MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
Transcranial Magnetic Stimulation for Treatment of Depression-OH MCD-MM-0233	01/01/2023-11/30/2023
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Transcranial Magnetic Stimulation for Treatment of Depression

B. Background

Transcranial Magnetic Stimulation (TMS) was originally introduced in 1985 as a noninvasive treatment modality for treatment-resistant Major Depressive Disorder (MDD) by sending brief, repetitive pulses of magnetic energy to the scalp via a large electromagnetic coil, generating a low level of electrical stimulation. These magnetic fields pass through the skull and induce electrical currents that depolarize neurons in a focal area of the surface cortex. The magnetic field generated by this type of stimulation is very small and cannot be felt by the patient but is strong enough to flow into the brain without inducing seizures or creating a need for anesthesia.

TMS is generally an outpatient procedure with awake patients and sessions that vary between (30) to forty (40) minutes. It can be delivered as a single pulse or as a series of pulses. Despite variability in the number of pulses delivered per session and the number of sessions per patient, research indicates that typical courses of TMS consist of treatment up to five (5) days a week for up to six (6) weeks. A tapering schedule is used to end treatment.

C. Definitions

- **Acute (Index) Course of Treatment** - The initial series of treatment given to relieve acute symptoms of the disorder.
- **Adequate Trial of an Antidepressant Drug** - Taking a drug for a duration of at least four (4) weeks at or near the maximum dose for the specific antidepressant as approved by the FDA, or documentation exists that higher doses were not tolerated when the dose is less than the FDA approved maximum.
- **Continuation TMS** - A course of treatment beginning after the acute/index course, lasting up to six (6) months, and designed to prevent worsening of symptoms and continue treatment for a depressive episode that has not yet remitted.
- **Depression Rating Scale** - Scales that have been standardized for national use to reliably assess the range of symptoms most commonly observed in adults with major depressive disorder. Many rating scales are available. Listed below are the most used scales that comprehensively survey the type and magnitude of symptoms present:
  - Beck Depression Inventory (BDI)
  - Geriatric Depression Scale (GDS)
  - Hamilton Depression Rating Scale (HAM-D)
  - Patient Health Questionnaire-9 (PHQ-9)
  - Quick Inventory of Depressive Symptomatology (QIDS)
- **Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR)** - The standard language by which clinicians, researchers, and public health officials in the United States communicate about mental disorders and subsequent criteria and classification.

- **Maintenance TMS** - Regularly scheduled TMS sessions on a weekly, biweekly, or monthly basis used to prevent relapse of depressive symptoms.
- **Major Depressive Disorder (MDD)** - Characterized by discrete episodes of at least 2 weeks' duration involving changes in affect, cognition, and neurovegetative functions and inter-episode remission evidenced by a combination of 5 or more symptoms that must include either depressed mood or anhedonia representing a change from previous functioning.
- **Medication Side Effects** - Unexpected effects of medications that cause significant distress, inhibit daily function, have the potential to worsen health, or are life threatening.
- **Remission** - The absence of significant signs or symptoms of a major depressive episode during the previous two (2) months.

D. Policy

I. A review of medical necessity is required for initial or continuation courses of TMS.

II. *Initial (acute/index) treatment is considered medically necessary when **ALL** the following criteria are met:*

A. Member is 18 years of age or older.

*B. Member has a confirmed diagnosis of major depressive disorder, single or recurrent, with a current severe episode as evidenced by a recent score on a standardized depression rating scale and at least **one** of the following:*

*1. Need for treatment, as indicated by **one** of the following:*

a. Resistance to treatment with documented adherence as evidenced by a lack of a clinically significant response during a current or previous depressive episode and two (2) or more classes of antidepressant *agents at or near maximum effective dose and duration approved by the FDA, **or***

b. Inability to tolerate pharmacotherapy as evidenced by two (2) antidepressants *with documented side effects.*

*2. Continuation of acute course of treatment, as indicated by **all** the following:*

*a. Continuation of symptoms after index (acute) course of treatment, **and***

b. Previous positive response to index (acute) course of treatment as evidenced by a reduction of 50% in a depression severity rating scale as compared to baseline.

*C. **None** of the following conditions or contraindications are present:*

1. No epilepsy or history of seizure or presence of other neurologic disease that may lower seizure threshold (e.g., cerebrovascular accident, severe head trauma, increased intracranial pressure).

2. No acute or chronic psychotic symptoms or disorders (e.g., schizophrenia, schizophreniform, or schizoaffective disorder).

3. No cochlear implant, deep brain stimulator, or vagus nerve stimulator.

4. No current use of substances that may significantly lower seizure threshold, such as alcohol or stimulants.

5. No metallic hardware or implanted magnetic-sensitive medical device (e.g., implanted cardioverter-defibrillator, pacemaker, metal aneurysm clips or coils)

at a distance within the electromagnetic field of the discharging coil (e.g., less than or equal to 30 cm to the discharging coil).

III. Additional treatment courses of TMS are considered medically necessary when **all** the following have been met:
   A. It has been 30 days since last session of TMS, **and**
   B. *There is a history of response to TMS in a previous depressive episode as evidenced by a greater than 50% improvement in a standardized depression rating scale,* **and**
   C. Medical necessity is met per Section II above.

IV. *Maintenance treatment with TMS is not considered medically necessary*. There is not sufficient evidence to support this treatment, and additional research is needed to assess net benefit versus harm for patients.

V. Additional criteria
   A. Transcranial magnetic stimulation must be administered by an FDA cleared device for the treatment of major depressive disorder in a safe and effective manner according to the manufacturer's user manual and specified stimulation parameters.
   B. *A treatment course should not exceed five (5) days a week for six (6) weeks (total of 30 sessions), followed by a 3- week taper of three (3) treatments in one (1) week, two (2) treatments the next week, and one (1) treatment in the last week.*
   C. TMS can be ordered by and performed under direction of a neurologist, licensed psychiatrist, or psychiatric nurse practitioner who has examined the member, reviewed the record when it is within his/her scope of practice, and has experience in administering TMS therapy within his/her scope of practice.

E. Conditions of Coverage
NA

F. Related Policies/Rules
Medical Necessity Determinations

G. Review/Revision History

	DATE	ACTION
Date Issued	07/12/2018	
Date Revised	11/11/2020 10/28/2021 08/31/2022 01/19/2023	Removed a definition, added neurologist. Revised and expanded definitions. Added Section II and IV. Updated background and definitions. Updated criteria (MCG 26th edition). Updated title for clarity.
Date Effective	01/01/2023	
Date Archived	11/30/2023	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

H. References

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revised. Depressive disorders. (March, 2022). ISBN 978-0890425763.
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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

Independent medical review – 06/2018