



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:

Navigated Transcranial Magnetic Stimulation (nTMS)

Policy #: 556

Latest Review Date: July 2023

Category: Medicine

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **navigated transcranial magnetic stimulation** as a **non-covered benefit** and **investigational** for all indications, including but not limited to the preoperative evaluation of individuals being considered for brain surgery.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

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 considered to be most accurately achieved with DCS, an intraoperative procedure that increases operating time and requires a wide surgical opening. Even if they are 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.

Noninvasive Mapping Techniques

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 the 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 for 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. The discussion also points out a major conceptual point in how fMRI and DCS “map” language areas. fMRI findings reflect 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.

Navigated transcranial magnetic stimulation (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 pre-surgical 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.

KEY POINTS:

The most recent literature review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 2, 2023.

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, observational studies and case series. Relevant outcomes are overall survival (OS), test accuracy, morbid events, and functional outcomes. Several 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 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. 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 pre-surgical 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, 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.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Navigated transcranial magnetic stimulation, nTMS, Nexstim® Nexstim NBS System 4, NexSpeech® Navigated Brain Stimulation System (NBS), NexStim NBS 5 Motor Mapping System, NBS 5 Speech Mapping System

APPROVED BY GOVERNING BODIES:

The Nexstim Navigated Brain Stimulation System (NBS) 5 Motor Mapping System and NBS 5 Speech Mapping System with NexSpeech® were cleared for marketing by the FDA through the 510(k) process for noninvasive mapping of the primary motor cortex of the brain to its cortical gyrus and for localization of cortical areas that do not contain speech function for pre-procedural planning.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

As of 01/01/2018, there is no specific CPT code for this procedure. Use the following CPT code:

64999	Unlisted procedure, nervous system
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POLICY HISTORY:

Adopted for Blue Advantage, April 2014

Available for comment April 1 through May 15, 2014

Medical Policy Group, February 2015

Medical Policy Group, July 2016

Medical Policy Group, June 2017

Medical Policy Group, December 2017

Medical Policy Group, June 2018

Medical Policy Group, December 2018

Medical Policy Group, July 2019

Medical Policy Group, July 2020

Medical Policy Group, July 2021

Medical Policy Group, June 2022

Medical Policy Group, July 2023

Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.