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| Medical Benefit | | Effective Date: 04/01/12 | Next Review Date: 11/19 |
| Preauthorization | No | Review Dates: 04/07, 05/08, 03/09, 01/10, 01/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16, 11/17, 11/18 | |

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

| Populations | Interventions | Comparators | Outcomes |
|---|---|---|---|
| Individuals: <ul style="list-style-type: none"> • With drug-resistant epilepsy and being evaluated for possible resective surgery | Interventions of interest are: <ul style="list-style-type: none"> • Magnetoencephalography/magnetic source imaging | Comparators of interest are: <ul style="list-style-type: none"> • Standard evaluation for seizure focus localization | Relevant outcomes include: <ul style="list-style-type: none"> • Test accuracy • Functional outcomes |
| Individuals: <ul style="list-style-type: none"> • With planned brain resection who require localization of eloquent function areas | Interventions of interest are: <ul style="list-style-type: none"> • Magnetoencephalography/magnetic source imaging | Comparators of interest are: <ul style="list-style-type: none"> • Wada test • Other standard evaluation | Relevant outcomes include: <ul style="list-style-type: none"> • Test accuracy • Functional outcomes |

DESCRIPTION

Magnetoencephalography (MEG) is a noninvasive functional imaging technique that records weak magnetic forces. When this information is superimposed on an anatomic image of the brain, typically a magnetic resonance imaging scan, the image is referred to as magnetic source imaging (MSI). MSI has been used to localize epileptic foci and to identify “eloquent” areas of the brain for neurosurgical planning.

SUMMARY OF EVIDENCE

For individuals who have drug-resistant epilepsy and are being evaluated for possible resective surgery who receive MEG/MSI, the evidence for MEG/MSI as an adjunct to standard clinical workup includes various types of case series. Relevant outcomes are test accuracy and functional outcomes. Published evidence on MEG is suboptimal, with no clinical trials demonstrating clinical utility. The literature on diagnostic accuracy has methodologic limitations, primarily selection and ascertainment bias. Studies of functional outcomes do not fully account for the effects of MEG, because subjects who received MEG were not fully accounted for in the studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a planned brain resection who require localization of eloquent function areas who receive MEG/MSI, the evidence includes comparative studies. Relevant outcomes include test accuracy and functional outcomes. Available studies have reported that this test has high concordance with the Wada test,

which is currently the main alternative to localize eloquent functions. While management is changed in some patients based on MEG testing, it has not been demonstrated that these changes lead to improved outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Magnetoencephalography/magnetic source imaging as part of the preoperative evaluation of patients with drug-resistant epilepsy may be considered **medically necessary** when standard techniques, such as magnetic resonance imaging and electroencephalogram, do not provide satisfactory localization of epileptic lesion(s) (see Policy Guidelines).

Magnetoencephalography/magnetic source imaging for the purpose of determining the laterality of language function, as a substitute for the Wada test, in patients being prepared for surgery for epilepsy, brain tumors, and other indications requiring brain resection, may be considered **medically necessary**.

Magnetoencephalography/magnetic source imaging is considered **investigational** for all other indications.

BACKGROUND

MAGNETOENCEPHALOGRAPHY

MEG is a noninvasive functional imaging technique that records weak magnetic forces associated with brain electrical activity. Using mathematical modeling, recorded data are then analyzed to provide an estimated location of electrical activity. This information can be superimposed on an anatomic image of the brain, typically a magnetic resonance imaging (MRI) scan, to produce a functional/anatomic image of the brain, referred to as MSI. The primary advantage of MSI is that, while conductivity and thus measurement of electrical activity as recorded by electroencephalogram is altered by the surrounding brain structures, magnetic fields are not. Therefore, MSI permits a high-resolution image.

Detection of weak magnetic fields requires gradiometer detection coils coupled to a superconducting quantum interference device, which requires a specialized room shielded from other magnetic sources. Mathematical modeling programs based on idealized assumptions are then used to translate detected signals into functional images. In its early evolution, clinical applications were limited by the use of only one detection coil requiring lengthy imaging times, which, because of body movement, also were difficult to match with the MRI. However, more recently, the technique has evolved to multiple detection coils in an array that can provide data more efficiently over a wide extracranial region.

Applications

One clinical application is the localization of epileptic foci, particularly for screening of surgical candidates and surgical planning. Alternative techniques include MRI, positron emission tomography, or single-photon emission computed tomography scanning. Anatomic imaging (i.e., MRI) is effective when epilepsy is associated with a mass lesion, such as a tumor, vascular malformation, or hippocampal atrophy. If an anatomic abnormality is not detected, patients may undergo a positron emission tomography scan. In a small subset of patients, extended electrocorticography or stereotactic electroencephalography with implanted electrodes is considered the criterion standard for localizing epileptogenic foci. MEG/MSI have principally been investigated as a supplement to or an alternative to invasive monitoring.

Another clinical application is the localization of the pre- and postcentral gyri as a guide to surgical planning in patients scheduled to undergo neurosurgery for epilepsy, brain neoplasms, arteriovenous malformations, or other brain lesions. These gyri contain the “eloquent” sensorimotor areas of the brain, the preservation of which is considered critical during any type of brain surgery. In normal situations, these areas can be identified ana-

tomically by MRI, but frequently, anatomy is distorted by underlying disease processes. In addition, the location of eloquent functions varies, even among healthy people. Therefore, localization of the eloquent cortex often requires such intraoperative invasive functional techniques as cortical stimulation with the patient under local anesthesia or somatosensory-evoked responses on extended electrocorticography. Although these techniques can be done at the same time as the planned resection, they are cumbersome and can add up to 45 minutes of anesthesia time. Furthermore, these techniques can sometimes be limited by the small surgical field. A preoperative test, which is often used to localize the eloquent hemisphere, is the Wada test. MEG/MSI has been proposed as a substitute for the Wada test.

REGULATORY STATUS

The Food and Drug Administration (FDA) regulates MEG devices as class II devices cleared for marketing through the 510(k) process. The FDA product codes OLX and OXY are used to identify the different components of the devices. OLX-coded devices are source localization software for electroencephalography or MEG; the software correlates the electrical activity of the brain using various neuroimaging modalities. This code does not include electrodes, amplitude-integrated electroencephalograph, automatic event-detection software used as the only or final electroencephalograph analysis step, electroencephalography software with comparative databases (normal or otherwise), or electroencephalography software that outputs an index, diagnosis, or classification.

OLY-coded devices are magnetoencephalographs that acquire, display, store, and archive biomagnetic signals produced by electrically active nerve tissue in the brain to provide information about the location of active nerve tissue responsible for certain brain functions relative to brain anatomy. This includes the magnetoencephalograph recording device (hardware, basic software).

The intended use of these devices is to “non-invasively detect and display biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained clinician, the data enhance the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.”¹ More recent approval summaries add: “MEG is routinely used to identify the locations of visual, auditory, somatosensory, and motor cortex in the brain when used in conjunction with evoked response averaging devices. MEG is also used to noninvasively locate regions of epileptic activity within the brain. The localization information provided by MEG may be used, in conjunction with other diagnostic data, in neurosurgical planning.”²

The MagView Biomagnetometer System (Tristan Technologies) has the unique intended use for patient populations who are neonates and infants and those children with head circumferences of 50 cm or less.³

Table 1 summarizes relevant MEG devices (hardware, software).

Table 1. Magnetoencephalography Devices Cleared by FDA (Product Codes OLX and OLY)

| Device | Manufacturer | Date Cleared | 510(k) No. |
|---|------------------------------------|--------------|------------|
| Neuromagneometer | Biomagnetic Technologies | Feb 1986 | K854466 |
| 700 Series Biomagnetometer | Biomagnetic Technologies | Jun 1990 | K901215 |
| Neuromag-122 | Philips Medical Systems | Oct 1996 | K962764 |
| Magnes 2500 Wh Biomagnetometer | Biomagnetic Technologies | May 1997 | K962317 |
| CTF Systems, Whole-Cortex Meg System | CTF Systems | Nov 1997 | K971329 |
| Magnes II Biomagnetometer | Biomagnetic Technologies | May 1998 | K941553 |
| Image Vue EEG | Sam Technology | Aug 1988 | K980477 |
| Electroencephalograph Software eemagine | eemagine Medical Imaging Solutions | Oct 2000 | K002631 |
| Curry Multimodal Neuroimaging Software | Neurosoft | Feb 2001 | K001781 |
| Neurosoft's Source | Neurosoft | Sep 2001 | K011241 |
| Megvision Model Eq1000c Series | Eagle Technology | Mar 2004 | K040051 |

| Device | Manufacturer | Date Cleared | 510(k) No. |
|---|------------------------------------|--------------|------------|
| Elekta Oy | Elekta Neuromag Oy | Aug 2004 | K041264 |
| MaxInsight | eemagine Medical Imaging Solutions | Jul 2007 | K070358 |
| Elekta Neuromag With Maxfilter | Elekta Neuromag Oy | Oct 2010 | K091393 |
| Geosource | Electrical Geodesics | Dec 2010 | K092844 |
| Babymeg Biomagnetometer System (also called Artemis 123 Biomagnetometer) | Tristan Technologies | Jul 2014 | K133419 |
| MagView Biomagnetometer System | Tristan Technologies | Apr 2016 | K152184 |

EEG: electroencephalogram; FDA: Food and Drug Administration.

In 2000, Biomagnetic Technologies acquired Neuromag and began doing business as 4-D NeuroImaging. The latter company ceased operations in 2009.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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