial TMS treatment guidelines continues to be met;
B. After 30 TMS sessions, demonstrated >50% reduction in baseline severity scores and approaching PHQ-9 scores of 9;
C. Response to prior treatment, one of the following:
   1. The member/enrollee has been responsive to TMS treatment in the past, evidenced by a ≥50% reduction of depression symptom severity in the baseline score, as measured by the Physician's Health Questionnaire-9 (PHQ-9) score (or other standardized depression scale) and the PHQ-9 score is approaching the score of 9;
   2. The member/enrollee has been shown to be a responder to TMS in the past but had a relapse of depression less than six months after the last TMS trial.

IV. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation 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.

V. It is the policy of Centene Advanced Behavioral Health and health plans affiliated with Centene Corporation that requests for retreatment with rTMS will be reviewed on a case-by-case basis by a Medical Director, informed by all of the following:

A. Criteria for initial TMS treatment guidelines continues to be met;
B. Current depressive symptoms have worsened to a PHQ-9 severity score > 15 (or other standardized depression severity scale);
C. Prior treatment response was at least a 50% drop from the baseline depression scores;
D. If the member/enrollee is not achieving remission, consideration of treatment augmentation or potential alternative treatment such as ECT.

Background

Major depression is one of the most common mental disorders in the Unites States. In 2020, an estimated 21.0 million adults in the United States had at least one major depressive episode. Major depression, also known as major depressive disorder (MDD), unipolar depression, or clinical depression, is a severe illness that results in significant disability and morbidity and is the leading cause of disability in many developed countries. Major depressive disorder (MDD) is a leading cause of global morbidity. It is largely characterized by changes in mood and cognition that last for > 2 weeks and interferes with one's daily activities.[2]

Psychotherapy is the standard non-medication treatment for major depression. Cognitive behavioral therapy and interpersonal therapy have both been found to be effective in the treatment of this disorder. ECT is the standard non-drug somatic therapy for depression.

Transcranial magnetic stimulation (TMS) is a noninvasive brain stimulation technique used for the treatment of psychiatric and neurological disorders to include MDD. TMS works by passing brief repetitive pulses of magnetic energy to the scalp via a large electromagnetic coil positioned on the scalp over the right or left dorsolateral prefrontal cortex (DLPFC), the mood center considered to be directly associated with depression. The magnetic pulses generate low levels of electrical current in underlying brain tissue, around 120% motor threshold (10Hz, 4-second train duration, 26 second inter-train interval, between 3000 and 5000 pulses per session), using a figure-eight solid core coil, which is postulated to 'entrain' local neuronal activity back to euthymia. TMS does not require anesthesia or surgery and may be performed on an out-patient basis but typically is repeated five times per week over the course of four to six weeks to achieve maximum response. TMS may be used alone or as an adjunct to antidepressant medication.[3]

In October, 2008, the Food and Drug Administration (FDA) approved the first transcranial magnetic stimulation (TMS) device for treatment of medication resistant depression of adult patients with Major Depression without psychosis (MDD) who "have not adequately responded to appropriate pharmacological treatment intervention.". In July 2011, the FDA issued a Class II TMS guidance detailing that special controls, when combined with the general controls, will be sufficient to provide the safety and effectiveness of repetitive Transcranial Stimulation (rTMS) systems for treatment with MDD in adult patients who have failed to achieve satisfactory improvement with one prior antidepressant medication at or above the minimal effective dose and duration in the current episode. [4]

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 2010, George and colleagues conducted a prospective, multisite, randomized, active sham-controlled (1:1 randomization) duration-adaptive design with 3 weeks of daily weekday treatment (fixed-dose phase) followed by continued blinded treatment for up to another 3 weeks in improvers. This study was sponsored by the National Institutes of Health. The objective of the trial was to test whether daily left prefrontal rTMS safely and effectively treats major depressive disorder. The study was conducted in four United States hospital clinics. Randomization of 199 antidepressant drug-free patients with unipolar nonpsychotic major depressive disorder, were placed into active and sham conditions. Treatment parameters were standardized at 120% magnetic field intensity relative to the patient's resting MT, at 10 pulses per second (10 Hz) for four seconds, with an intertrain interval of 26 seconds. Treatment sessions lasted for 37.5 minutes (75 trains) with 3000 pulses. There was a two-week lead-in phase, a three-week fixed-treatment phase and a variable three-week extension phase of clinical improvers. Primary outcome remitters: For the primary analysis of remission in the ITT sample (n = 190), there was a significant effect of treatment (odds ratio, 4.2; 95% confidence interval, 1.32-13.24; P = .02). There were 18 remitters (9.5% [14.1% in the active arm and 5.1% in the sham arm]). No covariates were significant. Secondary outcome: responders: The responder analysis had similar results. All remitters were also responders, but not all responders were remitters. There were 19 responders (10.0%) (15% active and 5% sham) in the ITT sample, 14 (9.1%) (14% active and 5% sham) in the completer sample, and 7 (5.8%) in the fully adherent sample. Similar to the remission analyses, logistic regression detected a main effect of treatment condition for the ITT (P = .009) and completer (P = .02) samples but not for the fully adherent sample (P = .14). In the ITT sample, the odds ratio of responding to rTMS vs sham was 4.6 (95% confidence interval, 1.47-14.42). [5]

The authors concluded that high-intensity rTMS for at least three weeks was significantly more likely than sham rTMS to induce remission in antidepressant medication–free patients with moderately treatment-resistant unipolar MDD. The results of this study suggest that prefrontal rTMS is a monotherapy with few adverse effects and significant antidepressant effects for unipolar depressed patients who do not respond to medications or who cannot tolerate them.[5]

Based upon randomized trials, multiple reviews have consistently concluded that repetitive transcranial magnetic stimulation (TMS) can be efficacious and is generally safe for patients with treatment-resistant unipolar major depression. 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.[6]

New forms of transcranial stimulation (TMS) have been developed, including theta burst stimulation (TBS) for the treatment of major depressive disorder (MDD). This technique involves shorter treatment sessions. TBS sessions commonly last only three to ten minutes, compared with conventional rTMS sessions (i.e., 10 Hz stimulation over the left hemisphere [HFL]), which can last up to 40 min. [6]

In 2021, Voigt and colleagues completed a systematic review and meta-analysis on TBS for the acute treatment of major depressive disorder. The objective of the study was to identify and meta-analyze efficacy data from all randomized controlled trials (RCTs) investigating TBS as a treatment for MDD. Published reports of RCTs (January 1, 2010 to October 23, 2020) were identified via systematic searches in computerized databases, followed by review of individual reports for inclusion. Inclusion criteria included primary diagnosis of MDD ≥ 1 week duration of therapy with ≥10 sessions, and treatment with any form of TBS. The Cochrane GRADE methodology and PRISMA criteria were used for evaluation of individual trials. Data from ten RCTs were included, representing 667 patients. Of these, eigh RCTs compared TBS to sham treatment and one compared TBS to standard rTMS (i.e., high frequency stimulation over left dorsolateral prefrontal cortex [HFL]). Quality of evidence assessment yielded high confidence in the finding of TBS being superior to sham on response measured by the Hamilton Depression Rating Scale (HRSD) (RR = 2.4; 95% CI: 1.27 to 4.55; P = 0.007; I2 = 40%). Comparison of HRSD response rates for TBS versus rTMS produced no statistically significant difference (RR = 1.02; 95% CI: 0.85 to 1.23; P = 0.80; I2 = 0%).[7]

In January 2023, Hayes published an article 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 suggest 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 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 Transcranial Magnetic Stimulation to CP. BH.200 Transcranial Magnetic Stimulation.	11/19	02/20
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	2/21	02/21

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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 remission criteria. Neuropsychological testing demonstrated no negative cognitive side effects to the background section.		
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; 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.	2/22	2/22

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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 allow 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"	5/31	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
Adhoc Review. Policy restructured. Added additional information to the description section with no impact to 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 "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".	11/22	12/22
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	02/23	03/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.		

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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.