Clinical Policy Title: Magnetoencephalography and magnetic source imaging

Clinical Policy Number: 09.01.07

Effective Date: January 1, 2015
Initial Review Date: July 16, 2014
Most Recent Review Date: June 5, 2018
Next Review Date: June 2019

Related policies:
CP# 09.01.05 Ambulatory and video electroencephalogram

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of magnetoencephalography and magnetic source imaging to be clinically proven and, therefore, medically necessary for either (InterQual®, 2017; American College of Radiology, 2014; American Academy of Neurology, 2009):

- Pre-surgical evaluation in persons with intractable focal epilepsy to identify and localize areas of epileptic form activity when other imaging studies (electroencephalogram (EEG) and anatomic imaging, e.g., magnetic resonance imaging) are discordant or nondiagnostic for location and extent of seizure focus, and member is a candidate for invasive electroencephalogram monitoring.
- Pre-surgical mapping of the eloquent cortex prior to surgical resection of brain tumor or surgery to correct vascular malformations.

Limitations:

Policy contains:
- Refractory epilepsy.
- Glioma.
- Magnetoencephalography.
- Magnetic source imaging.
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of magnetoencephalography and magnetic source imaging are not medically necessary.

**Alternative covered services**

- Electroencephalogram.
- Head computed tomography with contrast.
- Magnetic resonance imaging with or without contrast.
- Head functional magnetic resonance imaging without contrast.
- Positron emission tomography with F-18 fluorodeoxyglucose/head computed tomography.
- Ictal single photon emission computed tomography.
- Intracarotid amobarbital anesthesia test (Wada test).

**Background**

Functional mapping of the motor cortex is used to assist surgeons in delineating the location of functionally important brain tissue. Direct cortical stimulation is often the reference standard for brain mapping, but it is invasive and primarily used intraoperatively. Noninvasive preoperative methods have emerged that provide functional information to guide decisions concerning disease management. These methods include functional magnetic resonance imaging, positron emission tomography, and magnetoencephalography, among others (Hayes, 2008).

Magnetoencephalography involves external monitoring and recording of the weak magnetic fields associated with naturally-occurring electrical currents within the brain. Changes in the neuromagnetic field provide information about brain function. The most commonly-used type is the superconducting quantum interference device, or SQUID.

Magnetic source imaging co-registers a magnetoencephalograph with magnetic resonance imaging. It is a noninvasive technique for evaluating brain function and for preoperative planning in patients with a variety of neurological disorders, such as tumors, arteriovenous malformations, epilepsy, trauma, stroke, and neuropsychiatric conditions (Hayes, 2008). Purported clinical uses of magnetic source imaging include: diagnosis of seizure disorders and mass lesions not definable by standard methods; determination of cerebral characteristics in patients with psychiatric disorders; and assessment of normal and abnormal language development (Hayes, 2008).

Advantages of magnetic source imaging are high spatiotemporal resolution, insensitivity to conductivity differences (including skull defects and lesions), high signal-to-noise ratio in superficial areas, focus localization, and functional mapping. Disadvantages have been stated as metal implant artefact, cost,
insensitivity to radial sources, less sensitivity to deep sources (gradiometers), and limited long-term monitoring feasibility, i.e., low likelihood of ictal recordings (Stephan, 2011).

Searches

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 16, 2018. Search terms were: “magnetoencephalography (MeSH),” “MEG,” “Magnetic Source Imaging,” “MSI,” and “Brain Diseases” (MeSH).

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use pre-determined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and thus are rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

We identified one comprehensive review by Hayes (2008), along with two systematic reviews (Burch, 2012a; Lau, 2008), one cost-effectiveness analysis (Burch, 2012a), and one decision analysis (Widjaja, 2013) published subsequent to the Hayes review, which serve as the basis for this policy.

The preponderance of studies of magnetoencephalography and magnetic source imaging has been conducted in adults for the noninvasive, pre-surgical evaluation of localization-related refractory epilepsy. Conditions with less definitive evidence examined in the systematic reviews were pretreatment assessment and operative planning in patients with brain lesions (tumors and arteriovenous malformations) and assessment of neuropsychiatric and learning disorders.

**Pre-surgical evaluation in patients with intractable focal epilepsy:**

Evidence from systematic reviews is overall of low quality with a high degree of bias. Studies focus on diagnostic accuracy and lack sufficient information to determine the effect of magnetoencephalography on informing clinical practice with reasonable certainty.
That said, Burch (2012a) noted the difficulties in assessing diagnostic technologies used for the purpose of localizing surgical sites that may relieve seizures. The factors that result in surgical cure are not fully understood. An intracranial electroencephalogram is an imperfect reference standard, and, consequently, correlations to intracranial electroencephalogram are imperfect. An intracranial electroencephalogram is an invasive procedure that carries risks of complications, and many patients apparently drop out of the diagnostic workup before having this test. It is not an “independent” reference standard, because the results of prior diagnostic tests are taken into account in the decision as to where and how to place the electrodes. Finally, it does not always provide sufficient diagnostic information, and surgical cure can be achieved in the context of a positive or negative noninvasive test of any kind (Burch, 2012b).

All pre-surgical patients with epilepsy generally undergo magnetic resonance imaging and video electroencephalogram. Patients with lesional epilepsy, sufficiently localized on these studies, proceed to surgery. Patients who have unclear or discordant test results may proceed to other noninvasive tests, such as F-18 fluorodeoxyglucose-positron emission tomography, ictal single photon emission computed tomography, or magnetoencephalography to provide additional information known to correlate with seizure focus. At this point, a decision is made whether to proceed to intracranial electroencephalogram.

Existing studies of diagnostic accuracy suggest the sensitivity or specificity of magnetoencephalography alone is not sufficiently high to bypass intracranial electroencephalogram in patients proceeding to surgery or to stop the workup. Magnetoencephalography may help guide placement of intracranial electroencephalogram and, given the gravity of the situation and the uncertainty in determining who should receive surgery, magnetoencephalography may provide information that might influence a patient’s decision to undergo the risks of further testing or surgery if the outcome can be slightly better estimated. The decision to proceed to surgery appears to be based not on strict decision rules, but on the strength and consistency of findings that indicate the possibility of removing the part of the brain causing seizures (Burch, 2012b).

Some studies have documented positive post-surgical outcomes in epilepsy patients who had undergone magnetoencephalography/magnetic source imaging prior to surgery. One found 85 percent of patients with specific magnetoencephalography findings were seizure free, for mean period of 3.6 years (Englot, 2015). In another study, magnetic source imaging found non-redundant (from an electroencephalogram) information in 33 percent of epileptic patients, and the findings changed the surgical decision in 20 percent (Sutherling, 2008).

The evidence is sufficient to support the medical necessity of magnetoencephalography/magnetic source imaging for pre-surgical evaluation in persons with intractable focal epilepsy to identify and localize areas of epileptiform activity, when standard techniques, such as video electroencephalogram and magnetic resonance imaging, are inconclusive. The American College of Radiology (2014) and the American Academy of Neurology (2009) acknowledges the uncertainty in the information and
recommend using magnetoencephalography or magnetic source imaging as one of several neuroimaging options available, when surface electroencephalogram and anatomical imaging studies are inconclusive. To realize its optimum clinical potential, a comprehensive evaluation performed in epilepsy referral centers is necessary.

Other indications and populations:

Other purported uses include identifying Multiple Sclerosis, Alzheimer’s disease, Sjogren’s syndrome, chronic alcoholism, and facial pain; little conclusive information exists for the test’s ability to diagnose these conditions. Magnetoencephalography/magnetic source imaging is also used to study vision, audition, and language processing in the fetus and infant – also with no conclusive information on efficacy.

There is a paucity of evidence evaluating the clinical utility of magnetoencephalography/magnetic source imaging for other indications and, specifically, in pediatric populations. A critique of the state of knowledge of neuroimaging for language impairment in children identified similar methodological limitations in the literature to those cited by Burch (2012a): lack of an adequate control group, inadequate power, incomplete reporting of data, no correction for multiple comparisons, data dredging, and failure to analyze treatment effects appropriately (Bishop, 2013). Therefore, the evidence is insufficient to support the medical necessity of magnetoencephalography/magnetic source imaging for any other indication.

Policy updates:

In 2016, additional evidence is emerging on the use of magnetoencephalography/magnetic source imaging for brain tumors and vascular malformations. The American Academy of Neurology (2009) recommended magnetoencephalography for the pre-surgical evaluation of brain tumors and vascular malformations to identify, localize, and preserve eloquent cortex during respective surgery. Their recommendation was based on limited, low-quality evidence from two retrospective studies. Results from two additional, low-quality studies suggested magnetoencephalography could provide pre-surgical information of tissue functionality to guide more precise surgical strategy and patient counseling, thereby improving patient outcomes (Tarapore, 2012; Ganslandt, 2004). Although comparison of magnetoencephalography to intraoperative mapping and other non-invasive techniques is lacking, the evidence is sufficient to support magnetoencephalography/magnetic source imaging as one of several non-invasive, pre-surgical options for evaluating cortical motor function in patients with brain tumors or vascular malformations.

In 2017, we found no new information to add to the policy. No policy changes are warranted.

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Summary of clinical evidence:
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Englot (2015)</strong></td>
<td><strong>Key points:</strong></td>
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| Trial of post-surgical seizures in epilepsy patients with magnetoencephalography | - Cohort of 132 subjects with focal epilepsy who had surgery after magnetoencephalography, followed mean 3.6 years.  
- Eighty-six percent with specific magnetoencephalography findings were seizure-free.  
- Thirty-seven percent with non-specific magnetoencephalography findings were seizure free. |
| **Widjaja (2013)**     | **Key points:**                                                                                   |
| Pre-surgical evaluation of localization-related epilepsies | - Markov-based decision model: patients with suspected focal intractable epilepsy on video scalp electroencephalogram with normal magnetic resonance imaging findings.  
- Positron emission tomography + magnetoencephalography and single photon emission computed tomography were the preferred strategies in the base case. The choice of test depended on the sensitivity and specificity of test strategies and willingness to pay. High degree of uncertainty. |
| **Burch (2012a)**      | **Key points:**                                                                                   |
| Pre-surgical evaluation of localization-related epilepsies | - Systematic review of five diagnostic accuracy studies and one study of outcome prediction using magnetoencephalography/magnetic source imaging to define the seizure focus in surgical candidates with refractory partial epilepsy not caused by tumors, vascular malformations or trauma.  
- Overall quality of the available evidence was poor.  
- There is no acceptable reference standard; reporting of clinical outcomes tends to follow after surgery; and decision level and clinical effectiveness studies are lacking. The additional value of diagnostic technologies for the localization of epileptic foci is related to the impact on treatment decisions and the value of the treatments themselves; this needs to be considered fully in informing cost-effectiveness.  
- Available evidence is unreliable to inform clinical practice on the use of magnetoencephalography. |
| **Tarapore (2012)**    | **Key points:**                                                                                   |
| Magnetoencephalography ability to predict post-surgical neurological outcomes in subject with brain gliomas | - Seventy-nine subjects with focal brain gliomas, all had pre-surgical magnetoencephalography.  
- No subjects had new neurological deficits six months post-operatively.  
- Conclusion: magnetoencephalography provides valuable pre-surgical information on tissue functionality, optimizing pre-surgical patient counseling and surgical strategy in subjects with glioma. |
| **Hayes (2008)**       | **Key points:**                                                                                   |
| Magnetoencephalography/magnetic source imaging for | - Nineteen case series; sample sizes ranged from 40 to 455 patients.  
- Low quality with high risk of bias. |
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| epilepsy, structural brain lesions, psychiatric/learning disorders | - Lack of large, well-designed, randomized studies, lack of postsurgical outcomes, heterogeneity of study populations and the diversity among both interventions and outcome measures.  
- Mostly adult patients, very little evidence regarding the use in children.  
- Most of the available studies failed to report any follow-up, although five studies reported follow-up of ≥ 1 year.  
- No evidence magnetoencephalography/magnetic source imaging reduces the morbidity or mortality associated with epilepsy, brain lesions, or neuropsychiatric or learning disorders.  
- Insufficient evidence.                                                                                                                                               |
| Lau (2008) Pre-surgical evaluation of localization-related epilepsies | **Key points:**  
- Systematic review of 17 studies of magnetoencephalography/magnetic source imaging.  
- Sensitivity 0.84 (range: 0.20 – 1.0) values for all articles, specificity 0.52 (0.06 – 1.00) values, positive likelihood ratios (0.67 – 2.0) and negative likelihood ratios (0.40 – 2.13) for some studies compared with the reference standard of intracranial electroencephalogram and surgical outcome.  
- Insufficient evidence to support the relationship between the use of magnetoencephalography in surgical planning and seizure-free outcome after epilepsy surgery. |

**References**

**Professional society guidelines/other:**

ACR Appropriateness Criteria: Seizures and Epilepsy. 2014. ACR website.  


InterQual® 2017 Imaging Criteria. Magnetoencephalography (MEG), Brain. McKesson Corporation.


Peer-reviewed references:


CMS National Coverage Determinations (NCDs):
No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<tr>
<td>95965</td>
<td>Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex localization).</td>
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<td>Focal epilepsy, intractable, with status epilepticus</td>
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<td>G40.019</td>
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<th>Description</th>
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