MEDICAL POLICY STATEMENT
Kentucky Marketplace

Policy Name & Number	Date Effective
Transcranial Magnetic Stimulation KY MP MM-0239	02/01/2022-11/30/2022
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.

Table of Contents

A. Subject
Transcranial Magnetic Stimulation

B. Background
Transcranial Magnetic Stimulation (TMS) was originally introduced in 1985 as a noninvasive treatment that is used for treating major depressive disorder. Transcranial Magnetic Stimulation is a technique that sends brief repetitive pulses of magnetic energy to the scalp via a large electromagnetic coil. This technique generates a low level of electrical stimulation. The amount of electricity created by this type of stimulation is very small and cannot be felt by the patient but is still strong enough to flow into the brain without seizures or need for anesthesia. The electric charges cause the neurons to become active and lead to the release of neurotransmitters such as serotonin, norepinephrine and dopamine.

C. Definitions
- **Depression –** a mental disorder that is characterized by alterations in the mood secondary to psychological, social and biological factors.
- **Adequate trial of an antidepressant drug:** taking a drug for a duration of at least 4 weeks at or near 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.
- **Medication side effects:** unexpected effects of medications that cause significant distress, inhibit daily function, have the potential to worsen health, or are life threatening.
- **Major Depressive Disorder-** a combination 5 or more symptoms that must include either depressed mood or anhedonia. Symptoms must be present nearly every day in the same 2-week period and represent a change from previous functioning.
- **Depression Rating Scale:** Scales that have been standardized for national use to reliably assess the range of symptoms that are most observed in adults with major depression. There are many rating scales available; however, listed below are the most used scales that comprehensively survey the type and magnitude of symptom burden present:
  - Beck Depression Inventory (BDI)
  - Geriatric Depression Scale (GDS)
  - Hamilton Depression Rating Scale (HAM-D)
  - Personal Health Questionnaire Depression Scale (PHQ-9)
  - Quick Inventory of Depressive Symptomatology (QIDS)

D. Policy
I. Prior authorization is required
II. TMS is considered medically necessary when ALL of the following criteria are met:
  A. Member is 18 years of age or older AND

B. Member has a confirmed diagnosis of major depressive disorder (single or recurrent) with the current episode that is severe as evidenced by a current Physician's Health Questionnaire-9 (PHQ-9) score of > 15 or equivalent score on a similar, standardized depression rating scale AND
C. One or more of the following
    1. Resistance to treatment as evidenced by a lack of a clinically significant response during a current or previous depressive episode and adequate trials of 4 antidepressant agents which include at least 2 different agent classes, **at or near** maximum effective dose and duration for each class approved by the FDA (Note: see Definitions Section for Adequate Trial of an Antidepressant Depressant specifications)
    2. Where there has been a trial of at least 4 antidepressant agents which include at least 2 different agent classes and a failure to tolerate a therapeutic dose of the medication trials as evidenced by documentation via medical records and at least 2 of the treatment trials were administered at or near maximum effective dose and duration for each class approved by the FDA
    3. Inability to tolerate a therapeutic dose of antidepressants as evidenced by documentation via medical record of 4 trials of antidepressant agents from at least 2 different drug classes with significant intolerable side effects (Note: see Definitions Section for description of medication side ef fects) AND
D. Has completed a trial of evidence-based psychotherapy that is effective in the treatment of MDD with appropriate frequency and duration without significant improvement for 12 weeks alone or combined with psychopharmacologic agents AND
E. None of the following conditions or contraindications are present:
    1. Seizure disorder or any history of seizure (except those induced by electroconvulsive therapy or isolated febrile seizures in childhood without subsequent treatment or recurrence; OR
    2. Presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; OR
    3. Neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma or secondary tumors in the central nervous system ; OR
    4. Presence of an implanted magnetic-sensitive medical device located less than or equal to 30 centimeters from the transcranial magnetic stimulation magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator, pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples or stents OR
    5. Unstable medical disorder AND

III. For therapeutic TMS treatment, subsequent motor threshold redetermination with delivery and management will require separate preauthorization.

IV. Additional Treatment Course of TMS is considered medically necessary when
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 that reliably measures depressive symptoms (Note: see Definitions Section for Depression Rating Scale)
C. Maintenance treatment of TMS is not considered medically necessary as there is not sufficient evidence to support this at this time.

V. Additional criteria
A. Transcranial magnetic stimulation is 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 of transcranial magnetic stimulation should not exceed: 5 days a week for 6 weeks (total of 30 sessions), followed by a 3 week taper of 3 treatments in 1 week, 2 treatments the next week and 1 treatment in the last week.
C. TMS can be ordered by a neurologist, licensed psychiatrist, or psychiatric nurse practitioner who has examined the member and reviewed the record when it is within their scope of practice.
D. TMS can be performed under the direction of a neurologist, licensed psychiatrist or psychiatric nurse practitioner who has experience in administering TMS therapy when within their scope of practice.

E. Conditions of Coverage
NA

F. Related Policies/Rules
NA

G. Review/Revision History

	DATE	ACTION
Date Issued	07/12/2018	
Date Revised	11/11/2020 10/27/2021	Removed a definition, added neurologist Refined Definitions, Clarified Sec II B, Added section III and IV
Date Effective	02/01/2022	
Date Archived	11/30/2022	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.

H. References

1. "Brain Stimulation Therapies." *National Institute of Mental Health*, U.S. Department of Health and Human Services, June 2016, https://www.nimh.nih.gov
2. Holtzheimer, P. E., MD, Roy-Byrne, P. P., MD, & Solomon, D., MD. "Technique for Performing Transcranial Magnetic Stimulation (TMS)." *UpToDate*, September 2020 https://www.uptodate.com
3. Perera, T, et al. "The Clinical TMS Society Consensus Review and Treatment Recommendations for TMS Therapy for Major Depressive Disorder."2016, retrieved from wwww.pubmed.ncbi.nih.gov

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

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

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