Medicare Medical Policy

Transcranial Magnetic Stimulation

Effective Date: 7/1/2024

MEDICARE MEDICAL POLICY NUMBER: 268

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Last Review Date: 6/2024	POLICY CROSS REFERENCES	. 2
Next Annual Review: 11/2024	POLICY GUIDELINES	. 2
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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PRODUCT AND BENEFIT APPLICATION

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Transcranial Magnetic Stimulation (TMS)	Local Coverage Determination (LCD): Transcranial Magnetic Stimulation (TMS) (<u>L37088</u>)
	NOTE: According to the above LCD, all uses other than those described as medically necessary within the LCD are considered to be "experimental." Services which lack scientific evidence regarding safety and efficacy because they are investigational or experimental will be denied as not medically necessary for Medicare Plan members. (Medicare Claims Processing Manual, Ch. 23, §30 A)

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

None

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

Several transcranial magnetic stimulation devices have received FDA clearance, for a variety of indications. Examples of such systems include, but may not be limited to, the following:¹

Major Depressive Disorder

- Brainsway H-Coil Deep TMS System
- Neurostar TMS Therapy
- Horizon 3.0 TMS Therapy
- MagVita TMS Therapy System w/Theta Burst Stimulation
- Nextstim Navigated Brain Therapy (NBT) System 2
- Rapid2 Therapy System
- Neurosoft TMS

Obsessive Compulsive Disorder

• Brainsway Deep Transcranial Magnetic Stimulation System

Migraine with Aura

- Cerena Transcranial Magnetic Stimulator (TMS) Device
- SpringTMS®

Accelerated TMS System for Refractory Depression

 Stanford Neuromodulation Therapy (SNT; formerly Stanford Accelerated Intelligent Neuromodulation Therapy, or SAINT Neuromodulation System). May also be seen as the Magnus Neuromodulation System used with SAINT Technology.

For any TMS system not otherwise listed in this policy, please refer to the FDA's 510(k) Premarket Notification website using product code "OBP."

BILLING GUIDELINES AND CODING

GENERAL

See the associated local coverage article (LCA) for additional billing and coding guidance:

LCA: Billing and Coding: Transcranial Magnetic Stimulation (TMS) (A57693)

CODES*		
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	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
	90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management
HCPCS	None	

*Coding Notes:

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does not make a procedure medically reasonable or necessary or a covered benefit by Medicare. (Medicare Claims Processing Manual, Chapter 23 Fee Schedule Administration and Coding Requirements, §30 Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is
 submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted code is
 submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior authorization is
 recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy, Reimbursement Policy, Pharmacy</u> <u>Policy and Provider Information website</u> for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling
 edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and
 Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website
 for coding guidelines and applicable code combinations.

REFERENCES

U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification - Product Code OBP. Page Last Updated: 5/20/2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Last Accessed: 5/20/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
12/2022	Annual review (converted to new format 2/2023)
1/2024	Annual review, no change to criteria; Q1 2024 Code updates
7/2024	Q3 2024 Code updates