World Trade Center (WTC) Health Program Medical Coverage Determination
Repetitive Transcranial Magnetic Stimulation
Final Medical Coverage Determination
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I. Coverage Overview

This Medical Coverage Determination (MCD) outlines the coverage of medically necessary repetitive transcranial magnetic stimulation for WTC Health Program members.

Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive, non-systemic treatment using an FDA-approved device to generate brief magnetic pulses that induce an electrical field in a localized region of the brain for the purpose of treating major depressive disorder (MDD) without psychosis. The technique involves placing a small electromagnetic coil over the scalp and passing a rapidly alternating current through the coil wire to produce a magnetic field that passes unimpeded through the brain.

Depending on stimulation parameters (frequency, intensity, pulse duration, stimulation site), rTMS applied to specific cortical regions can change the excitability of the affected brain structures. The procedure is usually carried out in an outpatient setting and does not require anesthesia or analgesia. When used as antidepressant therapy, rTMS produces a clinical benefit without the systemic side effects of standard oral medications and without adverse effects on cognition. Unlike electroconvulsive therapy (ECT), rTMS does not induce amnesia or intentionally induce seizures.

The WTC Health Program may provide coverage of medically necessary rTMS services which meet relevant Level 2 Prior Authorization (PA2) criteria. The CCE/NPN Clinical Director or Designee may authorize rTMS services only when there is clinical documentation that the member has MDD that is a certified WTC-related health condition or medically associated health condition,[1] or the MDD is ancillary to another certified WTC-related health condition.[2] Members with certain medical or psychiatric conditions may not be a candidate for rTMS treatment. Coverage of rTMS services must be in accordance with Program guidelines[3] and all requirements described in this MCD.

II. Coverage Guidelines – General Eligibility Requirements for Medically Necessary rTMS for CCE and NPN Members

[1] A condition may be certified as a health condition medically associated with a certified WTC-related health condition when it results from the treatment or progression of a certified WTC-related health condition. *See* "Health Conditions Medically Associated with World Trade Center-Related Health," (Nov. 7, 2014), available at: https://www.cdc.gov/wtc/pdfs/policies/WTCHPMedicallyAssociatedHealthConditions7November2014-508.pdf.
[2] An ancillary condition refers to a health condition that does not meet requirements for certification under the Program but must be treated in order to manage, ameliorate, or cure a certified WTC-related health condition. *See* WTC Health Program Administrative Manual [Chapter 4, Section 2.4] at https://www.cdc.gov/wtc/ppm.html#medical_treatmentBenefit
[3] *See generally* WTC Health Program Administrative Manual for a full description of Program guidelines, policies, and procedures, at https://www.cdc.gov/wtc/ppm.html.

All rTMS services must meet the criteria below.

A. PA Level

1. Level 2 – Authorization by CCE/NPN Clinical Director

A PA2 is required for all rTMS services. The CCE/NPN Clinical Director or Designee will determine whether the rTMS services are medically necessary to treat the member's certified WTC-related MDD, certified WTC-related health condition with medically associated MDD, or certified WTC-related health condition with ancillary MDD. The CCE/NPN Clinical Director or Designee will also ensure that the member meets the PA criteria listed below in Section II.B. and confirm that the criteria are appropriately documented in the member's medical record.

For detailed PA procedures, see instructions found in the WTC Health Program's Administrative Manual.[4]

B. PA Criteria

The PA2 for rTMS services will cover an acute phase of ≤ 30 sessions and a taper phase ≤ 6 sessions. The order for treatment must be written by a Program-affiliated Licensed Psychiatric Physician[5] who has reviewed the below authorization criteria and has direct oversight of any rTMS treatment rendered. The maximum frequency for acute phase treatment sessions is 5 visits per week for a 6-week duration; a maximum duration of 7 weeks may be permitted if necessary due to circumstances outside the control of the patient or provider (i.e., weather, scheduling/staffing, or medical illness). If additional time is needed, the Program-affiliated Licensed Psychiatric Physician should notify the CCE/NPN to seek approval. The maximum frequency for taper phase treatment is 3 visits per week for a maximum duration of 2 weeks; a maximum duration of 3 weeks may be permitted if necessary due to circumstances outside the control of the patient or provider (i.e., weather, scheduling/staffing, or medical illness). If additional time is needed, the supervising physician should notify the CCE/NPN to seek approval.

1. Initial Authorization Criteria for rTMS Services

The CCE/NPN Clinical Director or Designee may authorize rTMS services if **ALL** the criteria below (**a.** through **d.**) are met and clearly documented in the member's medical record:

a. General Eligibility Requirements

[4] *See* WTC Health Program Administrative Manual, [Chapter 4, Section 3.4], at https://www.cdc.gov/wtc/ppm.html#medical_prior.

[5] The Licensed Psychiatric Physician (MD or DO) must be enrolled as a WTC Health Program-affiliated provider and be (1) either certified by the American Board of Psychiatry and Neurology (ABPN) or the American Osteopathic Board of Neurology and Psychiatry (AOBNP), or (2) have successfully completed a psychiatric residency program approved by the Accreditation Council for Graduate Medical Education ≤ 5 years from the rTMS treatment authorization request date. The Licensed Psychiatric Physician must have examined the member and reviewed the record before submitting the order for treatment. The Licensed Psychiatric Physician must have experience in administering rTMS therapy and the treatment must be given under direct supervision of this physician (i.e., they must be in the area and be immediately available). *See* Transcranial Magnetic Stimulation Local Coverage Determination (LCD), CMS, at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33398&ver=32.

1) Clinical documentation that the member has a certified WTC-related MDD, a certified WTC-related health condition with medically associated MDD, or a certified WTC-related health condition with ancillary MDD.

b. Diagnostic Assessment Requirements

1) Documentation that the member has been diagnosed with (or is currently presenting with any) treatment-resistant, moderate, or severe MDD without psychotic features.

2) Documentation that the member has received a comprehensive psychiatric evaluation by a Program-affiliated Licensed Psychiatric Physician who is requesting authorization for the rTMS treatment; the evaluation must have been completed ≤ 30 days from the planned rTMS treatment episode start date.

3) Documentation by a Program-affiliated Licensed Psychiatric Physician that medical conditions that can cause depressive symptoms have been ruled out as the cause of the treatment-resistant MDD.

4) Documentation by a Program-affiliated Licensed Psychiatric Physician that the requested rTMS treatment is intended to address the current presentation of MDD and not other comorbid conditions.

5) Documentation that the member does not have a history of any of the following psychiatric conditions:

i. Schizophrenia;

ii. Schizophreniform Disorder;

iii. Schizoaffective Disorder;

iv. MDD with psychotic features in the current depressive episode;[6]

v. Bipolar Disorder (Type I or II) with current episode manic or hypomanic;

OR

vi. Untreated substance or alcohol use disorder.[7]

6) Documentation that the member does not have a history of any of the following medical conditions:[8]

[6] *See* Transcranial Magnetic Stimulation LCD, CMS, at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33398&ver=32

[7] Logan, D. E., & Marlatt, G. A. (2010). Harm reduction therapy: a practice-friendly review of research. *Journal of clinical psychology*, *66*(2), 201–214. https://doi.org/10.1002/jclp.20669

[8] The WTC Health Program is not responsible for medical coverage of any diagnostic work-up, consultation, or testing required for any exclusionary condition(s).

i. Epilepsy, seizure disorder or any history of seizures (except those induced by electroconvulsive therapy (ECT) or isolated febrile seizures in infancy or childhood without subsequent treatment or recurrence); [9]

ii. Parkinson's disease;

iii. Multiple sclerosis;

iv. Cerebrovascular disease;

v. Dementia;

vi. Increased intracranial pressure;

vii. Repetitive or severe head trauma;

viii. Primary or secondary central nervous system tumor(s);

OR

ix. Any other degenerative neurologic condition (when there is a mild degenerative neurologic condition without seizures and MDD is clearly present, rTMS may still be appropriate as determined by the Program-affiliated Licensed Psychiatric Physician).

7) Documentation that the member does not have the presence of an implanted magnetic-sensitive medical device located less than or equal to 30 cm from the rTMS magnetic coil or other implanted metal items including, but not limited to a cochlear implant, implanted cardiac defibrillator (ICD), pacemaker, Vagus nerve stimulator (VNS), or metal aneurysm clips or coils, staples or stents. Dental amalgam fillings are not affected by the magnetic field and are acceptable for use with rTMS.[10]

AND

8) Documentation that the member is not actively hospitalized for any reason that is a clinical contraindication to rTMS or, if hospitalized, such hospitalization would not result in a barrier to timely completion of a course for rTMS, if rTMS is clinically indicated in accordance with MCD criteria.

c. Treatment History Requirements

The member's medical record must include documentation that establishes:

[9] *See* Transcranial Magnetic Stimulation LCD, CMS, at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33398&ver=32; *See also* DJ, Osburn S, Burns T, Pawlowska-Wajswol S, Walton R. Transcranial Magnetic Stimulation (RTMS) Safety with Respect to Seizures: A Literature Review. Neuropsychiatr Dis Treat. 2020; 16:2989-3000 https://doi.org/10.2147/NDT.S276635.

[10] *See* Transcranial Magnetic Stimulation LCD, CMS, at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33398&ver=32

1) Adherence to a regimen of evidence-based psychotherapy,[11] known to be effective in the treatment of MDD of an adequate frequency and duration that did not result in significant improvement in the member's depressive symptoms, as documented by standardized rating scales[12] that reliably measure depressive symptoms.

AND ONE OR MORE OF THE FOLLOWING:

2) Resistance to treatment with psychopharmacologic agents as evidenced by a lack of a clinically significant response[13] to one trial of psychopharmacologic agents in the current depressive episode from at least two different agent classes.[14] Each agent in the treatment trial must have been administered at an adequate course of mono- or poly-drug therapy;

OR

3) Inability to tolerate psychopharmacologic agents as evidenced by two trials of psychopharmacologic agents from at least two different agent classes, with distinct side effects;

OR

4) History of response to rTMS in a previous depressive episode. The WTC Health Program defines a response to prior treatment as having a greater than 50% improvement in standard rating scale measurements for depressive symptoms (e.g., GDS, PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR score;

OR

5) If a member is currently receiving electro-convulsive therapy (ECT), rTMS may be considered reasonable and necessary as a less invasive treatment option.

d. Treatment Plan Requirements

1) Documentation of the rTMS treatment plan for the requested rTMS treatment episode, completed by a Program-affiliated Licensed Psychiatric Physician

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[11] Evidence-based psychotherapy includes: Cognitive Therapy; Interpersonal Therapy; Behavioral Therapy; Cognitive Behavioral Analysis System of Psychotherapy; and Short-term Psychodynamic Psychotherapy.

[12] Standardized rating scales for assessing severity of depression include: Beck Depression Inventory (BDI); Hamilton Rating Scale for Depression (HAM-D); Inventory of Depressive Symptomatology – Clinician-Rated (IDS-C); Inventory of Depressive Symptomatology – Self-Report (IDS-SR); Montgomery-Asberg Depression Rating Scale (MADRS); Patient Health Questionnaire – 9 (PHQ-9); Quick Inventory of Depressive Symptomatology – Clinician-Rated (QIDSC); and Quick Inventory of Depressive Symptomatology – Self-Report (QIDS-SR). *See* https://www.apa.org/depression-guideline/assessment

[13] An antidepressant regimen is considered to be failed when the Licensed Psychiatric Physician requesting authorization of the rTMS treatment episode has either (1) personally prescribed all the antidepressant medications used during the current MDD episode, OR (2) has verified the member's antidepressant treatment history by reviewing **ALL** of the following: the member's medical record, the member's WTC Health Program pharmacy claims data (provided by the appropriate Data Center), and the member's non-WTC Health Program pharmacy records (for members who filled their prescriptions using a non-WTC Health Program pharmacy benefit). Where reasonable attempts to obtain records have failed, submissions may be reviewed on a case-by-case basis and a thorough history from the member and/or family may be reviewed.

[14] Currently available classes of antidepressants include selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs), and atypical antidepressants.

with direct oversight of rTMS treatment, which includes the expected frequency and duration of both the acute and taper treatment phases and the total expected number of visits planned for the entire rTMS treatment episode.

2. Subsequent Authorizations of rTMS Treatment

The PA2 for rTMS services signed and authorized by the CCE/NPN Clinical Director or Designee will only cover up to the 6-week acute phase (with a maximum of 7 weeks where there is an appropriate reason for an extension as noted above) and the 2-week taper phase (with a maximum of 3 weeks where there is an appropriate reason for an extension as noted above). The authorization period starts the day the member begins receiving rTMS services and ends when the taper phase is over.

A new PA2 is required if the member encounters a subsequent MDD episode or relapse of MDD symptoms ≥ 3 months after the final rTMS taper treatment session for the most recent prior rTMS treatment episode. No additional rTMS treatment can be rendered within 3 months of the final rTMS taper treatment session. The Program-affiliated Licensed Psychiatric Physician must furnish a plan of care to the CCE/NPN Clinical Director or Designee before the start of each new authorization period. The CCE/NPN Clinical Director or Designee must sign and authorize a new PA2 reconfirming that all of the following criteria are met and clearly documented in the member's medical record:

a. Documentation that the guidelines for initial rTMS treatment have been met and that the member subsequently developed a relapse of depressive symptoms after receiving rTMS treatment for a previous MDD episode.

b. Documentation that the member responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms (e.g., GDS, PHQ-9, BDI, HAM-D, MADRS, QIDS or IDS-SR score).

c. Documentation that a comprehensive psychiatric re-assessment has been performed by a Program-affiliated Licensed Psychiatric Physician ≤ 30 days from the planned start date of the subsequent rTMS treatment. The treatment shall be given under the direct supervision of this physician.

AND

d. Documentation that the planned start date of the subsequent rTMS treatment episode[15] is ≥ 3 months after the final rTMS taper treatment session for the most recent prior rTMS treatment episode.

III. Prior Authorization Request Submission Requirements

After performing the comprehensive psychiatric assessment of the member, the Program-affiliated Licensed Psychiatric Physician must submit an rTMS treatment authorization

[15] The WTC Health Program defines a subsequent rTMS treatment episode as a rTMS treatment episode provided to a member who has previously received any form of rTMS treatment regardless of whether the previous rTMS treatment was authorized by the WTC Health Program.

request that meets all of the above requirements to the CCE/NPN Clinical Director for review and PA2 determination. The WTC Health Program recommends that this authorization request be submitted using the approved "Repetitive Transcranial Magnetic Stimulation (rTMS) Treatment Request Form" to ensure that all of the above requirements are met and appropriately documented. All documentation for completed rTMS treatment authorization requests, including completed "Repetitive Transcranial Magnetic Stimulation (rTMS) Treatment Request Forms," must be maintained in the member's medical record.

All documentation for completed rTMS service authorizations is subject to audit by the WTC Health Program.

IV. Billing/Coding Guidelines

All applicable codes are listed in the WTC Health Program Codebook, located on the Centralized Accessible Real-time Enterprise (CARE) portal.

For consideration of codes that are not currently included in the WTC Health Program Codebook, please submit a WTC-5 Medical Code Request form to the TPA contractor via the standard WTCMedCode@csra.com mailbox process.

When filing claims for payment of WTC Health Program authorized rTMS treatment episodes, all fields on the claim form must be completed appropriately. Claims which do not include the names and provider identification information for the referring, rendering and billing provider will be considered incomplete and will not be processed until this information is received. Please be aware of the following requirements that will affect claims processing for rTMS treatment episodes:

A. A Licensed Psychiatric Physician requesting authorization for WTC Health Program coverage of the rTMS treatment episode should be listed as the referring provider on the claim and is responsible for direct oversight of any rTMS treatment rendered.

V. Revision History

A. August 10, 2023

1. Updated references to TMS to rTMS throughout to clarify that coverage does not apply to other types of TMS treatment.

2. Clarified that members with a history of PTSD are eligible for rTMS treatment, as well as members with a history of an isolated seizure without recurrence that has not required medication and those with dental amalgam fillings.

3. Added flexibility for scheduling conflicts.

4. Updated treatment history requirements to more closely align with CMS benchmark.

5. Clarified that the licensed psychiatric physician (LPP) is responsible for direct oversight of any rTMS treatment rendered.

6. Performed editorial updates to align with the latest MCD style conventions.