

Corporate Medical Policy

Navigated Transcranial Magnetic Stimulation (nTMS)

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Description of Procedure or Service

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 direct cortical stimulation (DCS), an intraoperative procedure that increases operating time and requires a wide surgical opening. Even if not completely accurate compared to 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 reviewed several studies comparing fMRI and DCS of language areas and found large variability in sensitivity and specificity of fMRI. The discussion also points 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. 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.

Navigated transcranial magnetic stimulation (nTMS) is a noninvasive imaging method for the evaluation of eloquent brain areas (e.g., controlling motor or language function). 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 (EMG) electrodes are attached to various limb muscles of the patient. Moving the magnetic

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stimulation source to various parts of the brain causes the 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. 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.

Regulatory Status

The Nexstim® (Helsinki, Finland) eXimia Navigated Brain Stimulation (NBS) System received U.S. Food and Drug Administration (FDA) 510(k) marketing clearance in 2009 for non-invasive mapping of the primary motor cortex of the brain to its cortical gyrus for preprocedural planning.

Similarly, the Nexstim® NBS System 4 and NBS System 4 with NexSpeech® received 510(k) clearance in May 2012 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.

Related Policies

Intraoperative Neurophysiologic Monitoring

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Navigated transcranial magnetic stimulation is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Navigated Transcranial Magnetic Stimulation is covered

Not Applicable.

When Navigated Transcranial Magnetic Stimulation is not covered

Navigated transcranial magnetic stimulation is considered investigational for all indications, including but not limited to the preoperative evaluation of patients under consideration 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.

Policy Guidelines

For individuals who have brain lesion(s) undergoing preoperative evaluation for localization of eloquent areas of the brain who receive nTMS, the evidence includes systematic reviews, 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

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muscle. Although the average distance in most studies is 10 mm 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 with those (generally pre-TMS historical controls) who did not undergo nTMS. Findings of the studies were mixed. A meta-analysis of observational studies found improved outcomes with preoperative nTMS mapping in patients with motor-eloquent brain tumors. However, in individual observational studies, outcomes were not consistently better in patients who underwent presurgical nTMS. For example, overall survival did not differ significantly between groups in two studies. 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 that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: There is no specific code for this procedure. Code 64999 may be used.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.90, 12/12/2013

Specialty Matched Consultant Advisory Panel – 10/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.90, 12/11/2014

Specialty Matched Consultant Advisory Panel – 10/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.90, 6/16/2016

Specialty Matched Consultant Advisory Panel – 10/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.90, 6/8/2017

Specialty Matched Consultant Advisory Panel – 10/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.90, 6/14/2018

Specialty Matched Consultant Advisory Panel – 10/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.90, 6/13/2019

Specialty Matched Consultant Advisory Panel – 10/2019

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.90, 7/16/2020

Specialty Matched Consultant Advisory Panel – 10/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.90, 6/10/2021

Specialty Matched Consultant Advisory Panel – 10/2021

Policy Implementation/Update Information

- 2/11/14 New policy. “Navigated transcranial magnetic stimulation is considered investigational for all indications, including but not limited to the preoperative evaluation of patients under consideration for brain surgery, when localization of eloquent areas of the brain (eg, controlling verbal or motor function) is needed for surgical planning.” Senior Medical Director review 1/29/14. (btw)
- 12/9/14 Specialty Matched Consultant Advisory Panel review 10/28/2014. No change to Policy statement. (sk)
- 3/10/15 Reference added. Background section updated. Policy Guidelines updated. No change to Policy statement. (sk)
- 11/24/15 Specialty Matched Consultant Advisory Panel review 10/29/2015. (sk)
- 7/26/16 Reference added. Policy Guidelines updated. (sk)
- 11/22/16 Specialty Matched Consultant Advisory Panel review 10/26/2016. (sk)
- 7/28/17 Reference added. (sk)
- 11/10/17 Specialty Matched Consultant Advisory Panel review 10/25/2017. (sk)
- 11/9/18 Reference added. Specialty Matched Consultant Advisory Panel review 10/24/2018. (sk)
- 8/27/19 Reference added. (sk)
- 11/26/19 Specialty Matched Consultant Advisory Panel review 10/16/2019. (sk)
- 11/10/20 Reference added. Specialty Matched Consultant Advisory Panel review 10/21/2020. (sk)
- 8/10/21 Reference added. Policy Guidelines updated. (sk)
- 3/31/22 Specialty Matched Consultant Advisory Panel review 10/20/2021. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.