BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Magnetoencephalography/Magnetic Source Imaging

Policy #: 338
Latest Review Date: March 2025
Category: Radiology

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 **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 as a **covered benefit**.

Blue Advantage will treat **magnetoencephalography/magnetic source imaging** as part of the preoperative evaluation of patients with drug-resistant epilepsy (seizures refractory to medical therapy) as a **covered benefit** when standard techniques, such as MRI, are inconclusive.

Blue Advantage will treat **magnetoencephalography/magnetic source imaging** as a **non-covered benefit** and as **investigational** for all other indications.

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' contracts 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:

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 that is often used to localize the eloquent hemisphere is the Wada test. MEG/MSI has been proposed as a substitute for the Wada test.

KEY POINTS:
The most recent literature review was performed through March 4, 2025.

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 sufficient to determine the effects of 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 individuals based on MEG testing, but it has not been demonstrated that these changes lead to improved outcomes. The evidence is sufficient to determine the effects of technology on health outcomes.
There is insufficient evidence to support the use of MSI/MEG for other indications including the diagnosis and treatment of various neurological conditions/diseases such as Alzheimer's disease, autism, cognitive and mental disorders, learning disabilities, developmental dyslexia, multiple sclerosis, Parkinson's disease, schizophrenia, stroke rehabilitation, and traumatic brain injury.

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 individuals 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 individuals with operable lesions preparing for surgery.

U.S. Preventative Service 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 magnetoencephalography 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 enhances 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. A sampling of 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
Orion Lifespan Meg	Compumedics Limited	Feb 2020	K191785
RICOH MEG	RICOH COMPANY, Ltd.	Jan 2021	K210199

EEG: electroencephalogram; FDA: Food and Drug Administration

BENEFIT APPLICATION:

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

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:

Adopted for Blue Advantage, January 2009
Available for comment January 24-March 10, 2009
Medical Policy Group, May 2011
Available for comment June 8 – July 25, 2011
Medical Policy Group, October 2011
Medical Policy Group, October 2012
Medical Policy Group, December 2013
Medical Policy Group, October 2014

Medical Policy Group, January 2016
Medical Policy Group, October 2017
Medical Policy Group, October 2018: Updates to Key Points, References, and Key Words: added: superconducting quantum interference device. No changes to policy statement or intent.
Medical Policy Group, October 2019
Medical Policy Group, November 2020
Medical Policy Group, March 2022: Reviewed by consensus. No new published peer-reviewed literature is available that would alter the coverage statement in this policy.
Medical Policy Group, March 2023: Reviewed by consensus. No new published peer-reviewed literature is available that would alter the coverage statement in this policy.
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, March 2024: Reviewed by consensus. No new published peer-reviewed literature is available that would alter the coverage statement in this policy.
UM Committee, March 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, March 2025: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
UM Committee, March 2025: Annual review of policy approved by UM Committee for use for Blue Advantage business.
