Navigated Transcranial Magnetic Stimulation

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Replaces N/A

Policy

Navigated transcranial magnetic stimulation (nTMS) is considered investigational for all purposes, including but not limited to the preoperative evaluation of patients 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.

Related Policies

None

Policy Guidelines

Coding

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>0310T</td>
<td>Motor function mapping using noninvasive navigated transcranial magnetic stimulation (nTMS) for therapeutic treatment planning, upper and lower extremity</td>
</tr>
</tbody>
</table>

Description

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

For individuals who have brain lesion(s) undergoing preoperative evaluation for localization of eloquent areas of the brain who receive nTMS, the evidence includes controlled observational studies and case series. Relevant outcomes are overall survival, test accuracy, morbid events, and functional outcomes. Several small studies have evaluated the distance between nTMS hotspots and direct cortical stimulation (DCS) hotspots for the same
muscle. Although the average distance in most studies is 1 cm or less, this does not take into account the degree of error in this average distance, or whether hotspots are missed. It is difficult to fully verify nTMS hotspots because only exposed cortical areas can be verified with DCS. Limited studies of nTMS evaluating language areas have shown high false-positive rates (low specificity) and sensitivity that may be insufficient for clinical use. Several controlled observational studies have compared outcomes in patients undergoing nTMS and other mapping techniques. Most outcomes were similar between groups, such as postsurgical motor impairment, paresis, and surgical complication rates. Overall survival did not differ significantly between groups. Another study found significantly higher mean survival rates in the nTMS group at 3, 6, and 9 (but not 12) months postsurgery. The controlled observational studies had various methodologic limitations and, being nonrandomized, may not have adequately controlled for differences in patient groups, which may have biased outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Background
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 considered to be most accurately achieved with DCS, an intraoperative procedure that increases operating time 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 operative 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.

The most commonly used tool for the noninvasive localization of brain functions is functional magnetic resonance imaging (fMRI). fMRI identifies regions of the brain where there are changes in localized cortical blood oxygenation, which correlates with neuronal activity associated with a specific motor or speech task being performed as the image is obtained. The accuracy and precision of fMRI is dependent 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 and DCS of language areas and found large variability in sensitivity and specificity of fMRI. (1) The discussion 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) also is used to map brain activity. In this procedure, electromagnetic recorders are attached to the scalp. In contrast to 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 improved spatial resolution. MEG is conducted in a magnetically-shielded room to screen out environmental electric or magnetic noise that could interfere with the MEG recording. See MPRM policy 6.01.21 for additional information about magnetoencephalography and magnetic source imaging.

nTMS is a noninvasive imaging method for the evaluation of 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 imaging (MRI) image of the patient’s brain. Surface electromyography (EMG) electrodes are attached to various limb muscles of the patient. Moving the magnetic stimulation source to various parts of the brain causes EMG 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. nTMS can be considered a noninvasive alternative to DCS, in which electrodes are directly applied to the surface of the cortex during craniotomy. nTMS is being evaluated as an alternative to other noninvasive cortical mapping techniques, such as fMRI and MEG, for presurgical identification of cortical areas involved in motor and language functions.

Regulatory Status
In 2009, the eXimia Navigated Brain Stimulation (NBS) System (Nexstim, Helsinki, Finland) 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 NBS System 4 and NBS System 4 with NexSpeech® were cleared for marketing by 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 the purposes of preprocedural planning.

Scope

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Benefit Application

N/A

Rationale

<table>
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<tr>
<th>Populations</th>
<th>Interventions of interest are:</th>
<th>Comparators of interest are:</th>
<th>Relevant outcomes include:</th>
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<tr>
<td>Individuals:</td>
<td>Navigated transcranial magnetic stimulation</td>
<td>Direct cortical stimulation, Magnetoencephalography, Functional magnetic resonance imaging</td>
<td>Overall survival, Test accuracy, Morbid events, Functional outcomes</td>
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This policy was initially created in December 2013 using references identified in the MEDLINE database through April 25, 2016. Following is the review of key literature.

Diagnostic Accuracy of Navigated Transcranial Magnetic Stimulation for Brain Lesions

Most studies of navigated transcranial magnetic stimulation (nTMS) are small case series of patients with brain tumors, cavernous angiomas, arteriovenous malformations, or other brain lesions; these are not ideal studies to ascertain diagnostic characteristics. Because nTMS and/or other methods are used to identify motor or language centers in the cortex to plan surgical approach, the reference standard of direct cortical stimulation (DCS) may be biased; that is, the DCS procedure may be limited or altered because of the tumor resection or other surgical factors. It is not possible to verify all nTMS sites identified, because the surgical field is limited. Because of this limited verification, it is difficult to ascertain diagnostic characteristics of nTMS. There are also a number of small nTMS studies evaluating healthy volunteers, but the studies do not add substantially to the evidence base. (7-11) Studies comparing nTMS and DCS findings are described next.

Distance Between nTMS and DCS Hotspots

Picht et al (2011) evaluated 17 patients with brain tumors using both nTMS and DCS. (12) Both techniques were used to elicit “hotspots,” the point at which either nTMS or DCS produced the largest electromyographic response in the target muscles. Target muscles were selected based on the needs of each particular patient with regard to 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 (SE) distance between nTMS and DCS hotspots was 7.83 (1.18) mm for the abductor pollicis brevis muscle (95% confidence interval [CI], 5.31 to 10.36) and 7.07 (0.88) mm for the tibialis anterior muscle. When DCS was performed during surgery, there was large variation in the number of stimulation points, and the
distance between nTMS and DCS was much less when a larger number of points were stimulated.

Forster et al (2011) performed a similar study in 11 patients. Functional magnetic resonance imaging (fMRI) also was performed in this study. The distance (SD) between corresponding nTMS and DCS hotspots was 10.49 (5.67) mm. The distance between the centroid of fMRI activation and DCS hotspots was 15.03 (7.59) mm. 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.

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

Mangravati et al (2013) evaluated the distance between nTMS and DCS hotspots in 7 patients. It is unclear how many hotspots were compared or how many potential comparisons were unavailable due to failure of either device to find a particular hotspot. It appeared 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. Interpreting this study is difficult because the navigation device employed appeared to differ from the 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 out the whole volume of the motor cortex, and a mean difference between the borders of the mapped motor cortex was calculated. Mean (SD) distance between the 2 methods was 4.4 (3.4) mm.

Section Summary
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 1 cm 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 in terms of the utility of the information for presurgical planning.

nTMS for Language Mapping
A 2013 study by Picht et al evaluated the accuracy of nTMS for identifying language areas. Twenty patients underwent evaluation of language areas over the whole left hemisphere, which was divided into 37 regions. DCS was performed only in areas accessible in the craniotomy site. Data for both methods were available in 160 regions for the 20 patients. Using DCS as the reference standard, there were 46 true-positive, 83 false-positive, 26 true-negative, and 5 false-negative findings. Considering the analysis as 160 independent data points for each brain region, nTMS had a sensitivity of 90%, specificity of 24%, positive predictive value (PPV) of 36%, and negative predictive value (NPV) of 84%. An analysis of regions considered to be in the classic Broca area (involved in speech production) showed a sensitivity of 100%, specificity of 13%, PPV of 57%, and NPV of 100%. This study, which found a high rate of false positives, raises concerns about the utility of nTMS for identifying language areas. Even if nTMS were used to rule out areas in which language areas are unlikely, sensitivity of 90% may result in some language areas not appropriately identified.

A 2013 study by Tarapore et al also evaluated nTMS for identifying language areas (N=12). MEG was also evaluated. A total of 183 regions were evaluated with both nTMS and DCS. In these 183 regions, using DCS as the reference standard, there were 9 true positives, 4 false positives, 169 true negatives, and 1 false negative, translating to a sensitivity of 90%, specificity of 98%, PPV of 69%, and NPV of 99%.

A research group in Germany published 2 studies of nTMS for mapping cortical language sites, 1 in healthy volunteers and 1 in patients with brain tumors. In a case series of 10 healthy volunteers, nTMS test-retest reliability varied across error type (eg, neologism, semantic error) and cortical region (ie, anterior, posterior), but, overall, both intra- and interobserver reliability were low (range of concordance correlation coefficients: intraobserver, -0.222 to 0.505; interobserver, -0.135 to 0.588). In a case report of 3 patients with language-eloquent brain tumors who underwent nTMS and DCS for both initial surgery and repeat surgery for recurrence, nTMS performance characteristics varied by definition of a positive nTMS finding (ie, a language error made in
response to stimulation).(19) For positivity defined by error rates (percentage of stimulations that produced errors) ranging from 5% to 25%, sensitivity was 90% to 10%, specificity was 28% to 89%, PPV was 21% to 17%, and NPV was 93% to 82%. Plasticity of language areas in both healthy volunteers and patients with brain lesions was identified as a source of variation in nTMS studies across time. As noted in 1 review, the language network appeared to spread over both hemispheres, increasing the complexity of presurgical language mapping.(20)

Safety of nTMS

In 2016, Tarapore et al evaluated the safety of nTMS in a large multicenter series of 733 patients.(21) Patients had tumors in eloquent or preeloquent regions of the brain and underwent nTMS as part of presurgical planning. nTMS frequencies of 5, 7, and/or 10 Hz were used. A total of 537 patients underwent single-pulse motor mapping, 38 had repetitive-pulse language mapping, and 158 had both of these. nTMS was successfully completed in all patients. No seizures (focal, complex, generalized) were reported and no patients reported hearing changes, cognitive or neuropsychological changes, or other transient adverse effects. Headache, reported by 28 (6%) patients, was the most commonly reported adverse events. A total of 72 (15.7) patients completed questionnaires after the procedure and 73 (11.9) reported discomfort during the procedure. Using a visual analog scale (VAS) from 1 to 10, 33 (25%) of 131 patients reported VAS scores of between 1 and 3 and the remaining 98 (75%) reported VAS scores greater than 3.

Clinical Utility

The ideal study would be a randomized controlled trial (RCT) comparing health outcomes after nTMS versus other strategies without nTMS in patients being considered for surgical resection of brain tumors. 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 of groups of patients with qualitatively different outcomes. For example, it is difficult to compare the health outcome 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.

A second study by this research group, with some overlap in enrolled patients, was published by Krieg et al in 2015.(23) It prospectively enrolled 70 patients who underwent nTMS and matched them with a historical control group of 70 patients who did not undergo presurgical nTMS. All patients had motor eloquently located supratentorial high-grade gliomas (HGG) and all underwent craniotomy by the same surgeons. As in the 2014 Krieg study, patients were matched by tumor location, preoperative paresis, and histology; the primary outcome was not specified. Outcome assessment was blinded. Craniotomy size (SD) was 25.3 cm² (9.7 cm²) in the nTMS group and 30.8 cm² (13.2 cm²) in the non-nTMS group; the size difference was statistically significant (p=0.006). There were no statistically significant differences between groups in rates of surgery-related paresis, rates of surgery-related complications on MRI, or degrees of motor impairment during follow-up. Median overall survival (SD) was 15.7 (10.9) months in the nTMS group and 11.9 (10.3) months in the non-nTMS group, which did not differ significantly between groups (p=0.131). 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 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.(24) 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 to IV gliomas; 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. British Medical Research Council and Karnofsky Performance Status scales were used to assess muscle strength and performance status, respectively. Outcomes were assessed at postoperative day 7 and then at 3-month intervals. At 3-month follow-up, 6.1% of the nTMS group and 8.5% of controls had new postoperative motor deficits (p=NS); changes in performance status postoperatively also were similar between groups. Other outcomes were reported for patients with glioma only (128 nTMS patients, 55 controls). Based on postoperative MRI, gross total resection was achieved in 59% of nTMS patients and in 42% of controls (p<0.05). At mean follow-up of 22 months (range, 6-62 months) in the nTMS group and 25 months (range, 9-57 months) in controls, mean progression-free survival (PFS) was similar between groups (mean PFS, 15.5 months [range, 3-51 months] nTMS vs 12.4 months [range, 3-38 months] controls; statistical test for survival outcomes not specified, p=NS). 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, 11-50 months] nTMS vs 15.4 months [range, 6-42 months] controls; p<0.05), and new postoperative motor deficits were similar (7.5% vs 9.5%, respectively; p=NS). Overall survival did not differ statistically between treatment groups.

One study used concurrent controls, but did not randomize patients to treatment group. Sollman et al (2015) matched 25 prospectively enrolled patients who underwent preoperative nTMS but whose results were not available to the surgeon during the operation (group 1) to 25 patients who underwent preoperative nTMS and results were available to the surgeon (group 2).(25) 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=0.015). Other outcomes, including duration of surgery, postoperative Karnofsky Performance Status scores, percent residual tumor, and peri- and postoperative complication rates did not differ significantly between groups.

One study identified assessed whether a change in management occurred as a result of knowledge of nTMS findings.(26) In this 2012 study, by Picht et al, 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 “objective benefit” of 27.4%.

Section Summary
Limitations of all studies discussed in this section include the single-center setting (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 outcome reporting (survival outcomes in glioma patients only), and uncertain validity of statistical analyses (primary outcome not identified and no correction for multiple testing). In addition, 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.

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

<table>
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<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>NCT02089464a</td>
<td>Pivotal Phase III, Prospective, Multicenter, Double Blinded, Randomized, Sham Controlled Trial to Determine the Therapeutic Effects of Navigation Guided 1 Hz rTMS Administered to the Contralesional Hemisphere as Adjuvant to Task Oriented</td>
<td>200</td>
<td>Apr 2016 (ongoing)</td>
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</table>
Summary of Evidence
For individuals who have brain lesion(s) undergoing preoperative evaluation for localization of eloquent areas of the brain who receive navigated transcranial magnetic stimulation (nTMS), the evidence includes controlled observational studies and case series. Relevant outcomes are overall survival, test accuracy, morbid events, and functional outcomes. Several small studies have evaluated the distance between nTMS hotspots and direct cortical stimulation (DCS) hotspots for the same muscle. Although the average distance in most studies is 1 cm or less, this does not take into account the degree of error in this average distance, or whether hotspots are missed. It is difficult to fully verify nTMS hotspots because only exposed cortical areas can be verified with DCS. Limited studies of nTMS evaluating language areas have shown high false-positive rates (low specificity) and sensitivity that may be insufficient for clinical use. Several controlled observational studies have compared outcomes in patients undergoing nTMS and other mapping techniques. Most outcomes were similar between groups, such as postsurgical motor impairment, paresis, and surgical complication rates. Overall survival did not differ significantly between groups. Another study found significantly higher mean survival rates in the nTMS group at 3, 6, and 9 (but not 12) months postsurgery. The controlled observational studies had various methodologic limitations and, being nonrandomized, may not have adequately controlled for differences in patient groups, which may have biased outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input Received 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 nTMS to be investigational.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force has not addressed navigated transcranial magnetic stimulation for any indication.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References


Appendix

N/A

History

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<td>02/10/14</td>
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<td>10/22/14</td>
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<td>01/05/15</td>
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<tr>
<td>02/25/15</td>
<td>Annual Review. Policy updated with literature review through November 20, 2014; references 4, 6-11, and 18-23 added; policy title changed (acronym deleted); policy statement unchanged.</td>
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