MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

Policy Number: MP.125.MH
Last Review Date: 11/03/2016
Effective Date: 01/01/2017

MP.125.MH – Transcranial Magnetic Stimulation

This policy applies to the following lines of business:
- ✓ MedStar MA – DSNP – CSNP

MedStar Health considers **Transcranial Magnetic Stimulation (TMS)** medically necessary for the following indications:

TMS is covered for members diagnosed with *severe Major Depression* (single or recurrent episode) and having at least one of the following:

- Resistance to treatment with psychopharmacologic agents as evidenced by a lack of clinically significant response to four trials of such agents, in the current depressive episode, from at least two different agent classes. At least one of the treatment trials must have been administered at an adequate course of mono- or poly–drug therapy;
- Inability to tolerate psychopharmacologic agents as evidenced by trials of four such agents with distinct side effects;
- History of good response to TMS in a previous episode;
- If member is currently receiving electro-convulsive therapy, TMS may be considered reasonable and necessary as a less invasive treatment option;

Cautionary Uses – The benefits of TMS use must be carefully considered against the risk of potential side effects in members with any of the following:
- Seizure disorder or any history of seizure (except those induced by electroconvulsive therapy or isolated febrile seizures in infancy without subsequent treatment or reoccurrence).
- The presence of vagus nerve stimulator leads in the carotid sheath.
- The presence of an implanted medical device located greater than30 cm from the TMS magnetic coil, including but not limited to pacemakers, implanted defibrillators, or vagus nerve stimulations.

Members meeting the criteria of this policy are covered for up to 30 visits over a 7 week period followed by 6 taper treatments one time.

Repeat acute treatment for relapse of depressive symptoms is medically necessary for 30 visits followed by 6 taper treatments only if member has responded to previous treatments, specifically greater than 50% improvement in a standard rating scale for

depressive symptoms (e.g. Geriatric Depression Scale (GDS), Personal Health Questionnaire (PHQ-9), Beck Depression Scale (BDI), Hamilton Rating Scale for Depression (HAM-D), Montgomery Asberg Depression Rating Scale (MADRS), Quick Inventory of Depressive Symptomology (QIDS), or Inventory for Depressive Symptomology Systems Review (IDS-SR) Score).

Limitations
TMS is not covered for members because it is considered not reasonable and necessary when used as a treatment with any of the following:

- Presence of psychotic symptoms in current depressive episode.
- Dementia or other degenerative neurologic conditions such as Parkinson's disease or Multiple Sclerosis.
- Chronic or acute psychotic disorder such as Schizophrenia, Schizophreniform Disorder, or Schizoaffective Disorder.
- TMS should not be used in patients who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head which are non-removable and within 30cm of the TMS magnetic coil. Examples include cochlear implants, implanted electrodes/stimulators, aneurysm clips or coil, stents, and bullet fragments.

TMS as a maintenance therapy is not considered medically necessary and not covered. Any additional use of TMS not specified in this policy is considered experimental, investigational, or unproven and therefore not covered.

Background
The Centers for Medicare and Medicaid (CMS) defines transcranial magnetic stimulation (TMS) is a non-invasive, non-systemic treatment that uses MRI-strength, pulsed, magnetic fields to induce an electric current in a localized region of the cerebral cortex. An electromagnetic coil is placed on the scalp that induces a focal current in the brain and temporary modulation of cerebral cortical function. Capacitor discharge provides electrical current in alternating on/off pulses. Depending on stimulation parameters, repetitive TMS to specific cortical regions can either decrease or increase the excitability of the targeted structures.

CMS describes TMS as a well-tolerated, non-pharmacologic alternative that does not require attendant anesthesia services and can be administered in an outpatient setting for patients with Major Depressive Disorder (MDD) who have failed to benefit from initial treatment of their depression. TMS produces a clinical benefit without the systemic side effects typical with oral medications, has no adverse effects on cognition, and unlike electroconvulsant therapy does not induce amnesia or seizures. NeuroStar® TMS was

granted FDA marketing clearance in 2008 as a Class II rTMS device for the treatment of MDD in patients who were unresponsive to antidepressant medication.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
90867	Transcranial Magnetic Stim Tx Plan
90868	Transcranial Magnetic Stim Tx Delivery
90869	Transcranial Magnetic Stim ReDetermine
ICD-9 codes covered if selection criteria are met:	
296.23	Major Depressive Affective Disorder Single Episode Severe Degree without Psychotic Behavior
296.33	Major Depressive Affective Disorder Recurrent Episode Severe Degree without Psychotic Behavior
ICD-10 codes covered if selection criteria are met:	
F32.2	Major Depressive disorder, single episode, severe without psychotic features
F32.9	Major Depressive disorder, single episode, unspecified
F33.2	Major Depressive disorder, recurrent severe without psychotic features

References

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2. Center for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) No. L34998 - Transcranial Magnetic Stimulation (TMS) for the Treatment of Depression. Revision Effective Date: 12/11/2016. (Contractor: Novitas Solutions, Inc.). https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34998&ver=4&Date=&DocID=L34998&bc=iAAAABAAAAAAAA%3d%3d&
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details.aspx?LCDId=34641&ver=8&Date=&DocID=L34641&bc=iAAAABAAAAAAAA%3d%3d&

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5. National Institute for Health and Clinical Excellence (NICE), Interventional Procedure Guidance (IPG). IPG242 Transcranial magnetic stimulation for severe depression: Guidance, Published Nov. 28, 2007. http://www.nice.org.uk/guidance/IPG242/Guidance/pdf
6. Rossi S, Hallett M, Rossini PM, Pascual-Leone A, and The Safety of TMS Consensus Group. Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research. Clin Neurophysiol. 2009 Dec; 120(12): 2008-2039. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3260536/
7. U.S. Food & Drug Administration (FDA). Approval letter to Neuronetics, Inc. for K601053 NeuroStar TMS System; Original Classification Order: October 7, 2008, Corrected Classification Order issued: March 23, 2011. http://www.accessdata.fda.gov/cdrh_docs/pdf6/K061053.pdf
8. U.S. Food & Drug Administration (FDA). Center for Devices and Radiological Health; Guidance for Industry and FDA staff- Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems. Issued July 26, 2011. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM265272.pdf.

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