

Magnetoencephalography/Magnetic Source Imaging

Policy # 00082

Original Effective Date: 03/25/2002

Current Effective Date: 01/13/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider magnetoencephalography/magnetic source imaging (MEG/MSI) 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, to be **eligible for coverage**.**

Based on review of available data, the Company may consider magnetoencephalography/magnetic source imaging (MEG/MSI) as part of the preoperative evaluation of patients with drug-resistant epilepsy when standard techniques, such as magnetic resonance imaging (MRI) and electroencephalogram (EEG), do not provide satisfactory localization of epileptic lesion(s), to be **eligible for coverage**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers magnetoencephalography/magnetic source imaging (MEG/MSI) for all other indications to be **investigational**.*

Background/Overview

Magnetoencephalography

MEG is a noninvasive functional imaging technique that records weak magnetic forces associated with brain electrical activity. Using mathematical modeling, recorded data are then analyzed to provide an estimated location of electrical activity. This information can be superimposed on an anatomic image of the brain, typically a 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 a measurement of electrical activity as recorded by electroencephalogram is altered by the surrounding brain structures, magnetic fields are not. Therefore, MSI permits a high-resolution image.

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

Applications

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

Another clinical application is the localization of the pre- and postcentral gyri as a guide to surgical planning in patients scheduled to undergo neurosurgery for epilepsy, brain neoplasms, arteriovenous malformations, or other brain lesions. These gyri contain the "eloquent" sensorimotor areas of the brain, the preservation of which is considered critical during any type of brain surgery. In normal situations, these areas can be identified anatomically by MRI, but frequently, anatomy is distorted by underlying disease processes. In addition, the location of eloquent functions varies, even among healthy people. Therefore, localization of the eloquent cortex often requires such intraoperative invasive functional techniques as cortical stimulation with the patient under local anesthesia or somatosensory-evoked responses on extended electrocorticography. Although these techniques can be done at the same time as the planned resection, they are cumbersome and can add up to 45 minutes of anesthesia time. Furthermore, these techniques can sometimes be limited by the small surgical field. A preoperative test, which is often used to localize the eloquent hemisphere, is the Wada test. MEG/MSI has been proposed as a substitute for the Wada test.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The U.S. FDA regulates MEG devices as class II devices cleared for marketing through the 510(k) process. The FDA product codes OLX and OXY are used to identify the different components of the devices. OLX-coded devices are source localization software for electroencephalography or MEG; the software correlates the electrical activity of the brain using various neuroimaging



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modalities. This code does not include electrodes, amplitude-integrated electroencephalography, 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." 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



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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

EEG: electroencephalogram; FDA: U.S. Food and Drug Administration.

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

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

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



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Summary of Evidence

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

For individuals who have a planned brain resection who require localization of eloquent function areas who receive MEG/MSI, the evidence includes comparative studies. Relevant outcomes include test accuracy and clinical utility. Available studies have reported that this test has high concordance with the Wada test, which is currently the main alternative to localize eloquent functions. While management is changed in some patients based on MEG testing, it has not been demonstrated that these changes lead to improved outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Additional Information

Clinical input obtained in 2011 supported the use of MEG/MSI for preoperative evaluation for resection brain surgery.

Clinical input obtained in 2011 supported the use of MEG/MSI for localization of eloquent function areas.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received 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 for localization of language function and as part of the preoperative evaluation of intractable seizures. Those providing input indicated that use of magnetoencephalography and magnetic source imaging in the preoperative evaluation leads to the identification of additional people whose epilepsy may be cured using a surgical approach.



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Practice Guidelines and Position Statements

American Clinical Magnetoencephalography Society

The American Clinical Magnetoencephalography Society (ACMS, 2009) released a position statement supporting the routine clinical use of MEG plus magnetic source imaging for presurgical evaluation of patients with medically intractable seizures.

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

Guideline 2 on presurgical functional brain mapping indicated that:

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

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

The ACMS (2017) issued another position statement supporting the routine use of MEG/magnetic source imaging 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.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov on August 3, 2020 did not identify any ongoing or unpublished trials that would likely influence this review.



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References

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Policy History

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03/21/2002 Medical Policy Committee review

03/25/2002 Managed Care Advisory Council approval

06/24/2002 Format revision. No substance change to policy.

03/08/2004 Medical Director review

03/16/2004 Medical Policy Committee review. Format revision. No substance change to policy.



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03/29/2004	Managed Care Advisory Council approval
03/09/2006	Medical Director review
03/15/2006	Medical Policy Committee review. Format changes. FDA information added. No change to coverage eligibility.
03/12/2008	Medical Director review
03/19/2008	Medical Policy Committee approval
03/04/2009	Medical Director review
03/18/2009	Medical Policy Committee approval. Coverage changed from investigational to eligible for coverage for determining the laterality of language function, as a substitute for the Wada test, in patients undergoing diagnostic workup for evaluation of surgery for epilepsy, brain tumors and other indications requiring brain resection.
03/05/2010	Medical Policy Committee review
03/19/2010	Medical Policy Implementation Committee approval. No changes to coverage.
03/03/2011	Medical Policy Committee review
03/16/2011	Medical Policy Implementation Committee approval. No changes to coverage.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Policy coverage changed from investigational to eligible for coverage to localize seizure focus for specific indications.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2019	Coding update
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.



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12/01/2022 Medical Policy Committee review
12/14/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/07/2023 Medical Policy Committee review
12/13/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2024 Medical Policy Committee review
12/11/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 12/2025

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	95965, 95966, 95967
HCPCS	S8035
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into



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standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company



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recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

