ASURIS NORTHWEST HEALTH

Medicare Advantage Policy Manual **Policy ID:** M-MED148

Transcranial Magnetic Stimulation as a Treatment of Depression and Other Disorders

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Transcranial Magnetic Stimulation (TMS) is a non-invasive treatment that uses pulsed magnetic fields to induce an electric current in a localized region of the cerebral cortex. An electromagnetic coil placed on the scalp induces focal current in the brain that temporarily modulates cerebral cortical function. Capacitor discharge provides electrical current in alternating on/off pulses. Stimulation parameters may be adjusted to alter the excitability of the targeted structures in specific cortical regions.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles.*	***Transcranial Magnetic Stimulation (TMS).***	LCD L37088
	Billing and Coding: Transcranial Magnetic Stimulation (TMS)	A57693
	**Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.	
Medical Policy Manual	*Medicare coverage guidance is not available externally applied transcranial magnetic stimulation with concomitant measurement of evoked cortical potentials (0858T) or accelerated transcranial magnetic stimulation protocols (0889T- 0892T). Therefore, the health plan's medical policy is applicable.* Transcranial Magnetic Stimulation as a Treatment of Depression and Other Disorders, Medicine, Policy No. 148 (see "NOTE" below)	

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- All chart notes and medical records pertinent to the request, such as History and Physical;
- Documentation of prior treatments (e.g., psychopharmacologic agents, prior rTMS treatments, electroconvulsive therapy [ECT], etc.), and the response to those treatments
- Number of requested treatment sessions, and indicate if the request is for an initial treatment or a retreatment.
- Name of device to be used for rTMS treatment *(according to LCA 57693, treatment must be provided by a device which has been FDA-cleared for the purpose of supplying TMS)*.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) granted 510(k) approval for the following devices:

- Brainsway™ H-Coil Deep TMS System (Brainsway, Ltd.) received FDA clearance for the treatment of depressive episodes in patients suffering from major depressive disorder who have failed to respond to antidepressant medications in their current episode of depression.
- Cerena™ TMS device (Eneura Therapeutics) received de novo marketing clearance for the acute treatment of pain associated with migraine headache with aura. Warnings, precautions, and contraindications include the following:
    - Safety and effectiveness have not been established in pregnant women, children under the age of 18, and adults over the age of 65.
- Magvita TMS Therapy System® is indicated for the treatment of Major Depressive Disorder in adult patients who failed to receive satisfactory improvement from prior antidepressant medication in the current episode.
- NeuroStar® (formerly known as NeoPulse®) TMS Therapy system (Neuronetics, Inc.) received de novo clearance for the treatment of major depressive disorder in adults who have failed a six-week course of one antidepressant medication. In March 2024, the Neurostar TMS therapy system was approved by the FDA for use in 15 - 25 year olds (K231926).
- Rapid2 Therapy System from Magstim Company Limited is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.
- SpringTMS® received FDA clearance for the treatment of migraines, with aura.
- Apollo TMS Therapy System (Mag & More) is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.
- Nexstim Navigated Brain Therapy (NBT®) System 2 is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.
- ALTMS Magnetic Stimulation Therapy System (also Blossom TMS Therapy System, approved in 2022) is indicated for the treatment of Major Depressive Disorder in adult patients, who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.
- The Magnus Neuromodulation System (MNS) with SAINT technology - model Number 1001K was FDA approved in 2022 for the treatment of Major Depressive Disorder (MD D) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. (K220177)
- Horizon 3.0 TMS Therapy System Magstim is indicated for Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (Cleared 1/13/2023 K222171).

Of note, the fact a service or procedure has been FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered

Medicare covered services. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Electrical Stimulation and Electromagnetic Therapy Devices, Durable Medical Equipment, Policy No. M-DME83

REFERENCES

None

CODING

Codes	Number	Description
CPT	0858T	Externally applied transcranial magnetic stimulation with concomitant measurement of evoked cortical potentials with automated report
	0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold–starting location, neuronavigation files and target report, review and interpretation
	0890T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day
	0891T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
	0892T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day
	90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
	90868	; subsequent delivery and management, per session
	90869	; subsequent motor threshold re-determination with delivery and management
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*