DRAFT Medical Coverage Policy | Navigated Transcranial Magnetic Stimulation

EFFECTIVE DATE: 00|00|2000
POLICY LAST UPDATED: 02|04|2020

OVERVIEW

Navigated transcranial magnetic stimulation (nTMS) is a noninvasive imaging method for evaluating eloquent brain areas (eg, 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.

For Transcranial Magnetic Stimulation for Behavioral Health disorders, see the related policy section.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Navigated transcranial magnetic stimulation 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 (eg, controlling verbal or motor function) is an important consideration in surgical planning.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

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. 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 evidence review 6.01.21 for additional information on MEG and magnetic resonance imaging.)

Navigated transcranial magnetic stimulation

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 (eg, 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.

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. The 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 hotspots for the same muscle. Although the average distance in most studies is 10 mm or less, this does not take into account the error margin in this average distance or whether hotspots are missed. It is difficult to verify nTMS hotspots fully because only exposed cortical areas can be verified with direct cortical stimulation. 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 with those (generally pre-TMS historical controls) who did not undergo nTMS. Findings of the studies were mixed; outcomes were not consistently better in patients who underwent presurgical nTMS. For example, overall survival did not differ significantly between groups in two studies and one reporting postoperative language deficits found significantly fewer deficits in the group that had presurgical nTMS. The controlled observational studies had various methodologic limitations and, being nonrandomized, might not have adequately controlled for differences in patient groups, which could have biased outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Regulatory Status

In 2009, the eXimia Navigated Brain Stimulation System (Nexstim) was cleared for marketing by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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.

CODING

There is not a specific code for this service. Claims must be filed with the following unlisted code
64999 Unlisted procedure, nervous system

RELATED POLICIES

Unlisted Procedures
Transcranial Magnetic Stimulation

PUBLISHED

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