Cigna Medical Coverage Policy

Subject **Magnetoencephalography (MEG)**

Effective Date **12/15/2013**
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Coverage Policy

Cigna covers magnetoencephalography (MEG) or magnetic source imaging (MSI) as medically necessary when EITHER of the following criteria is met:

- presurgical evaluation of individuals with intractable focal epilepsy to identify and localize area(s) of epileptiform activity when other neurological imaging studies designed to localize a focus are indeterminate
- presurgical mapping of the eloquent cortex, as an alternative to invasive testing (e.g., the Wada test), in individuals being prepared for surgery for brain tumors and vascular malformations.

Cigna does not cover MEG or MSI as a stand-alone test or as the first order of test after clinical and routine electroencephalography (EEG) diagnosis of epilepsy because it is considered experimental, investigational or unproven.

Cigna does not cover MEG or MSI for any other condition because they are considered experimental, investigational or unproven.

General Background

Magnetoencephalography (MEG) is a noninvasive functional imaging technique that externally records magnetic fields generated by brain activity. When the information is superimposed on an anatomic image of the brain

such as a magnetic resonance imaging (MRI) scan, the image is referred to as magnetic source imaging (MSI). Typical MEG recordings are made within a magnetically shielded room using a device that has 100—300 magnetometers or gradiometers (sensors). They are arranged in a helmet-shaped container called a Dewar. The Dewar is filled with liquid helium needed to produce superconductivity. This results in a visual display of normal brain activity such as the location of eloquent cortex for vision, touch, movement, or language and abnormal brain activity. Although MEG has been used for a number of conditions, the primary clinical applications studied are for identifying eloquent areas of the brain for neurosurgical planning in patients scheduled to undergo neurosurgery for medically intractable epilepsy, brain neoplasms, arteriovenous malformations or other brain disorders and for use in localization of epileptic foci in individuals being considered for surgery (American Academy of Neurology Professional Association [AANPA]; ECRI, 2008).

MEG is a newer technology when compared to MRI, PET, SPECT, intracranial electroencephalography (IEEG) and the Wada test. For presurgical localization and functional identification some of the earlier tests have become the standard of practice, by default of chronologic precedence. Not all of them have undergone rigorous comparative critical appraisals (AANPA, 2009).

IEEG is often used as the gold standard for localizing an epileptic focus in presurgical evaluation of epilepsy patients. The invasive IEEG is not without morbidity and may occasionally yield incorrect findings or may not detect a focus. Therefore, in some centers, a prior MEG recording has guided an IEEG, thus avoiding incorrect invasive electrode placements. For decades, the Wada test has also been successful for language and memory localization. It is invasive, uncomfortable and carries certain morbidity. Depending on the diagnostic need and patient characteristics, functional magnetic resonance imaging (fMRI), neurobehavioral testing, PET-SPECT scans and MEG are emerging as possible alternatives to the Wada test (AANPA, 2009).

MEG is not the first order of test after clinical and routine EEG diagnosis of epilepsy. It has been proposed as one of several advanced pre-surgical investigative technologies. The need for MEG is much lower than surface EEG and anatomical imaging studies. MEG cannot replace, but may guide the placement of intracranial EEG and, in some patients, therefore possibly avoiding an unnecessary intracranial EEG. MEG is not a stand-alone test. To realize its optimum clinical potential a comprehensive team evaluation, such as that available in comprehensive epilepsy centers, is necessary. The team usually comprises a neurologist with expertise in epilepsy, a neurosurgeon, MEG-physicists, psychologists, nurses and staff experienced in treatment of seizure disorders (AANPA, 2009).

U.S. Food and Drug Administration (FDA)
MEG machines are classified by the FDA as Class II devices. Class II devices are cleared through the FDA's 510(k) process and require special controls but do not require premarket application approval.

Literature Review
The published evidence for MEG of the brain consists of a number of prospective uncontrolled case series, prospective controlled or comparative studies, retrospective studies, and systematic reviews. The proposed applications of MEG have not been assessed in detail with randomized control groups, including sham measurements to display effects on clinical outcome (Tharin, et al., 2007; Makela, et al., 2006; Papanicolaou, et al., 2005a).

Epilepsy: Due to the heterogeneity of etiologies of intractable epilepsy, lesions, extent of surgical resections, and outcomes, direct validation or strict proof of the utility or superiority of MEG, which is noninvasive, over the gold standard of IEEG is challenging. MEG's exact predictive value in surgical epilepsy has yet to be quantified. Studies suggest that MEG may be a valuable adjunct tool when used in conjunction with other diagnostic tests because MEG provides information preoperatively that can assist the surgical team in pre-surgical planning. While the supporting evidence is not robust, the use of MEG has become a standard of care in a subset of individuals as an adjunct rather than as an alternative to other seizure focus localization methods, such as IEEG (De Tiège, et al., 2012; Knowlton, et al., 2009; Agirre-Arrizubieta, et al., 2009; Sutherling, et al., 2008; Knowlton, et al., 2008a; Knowlton, et al., 2008b; Guggisberg, et al., 2008b; Ramachandrannair, et al., 2007; Paulini, et al., 2007; Iida, et al., 2006; Wu, et al., 2006; Jansen, et al., 2006; Kamimura, et al., 2006; Oishi, et al., 2006; Knowlton, et al., 2006; Wolff, et al., 2005; Papanicolaou, et al., 2005b; Pataraia, et al., 2004; Stefan, et al., 2003; Eliashiv, et al., 2002; Wheless, et al., 1999).

Presurgical Evaluation of Eloquent Cortex/Brain Tumors and Arteriovenous Malformations: While the supporting evidence is not robust, the use of MEG has become a standard of care in a subset of individuals for presurgical mapping of the eloquent cortex, as an alternative to invasive testing (e.g., the Wada test), in individuals being prepared for surgery for brain tumors and vascular malformations (Tarapore, et al., 2012; Jin, et al., 2007; Korvenoja, et al., 2006; Ganslandt, et al., 2004; Schiffbuer, et al., 2001; Doss, et al., 2009; Grummich, et al., 2006; Grover, et al., 2006; Kamada, et al., 2003).

Other Conditions: There is a lack of evidence in the published, peer-reviewed literature to permit conclusions regarding the accuracy, reproducibility, and clinical utility of MSI/MEG for other indications including fetal neurological assessment and the diagnosis and treatment of various neurological conditions such as autism, Gilles de la Tourette syndrome, cognitive and mental disorders, learning disorders, schizophrenia, stroke, post surgical seizures, post-traumatic stress disorder (PTSD), concussion and traumatic brain injury. There is limited data from well designed clinical studies that MEG/MSI improves clinical outcomes in patients for these indications (Shigihara, et al. 2013; Tormenti, et al. 2012; Franzkowiak, et al., 2012; Hinkley, et al., 2011; Haddad, et al., 2011; Siekmeier, et al., 2010; Bachman, et al., 2010; Georgopoulos, et al., 2010; Lee, et al., 2010; Lowery, et al., 2009; Breier, et al., 2005; Fehr, et al., 2001; Lewine, et al., 1999; Reite, et al., 1997).

Technology Assessments/Reviews
In a systematic review, Lau et al. (2008) determined the effectiveness of MEG/MSI in the presurgical evaluation of localization-related epilepsies. The authors searched MEDLINE, the Cochrane library, and EMBASE between 1987 and 2006 for English articles. Studies including a minimum of four patients with at least six months follow-up after surgery were reviewed. In each study, surgical outcome (seizure freedom) was correlated with the concordance of MEG source localization and resection area. Twenty-eight studies satisfied the inclusion criteria. Eleven of the 28 studies were excluded due to an inability to determine the concordance between the MEG epileptic focus and the resected area based on the published data. Data from the remaining studies found sensitivity (range: 0.20—1.0) values for all articles, and specificity (0.06—1.00) values, positive likelihood ratios (0.67—2.0) and negative likelihood ratios (0.40—2.13) for some studies. The authors reported that as a primary diagnostic tool the sensitivity and/or specificity of MEG has not been consistently high. The authors noted that there are multiple sources of variation between studies, and the sample size of each population was fairly small. More controlled and consistent studies need to be done to determine whether MEG is an adequate replacement as a diagnostic tool for IEEG. There is insufficient evidence in the current literature to support the relationship between the use of MEG in surgical planning and seizure-free outcome after epilepsy surgery.

Professional Societies/Organizations
In May 2009, the Medical Economics and Management Committee (MEM) of The American Academy of Neurology (AAN) published a model medical policy for MEG. The policy states the following indications for MEG:

- Epilepsy—Pre-surgical evaluation in patients with intractable focal epilepsy to identify and localize area(s) of epileptiform activity. MEG can be valuable when discordance or continuing questions arise from amongst other techniques designed to localize a focus.
- Tumors and Arteriovenous Malformation Surgeries—Pre-surgical evaluation of brain tumors and vascular malformations. The aim is to identify, localize and preserve eloquent cortex during resective surgery.

The AAN policy reported the results of a number of clinical trials but do not provide an analysis of the quality of the studies. The model policy does not describe the process by which the evidence was used to reach conclusions. The AAN continues to develop an updated MEG clinical practice guideline for epilepsy.

The American Clinical Magnetoencephalography Society (ACMEGS) Position Statement on the value of MEG/MSI in noninvasive presurgical evaluation of patient with medically intractable localization-related epilepsy states that after considering the entire body of published evidence through April 20, 2009, including what the ACEGS refers to as the most sophisticated clinical MEG studies designed and published internationally (Knowlton et al., 2008a,b; Sutherling, et al., 2008), the ACMEGS acknowledges that sufficient credible evidence has been published to support a position statement regarding the value of MEG in the presurgical evaluation of patients with medically intractable localization-related epilepsy. The ACMEGS intends to enhance the practice of clinical MEG/MSI further by developing practice parameters. The authors do not describe the process by which the evidence was used to reach conclusions. The ACMEGS supports (Bagic, et al., 2009):

- Routine clinical use of MEG/MSI in obtaining noninvasive, nonredundant localizing information in presurgical evaluation of patients with medically intractable localization-related epilepsy.
- Determination of MEG/MSI indications for an individual patient by an epileptologist or a clinical team associated with a National Association of Epilepsy Centers-designated epilepsy center.
- Routine use of MEG/MSI when traditional EEG methods and magnetic resonance imaging are implemented and provide insufficient localizing information.
- Uses for MEG/MSI indicated by accepted standards of clinical judgment and care and the rational utilization of resources without further restrictions.
- Further systematic clinical research that seeks to establish other clinical indications for MEG/MSI.

The 2011 Clinical Practice Guideline Committee of the ACMEGS for recording and analysis of spontaneous cerebral activity states that "Currently, MEG–EEG recordings of spontaneous cerebral activity are indicated and accepted for detecting abnormalities in background rhythms and identifying interictal epileptiform discharges(IIEDs) for the purpose of epileptic focus localization" (Bagic, 2011b).

The American Academy of Neurology (AAN) and American Epilepsy Society (AES) practice parameters for the use of neuroimaging and EEG for evaluation of an apparent unprovoked first time seizure in adults recommends that brain imaging using computed tomography (CT) or MRI should be considered as part of the neurodiagnostic evaluation of adults presenting with an apparent unprovoked first seizure (Krumholz et al., 2007). There is no mention of MEG/MSI in the practice parameter.

The 2011 American College of Radiology (ACR) Appropriateness Criteria™ summary of literature for seizure and epilepsy states, "Some patients may have more than one lesion and/or discordance between electrical findings on EEG and imaging localization. In these types of special circumstances FDG-PET, MEG, and SPECT imaging may help define the most likely ictal onset zone." The ACR appropriateness criteria scale ranges from 1–9, with a score of 1 indicating the least appropriate imaging examination and a 9 indicating the most appropriate. The ACR gave MEG/MSI a rating of 2 for most variants. For the variant medically refractory epilepsy; surgical candidate and/or surgical planning, ACR gave MEG/MSI a rating of 6, stating may identify IOZ in nonlesional patients (normal MRI), can provide confirmatory localization information, may guide placement iEEG. May substitute for invasive testing, and may be useful when other tests are discordant (ACR, 2011).

The Report of the Quality Standards Subcommittee of the American Academy of Neurology (AAN) and the Child Neurology Society states that there is insufficient evidence to suggest a role for event-related potentials or MEG in the evaluation of autism (Filipek, et al., 2000). This report has not been updated since 2000.

Use Outside of the US (For Informational Purposes Only)
In January 2007, the Ontario Health Technology Advisory Committee (OHTAC) reviewed the clinical utility of functional brain imaging (e.g., MEG) in the diagnosis or management of patients with epilepsy. The authors reported, "MEG provides a possible opportunity to replace the invasive EEG because it can potentially localize the seizure foci noninvasively. There is some limited observational data (five studies, n=190) to suggest that MEG may be as accurate as invasive EEG at localizing the seizure foci. MEG is not only non-invasive but the investigation is performed during a single examination." Based on the results of the health technology and policy assessment the OHTAC recommendation for epilepsy states that a field evaluation needs to be conducted to determine the potential substitutive role of MEG versus IEEG.

Summary
Magnetoencephalography (MEG) or magnetic source imaging (MSI) has been used for a number of conditions, the primary clinical applications studied are for identifying eloquent areas of the brain for neurosurgical planning in patients scheduled to undergo neurosurgery for medically intractable epilepsy, brain neoplasms, arteriovenous malformations or other brain disorders and for use in localization of epileptic foci in individuals being considered for surgery.

Evidence in the published, peer-reviewed scientific literature has shown a correlation between MEG or MSI findings and other noninvasive and invasive diagnostic tests such as invasive and noninvasive electroencephalography (EEG) or Wada test. However, these studies are inconclusive regarding the accuracy, reproducibility, and clinical utility of MEG of such patients, and whether patient health outcomes were improved

as a result of the additional diagnostic information. However, studies suggest that in a subset of patients MEG may be a valuable adjunct tool when used in conjunction with other diagnostic tests because MEG provides information preoperatively that can assist the surgical team in pre-surgical planning. Additional studies need to clarify the role and utility of MEG in conjunction with other invasive and non-invasive neurofunctional tests, as well as address the impact of MEG on complication rates and long-term outcomes.

There is a lack of evidence in the published, peer-reviewed literature to permit conclusions regarding the accuracy, reproducibility, health outcomes and clinical utility of MEG for other indications including, but not limited to, fetal neurological assessment and the diagnosis and treatment of various neurological conditions such as autism, cognitive and mental disorders, learning disorders, schizophrenia, stroke, post surgical seizures and traumatic brain injury.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Covered when medically necessary:

CPT* Codes	Description
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 Codes	Description
S8035	Magnetic source imaging

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