FEP Medical Policy Manual

FEP 2.01.90 Navigated Transcranial Magnetic Stimulation

Effective Policy Date: October 1, 2022

Original Policy Date: March 2014

Related Policies:

7.01.58 - Intraoperative Neurophysiologic Monitoring

Navigated Transcranial Magnetic Stimulation

Description

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether presurgical navigated transcranial magnetic stimulation improves the net health outcome in individuals 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 **investigationa**l 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 (eg, controlling verbal or motor function) is an important consideration in surgical planning.

POLICY GUIDELINES

None

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 (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

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 systematic reviews, controlled observational studies, and case series. Relevant outcomes are overall survival (OS), 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 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 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, OS did not differ significantly between groups in 2 studies. 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2014	New policy	Navigated transcranial magnetic stimulation is considered investigational for all purposes.
March 2015	Replace policy	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
December 2016	Replace policy	Policy updated with literature review; references 10-11, 21, 23, and 25 added. Policy statement unchanged.
September 2018	Replace policy	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.
September 2019	Replace policy	Policy updated with literature review through May 17, 2019, no references added. Policy statement unchanged.
September 2020	Replace policy	Policy updated with literature review through May 27, 2020; no references added. Policy statement unchanged.
September 2021	Replace policy	Policy updated with literature review through April 15, 2021; references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated with literature review through April 25, 2022; no references added. Policy statement terminology changed from "patients" to "individuals"; intent unchanged.