Clinical Policy: Transcranial Magnetic Stimulation for Treatment Resistant Major Depression

Reference Number: CP.BH.200
Date of Last Revision: 03/24

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 non-invasive brain stimulation technique used for the treatment of psychiatric and neurological disorders, including major depressive disorder (MDD). The treatment uses pulsed magnetic fields to induce an electric current into a localized region of the cerebral cortex. An electromagnetic coil is placed over the scalp inducing a focal pulse of electrical 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. The objective is to stimulate areas of the brain involved in mood regulation to lessen the duration or severity of depressive episodes. Commercially available TMS devices can administer distinct types of stimulation including surface cortical stimulation, deep stimulation, and theta burst stimulation.[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. The member/enrollee is ≥ 18 years of age;
   B. 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. 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 (single episode or recurrent) without psychosis, per most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM);
   D. Planned use of a depression severity standardized rating scale by the TMS provider to monitor response during treatment, with pre-TMS score documented;
   E. The major depressive disorder diagnosis is not part of a presentation with multiple psychiatric comorbidities and there is no evidence of psychosis;

F. Direct supervision of treatment is provided by a licensed psychiatrist except where state scope of practice acts allows for other provider types to supervise;
G. Failure of or intolerance to psychopharmacologic therapy, with the Physician's Health Questionnaire-9 (PHQ-9) score of > 15 throughout the current course of treatment (or other equivalent standardized scale indicating moderately severe to severe depression), at least one of the following:
    1. Failure of two trials of psychopharmacologic agents from at least two different agent classes 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. Member/enrollee is unable to take antidepressants due to documentation of both of the following:
        a. Major adverse drug interactions with medically necessary medications;
        b. Inability to tolerate antidepressant agents as evidenced by trials (and discontinuation) of at least four antidepressants representing at least two different drug classes that were clearly causative of intolerable side effects in the current episode;
H. Failure of an evidence-based psychotherapy such as a formal trial of cognitive behavioral therapy and/or interpersonal therapy 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 equivalent standardized scale indicating moderately severe to severe depression). Note: this therapy should overlap with the medication trials;
I. Failure of an adequate trial of electroconvulsive therapy (ECT) unless its use is contraindicated or physician documentation states why TMS is clinically preferable;
J. Does not have any of the following contraindications:
    1. History of seizures;
    2. Presence of conductive or ferromagnetic or other magnetic-sensitive metals implanted or embedded in head or neck within 30 cm of TMS coil placement other than dental fillings to include but not limited to the following:
        a. Cochlear implant;
        b. Implanted electrodes/stimulators;
        c. Aneurysm clips or coils;
        d. Stents;
        e. Bullet fragments;
        f. Metallic dyes in tattoos;
    3. Vagus nerve stimulator leads in the carotid sheath;
    4. Other implanted stimulators controlled by or that use electrical or magnetic signals such as but not limited to the following:
        a. Deep brain stimulation;
        b. Cardiac pacemaker;
        c. Cardioverter defibrillator;
        d. Intracardiac lines;
        e. Medication pumps;
    5. Less than three months of substantiated remission from substance use disorder;
    6. Concomitant esketamine intranasal, ketamine infusion or other infusion therapies;

7. Severe dementia;
8. Severe cardiovascular disease;
9. Known non-adherence with previous treatment for depression;
10. No acute psychotic disorders in the current depressive episode;
11. No active suicidal ideation with intent.

II. It is the policy of 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 (nine);
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 equivalent standardized depression severity scale) and the PHQ-9 score is approaching the score of (nine);
    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, with duration of response documented;
D. If the member/enrollee is not achieving remission, consideration of treatment augmentation or potential alternative treatment such as ECT.

Background

Major depressive disorder (MDD) is one of the most common mental health disorders. According to the National Institute of Mental Health, the results from the 2021 national survey on drug use and health, indicated that an estimated 21.0 million adults in the United States (U.S.)

have had at least one major depressive episode. This number represents 8.3% of all adults in the U.S. The survey estimated that 61.0% of adults aged 18 or older with major depressive episode received treatment in the 2021 and 74.8% of adults with major depressive episode with severe impairment received treatment.[2]

Psychotherapy and pharmacology are often the standard treatment for MDD. Member/enrollees who do not respond to this treatment are candidates for repetitive transcranial magnetic stimulation (TMS) and electroconvulsive therapy (ECT). Although ECT is more efficacious than TMS, studies have shown that TMS is preferred because the procedure does not require general anesthesia and it does not induct seizures. The effect of repetitive TMS, varies according to the frequency. High frequency surface cortical stimulation is thought to excite the targeted neurons (and is typically used to activate the left prefrontal cortex), whereas low frequency surface cortical stimulation inhibits cortical activity (and is usually directed at the right prefrontal cortex).[3] Magnezi, et.al compared the clinical effectiveness of ECT and TMS. The results concluded that ECT was more effective than TMS in TRD patients. However, ECT patients reported more side effects, with the TMS treatment scoring better in patient preference.[4]

Repetitive transcranial magnetic stimulation (TMS) is an outpatient procedure, in which patients are awake and seated in a reclining chair during treatment. Anesthesia is not used, which allows patients the ability to drive themselves to and from sessions. During a course of repetitive transcranial magnetic stimulation, patients are evaluated at each session for adverse effects and depressive symptoms are monitored with a clinician-administered or patient self-report standardized instrument that is administered weekly or every two weeks.[5] During the first treatment session, a TMS procedure is conducted to correctly establish the optimal site for motor response and individual motor threshold (MT) to minimize side effects. Parameter selection in rTMS can have different effects on the brain depending on the location of the coil and treatment parameters including intensity, pulse frequency, train duration, intertrain interval, and the number of pulses per session. Treatment intensity of the magnetic field is based on the individual patient's level of cortical excitability or resting MT.[6]

In the context of MDD treatment, rTMS is often delivered at a frequency ≥ 10 Hertz (Hz) and generally targets the dorsolateral prefrontal cortex, a region important for high order executive function.[7] An alternative to conventional rTMS is Theta Burst Stimulation (TBS), 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).[7]

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). Two additional network meta-analyses were reviewed, comparing different TMS protocols including surface cortical TMS, theta burst TMS, and deep TMS, as well as experimental modalities such as an accelerated TMS and bilateral TMS, using results from direct comparisons between the modalities, as well as indirectly comparing modalities through their relative effect

with a common comparator (e.g., sham stimulation). Each study found that response and all-cause discontinuation were comparable among surface cortical TMS, theta burst TMS, and deep TMS. Among patients who respond to acute treatment, the benefit of TMS is often stable in the short-term (e.g., four weeks posttreatment) and response to TMS may endure for at least one year.[8]

The National Network of Depression Centers (NNDC) collaborated with the American Psychiatric Association Council on Research (APA CoR) Task Force on Novel Biomarkers and Treatments to create a consensus on rTMS clinical application recommendations. The recommendations were based off available published research that included three large randomized controlled trials in MDD, systematic reviews, and meta-analyses of smaller, sham-controlled trials. The information was conducted via literature review dated from 1990 through 2016. The results indicate that rTMS is appropriate as a treatment in patients with MDD, even if the patient is medication resistant or has significant comorbid anxiety. However, additional research is needed to establish the most beneficial treatment protocols.[6]

Diagnostic and Statistical Manual of Mental Disorder[9]
The DSM-5-TR outlines the following criteria for a ***major depressive*** *episode*:

A. The individual must be experiencing five or more of the following symptoms during the same two-week period representing a change from previous functioning. At least one of the symptoms should be either depressed mood or loss of interest or pleasure:
   1. Depressed mood most of the day, nearly every day, (as indicated by a subjective account or observation);
   2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation);
   3. Significant weight loss when not dieting or weight gain or decrease or increase in appetite nearly every day;
   4. Insomnia or hypersomnia nearly every day;
   5. A slowing down of thought and a reduction of physical movement (observable by others, not merely subjective feelings of restlessness or being slowed down);
   6. Fatigue or loss of energy nearly every day;
   7. Feelings of worthlessness or excessive or inappropriate guilt nearly every day;
   8. Diminished ability to think or concentrate, or indecisiveness, nearly every day;
   9. Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide;
B. The symptoms cause clinically significant distress or impairment in social, occupational, or other major areas of functioning;
C. The episode is not attributable to the direct physiological effects of a substance or to another medical condition;
   NOTE: Criteria A through C represent a major depressive episode
D. The occurrence of the major depressive episode is not better explained by schizoaffective disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic disorders;
E. There has never been a manic or hypomanic episode.

Food and Drug Administration (FDA)[10]:
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 those special controls, that 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. In August 2018, Intermittent Theta Burst Stimulation (iTBS) was cleared for severe Major Depressive Disorder (MDD) in 2018 based on a non-inferiority study comparing it to a standard 10 Hz protocol.

Clinical TMS Society[1]
TMS delivers magnetic pulses to certain brain regions, producing changes in the activity of the brain cells. The frequency of pulse delivery influences whether brain activity is increased or decreased in the affected cells. This means that the effects of TMS treatment can be long lasting because it changes the patterns by which nerve cells and brain networks connect and communicate with each other. Treatment must be provided by a device cleared by the FDA for the purpose of TMS for depression, using an evidence-based protocol. It is expected that the services will be performed as indicated by current medical literature and standards of practice. The TMS society published coverage guidance on TMS for Major Depressive Disorder (MDD) in 2021.

Types of TMS:
Repetitive TMS (rTMS)[1]:
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.

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]:
Theta burst (or intermittent theta burst) repetitive TMS involves high frequency magnetic pulses that are administered at 50 hertz five times per second and are intended to mimic endogenous theta rhythms.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are

from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
90867	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery, and management
90868	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent motor threshold re-determination with delivery and management
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes

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 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 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.		
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 in order 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 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.	03/24	03/24

References

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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.