MEDICAL POLICY

POLICY TITLE	MAGNETOENCEPHALOGRAPHY /MAGNETIC SOURCE IMAGING
POLICY NUMBER	MP-5.011

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**8/25/2020**
Effective Date:	**11/1/2020**

I. POLICY

Magnetoencephalography/magnetic source imaging as part of the preoperative evaluation of patients with intractable epilepsy (seizures refractory to at least two first-line anticonvulsants) may be considered **medically necessary** when standard techniques, such as MRI and EEG, do not provide satisfactory localization of epileptic lesion(s).

Magnetoencephalography/magnetic source imaging for the purpose of determining the laterality of language function, as a substitute for the Wada test, in patients being prepared for surgery for epilepsy, brain tumors, and other indications requiring brain resection, may be considered **medically necessary**.

Magnetoencephalography / magnetic source imaging is considered **investigational** for all other indications. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

III. DESCRIPTION/BACKGROUND TOP

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

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

REGULATORY STATUS

POLICY TITLE	MAGNETOENCEPHALOGRAPHY /MAGNETIC SOURCE IMAGING
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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.

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).

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.

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-	CTF Systems	Nov 1997	K971329

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

IV. RATIONALE

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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. The relevant outcomes are test accuracy and functional outcomes. 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. The 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 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.

V. DEFINITIONS

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GYRI refer to one of the convolutions of the cerebral hemispheres of the brain.

MAGNETIC RESONANCE IMAGING is a type of diagnostic imaging that uses the characteristic behavior of protons (and other atomic nuclei) when placed in powerful magnetic fields to make images of tissues and organs.

NONINVASIVE refers to a device or procedure that does not penetrate the skin or enter any orifice in the body.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

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VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement

Covered when medically necessary:

CPT Codes®								
95965	95966	95967						

HCPCS Code	Description
S8035	Magnetic source imaging

ICD-10-CM Diagnosis Code	Description
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C71.9	Malignant neoplasm of brain, unspecified
C79.31	Secondary malignant neoplasm of brain
D33.0	Benign neoplasm of brain, supratentorial
D33.1	Benign neoplasm of brain, infratentorial
D33.2	Benign neoplasm of brain, unspecified
D43.0	Neoplasm of uncertain behavior of brain, supratentorial
D43.1	Neoplasm of uncertain behavior of brain, infratentorial
D43.2	Neoplasm of uncertain behavior of brain, unspecified
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus

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ICD-10-CM Diagnosis Code	Description
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
G40.111	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.501	Epileptic seizures related to external causes, not intractable, with status epilepticus
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus
G40.801	Other epilepsy, not intractable, with status epilepticus
G40.802	Other epilepsy, not intractable, without status epilepticus
G40.803	Other epilepsy, intractable, with status epilepticus
G40.804	Other epilepsy, intractable, without status epilepticus
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus

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ICD-10-CM Diagnosis Code	Description
G40.89	Other seizures
G40.A01	Absence epileptic syndrome, not intractable, with status epilepticus
G40.A09	Absence epileptic syndrome, not intractable, without status epilepticus
G40.A11	Absence epileptic syndrome, intractable, with status epilepticus
G40.A19	Absence epileptic syndrome, intractable, without status epilepticus
G40.B01	Juvenile myoclonic epilepsy, not intractable, with status epilepticus
G40.B09	Juvenile myoclonic epilepsy, not intractable, without status epilepticus
G40.B11	Juvenile myoclonic epilepsy, intractable, with status epilepticus
G40.B19	Juvenile myoclonic epilepsy, intractable, without status epilepticus
I67.1	Cerebral aneurysm, nonruptured
Q28.2	Arteriovenous malformation of cerebral vessels
Q28.3	Other malformations of cerebral vessels

IX. REFERENCES

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Other:

Taber's Cyclopedic Medical Dictionary, 19th edition.

X. POLICY HISTORY

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MP 5.011	**CAC 10/28/03**
	CAC 10/26/04
	CAC 10/25/05
	CAC 5/30/06
	CAC 6/26/07
	CAC 5/27/08
	CAC 1/27/09
	CAC 7/1/09 Cross-Reference added for Pervasive Developmental Disorders
	CAC 1/26/10 Consensus review.
	CAC 7/26/11 Adopt BCBSA. An additional policy statement was added that Magnetoencephalography/magnetic source imaging as part of the preoperative evaluation of patients with intractable epilepsy may be considered medically necessary when standard techniques, such as MRI, are inconclusive. An FEP variation added.
	CAC 8/28/12 Consensus review. Slight change in wording does not impact meaning of policy statement. References updated. Changed FEP variation from standard to reference FEP Medical Policy Manual MP-6.01.24 Magnetic Resonance Spectroscopy. Codes reviewed 8/20/12
	CAC 7/30/13 Consensus review. References updated. No changes to the policy statements. FEP variation revised to also refer to FEP policy manual for Magnetoencephalography/Magnetic Source Imaging.

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	CAC 3/25/14 Consensus review. References updated. No changes to the policy statements. Rationale added. No coding changes.
	CAC 9/30/14 Minor revision. Policy is being revised to remove magnetic resonance spectroscopy coverage criteria which after 1/1/15 will be handled by National Imaging Associates (NIA) Title changed to: "Magnetoencephalography/Magnetic Source Imaging". For management of Magnetic Resonance Spectroscopy, please refer to the National Imaging Associates (NIA) Radiology Standard Clinical Guidelines www.radmd.com
	04/02/15 Administrative update. Code review completed. Codes unchanged. 76390 Removed from the policy as this is managed by NIA.
	CAC 9/29/15 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed.
	CAC 11/29/16 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed. Variation reformatting.
	12/19/17 Consensus review. No change to policy statements. References and rationale updated.
	11/15/18 Consensus review. No change to the policy statements. References reviewed. Rationale revised.
	10/2/19 Consensus review. No change to the policy statements. References reviewed. FEP variation removed since archived.
	8/25/2020 Consensus review. References updated, no change to policy statements.

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