MEDICAL POLICY STATEMENT
OHIO MARKETPLACE

Policy Name	Policy Number	Effective Date
Transcranial Magnetic Stimulation	MM-0235	2/1/2020
Policy Type		
MEDICAL	Administrative	Pharmacy	Reimbursement

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) 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.

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A. Subject

Transcranial Magnetic Stimulation

B. Background

Transcranial Magnetic Stimulation 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 mood secondary to psychological, social and biological factors. In the United States, by the year 2020, depressive illness will be the second leading cause of disability.
- **Adequate trial of an antidepressant drug**: taking a drug for a duration of at least 4 weeks at 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.
- **Augmentation therapy**: a drug regimen that consist of treating a patient with more than one drug, one of which is not an antidepressant, to increase therapeutic outcomes.
- **Dysthymia**: a form of depression that inhibits a person's ability to function at a high level or to feel well secondary to long-term, chronic symptoms of depression. This type of depression does not disable the person.
- **Depression Rating Scale**: Scales that have been standardized for national use to reliable assess the range of symptoms that are most commonly observed in adults with major depression. There are many rating scales available; however, listed below are the most commonly 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)
- **Major Depressive Disorder**: a combination of depressive symptoms that become so severe that they are disabling and make daily functioning impossible.

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 treatment-resistant severe depressive disorder (single or recurrent episode); 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 ALL of the following:
      a. Adequate trials of 4 psychopharmacologic agents which include at least 2 different agent classes, at the maximum effective dose and duration for each class as approved by the FDA (Note: see Definitions section for Adequate Trial of an Antidepressant Depressant specifications) AND

b. Adequate trial of evidence-based psychotherapy for a minimum of 12 weeks alone or combined with psychopharmacologic agents as stated above.

2. Inability to tolerate a therapeutic dose of medications as evidenced by documentation via medical record of 4 trials of psychopharmacologic agents with distinct side effects OR
3. History of response to transcranial magnetic stimulation in a previous depressive episode as evidenced by a greater than 50% improvement in a standard rating scale that reliably measures depressive symptoms (Note: see Definitions section for Depression Rating Scale) OR
4. Is currently receiving or is a candidate for and has declined electroconvulsive therapy, and TMS is considered a less invasive treatment option

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 as noted by a standardized reliable scale to measure depression symptom 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 infancy 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 with primary 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
F. Last successful TMS treatment was greater than 30 days prior to requested start date

III. 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 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 licensed psychiatrist or psychiatric nurse practitioner who has experience in administering TMS therapy when it is within their scope of practice.

E. Conditions of Coverage

F. Related Polices/Rules

G. Review/Revision History

	DATE	ACTION
Date Issued	7/12/2018	
Date Revised	1/1/2019 10/2/2019	Clarified PA requirement, Changed definition of adequate trial, Added IIA, IIC4, IID. IIE5, IIF, IIIC, IIID
Date Effective	2/1/2020	

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/health/topics/brain-stimulation-therapies/brain-stimulation-therapies.shtml.
2. Holtzheimer, P. E., MD, Roy-Byrne, P. P., MD, & Solomon, D., MD. "Technique for Performing Transcranial Magnetic Stimulation (TMS)." *UpToDate*, Aug. 2019, https://www.uptodate.com/contents/technique-for-performing-transcranial-magnetic-stimulation-tms.
3. Perera, T, et al. "The Clinical TMS Society Consensus Review and Treatment Recommendations for TMS Therapy for Major Depressive Disorder." *Brain Stimulation*, 2016AD, pp. 336–346., doi:10.1016/j.brs.2016.03.010.

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

Independent medical review – 6/2018