MAGNETOENCEPHALOGRAPHY AND MAGNETIC SOURCE IMAGING FOR SPECIFIC NEUROLOGICAL APPLICATIONS

Policy Number: DIAGNOSTIC 029.16 T2

Effective Date: July 1, 2017

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INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

CONDITIONS OF COVERAGE

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<th>Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)</th>
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<th>Special Considerations</th>
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<td>¹Review by a Medical Director or their designee is required.</td>
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BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Magnetoencephalography and magnetic source imaging (MEG/MSI) are proven and medically necessary for the following:
- Presurgical evaluation in patients with intractable focal epilepsy
- Presurgical evaluation of brain tumors and vascular malformations
- Presurgical planning for refractory epilepsy when other methods do not localize a seizure focus.

Magnetoencephalography and magnetic source imaging (MEG/MSI) are unproven and not medically necessary for evaluating brain function in patients with the following indications:
- Trauma
- Stroke
- Learning disorders, or
- ALL other neurologic disorders and psychiatric conditions including but not limited to schizophrenia.

There is insufficient evidence to conclude that the use of MEG/MSI improves health outcomes such as improved diagnostic accuracy and treatment planning for patients with trauma, stroke, learning disorders, or other neurologic disorders and psychiatric conditions. Further clinical trials demonstrating the clinical usefulness of this procedure are necessary before it can be considered proven to have a benefit on health outcomes for these conditions.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

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<td>Magnetoencephalography (MEG), recording and analysis; for evoked magnetic fields, single modality (e.g., sensory, motor, language, or visual cortex localization)</td>
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HCPCS Code | Description |
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<tr>
<td>S8035</td>
<td>Magnetic source imaging</td>
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DESCRIPTION OF SERVICES

Magnetic source imaging (MSI) is an imaging technique that has been used to evaluate brain function in patients with tumors, arteriovenous malformations (AVM), epilepsy, trauma, stroke, or other neurologic disorders and psychiatric conditions such as schizophrenia. MSI combines functional data obtained via magnetoencephalography (MEG) with
structural data obtained via magnetic resonance imaging (MRI) to provide a detailed picture mapping brain function onto brain structure.

Although MEG has been used for a number of conditions, the primary clinical applications of MSI are preoperative: (1) to locate epileptic foci in people being considered for surgery, and (2) to locate brain masses (tumors, cortical lesions, AVMs) and (3) to map the brain function (including language, motor, somatosensory, vision, auditory) of adjacent unaffected brain tissue. In these cases, neurosurgical intervention is complicated by the conflicting goals of removing diseased tissue while sparing surrounding healthy tissue.

MSI has been investigated as an alternative or as an adjunct to other methods of locating epileptic foci and/or brain masses. These other methods include scalp electroencephalograms (EEGs) for evaluating the electrical activity of the brain; invasive EEGs requiring craniotomies, the "gold standard"; subdural electrocorticography (ECoG) and stereotactic electroencephalograph potentials (SEEP); functional neuroimaging procedures: positron emission tomography (PET), single-photon emission computed tomography (SPECT), and functional MRI (fMRI); and anatomic imaging modalities such as MRI and computed tomography (CT). The intracarotid amobarbital test (Wada test) has long been as the standard to map language and memory functions. However, the Wada test is invasive and it carries the risk of morbidity.

CLINICAL EVIDENCE

Epilepsy

A prospective, blinded, intention to treat study assessed the clinical added value of magnetic source imaging (MSI) in the presurgical evaluation of patients with refractory focal epilepsy (RFE). A total of 70 consecutive patients with RFE from two centers were prospectively included. All patients underwent conventional non-invasive presurgical evaluation (CNIPE) and a whole head magnetoencephalography recording. Results of CNIPE were first discussed blinded to the MSI results in respective multidisciplinary epilepsy surgery meetings to determine the presumed localization of the epileptogenic zone and to set surgical or additional presurgical plans. MSI results were then discussed. MSI influence on the initial management plan was assessed. Based on CNIPE, 21 patients had presumed extratemporal lobe epilepsy, 38 had presumed temporal lobe epilepsy and 11 had undetermined localization epilepsy. MSI showed interictal epileptiform discharges (IED) in 52 patients (74.5%) and changed the initial management in 15 patients (21%). MSI related changes were significantly more frequent in patients with presumed extratemporal lobe or undetermined localization epilepsy compared with patients with presumed temporal lobe epilepsy. These changes had a clear impact on clinical management in 13% of all patients. The authors concluded that MSI is a clinically relevant, non-invasive neuroimaging technique for the presurgical evaluation of patients with refractory focal epilepsy and, particularly, in patients with presumed extratemporal lobe and undetermined localization epilepsy (De Tiege, 2012).

Nissen and colleagues (2016) evaluated whether a prediction could be made up-front as to whether MEG would be able to generate a hypothesis about the location of the epileptogenic zone (EZ). MEG recordings of 382 patients with epilepsy and inconclusive findings regarding EZ localization were evaluated and categorized for several demographic, clinical and MEG variables. Due to the complex and diverse etiology of the patient group, the authors reported that they were unable to predict the effect of MEG localization up-front, although the odds of a recording with MEG location were significantly higher in the absence of a tumor and in the presence of widespread MRI abnormalities. MEG potentially adds information about the location of the EZ even in patients with a complex etiology, and the author’s clinical advice is to not withhold MEG in epilepsy surgery candidates. The authors conclude that providing a hypothesis about the location of the EZ using MEG may be difficult in patients with inconclusive EEG and MRI findings, and in the absence of specific epileptiform activity.

In a review of surgery in childhood epilepsy, Jayalakshmi et al. (2014) reported that advances in neuroimaging (including MEG) and neurosurgical techniques have helped in selecting an increasing number of children with refractory epilepsies into the pediatric epilepsy surgery programs. The authors recommend that children with intractable epilepsies should be evaluated early at specialized epilepsy surgery centers to avoid the long-term consequences and morbidity associated with epilepsy. Whole-head MEG facilitates simultaneous recording from the entire brain surface. Localizations of interictal spike zone with MEG showed excellent agreement with invasive EEG recordings. MEG is useful for the study of patients with nonlesional neocortical epilepsy and in patients with large lesions; it provides unique information on the epileptogenic zone. MEG can be used to map the sensorimotor cortex and language cortex. Based on their review, the authors conclude that both EEG and MEG yield complementary and confirmatory information and have an important role in the multi-disciplinary approach to pre-surgical evaluation.

Sutherland et al. (2008) evaluated whether magnetic source imaging (MSI) changed the surgical decision in a prospective, blinded, crossover-controlled, single-treatment, observational case series. Sixty-nine sequential patients diagnosed with partial epilepsy of suspected neocortical origin had video-electroencephalography (EEG) and imaging. MSI gave non-redundant information in 23 patients (33%). MSI added intracranial EEG (ICEEG) electrodes in 9 (13%) and changed the surgical decision in another 14 (20%). Based on MSI, 16 patients (23%) were scheduled for different
ICEEG coverage. MSI avoided contralateral electrodes in 2, who both localized on ICEEG. MSI added information to ICEEG in 1. According to the investigators, in those who have undergone surgery to date, MSI added useful information that changed treatment in 6 (9%) without increasing complications. MSI benefited 21% who underwent surgery.

Knowlton et al. (2009) evaluated whether MSI can supplement ICEEG by affecting electrode placement to improve sampling of the seizure onset zone(s). A total of 160 patients were prospectively enrolled by insufficient localization from seizure monitoring and magnetic resonance imaging results. Before presenting MSI results, decisions were made whether to proceed with ICEEG, and if so, where to place electrodes such that the hypothetical seizure-onset zone would be sampled. MSI results were then provided with allowance of changes to the original plan. MSI indicated additional electrode coverage in 18 of 77 (23%) ICEEG cases. In 39%, seizure-onset ICEEG patterns involved the additional electrodes indicated by MSI. Sixty-two patients underwent surgical resection based on ICEEG recording of seizures. Highly localized MSI was significantly associated with seizure-free outcome (mean, 3.4 years; minimum, greater than 1 year) for the entire surgical population (n = 62). According to the investigators, MSI spike localization increases the chance that the seizure-onset zone is sampled when patients undergo ICEEG for presurgical epilepsy evaluations. The clinical impact of this effect, improving diagnostic yield of ICEEG, should be considered in surgery candidates who do not have satisfactory indication of epilepsy localization from seizure semiology, electroencephalogram, and magnetic resonance imaging.

**Brain Tumors and Arteriovenous Malformations**

Korvenoja et al. (2006) prospectively evaluated magnetoencephalography (MEG) and functional magnetic resonance (MR) imaging, as compared with intraoperative cortical mapping, for identification of the central sulcus in fifteen patients with a lesion near the primary sensorimotor cortex (13 gliomas, one cavernous hemangioma, and one meningioma). The authors found that although both MEG and functional MR imaging can provide useful information for neurosurgical planning, MEG proved to be superior for locating the central sulcus. Activation of multiple nonprimary cerebral areas may confound the interpretation of functional MR imaging results.

Doss et al. (2009) evaluated the use of MEG/MSI for presurgical language lateralization by comparing results against the Wada test, or intracarotid amobarbital procedure (IAP). The study included 35 patients with epilepsy and/or brain tumor undergoing presurgical evaluation at the Minnesota Epilepsy Group. All patients received both an IAP and MSI to determine hemispheric language dominance. The MSI and IAP were concordant in determining language in the hemisphere to be treated in 86% of the cases with sensitivity and specificity values of 80% and 100%, respectively. According to the investigators, MSI is a viable noninvasive alternative to the IAP in the presurgical determination of language lateralization.

In a retrospective study by Guggisberg et al. (2008a) magnetoencephalography recordings of spontaneous cortical activity during resting state were obtained from 15 consecutive patients with focal brain lesions and from 14 healthy control subjects. Patients with lesion-induced neurological deficits displayed decreased connectivity estimates in the corresponding brain area compared with intact contralateral regions. In tumor patients without preoperative neurological deficits, brain areas showing decreased coherence could be surgically resected without the occurrence of postoperative deficits. This study concluded that the resting state coherence measured with magnetoencephalography is capable of mapping the functional connectivity of the brain, and can therefore offer valuable information for use in planning resective surgeries in patients with brain lesions, as well as investigations into structural-functional relationships in healthy subjects.

To avoid neurological impairment during surgery near language-related eloquent brain areas, Grummich et al. (2006) performed presurgical functional brain mapping with functional magnetic resonance imaging (fMRI) and magnetoencephalography (MEG) in 172 patients using language tasks. Of the 124 patients who had surgery, only 7 patients (5.6%) experienced a transient language deterioration, which resolved in all cases. The authors used MEG and fMRI to show different aspects of brain activity and to establish validation between MEG and fMRI. They conclude that measurement by both MEG and fMRI increases the degree of reliability of language area localization and that the combination of fMRI and MEG is useful for presurgical localization of language-related eloquent cortex.

**Other Conditions**

A retrospective and single-blind study of imaging data was completed by Lewine et al. (2007) to determine to what extent magnetic resonance imaging (MRI), single photon emission computed tomography (SPECT), and magnetoencephalography (MEG) can provide objective evidence of brain injury in adult patients with persistent postconcussive symptoms following mild blunt head trauma. The study included 30 patients with complete data sets (MRI, SPECT, MEG, and neuropsychological testing results). It was found that MRI was abnormal for 4 patients. SPECT showed regions of hypoperfusion in 12 patients, while MEG showed abnormal activity in 19 patients. None of the imaging methods produced findings statistically associated with postconcussive psychiatric symptoms. For patients with cognitive complaints, abnormalities were more likely to be detected by MEG (86%) than either SPECT (40%) or MRI (18%). MEG also revealed significant associations between temporal lobe DSWA and memory problems, parietal
DSWA and attention problems, and frontal DSWA and problems in executive function. The investigators concluded that functional brain imaging data collected in a resting state can provide objective evidence of brain injury in mild blunt head trauma patients with persistent postconcussive somatic and/or cognitive symptoms. MEG proved to be particularly informative for patients with cognitive symptoms. These findings require confirmation in a larger study.

Wang et al. (2014) investigated the right and left hemispheric auditory sensory gating of the M50 (preattentive processing) and M100 (early attentive processing) in patients diagnosed with bipolar I disorder by utilizing magnetoencephalography (MEG). Whole-head MEG data were acquired during the standard paired-click paradigm in 20 patients with bipolar I disorder and 20 healthy controls. The M50 and the M100 responses were investigated, and dipole source localizations were also investigated. Sensory gating was determined by measuring the strength of the M50 and the M100 response to the second click divided by that of the first click (S2/S1). In every subject, M50 and M100 dipole sources localized to the left and right posterior portion of superior temporal gyrus (STG). Bipolar I disorder patients showed bilateral gating deficits in M50 and M100. The bilateral M50 S2 source strengths were significantly higher in the bipolar I disorder group compared to the control group. More studies with larger sample sizes are warranted to evaluate the use of MEG in this patient population.

Several studies have evaluated the efficacy of MEG for identification of structural characteristics of the brain in patients with schizophrenia. Escudero et al. (2013) evaluated the frequency spectrum of the magnetoencephalogram (MEG) background activity in 15 schizophrenia (SCH) patients with predominant positive symptoms and 17 age-matched healthy control subjects. The authors classified the MEG signals by means of a cross-validated feature selection process followed by a logistic regression. The subjects were classified with 71.3% accuracy. According to the authors, the spectral and classification analysis of the MEG in SCH may provide insights into how this condition affects the brain activity and may help in its early detection. Hinkley et al. (2011) used magnetoencephalography (MEG) to identify brain regions that exhibit abnormal resting-state connectivity in patients with schizophrenia and investigated associations between functional connectivity and clinical symptoms in stable outpatient participants. Thirty patients with schizophrenia and 15 healthy comparison participants underwent MEG. The authors concluded that there are direct functional disconnections in schizophrenia between specific cortical fields within low-frequency resting-state oscillations. According to the authors, the findings of the study indicate that this level of functional disconnection between cortical regions is an important treatment target in schizophrenia. These studies were limited by lack of randomization and small sample size. Based on the theory that the gating deficit in schizophrenia patients constitutes a genetic trait, Bachmann et al. (2010) expected to demonstrate the phenomenon in first-episode schizophrenia patients by using MEG. Eighteen inpatients in remission of their first psychotic episode and 24 healthy, age- and sex-matched control subjects participated in the study. According to the investigators, MEG did not reveal impaired sensory gating in schizophrenia patients.

Domínguez et al. (2013) evaluated an approach to discriminate between typical and atypical brains from macroscopic neural dynamics recorded as magnetoencephalograms (MEG). Functional connectivity and background noise in juvenile patients (n=9) with Asperger’s syndrome (ASD) was compared to age-matched juvenile control subjects (n=10). The analysis revealed significant alterations in both functional brain connectivity and background noise in ASD patients. Although the detailed physiological mechanisms underlying these alterations cannot be determined from macroscopic brain recordings, the authors speculated that enhanced occipital-frontal excitation may result from changes in white matter density in ASD. The authors concluded that the results of this study demonstrate a promising potential of this approach as an efficient biomarker for altered brain dynamics associated with a cognitive phenotype. Further research is needed to determine the clinical relevance of these findings.

There is insufficient evidence to support the use of MSI/MEG for other indications including the diagnosis and treatment of various neurological conditions such as autism, cognitive and mental disorders, learning disorders, schizophrenia, stroke, and traumatic brain injury. There is no reliable data from well designed clinical studies that report the test performance and clinical utility of MSI/MEG for these indications.

The clinical evidence was reviewed on March 7, 2017 with no information identified that would change the conclusion of unproven.

**Professional Societies**

**American Academy of Neurology (AAN)**

The 2009 AAN policy for use of MEG states that MEG indications include:

- 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.
- Pre-surgical evaluation of brain tumors and vascular malformations. The aim is to identify, localize, and preserve eloquent cortex during resective surgery.

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According to the AAN, the limitations of MEG include:

- MEG cannot replace, but may guide the placement of intracranial EEG and, in some patients, avoid an unnecessary intracranial EEG.
- MEG is not the first order of test after clinical and routine EEG diagnosis of epilepsy. It is one of several advanced pre-surgical investigative technologies. The need for MEG is much lower than surface EEG and anatomical imaging studies.
- 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.

American College of Radiology (ACR)
The ACR has developed Appropriateness Criteria for a number of clinical conditions, including epilepsy. MEG/MSI was assigned an appropriateness score of 2 out of a possible 9 for new on-set seizure variants. The ACR gave MEG/MSI a rating of 6 for medically refractory epilepsy; surgical candidate or surgical planning. The ACR criteria for this variant states that MEG/MSI may identify ictal onset zone (IOZ) in nonlesional patients (normal MRI), can provide confirmatory localization information, and may guide placement of intracranial electrodes (Ieeg). MEG/MSI may also substitute for invasive testing and may be useful when other tests are discordant. The ACR Rating Scale is as follows: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate (ACR, 1996, Updated 2014).

American Clinical Magnetoencephalography Society (ACMEGS)
The ACMEGS published a position statement on the value of MEG/MSI in noninvasive presurgical evaluation of patient with medically intractable localization-related epilepsy. According to the ACMEGS statement, it is only when traditional electroencephalograms (EEG) studies (routine laboratory, ambulatory, and video-EEG long-term monitoring) fail to deliver sufficient localizing information for planning a direct surgical intervention or invasive monitoring that MEG is indicated.

After considering the entire body of published evidence through April 20, 2009, including a milestone class I study (Sutherland, et al., 2008), the ACMEGS supports the following (Bagic, et al., 2009):

- Routine clinical use of MEG/MSI in obtaining noninvasive, non-redundant 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.

According to the Clinical Practice Guideline Committee of the American Clinical Magnetoencephalography Society for recording and analysis of spontaneous cerebral activity, 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, 2011).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)
Magnetoencephalography (MEG) devices are classified 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. A number of devices have been cleared for marketing. See the following web site for more information (use product codes GWQ (electroencephalograph); LNH (system, nuclear magnetic resonance imaging); OLY (magnetoencephalograph); OLX (source localization software for electroencephalograph or magnetoencephalograph). Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed March 7, 2017)

Additional Product Information
There are several types of magnetoencephalography (MEG) equipment available including: Whole-Cortex MEG System (VSM MedTech Ltd and its subsidiary, CTF Systems Inc, Port Coquitlam, BC, Canada); Magnes® WH MEG 2500 and 3600 Series (4-D Neuroimaging, formerly Biomagnetic Technologies Inc, San Diego, CA); MEGvision EQ1000C Series (Eagle Technologies, Santa Fe, NM, a subsidiary of Yokogawa in Japan); Neuromag™ (Elekta, AB, Sweden).

REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2017T0172Q]


POLICY HISTORY/REVISION INFORMATION

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| 07/01/2017   | • Updated coverage rationale; removed language indicating services are “considered to be” proven/medically necessary or unproven/not medically (no change to coverage guidelines)  
• Updated supporting information to reflect the most current clinical evidence and references  
• Archived previous policy version DIAGNOSTIC 029.15 T2                                      |