

2.01.90 Navigated Transcranial Magnetic Stimulation			
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Section:	2.0 Medicine	Page:	Page 1 of 13

Policy Statement

- I. Navigated transcranial magnetic stimulation is considered **investigational** for all purposes, including but not limited to the preoperative evaluation of individuals being considered for brain surgery when localization of eloquent areas of the brain (e.g., controlling verbal or motor function) is an important consideration in surgical planning.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

The following unlisted code may be billed:

- **64999:** Unlisted procedure, nervous system

The use of the following therapeutic repetitive transcranial magnetic stimulation CPT codes has also been reported:

- **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

Description

Navigated transcranial magnetic stimulation (nTMS) is a noninvasive imaging method for evaluating eloquent brain areas (e.g., those controlling motor or language function). Navigated TMS is being evaluated as an alternative to other noninvasive cortical mapping techniques for presurgical identification of eloquent areas.

Related Policies

- Functional Magnetic Resonance Imaging of the Brain
- Intraoperative Neurophysiologic Monitoring
- Magnetoencephalography/Magnetic Source Imaging

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these

instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2009, the eXimia Navigated Brain Stimulation System (Nexstim) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for noninvasive mapping of the primary motor cortex of the brain to its cortical gyrus for preprocedural planning.

Similarly, in May 2012, the Nexstim Navigated Brain Stimulation System 4 and Navigated Brain Stimulation System 4 with NexSpeech® were cleared for marketing by the FDA through the 510(k) process for noninvasive mapping of the primary motor cortex and for localization of cortical areas that do not contain speech function for preprocedural planning.

Rationale

Background

Management of Brain Tumors

Surgical management of brain tumors involves resecting the brain tumor and preserving essential brain function. "Mapping" of brain functions, such as body movement and language, is most accurately achieved with direct cortical stimulation (DCS), an intraoperative procedure that lengthens operating times and requires a wide surgical opening. Even if not completely accurate compared with DCS, preoperative techniques that map brain functions may aid in planning the extent of resection and the surgical approach. Although DCS is still usually performed to confirm the brain locations associated with specific functions, preoperative mapping techniques may provide useful information that improves patient outcomes.

Noninvasive Mapping Techniques

The most commonly used tool for the noninvasive localization of brain functions is functional magnetic resonance imaging (fMRI). Functional MRI identifies regions of the brain where there are changes in localized cortical blood oxygenation, which correlate with the neuronal activity associated with a specific motor or speech task being performed as the image is obtained. The accuracy and precision of fMRI depend on the patient's ability to perform the isolated motor task, such as moving the single assigned muscle without moving others. This may be difficult in patients in whom brain tumors have caused partial or complete paresis. The reliability of fMRI in mapping language areas has been questioned. Guissani et al (2010) reviewed several studies comparing fMRI with DCS of language areas and found large variability in the sensitivity and specificity rates of fMRI.¹ Reviewers also pointed out a major conceptual point in how fMRI and DCS "map" language areas: fMRI identifies regional oxygenation changes, which show that a particular region of the brain is involved in the capacity of interest, whereas DCS locates specific areas in which the activity of interest is disrupted. Regions of the brain involved in a certain activity may not necessarily be required for that activity and could theoretically be safely resected.

Magnetoencephalography (MEG) is also used to map brain activity. In this procedure, electromagnetic recorders are attached to the scalp. Unlike electroencephalography, MEG records magnetic fields generated by electric currents in the brain, rather than the electric currents themselves. Magnetic fields tend to be less distorted by the skull and scalp than electric currents, yielding an improved spatial resolution. MEG is conducted in a magnetically shielded room to screen out environmental electric or magnetic noises that could interfere with the MEG recording. (See Blue Shield of California Medical Policy: Magnetoencephalography/Magnetic Source Imaging for additional information on MEG and magnetic resonance imaging.)

Navigated transcranial magnetic stimulation (nTMS) is a noninvasive imaging method for evaluating eloquent brain areas. Transcranial magnetic pulses are delivered to the patient as a navigation system calculates the strength, location, and direction of the stimulating magnetic field. The locations of these pulses are registered to a magnetic resonance image of the patient's brain. Surface electromyography electrodes are attached to various limb muscles of the patient. Moving the magnetic stimulation source to various parts of the brain causes electromyography electrodes to respond, indicating the part of the cortex involved in particular muscle movements. For evaluation of language areas, magnetic stimulation areas that disrupt specific speech tasks are thought to identify parts of the brain involved in speech function. Navigated TMS can be considered a noninvasive alternative to DCS, in which electrodes are directly applied to the surface of the cortex during craniotomy. Navigated TMS is being evaluated as an alternative to other noninvasive cortical mapping techniques (e.g., fMRI, MEG) for presurgical identification of cortical areas involved in motor and language functions. Navigated TMS, used for cortical language area mapping, is also being investigated in combination with diffusion tensor imaging tractography for subcortical white matter tract mapping.

Literature Review

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Preoperative Localization of Eloquent Areas of the Brain

Clinical Context and Test Purpose

The purpose of navigated transcranial magnetic stimulation (nTMS) in patients who have brain lesions is to aid in the localization of eloquent areas of the brain to reduce damage to verbal and motor functions during surgery.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who have brain lesions and are undergoing surgery that could harm eloquent areas of the brain (e.g., those controlling motor or language function).

Interventions

The intervention of interest is nTMS, a noninvasive imaging method for evaluating eloquent brain areas.

Comparators

Several tools are used for the noninvasive localization of brain functions. They include functional magnetic resonance imaging (fMRI) and magnetoencephalography (MEG). Whether noninvasive presurgical tools are used, direct cortical stimulation (DCS) is usually performed during surgery to confirm the brain locations associated with specific functions.

Outcomes

The outcomes of interest are a surgical improvement in survival or in functional measures such as speaking and walking or a reduction in morbidity.

Study Selection Criteria

For the evaluation of clinical validity of the nTMS, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard (DCS, fMRI, or MEG)
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

Several studies were excluded from the evaluation of the clinical validity of the nTMS test because they did not use the marketed version of the test, did not use an appropriate reference standard or reference standard was unclear, did not adequately describe the patient characteristics, or did not adequately describe patient selection criteria.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

**Review of Evidence
Language Mapping****Systematic Review**

Jeltema et al (2020) published a systematic review of articles that compared nTMS to intraoperative DCS for mapping of motor or language function.² Among 8 articles which evaluated mapping language function, sensitivity ranged from 10% to 100% and specificity ranged from 13.3% to 98% when nTMS was compared to DCS. The positive predictive value (PPV) ranged from 17% to 75% and the negative predictive value ranged from 57% to 100%.

Observational Studies and Case Series

Most studies of nTMS are case series or cohort studies evaluating patients with brain tumors^{3, 4, 5}, cavernous angiomas,⁶ arteriovenous malformations,⁷, gliomas^{8, 9} or other brain lesions; case series are not ideal studies to ascertain diagnostic characteristics. A number of nTMS studies have also evaluated healthy volunteers but they do not add substantially to the evidence base.^{6, 10, 11, 12, 13, 14} Studies comparing nTMS with DCS, MEG, and/or fMRI and/or using DCS as the reference standard are described next.

Distance Between Navigated Transcranial Magnetic Stimulation and Direct Cortical Stimulation Hotspots

Several studies have evaluated the accuracy of nTMS by measuring the distance between nTMS "hotspots" (the point at which stimulation produced the largest electromyographic response in the target muscles) during preoperative cortical mapping and the gold standard of intraoperative DCS hotspots.

Picht et al (2011) evaluated 17 patients with brain tumors using nTMS and DCS.¹⁵ Both techniques were used to elicit hotspots. Target muscles were selected based on the needs of each patient concerning tumor location and clinical findings. Intraoperative DCS locations were chosen independently of nTMS, and the surgeon was unaware of the nTMS hotspots. For 37 muscles in 17 patients, nTMS and DCS data were both available. Mean distance between nTMS and DCS hotspots was 7.83 mm (standard error, 1.18) for the abductor pollicis brevis muscle (95% confidence interval [CI], 5.31 to 10.36 mm) and 7.07 mm (standard error, 0.88) for the tibialis anterior muscle. When DCS was performed during surgery, there were large variations in the number of stimulation points, and the distance between nTMS and DCS was much smaller when a larger number of points were stimulated. Forster et al (2011) performed a similar study in 11 patients.¹⁶ Functional MRI also was performed in this study. The distance between corresponding nTMS and DCS hotspots was 10.49 mm (standard deviation [SD], 5.67). The distance between the centroid of fMRI activation and DCS hotspots was 15.03 mm (SD=7.59). However, it was unclear whether hotspots elicited by 1 device could be elicited by the other and vice versa. In at least 2 excluded patients, hotspots were elicited by DCS but not by nTMS.

Tarapore et al (2012) evaluated the distance between nTMS and DCS hotspots.¹⁷ Among 24 patients who underwent nTMS, 18 of whom also underwent DCS, 8 motor sites in 5 patients corresponded. The median distance between nTMS and DCS hotspots was 2.13 mm (standard error of the mean, 0.29). In the craniotomy field where DCS mapping was performed, DCS elicited the same motor sites as nTMS. The study also evaluated MEG; the median distance between MEG motor sites and DCS sites was 12.1 mm (standard error of the mean, 8.2).

Mangravati et al (2013) evaluated the distance between nTMS and DCS hotspots in 7 patients.⁴ It is unclear how many hotspots were compared or how many potential comparisons were unavailable due to a failure of either device to find a particular hotspot. It appears that the mean distance between hotspots was based on locations of hotspots for 3 different muscles. The overall mean difference between nTMS and DCS was 8.47 mm, which was less than the mean difference between the fMRI centroid of activation and DCS hotspots (12.9 mm).

Krieg et al (2012) compared nTMS with DCS in 14 patients.¹⁸ Interpreting this study is difficult because the navigation device employed appeared to differ from the U.S. Food and Drug Administration-approved device. Additionally, the comparison of nTMS to DCS used a different methodology. Both nTMS and DCS were used to map the whole volume of the motor cortex, and a mean difference between the borders of the mapped motor cortex was calculated. The mean distance between the 2 methods was 4.4 mm (SD=3.4).

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

The ideal study to determine whether nTMS improves health outcomes in patients being considered for surgical resection of brain tumors would be an RCT comparing nTMS with strategies that do not use nTMS. There are challenges in the design and interpretation of such studies. Given that results of diagnostic workups of brain tumor patients may determine which patients undergo surgery, the counseling given to patients, and the type of surgery performed, it would be difficult to compare outcomes for groups of patients with qualitatively different outcomes. For example, it is difficult to compare the health outcomes of a patient who ends up not having surgery, who conceivably has a

shorter overall lifespan but a short period of very high quality of life, with a patient who undergoes surgery and has some moderate postoperative disability but a much longer lifespan.

Systematic Review

No RCTs were identified. However, controlled observational studies are available. Raffa et al (2019) published a systematic review and meta-analysis of observational studies in patients with motor-eloquent brain tumors who underwent presurgical nTMS motor mapping compared to patients without nTMS.¹⁹ Eight observational studies with 1031 patients were included in the analysis (n=593 with preoperative nTMS mapping and n=438 without nTMS mapping). Included patients had low and high grade gliomas, glioblastoma, brain metastasis, vascular malformations, and cavernous and artero-venous malformations. In pooled analyses, use of nTMS was associated with a lower risk of postoperative new permanent motor deficits (odds ratio [OR], 0.54; 95% CI, 0.37 to 0.79; $p=.001$), a higher probability of achieving the gross total resection rate (removal of 100% of tumor tissue at early postoperative magnetic resonance scan) (OR, 2.32; 95% CI, 1.73 to 3.1; $p<.001$), and reduced craniotomy size (-6.24 cm^2 ; $p<.001$). Length of surgery was non-significantly lower with nTMS (-10.3 minutes; $p=.38$).

Key Studies Included in the Systematic Review

Two studies included in the systematic review by Raffa et al (2019) included survival as an outcome. Krieg et al (2015) prospectively enrolled 70 patients who underwent nTMS and matched them with a historical control group of 70 patients who did not have preoperative nTMS.²⁰ All patients had motor eloquently located supratentorial high-grade gliomas and all underwent craniotomy by the same surgeons. Patients were matched by tumor location, preoperative paresis, and histology; the primary outcome was not specified. Outcome assessment was blinded. Median overall survival (OS) was 15.7 months (SD=10.9) in the nTMS group and 11.9 months (SD=10.3) in the non-nTMS group, which did not differ significantly between groups ($p=.131$). Mean survival at 3, 6, and 9 months was significantly higher in the nTMS group than in the non-nTMS group but did not differ statistically between groups at 12 months.

Frey et al (2014) enrolled 250 consecutive patients who underwent nTMS preoperative mapping and identified 115 historical controls who met the same eligibility criteria.²¹ Criteria included being evaluated for surgery for a tumor in a motor eloquent area and without seizures more than once a week or cranial implants. Fifty-one percent of the nTMS group and 48% of controls had World Health Organization grade II, III, or IV gliomas; the remaining patients had brain metastases from other primary cancers or other lesions. Intraoperative motor cortical stimulation to confirm nTMS findings was performed in 66% of the nTMS group. The Medical Research Council scale and Karnofsky Performance Status were used to assess muscle strength and performance status, respectively. Outcomes were assessed at postoperative day 7 and then at 3 month intervals. Progression-free survival (PFS) and OS were reported for patients with glioma only (128 nTMS patients, 55 controls). At a mean follow-up of 22 months (range, 6 to 62 months) in the nTMS group and 25 months (range, 9 to 57 months) in controls, mean PFS was similar between groups (mean PFS, 15.5 months [range, 3 to 51 months] for nTMS vs. 12.4 months [range, 3 to 38 months] for controls; not significantly different). In the subgroup of patients with low-grade (grade II) glioma (38 nTMS patients, 18 controls), mean PFS was longer in the nTMS group (mean PFS, 22.4 months; range, 11 to 50 months) than in the control group (15.4 months; range, 6 to 42 months; $p<.05$). Overall survival did not differ statistically between treatment groups.

Observational Studies

Three additional observational studies were not included in the systematic review by Raffa et al (2019) because they did not evaluate motor mapping or did not include relevant outcome data. Hendrix et al (2017) reported on 20 consecutive patients with malignant brain tumors and lesions in language-eloquent areas who underwent preoperative nTMS and matched them to patients treated in the pre-nTMS era.²² Patients were matched on tumor location, tumor and edema volume, preoperative language deficits, and histopathology. The primary efficacy outcome was not specified.

Patients underwent clinical language assessments before and after surgery at postoperative day 1 and weeks 1, 6, and 12 post surgery. Language performance status was characterized as no language deficit (grade 0), mild deficit (grade 1), medium deficit (grade 2); and severe deficit (grade 3). The complication rates, gross resection rates, and residual tumor volumes on fMRI did not differ significantly between groups. The group that had presurgical nTMS had shorter surgery durations than patients treated pre-nTMS (mean, 104 minutes and 135 minutes, respectively, $p=.039$) and a shorter inpatient stay (mean, 9.9 days vs. 15 days, $p=.001$). Language deficits did not differ between groups preoperatively, or at postoperative day 1, week 1, or week 12. For example, at week 12, 15 patients in the nTMS group and 14 patients in the pre-TMS group had a grade 0 deficit ($p=.551$). There was a statistically significant difference at week 6 ($p=.048$); the p -value was not adjusted for multiple comparisons (i.e. assessment at multiple time points). Groups might have differed in other ways that affected outcomes and procedures might have changed over time in ways that affected surgical duration, complication rates, and inpatient stays.

A retrospective cohort study by Schiller et al (2020) evaluated pediatric and adult patients with epilepsy or brain tumor who underwent TMS language mapping and functional MRI language mapping as part of a presurgical evaluation.²³ There were 106 patients with complete TMS language maps that were identified; of those patients, 84 also underwent functional MRI language mapping. The overall accuracy of TMS across all language areas when compared to functional MRI was 71% (which was mainly due to its high specificity of 83%), with a diagnostic odds ratio of 1.27; TMS was more accurate in determining the dominant hemisphere for language as well (diagnostic OR, 6). TMS was able to reliably localize cortical areas that are not essential for speech function, however, TMS demonstrated only slight concordance between TMS and functional MRI-derived language areas, which demonstrated low accuracy in localization of specific language cortices.

One nonrandomized study used concurrent controls. Sollmann et al (2015) matched 25 prospectively enrolled patients who underwent preoperative nTMS but whose results were not available to the surgeon during the procedure (group 1) to 25 patients who underwent preoperative nTMS whose results were available to the surgeon (group 2).¹³ All patients had language eloquently located brain lesions within the left hemisphere. Primary outcomes were not specified. Three months postsurgery, 21 patients in group 1 had no or mild language impairment, and 4 patients had moderate-to-severe language deficits. In group 2, 23 patients had no or mild language impairment, and 2 patients had moderate-to-severe deficits. The difference between groups in postoperative language deficits was statistically significant ($p=.015$). Other outcomes, including duration of surgery, postoperative Karnofsky Performance Status scores, the percentage of residual tumor, and peri- and postoperative complication rates did not differ significantly between groups.

Picht et al (2012) assessed whether a change in management occurred as a result of knowledge of nTMS findings.²⁴ In this study, surgeons first made a plan based on all known information without nTMS findings. After being informed of nTMS findings, the surgical plan was reformulated if necessary. Among 73 patients with brain tumors in or near the motor cortex, nTMS was judged to have changed the surgical indication in 2.7%, changed the planned extent of resection in 8.2%, modified the approach in 16.4%, added awareness of high-risk areas in 27.4%, added knowledge not used in 23.3%, and only confirmed the expected anatomy in 21.9%. The first 3 surgical categories, judged to have been altered because of nTMS findings, were summed to determine an "objective benefit" of 27.4%.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Current evidence on clinical validity does not permit construction of a chain of evidence to support the use of nTMS for presurgical mapping of eloquent areas of the brain.

Section Summary: Preoperative Localization of Eloquent Areas of the Brain

The studies assessing the distance between nTMS and DCS hotspots appear to show that stimulation sites eliciting responses from both techniques tended to be mapped within 10 mm of each other. This distance tends to be less than the distance between fMRI centers of activation and DCS hotspots. It is difficult to assess the clinical significance of these data for presurgical planning. The available studies of the diagnostic accuracy of nTMS evaluating language areas have shown a sensitivity range of 10% to 100% and specificity range of 13.3% to 98%. The PPV ranged from 17% to 75% and the negative predictive value ranged from 57% to 100%. Even if nTMS were used to rule out areas in which language areas are unlikely, the sensitivity of 10% to 100% might result in some language areas not appropriately identified.

No RCTs have compared health outcomes in patients who did and did not have presurgical nTMS before brain surgery. There is direct evidence from several nonrandomized comparative studies of patients undergoing nTMS, mainly compared with historical controls. A meta-analysis of observational studies found that use of nTMS improved outcomes, including risk of postoperative new permanent motor deficits, gross total resection rate, and craniotomy size, in patients with motor-eloquent brain tumors who underwent preoperative nTMS mapping compared to those who did not undergo nTMS mapping. Two observational studies reported survival rates. In both, OS did not differ significantly between groups. One of the studies found significantly higher mean survival rates in the nTMS group at 3, 6, and 9 months postsurgery but not at 12 months. Limitations of all studies discussed in this section include the single-center settings (because nTMS is an operator-dependent technology, applicability may be limited), lack of randomization and/or use of historical controls (surgeon technique and practice likely improved over time), selective outcomes reporting (survival outcomes in glioma patients only), and uncertain validity of statistical analyses (primary outcome not identified and no correction for multiple testing). Additionally, studies either matched patients to controls on a few variables or used controls who met similar eligibility criteria. These techniques may not adequately control for differences in patient groups that may affect outcomes.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2013 Input

In response to requests, input was received from 1 physician specialty society (2 reviewers) and 2 academic medical centers while this policy was under review in 2013. Most reviewers considered navigated transcranial magnetic stimulation to be investigational.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04062305	nTMS in Planning Stereotactic Radiosurgery in Patients With Brain Metastases in the Motor Cortex	22	May 2023
NCT02741193^a	Validation of Presurgical Motor Mapping With Transcranial Magnetic Stimulation (TMS) in Patients With Epilepsy	14	Dec 2023
<i>Unpublished</i>			
NCT03974659	Through the Navigation Transcranial Magnetic Stimulation Over the Language Key Areas of Cerebellar to Enhance Language Function Recovery After Brain Tumor Resection	106	Oct 2021
NCT02879682	Randomized Controlled Multicenter Trial on the Impact of Presurgical Navigated Transcranial Magnetic Stimulation for Motor Mapping of Rolandic Lesions	330	Feb 2022

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	64999	Unlisted procedure, nervous system
	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	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
08/01/2016	BCBSA Medical Policy adoption
08/01/2017	Policy revision without position change
01/01/2018	Coding update
08/01/2018	Policy revision without position change
09/01/2019	Policy revision without position change
09/01/2020	Annual review. No change to policy statement. Literature review updated.
08/01/2021	Annual review. No change to policy statement. Literature review updated.
08/01/2022	Annual review. Policy statement and Literature review updated.
08/01/2023	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent

with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<div>Navigated Transcranial Magnetic Stimulation 2.01.90</div> <div>Policy Statement:</div> <div>I. Navigated transcranial magnetic stimulation is considered investigational for all purposes, including but not limited to the preoperative evaluation of individuals being considered for brain surgery when localization of eloquent areas of the brain (e.g., controlling verbal or motor function) is an important consideration in surgical planning.</div>	<div>Navigated Transcranial Magnetic Stimulation 2.01.90</div> <div>Policy Statement:</div> <div>I. Navigated transcranial magnetic stimulation is considered investigational for all purposes, including but not limited to the preoperative evaluation of individuals being considered for brain surgery when localization of eloquent areas of the brain (e.g., controlling verbal or motor function) is an important consideration in surgical planning.</div>