



United Behavioral Health

Supplemental Clinical Criteria: Missouri Medicaid Transcranial Magnetic Stimulation

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INTRODUCTION & INSTRUCTIONS FOR USE

The following *State or Contract Specific Clinical Criteria*¹ defined by state regulations or contractual requirements are used to make medical necessity determinations, mandated for members of behavioral health plans managed by Optum and U.S. Behavioral Health Plan, California (doing business as OptumHealth Behavioral Solutions of California ("Optum-CA")).

Other *Clinical Criteria*² may apply when making behavioral health medical necessity determinations for members of behavioral health plans managed by Optum®³. These may be externally developed by independent third parties used in conjunction with or in place of these Clinical Criteria when required, or when state or contractual requirements are absent for certain covered services. When deciding coverage, the member's specific benefits must be referenced.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the member's benefits prior to using these Clinical Criteria. In the event that the requested service or procedure is limited or excluded from the benefit, is defined differently or there is otherwise a conflict between this Clinical Criteria and the member's specific benefit, the member's specific benefit supersedes these Clinical Criteria.

These Clinical Criteria are provided for informational purposes and do not constitute medical advice.

¹ **Clinical Criteria (State or Contract Specific):** Criteria used to make medical necessity determinations for mental health disorder benefits when there are explicit mandates or contractual requirements.

² **Clinical Criteria**

(Level of Care Utilization System-LOCUS) Standardized level of care assessment tool developed by the American Association of Community Psychiatrists used to make medical necessity determinations and placement decisions for adults ages 19 and older.

Child and Adolescent Level of Care Utilization System/Child and Adolescent Service Intensity Instrument (CALOCUS-CASII) Standardized assessment tool developed by the American Association of Community Psychiatrists and the American Academy of Child and Adolescent Psychiatry used to make clinical determinations and to provide level of service intensity recommendations for children and adolescents ages 6-18.

(Early Childhood Service Intensity Instrument-ECSII) - Standardized assessment tool developed by the American Academy of Child and Adolescent Psychiatry used to make medical necessity determinations and to provide level of service intensity recommendations for children ages 0-5.

(ASAM Criteria) Criteria used to make medical necessity determinations for substance-related disorder benefits.

³ Optum is a brand used by United Behavioral Health and its affiliates.

Transcranial magnetic stimulation (TMS) is a noninvasive method of brain stimulation. The technique involves placement of a small coil over the scalp and passing a rapidly alternating current through the coil wire, which produces a magnetic field that passes unimpeded through the brain. Depending on stimulation parameters (frequency, intensity, pulse duration, stimulation site), repetitive TMS to specific cortical regions can either increase or decrease the excitability of the affected brain structures. Providers typically perform TMS on an outpatient basis, and it does not require anesthesia or analgesia. When used as an antidepressant therapy, TMS produces a clinical benefit without the systemic side effects that may be associated with oral medications. TMS does not produce adverse effects on cognition. Unlike electroconvulsive therapy, TMS does not induce amnesia or seizures. (CMS: Local Coverage Determination TMS L34641).

Participant Eligibility

- Participant must be at least 18 years of age;
 - Has a confirmed diagnosis of major depressive disorder (MDD), severe (either recurrent or single episode), per DSM-5 criteria;
 - F32.2 - Major depressive disorder, single episode, severe without psychotic features
 - F33.2 - Major depressive disorder, recurrent, severe without psychotic Features
- AND
- One or more of the following:
 - Resistance to treatment with psychopharmacologic agents as evidenced by a lack of clinically significant response to one trial of psychopharmacologic agents in the current depressive episode from at least two different agent classes. Each agent in the treatment trial must have been administered at an adequate course of mono- or poly-drug therapy; or
 - 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
 - History of good response to TMS in a previous depressive episode as evidenced by a greater than 50% improvement in a standardized rating scale for depressive symptoms; or
 - Is a candidate for and has declined electroconvulsive therapy, and TMS is considered a less invasive treatment option;
- AND
- A prior trial (recent or by history) of an evidence-based psychotherapy known to be effective in the treatment of MDD (e.g., cognitive-behavioral therapy; interpersonal therapy) of an adequate frequency and duration without significant improvement in depressive symptoms as documented by a standardized rating scale for depressive symptoms.

Provider Qualifications

- An MHD enrolled psychiatrist who has examined the participant and reviewed the record must write the order for treatment. The psychiatrist must have experience in administering TMS therapy. The psychiatrist must directly supervise the treatment (must be present in area but does not necessarily personally provide the treatment).
- AND
- Provider must administer TMS with a US Food and Drug Administration (FDA) cleared device for the treatment of MDD in a safe and effective manner according to the manufacturer's user manual and specified stimulation parameters.

Retreatment

- Retreatment may be considered for participants who met the guidelines for initial TMS treatment and subsequently develop relapse of depressive symptoms if the patient responded to prior TMS treatments as evidenced by a greater than 50% improvement in a standardized rating scale for depression.

Standardized Rating Scales for Depression

- Standardized rating scales that reliably measure depressive symptoms include but are not limited to the following:
 - Patient Health Questionnaire-9 (PHQ-9),
 - Beck Depression Inventory (BDI),
 - Hamilton Depression Rating Scale (HAM-D),
 - Montgomery Asberg Depression Rating Scale (MADRS),
 - Quick Inventory of Depressive Symptomatology (QIDS),
 - Inventory for Depressive Symptomatology Systems Review (IDS-SR).

Exclusions

- None of the following conditions or contraindications to TMS are present:
 - Seizure disorder or any history of seizures (except those induced by ECT or isolated febrile seizures in infancy without subsequent treatment or recurrence); or
 - Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; or
 - Neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive or severe head trauma, or primary or secondary tumors in the central nervous system, or
 - Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 cm from the TMS 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 TMS).
- TMS is not indicated for maintenance treatment. There is insufficient evidence in the published peer reviewed literature to support the efficacy of maintenance therapy with TMS.

REFERENCES

1. Missouri Department of Social Services, MoHealthNet. (2021). Provider Bulletin: Transcranial Magnetic Stimulation for Major Depressive Disorder, 44(23), Missouri HealthNet website: <https://dss.mo.gov/mhd/>.

REVISION HISTORY

Date	Action/Description
November, 2021	<ul style="list-style-type: none">• Version 1