Navigated Transcranial Magnetic Stimulation

**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.

Navigated transcranial magnetic stimulation (TMS) 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.

**OBJECTIVE**

The objective of this evidence review is to determine whether presurgical navigated transcranial magnetic stimulation improves the net health outcome in patients who have brain lesions and are about to undergo surgery that could harm eloquent areas of the brain.

**POLICY STATEMENT**

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 (e.g., controlling verbal or motor function) is an important consideration in surgical planning.
FEP 2.01.90 Navigated Transcranial Magnetic Stimulation

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA 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.

**RATIONALE**

**Summary of Evidence**

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, morbidity 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 2 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.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

No guidelines or statements were identified.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**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**


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.


FEP 2.01.90 Navigated Transcranial Magnetic Stimulation


POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2014</td>
<td>New Policy</td>
<td></td>
</tr>
<tr>
<td>March 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review through November 20, 2014; references 4, 6-11 and 18-23 were added. Policy title changed, acronym was deleted. Magnetoencephalography was added to the background information. There was no change to the policy statement.</td>
</tr>
<tr>
<td>December 2016</td>
<td></td>
<td>Policy updated with literature review; references 10-11, 21, 23, and 25 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>September 2018</td>
<td></td>
<td>Policy updated with literature review through April 9, 2018; no references added. Policy statement unchanged except “not medically necessary” corrected to “investigational” due to FDA 510(k) clearance.</td>
</tr>
</tbody>
</table>

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.