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.

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<tr>
<td>Individuals: • With planned brain resection who require localization of eloquent function areas</td>
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Description

Magnetoencephalography (MEG) is a noninvasive functional imaging technique in which weak magnetic forces are recorded externally. 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

The evidence for MEG/MSI in patients who have intractable seizures and are being evaluated for possible resective surgery 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. 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 are not fully accounted for in the studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for MEG/MSI in patients who have planned brain resection and require localization of eloquent function areas includes studies correlating MEG with other methods of localization. Relevant outcomes include test accuracy and functional outcomes. Available studies report that this test has high concordance with the Wada test, which is currently the main alternative for localizing eloquent functions. Management is changed in
some patients based on MEG testing, but 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 a part of the preoperative evaluation of patients with intractable epilepsy (seizures refractory to at least two first-line anticonvulsants) may be considered medically necessary when standard techniques, such as MRI and EEG, do not provide satisfactory localization of epileptic lesion(s).

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
MEG is a noninvasive functional imaging technique in which weak magnetic forces associated with brain electrical activity are recorded externally. 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 surrounding brain structures, magnetic fields are not. Therefore, MSI permits a high-resolution image.

The technique is sophisticated. 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.

One clinical application is localization of epileptic foci, particularly for screening of surgical candidates and surgical planning. Alternative techniques include MRI, positron emission tomography (PET), 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 PET scan. In a small subset of patients, extended electrocorticography (ECoG) or stereotactic electroencephalography with implanted electrodes is considered the criterion standard for localizing epileptogenic foci. MEG/MSI has principally been investigated as a supplement to or an alternative to invasive monitoring.

Another clinical application is 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 disorders. 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 anatomically by MRI, but frequently, anatomy is distorted by underlying disease processes. In addition, 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 ECoG. 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**

MEG devices cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process include: the 700 Series Biomagnetometer (Biomagnetic Technologies, San Diego, CA) cleared in 1990 and subsequent devices (K901215, K941553, K962317, K993708); the CTF Whole-Cortex MEG System (CTF Systems, British Columbia, Canada) cleared in 1997 and subsequent devices (K971329, K030737); and the Elekta Oy (Eleka NeuroMag, Helsinki, Finland) cleared in 2004 and subsequent devices (K041264, K050035, K081430, K091393). FDA Product code: OLX.

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.” 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.”

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.


16. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Magnetoencephalography (MEG) and magnetic source imaging (MSI): presurgical localization of epileptic lesions and presurgical function mapping. TEC Assessments 2003; Volume 18, Tab 6.


