Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 7/1/25**
(See policy history boxes for previous effective dates)

Title: Magnetoencephalography/Magnetic Source Imaging

Description/Background

Magnetoencephalography (MEG) is a noninvasive functional imaging technique that records weak magnetic forces associated with brain electrical activity. Using mathematical modeling, the 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 (MSI). The primary advantage of MSI is that, while conductivity and thus a measurement of electrical activity as recorded by the electroencephalogram is altered by surrounding brain structures, magnetic fields are not. Therefore, MSI permits a high-resolution image.

Detection of the 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 the detected signals into functional images. In its early evolution, clinical applications were limited by the use of only 1 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 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 (PET) 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 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 post-central gyri as a guide to surgical planning in individuals 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, 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 individual 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 regulates MEG devices as class II devices cleared for marketing through the 510(k) process. The Food and Drug Administration 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 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, 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.”

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.

Table 1 summarizes a sampling of 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
Elekta Oy	Elekta Neuromag Oy	Aug 2004	K041264
Elekta Neuromag with Maxwell Filter	Elekta Neuromag Oy	Jan 2005	K050035
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
PreOp	Epilog	Jan 2018	K172858
Orion Lifespan Meg	Compumedics Limited	Feb 2020	K191785
EZTrack	Neurologic LLC	Dec 2020	K201910
Ricoh Meg	Ricoh Company	July 2021	K210199
Sourcerer	Brain Electrophysiology Laboratory Company, LLC	Sept 2024	K241513
TRUIX™	Megin Oy	May 2024	K233985

EEG: electroencephalogram; FDA: Food and Drug Administration.

Medical Policy Statement

The safety and effectiveness of magnetoencephalography and magnetic source imaging have been established. They may be considered useful diagnostic options when indicated for selected individuals.

Inclusionary and Exclusionary Guidelines

Inclusions:
Magnetoencephalography/magnetic source imaging is considered established in the following situations:

- For the purpose of determining the laterality of language function, as a substitute for the Wada test, in individuals being prepared for surgery for epilepsy, brain tumors, and other indications requiring brain resection.
- As part of the preoperative evaluation of individuals with drug-resistant epilepsy when standard techniques, such as MRI and EEG, do not provide satisfactory localization of epileptic lesion(s).

Exclusions:
Magnetoencephalography/magnetic source imaging is considered experimental and investigational for all other indications.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

S8035 95965 95966 95967

Other codes (investigational, not medically necessary, etc.):

N/A

Note: The code(s) listed above may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

Hegazy et al (2021) discusses the fundamental understanding of neurophysiology, the physics of MEG, the practical issues related to implementation analysis, and clinical applications, along with the misunderstandings that accompany the technology. Unlike MRI, MEG is not an imaging modality and cannot produce images of the brain, nor does it involve emitting magnetic fields, or any form of radiation. MEG is considered a neurophysiological technique that measures the magnetic fields associated with neuronal activity in the brain.

Magnetoencephalography/magnetic source imaging has been well-established for clinical use regarding both the localization of epileptic activity in individuals with drug resistant epilepsy and the localization of eloquent cortex for pre-surgical planning in individuals undergoing resective neurosurgery.

Localization of Seizure Focus – Drug Resistant Epilepsy and Magnetoencephalography
This section of the review is based on a TEC Special Report (2008) that reviewed the evidence on MEG for localization of epileptic lesions. MEG has been proposed as a method for localizing seizure foci for individuals with normal or equivocal magnetic resonance imaging and negative video-electroencephalogram (EEG) examinations, so-called "nonlesional" epilepsy. Such individuals often undergo MEG, positron emission tomography, or ictal-single photon emission computed tomography 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.

Ideally, a randomized trial comparing the outcomes of individuals who receive MEG as part of their diagnostic workup compared to individuals who do not receive MEG could determine whether MEG improves overall health outcomes. However, almost all of the studies evaluating MEG have been retrospective, where MEG, other tests, and surgery have been selectively applied.

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.

A representative study of MEG by Knowlton et al (2008) demonstrates many of the problematic issues of evaluating MEG. In this study of 160 subjects 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 participants 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 potential morbidity in a subset of subjects.

One study more specifically addresses whether MEG can improve the yield of IC-EEG, thus, allowing more participants to receive surgery. In another study by Knowlton et al (2009), MEG results modified the placement of electrodes in 18 (23%) of the 77 individuals who were recommended to have IC-EEG. Seven (39%) of 18 subjects had positive intracranial seizure recordings involving additional electrode placement because of MEG results. It was concluded that 4 (5%) individuals were presumed to have had surgery modified as a result of the effect of MEG electrode placement.

Several studies correlated MEG findings with surgical outcomes. Lau et al (2008) performed a systemic review of 17 such studies. In this review, sensitivity and specificity had unorthodox definitions. Sensitivity was the proportion of individuals cured with surgery in whom the MEG-defined epileptic region was resected, and specificity was the proportion of subjects not cured with surgery in whom the MEG-defined epileptic region was not resected. Pooled sensitivity was 84%, meaning that among the total number of cured individuals, 16% occurred despite the MEG-defined region not being resected. Pooled specificity was 52%, meaning that among 48% of individuals not cured, the MEG-localized region was resected. Another more recent systematic review by Mouthaan et al (2019) from the E-PILEPSY consortium which used a

more conservative analytic approach to pool data from a smaller subset of studies found similar but slightly lower MSI sensitivity (79% vs 84%) and specificity (46% vs 52%). 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.

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 post-operatively was 67%, 14%, 63%, and 17%, respectively.

Other studies implied a value of MEG, but it is difficult to make firm conclusions regarding its value. In a study by Schneider et al, 14 participants with various findings on MEG, IC-EEG, and interictal single photon emission computed tomography underwent surgery for non-lesion neocortical focal epilepsy. Concordance of IC-EEG and MEG occurred in 5 subjects, 4 of whom became seizure-free. This concordance of the 2 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 is correlated with better seizure outcomes. 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.

A study by Albert et al (2014) reviewed a series of pediatric subjects 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 individuals, 62.5% were seizure-free following surgery, and 20% experienced improvement. Two cases required additional surgery with invasive monitoring. Authors concluded that MEG is a viable alternative to invasive monitoring with intracranial electrodes for planning of resective surgery in carefully selected pediatric subjects with localization-related epilepsy.

A study by Koptelova et al (2013) compared MEG with video EEG monitoring in 22 individuals. Of 75 “irritative” zones identified in the 22 individuals by either method, a higher proportion was identified by MEG. 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 individuals.

The American Clinical Magnetoencephalography Society (2009) released a position statement that supported the routine clinical use of MEG/MSI for pre-surgical evaluation of individuals with medically intractable seizures. This statement cited 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 Sutherling et al (2008) study described it as a “prospective, blinded crossover-controlled, single-treatment, observational case series.” The study attempted to determine the proportion of subjects in whom the diagnostic or treatment strategy was changed as a consequence of MEG. They concluded that the test provided nonredundant information in 33% of participants, changed treatment in 9% of surgical subjects, and benefited

21% of individuals who had surgery. A similar study by De Tiege et al (2012) also attempted to determine the number of individuals in whom management decisions were altered based on MEG results. They concluded that clinical management was altered in 13% of individuals.

Madaan et al (2021) reviewed a randomized controlled trial which provided class I evidence for epilepsy surgery in pediatric drug resistant epilepsy. Authors concluded that magnetoencephalography (MEG) may be required in selected cases especially when brain MRI is normal, and further evidence for anatomo-electro-clinical concordance is necessary to refine candidacy for surgery and surgical strategy.

Otsubo et al (2021) released an update for best practice for the use of MEG in pediatric epilepsy. The contributions of MEG for localizing the epileptogenic zone were discussed, in particular in extra-temporal lobe epilepsy and focal cortical dysplasia, which are common in children, as well as in difficult to localize epilepsy such as operculo-insular epilepsy. Expert opinion determined that MEG could change the clinical management of children with drug resistant epilepsy by directing placement of intracranial electrodes thereby enhancing their yield.

Localization of Eloquent and Sensorimotor Areas
There are 2 ways to analyze the potential utility of MEG to map eloquent and sensorimotor brain areas accurately, localize these areas, and reduce postoperative functional impairment. 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 language laterality 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 provided 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 (n=85), Papanicolaou et al (2004), reported concordance between the MEG and Wada tests in 74 (87%) subjects. In no cases were the tests discordant in a way that the findings were completely opposite. Discordant cases occurred mostly when the Wada test indicated left dominance and the MEG indicated bilateral language function. In an alternative type of analysis, when 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” 1 case where such an approach would be needed (false-negative MEG) and resulted in 5 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 (95%) of 20 cases.

The Epilepsy Foundation (2013) supports use of MEG to improve the detection of potential sources of seizures when an MRI scan shows a lesion or spot, but the EEG findings give different information. MEG may be able to map the exact location of the normally functioning

areas near the lesion thus allowing the surgeon to focus incisions and operative measures and thus lessen post-operative weakness or loss of brain function. The use of MEG may be able to map the exact location of the normally functioning areas near the lesion. MEG measures small electrical currents arising inside the neurons of the brain. These currents produce small magnetic fields. The skull and the tissue surrounding the brain, affect the magnetic fields measured by MEG much less than they affect the electrical impulses measured by EEG. This makes the MEG more accurate than an EEG in some ways. MEG can provide more reliable information about the location of normal brain function versus seizure activity. A remarkably accurate representation of the magnetic fields produced by the neurons is generated with the use of MEG. In individuals who have had past brain surgery, the electrical field measured by EEG may be distorted by the changes in the scalp and brain anatomy. If further surgery is needed, MEG may be able to provide necessary information without invasive EEG studies.

SUMMARY OF EVIDENCE

Available evidence comprises studies that correlate the results of MEG with results of the Wada test, which is an alternative method for localization. Evidence has generally shown that concordance between MEG and the Wada test is high. Whereas an IC-EEG is an invasive technique that requires electrodes to be implanted in the brain. IC-EEG is limited in its use because not all brain areas are safe to access. MEG allows for accurate mapping of electrical activity in the brain via a non-invasive method, allowing for mapping throughout the entire brain. Clinical experts and multiple guidelines support the use of MEG (see Supplemental section). The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information

Clinical Input from Physician Specialty Societies and Academic Medical Centers

In response to requests, Blue Cross Blue Shield Association received input from 2 physician specialty societies (5 reviewers) and 2 academic medical centers while this policy was under review in 2011. There was support for use of magnetoencephalography and magnetic source imaging (MEG/MSI) for localization of language function and as part of the preoperative evaluation of intractable seizures. Those providing clinical input indicated that use of MEG/MSI in the preoperative evaluation leads to identification of additional people whose epilepsy may be cured using a surgical approach.

PRACTICE GUIDELINES AND POSITION STATEMENTS

The American Clinical Magnetoencephalography Society (2009) released a position statement supporting routine clinical use of MEG plus magnetic source imaging for pre-surgical evaluation of individuals with medically intractable seizures.

The ACMEGS (2011) issued a series of practice guidelines on magnetic evoked fields addressing different aspects of this technology (recording and analysis of spontaneous cerebral activity, pre-surgical functional brain mapping using magnetic evoked fields, MEG and EEG reporting, and qualifications of MEG-EEG personnel). Methods of guideline development were not described.

Guideline 2 on pre-surgical functional brain indicated 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.

The ACMEGS (2017) 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 pre-surgical evaluation of individuals with operable lesions preparing for surgery.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

Government Regulations
National/Local:

There are no national or local coverage determinations on magnetoencephalography or magnetic source imaging.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Navigated Transcranial Magnetic Stimulation (nTMS)

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 1/29/25, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/20/04	5/20/04	6/29/04	Joint policy established
6/15/05	6/15/05	5/21/05	Routine maintenance
5/1/07	3/1/07	3/30/07	Routine maintenance
3/1/10	1/4/10	12/8/09	Policy updated with TEC Special Report and literature review. Rationale and references completely revised. Policy statement changed to state that use of magnetoencephalography and magnetic source imaging is considered established when done for the purpose of • Determining the laterality of language function, as an alternative to invasive testing, such as the Wada test, in patients being prepared for surgery for epilepsy, brain tumors and other indications requiring brain resection. • Establishing epileptic focus in patients with seizures when other noninvasive tests are inconclusive or contradictory in localizing site of abnormality, as an alternative to invasive testing. All other uses of MEG considered investigational.
9/1/11	6/21/11	6/21/11	Policy statement changed to “The safety and effectiveness of magnetoencephalography and magnetic source imaging have been established. They may be considered useful diagnostic options when indicated for selected patients.” References updated.
3/1/13	12/11/12	12/31/12	Policy reformatted to mirror BCBSA.
9/1/14	6/20/14	6/23/14	Routine maintenance
11/1/15	8/24/15	9/14/15	Routine maintenance

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/16	8/16/16	8/16/16	Routine maintenance
11/1/17	8/15/17	8/15/17	Routine maintenance
11/1/18	8/21/18	8/21/18	Routine maintenance
7/1/19	4/16/19		Routine maintenance
7/1/20	4/14/20		Routine maintenance
7/1/21	4/20/21		Routine maintenance
7/1/22	4/19/22		Routine maintenance
7/1/23	4/18/23		Routine maintenance (slp) Vendor Managed: N/A
7/1/24	4/16/24		Routine maintenance (slp) Vendor managed: N/A
7/1/25	4/15/25		Routine maintenance (slp) Vendor managed: N/A

Next Review Date: 2nd Qtr, 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MAGNETOENCEPHALOGRAPHY/MAGNETIC SOURCE IMAGING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.