BlueCross BlueShield of Alabama

Name of Policy:
Magnetoencephalography/Magnetic Source Imaging

Policy #: 338
Category: Radiology
Latest Review Date: October 2018
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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 (MRI) 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.

Magnetoencephalography

Magnetoencephalography (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 magnetic source imaging or magnetic source imaging (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.

Detection of weak magnetic fields requires gradiometer detection coils coupled to a superconducting quantum interference device (SQUID), which requires a specialized room shielded from other magnetic sources. Mathematical modeling programs based on idealized assumptions are then used to translate the 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, were also 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 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 (SPECT) 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 EEG (SEEG) 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 post-central 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 anatomically by MRI, but frequently the anatomy is distorted by underlying disease processes. In addition, the location of the 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 (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 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.

Policy:

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, meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

Magnetoencephalography/magnetic source imaging as part of the **preoperative evaluation of patients with drug-resistant epilepsy (seizures refractory to medical therapy) meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage **when standard techniques, such as MRI, are inconclusive.**

Magnetoencephalography/magnetic source imaging does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational** for all other indications.

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate 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.

Key Points:

The most recent literature review was performed through July 26, 2018.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Localization of Seizure Foci

Clinical Context and Test Purpose

The purpose of magnetoencephalography (MEG) and magnetic source imaging (MSI) in the mapping of epileptic foci is to facilitate surgical treatment planning for persons with drug-resistant epilepsy.

The question addressed in this evidence review is: Does the use of MEG/MSI enhance localization of epileptic foci in conjunction with other noninvasive testing or replace invasive testing and, thus, result in changes in management and improvement in health outcomes?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is patients with drug-resistant epilepsy being evaluated for resective surgery.

Interventions

The intervention of interest is MEG/MSI used to map epileptic foci.

Comparators

The following practice is currently being used to make decisions about managing drug-resistant epilepsy: standard evaluation for seizure focus localization.

Outcomes

Outcomes of interest are diagnostic accuracy include test accuracy, test validity (e.g., sensitivity, specificity) and clinical utility that includes consideration of avoidance of invasive testing.

Timing

MEG/MSI is used when a patient with drug-resistant epilepsy is being evaluated for interventional surgery.

Setting

MEG/MSI is provided in an interdisciplinary specialty care setting.

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

This section is based on a 2008 TEC Special Report reviewing the evidence regarding MEG for localization of epileptic lesions. MEG has been proposed as a method for localizing seizure foci for patients with normal or equivocal magnetic resonance imaging and negative video-EEG

examinations, so-called "nonlesional" epilepsy. Such patients often undergo MEG, positron emission tomography, or ictal SPECT tests to attempt to localize the seizure focus. They then often undergo invasive intracranial EEG (IC-EEG), a surgical procedure in which electrodes are inserted next to the brain. Definitive proof that MEG is effective would be comparative evidence that when compared with not using MEG, it improved patient outcomes. Such improvement in outcomes would include more patients being rendered seizure-free, use of a less invasive and morbid diagnostic workup, and overall improved patient outcomes. This is a complicated array of outcomes that has not been thoroughly evaluated in a comprehensive manner. Because MEG is used to make decision regarding further diagnostic testing, which may affect the decision to have surgery and the extent of surgery, solely examining surgical outcomes excludes the assessment of outcomes of patients who did not have surgery.

Ideally, a randomized trial comparing the outcomes of patients who receive MEG as part of their diagnostic workup compared to patients who do not receive MEG could determine whether MEG improves patient outcomes. However, almost all of the studies evaluating MEG have been retrospective, where MEG, other tests, and surgery have been selectively applied to patients. Since patients often drop out of the diagnostic process before having intracranial EEG (IC-EEG), and many patients ultimately do not undergo surgery, most studies of associations between diagnostic tests and between diagnostic tests and outcomes are biased by selection and ascertainment biases. For example, studies that evaluate the correlation between MEG and IC-EEG invariably do not account for the fact that MEG information was sometimes used to deselect a patient from undergoing IC-EEG. In addition, IC-EEG findings only imperfectly correlate with surgical outcomes, meaning that it is an imperfect reference standard.

Numerous studies have shown associations between MEG findings and other noninvasive and invasive diagnostic tests, including IC-EEG, and between MEG findings and surgical outcomes. However, such studies do not allow any conclusions regarding whether MEG added incremental information to aid the management of such patients and whether patients' outcomes were improved as a result of the additional diagnostic information.

A representative study of MEG by Knowlton et al (2008) demonstrated many of the problematic issues of evaluating MEG. In this study of 160 patients with nonlesional epilepsy, all had MEG, but only 72 proceeded to IC-EEG. The calculations of diagnostic characteristics of MEG are biased by incomplete ascertainment of the reference standard. However, even examining the diagnostic characteristics of MEG using the 72 patients who underwent IC-EEG, sensitivities and specificities were well below 90%, indicating the likelihood of both false-positive and false-negative studies. Predictive values based on these sensitivities and specificities mean that MEG can neither rule in nor rule out a positive IC-EEG, and that MEG cannot be used as a triage test before IC-EEG to avoid the potential morbidity in a subset of patients.

One study more specifically addressed the concept that MEG may improve the yield of IC-EEG, thus, allowing more patients to ultimately receive surgery. In a 2009 study by Knowlton et al, MEG results modified the placement of electrodes in 18 (23%) of 77 patients who were recommended to have IC-EEG. Seven (39%) of 18 patients had positive intracranial seizure recordings involving the additional electrodes placement because of MEG results. It was

concluded that four patients (5%) were presumed to have had surgery modified as a result of the effect of MEG electrode placement.

Section Summary: Clinical Validity

There are no clinical trials or other high quality studies demonstrating diagnostic accuracy of MEG in determining location of seizure foci. Available evidence on diagnostic accuracy is limited by ascertainment and selection biases because MEG findings were used to select and deselect patients in the diagnostic pathway, thus making it difficult to determine the role of MEG for the purpose of seizure localization.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

Several studies correlated MEG findings with surgical outcomes. Lau et al (2008) performed a meta-analysis of 17 such studies. In this meta-analysis, sensitivity and specificity have unorthodox definitions. Sensitivity was the proportion of patients cured with surgery in whom the MEG-defined epileptic region was resected, and specificity was the proportion of patients not cured with surgery in whom the MEG-defined epileptic region was not resected. The pooled sensitivity was 84%, meaning that among the total number of cured patients, 16% occurred despite the MEG-defined region not being resected. Pooled specificity was 52%, meaning that among 48% of patients not cured; the MEG-localized region was resected. These results are consistent with an association between resection of the MEG-defined region and surgical cure, but that it is an imperfect predictor of surgical success. However, it does not address the question as to whether MEG contributed original information to improve the probability of cure. In a retrospective review of 22 children with medically intractable focal epilepsy (median age at epilepsy surgery, 11 years), Kim et al (2013) used a cutoff of 70% or more for the number of MEG-identified spike dipole sources located within the resection margin to define a positive study. Sensitivity, specificity, and positive and negative predictive values for seizure-free status postoperatively was 67%, 14%, 63%, and 17%, respectively.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Other studies imply a value to MEG, but it is difficult to make firm conclusions regarding its value. In a study (2013) by Schneider et al, 14 patients with various findings on MEG, IC-EEG, and interictal SPECT underwent surgery for nonlesional neocortical focal epilepsy. Concordance of IC-EEG and MEG occurred in five patients, four of whom became seizure-free. This concordance of the two tests was the best predictor of becoming seizure-free. Although this was prognostic for success, whether this would actually change surgical decision making, such as

declining to operate where there is not such concordance, is uncertain. A similar study by Widjaja et al (2013) showed that concordance of MEG findings with the location of surgical resection was correlated with better seizure outcomes. However, the authors acknowledged that MEG was entrenched in clinical practice, and the decision to proceed further in diagnostic and therapeutic endeavors was based on the results of MEG and other tests.

Other case series of surgical patients have suggested a value to MEG. A study by Albert et al (2014) reviewed a series of pediatric patients undergoing surgery for epilepsy who had only undergone noninvasive monitoring prior to surgery. MEG was proposed to have avoided the need for the morbidity associated with invasive monitoring. Of 16 patients, 62.5% were seizure-free following surgery, and 20% experienced improvement. Two cases required additional surgery with invasive monitoring. Although most patients improved, it cannot be determined whether the outcomes were equivalent to the standard practice of pre-resection invasive monitoring. A study by Wang et al (2015) compared fluorine 18 fluorodeoxyglucose positron emission tomography (FDG-PET) and MEG in identifying the epileptogenic zone, using invasive monitoring as the reference standard. FDG-PET identified the zone in eight (50%) of the patients and MEG identified the zone in 12 (75%) of the patients.

Although MEG was more sensitive than FDG-PET in this study, it still missed epileptogenic areas identified by invasive monitoring. Another recent study by Koptelova et al (2013) compared MEG with video EEG monitoring in 22 patients. Of 75 "irritative" zones identified in the 22 patients by either method, a higher proportion was identified by MEG. Note that there is no true reference standard in this type of analysis. However, in analyses of intraoperative EEG, several zones identified only with this method were only identified by MEG, confirming to some extent increased sensitivity over video EEG. These recent studies suggest clinical utility for MEG in evaluation of epilepsy patients, but, due to the aforementioned problems, firm conclusions about the clinical utility of MEG cannot be determined.

In 2009, the American Clinical Magnetoencephalography Society released a position statement that supported routine clinical use of MEG/MSI for presurgical evaluation of patients with medically intractable seizures. In this statement, a 2008 study by Sutherling et al as being a "milestone Class I study." Class I evidence usually refers to randomized comparisons of treatment. However, the study by Sutherling et al (2008) is called by its authors a "prospective, blinded crossover-controlled, single-treatment, observational case series." The study attempted to determine the proportion of patients in whom diagnostic or treatment strategy was changed as a consequence of MEG. They concluded that the test provided non-redundant information in 33% of patients, changed treatment in 9% of surgical patients, and benefited 21% of patients who had surgery. There was no control group in this study. Benefit of MEG was inferred by assumptions of what might have occurred in the absence of the MEG result. Less than half of the 69 patients went on to receive IC-EEG; thus, there appears to be incomplete accounting for outcomes of all patients in the study. A similar study by De Tiege et al (2012) also attempted to determine the number of patients in whom management decisions were altered based on MEG results. They concluded that clinical management was altered in 13% of all patients.

Section Summary: Clinically Useful
Evidence supporting the effect of MEG on patient outcomes is indirect and incomplete. Surgical management may be altered in a minority of patients based on MEG, but the evidence does not support conclusion that outcomes are improved as a result of these management changes. Trials with a control group are needed to determine whether improved outcomes can be attributed to the change in management induced by knowledge of MEG findings.

Localization of Eloquent and Sensorimotor Areas
Clinical Context and Test Purpose
The purpose of MEG/MSI in the localization of eloquent and sensorimotor areas of the brain in persons with cortical brain lesions is to create a precise surgical plan for resective procedures to avoid postoperative speech, sensory and motor dysfunction where possible.

The question addressed in this evidence review is: Does the use of MEG/MSI to map eloquent and sensorimotor brain areas accurately localize these areas and reduce postoperative functional impairment and, thus, result in changes in management and improvement in health outcomes?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is patients with brain lesions being evaluated for resective surgery.

Interventions
The intervention of interest is the use of MEG/MSI to map eloquent and sensorimotor brain areas. MEG/MSI is a noninvasive alternative to the preoperative Wada test (intracarotid sodium amobarbital procedure) used to map eloquent brain areas.

Comparators
The following test and practice are currently being used to make decisions about localization of eloquent function areas: the Wada test and other standard evaluations.

Outcomes
Outcomes of interest are diagnostic accuracy include test accuracy, test validity (e.g., sensitivity, specificity) and clinical utility that includes consideration of avoidance of invasive testing.

Timing
MEG/MSI is used when a patient with a brain lesion in close proximity to eloquent or sensorimotor areas is being evaluated for interventional surgery.

Setting
MEG/MSI is provided in an interdisciplinary specialty care setting.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and

unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

The 2003 TEC Assessment of MEG/MSI concluded that evidence for this particular indication was insufficient to demonstrate efficacy. At that time, studies reviewed had relatively weak designs and small sample sizes. There are two ways to analyze the potential utility of MEG for this indication. MEG could potentially be a noninvasive substitute for the Wada test, which is a standard method of determining hemispheric dominance for language. The Wada test requires catheterization of the internal carotid arteries, which carries the risk of complications. The determination of the laterality of the language function is important to know to determine the suitability of a patient for surgery and what types of additional functional testing might be needed before or during surgery. If MEG provides concordant information with the Wada test, then such information would be obtained in a safe, noninvasive manner.

Several studies have shown high concordance between the Wada test and MEG. In the largest study, by Papanicolaou et al (2004), among 85 patients, there was concordance between the MEG and Wada tests in 74 (87%). In no cases were the tests discordant in a way that the findings were completely opposite. The discordant cases occurred mostly when the Wada test indicated left dominance and the MEG indicated bilateral language function. In an alternative type of analysis, where the test is being used to evaluate the absence or presence of language function in the side in which surgical treatment is being planned, using the Wada procedure as the criterion standard, MEG was 98% sensitive and 83% specific. Thus, if the presence of language function in the surgical site requires intraoperative mapping and/or a tailored surgical approach, use of MEG rather than Wada would have "missed" one case where such an approach would be needed (false-negative MEG), and resulted in five cases where such an approach was unnecessary (false-positive MEG). However, it should be noted that the Wada test is not a perfect reference standard, and some discordance may reflect inaccuracy of the reference standard. In another study by Hirata et al (2004), MEG and the Wada test agreed in 19/20 (95%) of cases.

Section Summary: Clinically Valid

Available evidence comprises studies that correlate results of MEG with the intracarotid amobarbital injection (Wada test), which is an alternative method for localization. Evidence generally shows that concordance between MEG and the Wada test is high. However, the studies have not been replicated and their generalizability is limited.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

One potential use (utility) of MEG would be to map the sensorimotor area of the brain to avoid such areas in the surgical resection area. Intraoperative mapping just before resection is generally done as the reference standard. Preoperative mapping as potentially done by MEG might aid in determining the suitability of the patient for surgery or for assisting in the planning of other invasive testing. Similar to the situation for localization of epilepsy focus, the literature is problematic in terms of evaluating the comprehensive outcomes of patients due to ascertainment and selection biases. Studies tend to be limited to correlations between MEG and intraoperative mapping. The intraoperative mapping would be performed anyway in most resection patients. Several of the studies evaluated in the 2003 TEC Assessment showed good to high concordance between MEG findings and intraoperative mapping. A 2006 technology assessment on functional brain imaging prepared by the Ontario Ministry of Health reviewed ten studies of MEG and invasive functional mapping and showed good to high correspondence between the two tests. However, these studies do not demonstrate that MEG would replace intraoperative mapping or reduce the morbidity of such mapping by allowing a more focused procedure.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Recent studies of the use of MEG in localizing the sensorimotor area provide only indirect evidence of utility. A 2013 study by Niranjan et al reviewed the results of 45 patients in whom MEG was used for localizing somatosensory function. In 32 patients who underwent surgery, surgical access routes were planned to avoid regions identified as somatosensory by MEG. All patients retained somatosensory function. It is unknown to what extent MEG provided unique information not provided by other tests. In a 2012 study by Tarapore et al, 24 patients underwent MEG, transcranial magnetic stimulation, and intraoperative direct cortical stimulation to identify the motor cortex. MEG and navigated transcranial magnetic stimulation were both able to identify several areas of motor function, and the median distance between corresponding motor areas was 4.71mm. When comparing MEG with direct cortical stimulation, the median distance between corresponding motor sites (12.1mm) was greater than the distance between navigated transcranial magnetic stimulation and direct cortical stimulation (2.13mm). This study cannot determine whether MEG provided unique information that contributed to better patient outcomes.

Section Summary: Clinically Useful

There are no clinical trials that demonstrate the utility of using MEG for localization and lateralization of eloquent and sensorimotor regions of the brain. Because MEG is a less invasive alternative to the Wada test, this evidence indicates that it is a reasonable alternative. There is also some evidence that the correlation of MEG with intraoperative mapping of eloquent and sensorimotor regions is high, but the test has not demonstrated sufficient accuracy to replace intraoperative mapping.

Summary of Evidence
For individuals who have drug-resistant epilepsy and are being evaluated for possible resective surgery, 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. 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 brain lesions and a planned brain resection, the evidence for MEG/MSI for localization of eloquent function areas 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 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.

Practice Guidelines and Position Statements
The American Clinical Magnetoencephalography Society (ACMEGS)
The American Clinical Magnetoencephalography Society (ACMEGS) released a position statement that supported routine clinical use of MEG plus magnetic source imaging (MSI) for pre-surgical evaluation of patients with medically intractable seizures.

In 2011, ACMEGS issued a series of clinical practice guidelines on magnetic evoked fields (MEFs) addressing different aspects of this technology (recording and analysis of spontaneous cerebral activity, presurgical functional brain mapping using MEFs, MEG-EEG reporting, and qualifications of MEG-EEG personnel). Method of guideline development was not described.

Guideline 2 on presurgical functional brain mapping indicates that:

> "Magnetoencephalography shares with EEG high temporal resolution, but its chief advantage in pre-surgical functional brain mapping is in its high spatial resolution. Magnetic evoked fields are therefore done for localization; unlike electrical evoked potentials (EPs), MEF latencies and latency asymmetries are not typically used to detect abnormalities."

Proposed indications for MEG include localization of somatosensory, auditory, language, and motor evoked fields.

In 2017, ACMEGS issued another position statement supporting routine use of MEG/MSI for obtaining noninvasive localizing or lateralizing information regarding eloquent cortices (somatosensory, motor, visual, auditory, and language) in the presurgical evaluation of patients with operable lesions preparing for surgery.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Key Words:
Magnetoencephalography, MEG (Magnetoencephalography), Magnetic Source Imaging, MSI (Magnetic Source Imaging), superconducting quantum interference device (SQUID)

Approved by Governing Bodies:
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 electroencephalograph or magnetoencephalography; the software correlates 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, electroencephalograph software with comparative databases (normal or otherwise) or electroencephalography software that outputs an index, diagnosis, or classification.

The 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).

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."

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. MEG devices (hardware, software) are summarized in Table 1.

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
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 January 2000, Biomagnetic Technologies acquired Neuromag, a Finnish MEG company, and began doing business as 4-D Neuro-Imaging. The latter company ceased operations in 2009.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity

Current Coding:

CPT Codes:

95965	Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization)
95966	Magnetoencephalography (MEG), recording and analysis; for evoked magnetic fields, single modality (e.g., sensory, motor, language, or visual cortex localization
95967	Magnetoencephalography (MEG), recording and analysis; for evoked magnetic fields, each additional modality (e.g., sensory, motor, language, or visual cortex localization) (List separately in addition to code for primary procedure)

HCPCS:

S8035	Magnetic Source Imaging

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Policy History:

Medical Policy Group, January 2009 **(4)**
Medical Policy Administration Committee, February 2009
Available for comment February 6-March 23, 2009
Medical Policy Panel, May 2011
Medical Policy Group, May 2011 **(2)**
Medical Policy Administration Committee, June 2011
Available for comment June 8 – July 25, 2011
Medical Policy Group, October 2012 **(2)**: 2012 Updates to Description, Key Points and References
Medical Policy Panel, October 2013
Medical Policy Group, December 2013 **(2):** Policy statement unchanged. Key Points and References updated with literature review through September 2013.
Medical Policy Panel, October 2014
Medical Policy Group, October 2014 **(3):** 2014 Updates to Key Points, Key Words, Governing Bodies & References; removal of policy statements for DOS prior to July 26, 2011; no change in policy statement
Medical Policy Panel, December 2015
Medical Policy Group, January 2016 **(3):** 2016 Updates to Key Points, Approved Governing Bodies and References. No change to policy statement.
Medical Policy Panel, September 2017
Medical Policy Group, October 2017 **(3):** 2017 Updates to Description, Key Points, Approved by Governing Bodies & References; clarification made to Policy statement but no change to policy intent.
Medical Policy Panel, September 2018
Medical Policy Group, October 2018 (**3**): Updates to Key Points, References, and Key Words: added: superconducting quantum interference device. No changes to policy statement or intent.