Magnetoencephalography/Magnetic Source Imaging

Policy # 00082
Original Effective Date: 03/25/2002
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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 intractable epilepsy (seizures refractory to at least two first-line anticonvulsants) 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 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 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.

The technique is sophisticated. 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 1 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.

One clinical application is localization of epileptic foci, particularly for screening of surgical candidates and surgical planning. Alternative techniques include MRI, positron emission tomography (PET), 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 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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
FDA-cleared magnetoencephalography devices include the 700 Series Biomagnetometer (Biomagnetic Technologies, San Diego, CA) cleared in 1990 and subsequent devices (K901215, K941553, K962317, K993708); the CTF Whole-Cortex MEG System (CTF Systems, British Columbia, Canada) cleared in 1997 and subsequent devices (K971329, K030737); and the Elekta Oy (Elekta Neuromag, Helsinki, Finland) cleared in 2004 and subsequent devices (K041264, K050035, K081430, K091393). FDA Product code: OLX.

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."1 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."

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Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source
The most recent literature review covers the period through November 2015. The literature review will discuss in separate sections the rationale for use of magnetoencephalography (MEG)/magnetic source imaging (MSI) for (1) localization of seizure focus and (2) localization of eloquent areas.

Localization of Seizure Focus
This section is based on a 2008 Technology Evaluation Centers (TEC) Special Report reviewing the evidence regarding MEG for localization of epileptic lesions. Magnetoencephalography has been proposed as a method for localizing seizure foci for patients with normal or equivocal MRI and negative video-EEG examinations, so-called "nonlesional" epilepsy. Such patients often undergo MEG, PET, or ictal-SPECT tests to attempt to localize the seizure focus. They then often undergo invasive intracranial EEG, a surgical procedure in which electrodes are inserted next to the brain. Magnetoencephalography would be considered useful if, when compared to not using MEG, it improved patient outcomes. Such improvement in outcomes would include more patients being rendered seizure-free, use of a less invasive and morbid diagnostic workup, and increased surgical success rates. This is a complicated array of outcomes that has not thoroughly been evaluated in a comprehensive manner. Because MEG is used to make decision regarding further diagnostic testing, which may affect the decision to have surgery and the extent of surgery, solely examining surgical outcomes excludes the assessment of outcomes of patients who did not have surgery.

Ideally, a randomized trial comparing the outcomes of patients who receive MEG as part of their diagnostic workup compared to patients who do not receive MEG could determine whether MEG improves patient outcomes. However, almost all of the studies evaluating MEG have been retrospective, where MEG, other tests, and surgery have been selectively applied to patients. Since patients often drop out of the diagnostic process before having intracranial electroencephalography (IC-EEG), and many patients ultimately do not undergo surgery, most studies of associations between diagnostic tests and between diagnostic tests and outcomes are irreparably biased by selection and ascertainment biases. For example, studies that evaluate the correlation between MEG and IC-EEG invariably do not account for the fact that MEG information was used to deselect a patient from undergoing IC-EEG. In addition, IC-EEG findings only imperfectly correlate with surgical outcomes, meaning that it is an imperfect reference standard.

Numerous studies have shown associations between MEG findings and other noninvasive and invasive methods diagnostic tests, including IC-EEG, and between MEG findings and surgical outcomes. However, such studies do not allow any conclusions regarding whether MEG added incremental information to aid the management of such patients and whether patients' outcomes were improved as a result of the additional diagnostic information.
A representative study of MEG by Knowlton and colleagues demonstrates many of the problematic issues of evaluating MEG. In this study of 160 patients with nonlesional epilepsy, all had MEG, but only 72 proceeded to IC-EEG. The calculations of diagnostic characteristics of MEG are biased by incomplete ascertainment of the reference standard. However, even examining the diagnostic characteristics of MEG using the 72 patients who underwent IC-EEG, sensitivities and specificities were well below 90%, indicating the likelihood of both false-positive and false-negative studies. Predictive values based on these sensitivities and specificities mean that MEG can neither rule in nor rule out a positive IC-EEG, meaning that MEG cannot be used as a triage test before IC-EEG to avoid the potential morbidity in a subset of patients.

One study more specifically addresses the concept that MEG may improve the yield of IC-EEG, thus allowing more patients to ultimately receive surgery. In a study by Knowlton et al., out of 77 patients who were recommended to have IC-EEG, MEG results modified the placement of electrodes in 18 of the 77 cases. Seven cases out of the 18 had positive intracranial seizure recordings involving the additional electrodes placed because of the MEG results. It was concluded that 4 patients are presumed to have had surgery modified as a result of the effect of MEG on altering the placement of electrodes.

Several studies correlate MEG findings to surgical outcomes. Lau et al. performed a meta-analysis of 17 such studies. In this meta-analysis, sensitivity and specificity have unorthodox definitions. Sensitivity is the proportion of patients cured with surgery in whom the MEG-defined epileptic region was resected, and specificity is the proportion of patients not cured with surgery in whom the MEG-defined epileptic region was not resected. The pooled sensitivity was 0.84, meaning that among the total number of cured patients, 16% occurred despite the MEG-defined region not being resected. Pooled specificity was 0.52, meaning that among 48% of patients not cured, the MEG-localized region was resected. These results are consistent with an association between resection of the MEG-defined region and surgical cure, but that it is an imperfect predictor of surgical success. However, it does not address the question as to whether MEG contributed original information to improve the probability of cure. In a retrospective review of 22 children with medically intractable focal epilepsy (median age at epilepsy surgery, 11 years), Kim et al (2013) used a cutoff of 70% or more for the number of MEG-identified spike dipole sources located within the resection margin to define a positive study. Sensitivity, specificity, and positive and negative predictive values for seizure-free status postoperatively was 67%, 14%, 63%, and 17%, respectively.

Other studies imply a value to MEG, but it is difficult to make firm conclusions regarding its value. In a study by Schneider et al., 14 patients with various findings on MEG, IC-EEG, and interictal SPECT underwent surgery for nonlesional neocortical focal epilepsy. Concordance of IC-EEG and MEG occurred in 5 patients, 4 of whom became seizure-free. This concordance of the 2 tests was the best predictor of becoming seizure-free. Although this was prognostic for success, whether this would actually change surgical decision making, such as declining to operate where there is not such concordance, is uncertain. A similar study by Widjaja et al. shows that concordance of MEG findings with the location of surgical resection is correlated with better seizure outcomes. However, the authors admit that MEG is entrenched in clinical practice, and the decision to proceed further in diagnostic and therapeutic endeavors is based on the results of MEG and other tests.
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Other case series of surgical patients have suggested a value to MEG. A study by Albert et al reviewed a series of pediatric patients undergoing surgery for epilepsy who had only undergone noninvasive monitoring prior to surgery. MEG was proposed to have avoided the need for the morbidity associated with invasive monitoring. Of 16 patients, 62.5% were seizure-free following surgery, and 20% experienced improvement. Two cases required additional surgery with invasive monitoring. Although most patients improved, it cannot be determined whether the outcomes were equivalent to the standard practice of pre-resection invasive monitoring. A study by Wang et al compared 18-fluoro-deoxyglucose positron emission tomography (FDG-PET) and MEG in identifying the epileptogenic zone, using invasive monitoring as the reference standard. FDG-PET identified the zone in 8 (50%) of patients and MEG identified the zone in 12 (75%) of patients. Although MEG was more sensitive than FDG-PET in this study, it still missed epileptogenic areas identified by invasive monitoring. Another recent study by Koptelova et al compared MEG with video EEG monitoring in 22 patients. Of 75 “irritative” zones identified in the 22 patients by either method, a higher proportion was identified by MEG. Note that there is no true reference standard in this type of analysis. However, in analyses of intraoperative EEG, several zones identified only with this method were only identified by MEG, confirming to some extent increased sensitivity over video EEG. These recent studies suggest clinical utility for MEG in evaluation of epilepsy patients, but, due to the aforementioned problems, firm conclusions about the clinical utility of MEG cannot be determined.

In 2009, the American Clinical MEG Society released a position statement that supported routine clinical use of MEG/MSI for presurgical evaluation of patients with medically intractable seizures. In this statement, a 2008 study by Sutherling et al is cited as being a “milestone class I study.” Class I evidence usually refers to randomized comparisons of treatment. However, the study by Sutherling et al is called by its authors a “prospective, blinded crossover-controlled, single-treatment, observational case series.” The study attempted to determine the proportion of patients in whom diagnostic or treatment strategy was changed as a consequence of MEG. They concluded that the test provided nonredundant information in 33% of patients, changed treatment in 9% of surgical patients, and benefited 21% of patients who had surgery. There was no control group in this study. Benefit of MEG was inferred by assumptions of what might have occurred in the absence of MEG results. Less than half of 69 enrolled patients went on to receive IC-EEG; thus, there appeared to be incomplete accounting for outcomes of all patients in the study. A similar study by De Tiege et al (2012) also attempted to determine the number of patients in whom management decisions were altered based on MEG results. The authors concluded that clinical management was altered in 13% of patients.

Section Summary: Localization of Seizure Focus
There are no clinical trials demonstrating clinical utility of MEG in determining location of seizure focus and no high-quality studies of diagnostic accuracy. Available evidence on diagnostic accuracy is limited by ascertainment and selection biases because MEG findings were used to select and deselect patients in the diagnostic pathway, thus making it difficult to determine the role of MEG for the purpose of seizure localization. Evidence supporting the effect of MEG on patient outcomes is indirect and incomplete. Surgical management may be altered in a minority of patients based on MEG, but there is insufficient evidence to conclude that outcomes are improved as a result of these management changes. Trials with a control group are needed to determine whether good outcomes can be attributed to the change in management induced by knowledge of MEG findings.
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Localization of Eloquent and Sensorimotor Areas
A 2003 TEC Assessment of MEG concluded that evidence for this particular indication was insufficient to
demonstrate efficacy. At that time, studies reviewed had relatively weak designs and small sample sizes.
There are 2 ways to analyze the potential utility of MEG for this indication: MEG could potentially be a
noninvasive substitute for the Wada test, which is a standard method of determining hemispheric
dominance for language. The Wada test requires catheterization of the internal carotid arteries, which
carries the risk of complications. The determination of language laterality is important to know to determine
the suitability of a patient for surgery and what types of additional functional testing might be needed before
or during surgery. If MEG provided concordant information with the Wada test, then such information would
be obtained in a safe, noninvasive manner.

Several studies have shown high concordance between the Wada test and MEG. In the largest study, by
Papanicolaou et al (2004), among 85 patients, there was concordance between the MEG and Wada tests in
74 (87%). In no cases were the tests discordant in a way that the findings were completely opposite.
Discordant cases occurred mostly when the Wada test indicated left dominance and MEG indicated
bilateral language function. In an alternative type of analysis, when the test is being used to evaluate the
absence or presence of language function in the side in which surgical treatment is being planned, using
the Wada procedure as the criterion standard, MEG was 98% sensitive and 83% specific. Thus, if the
presence of language function in the surgical site requires intraoperative mapping and/or a tailored surgical
approach, use of MEG rather than Wada would have “missed” 1 case where such an approach would be
needed (false-negative MEG), and resulted in 5 cases where such an approach was unnecessary (false
positive MEG). However, it should be noted that the Wada test is not a perfect reference standard, and
some discordance may reflect inaccuracy of the reference standard. In another study by Hirata et al (2004),
MEG and the Wada test agreed in 19 (95%) of 20 cases.

The other potential use (utility) of MEG would be to map the sensorimotor area of the brain, again to avoid
such areas in the surgical resection area. Intraoperative mapping just before resection is generally done as
the reference standard. Preoperative mapping as potentially done by MEG might aid in determining the
suitability of the patient for surgery or for assisting in the planning of other invasive testing. Similar to the
situation for localization of epilepsy focus, the literature is problematic in terms of evaluating the
comprehensive outcomes of patients due to ascertainment and selection biases. Studies tend to be limited
to correlations between MEG and intraoperative mapping. Intraoperative mapping would be performed
anyway in most resection patients. Several studies evaluated in the 2003 TEC Assessment showed good to
high concordance between MEG findings and intraoperative mapping. A 2006 technology assessment of
functional brain imaging prepared by the Ontario Ministry of Health reviewed 10 studies of MEG and
invasive functional mapping and showed good to high correspondence between the 2 tests. However, these
studies do not demonstrate that MEG would replace intraoperative mapping or reduce the morbidity of such
mapping by allowing a more focused procedure.

Recent studies of the use of MEG in localizing the sensorimotor area provide only indirect evidence of
utility. A 2013 study by Niranjan et al reviewed results of 45 patients in whom MEG was used for localizing
somatosensory function. In 32 patients who underwent surgery, surgical access routes were planned to
avoid regions identified as somatosensory by MEG. All patients retained somatosensory function. It is
unknown to what extent MEG provided unique information not provided by other tests. In a 2012 study by Tarapore et al, 24 patients underwent MEG, transcranial magnetic stimulation, and intraoperative direct cortical stimulation to identify the motor cortex. MEG and navigated transcranial magnetic stimulation were both able to identify several areas of motor function, and the median distance between corresponding motor areas was 4.71 mm. When comparing MEG with direct cortical stimulation, median distance between corresponding motor sites (12.1 mm) was greater than the distance between navigated transcranial magnetic stimulation and direct cortical stimulation (2.13 mm). This study cannot determine whether MEG provided unique information that contributed to better patient outcomes.

Section Summary: Localization of Eloquent and Sensorimotor Areas
There are no clinical trials that demonstrate the clinical utility of using MEG for localization and lateralization of eloquent and sensorimotor regions of the brain. Available evidence comprises studies that correlate results of MEG with the Wada test, which is an alternative method for localization. Evidence generally shows that concordance between MEG and the Wada test is high. Because MEG is a less invasive alternative to the Wada test, this evidence indicates that it is a reasonable alternative. There is also some evidence that the correlation of MEG with intraoperative mapping of eloquent and sensorimotor regions is high, but the test has not demonstrated sufficient accuracy to replace intraoperative mapping.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
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<td>Partial epilepsy</td>
<td>Contribution of Multimodal Imaging (MRI, PET, MEG) in Pre-surgical Evaluation of Drug-resistant Focal Epilepsy</td>
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<td>May 2016</td>
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<td>Cerebral primitive tumor</td>
<td>Magnetoencephalographic Study of Glial Tumors Electromagnetic Signature</td>
<td>28</td>
<td>Aug 2017</td>
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<td>Fibromyalgia</td>
<td>Brain Rhythms in Fibromyalgia: A Magnetoencephalography (MEG) Study (FMP)</td>
<td>40</td>
<td>Jun 2015 (completed)</td>
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<td>Schizophrenia</td>
<td>Multi-site Communication Deficits Underlying Cognitive Dysfunction in the Prodromal Phase and First Episode of Schizophrenia</td>
<td>144</td>
<td>Jun 2016</td>
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<td>Movement disorders</td>
<td>Defining Cognitive and Motor Phenotypes of Parkinson's Disease (PD) With Magnetoencephalography</td>
<td>18</td>
<td>Dec 2015</td>
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<td>Mild traumatic brain injury</td>
<td>Multimodal Approach to Testing the Acute Effects of Mild Traumatic Brain Injury (mTBI)</td>
<td>200</td>
<td>Feb 2017</td>
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<tr>
<td>Cognition</td>
<td>Functional Brain Imaging in Healthy Volunteers to Study Cognitive Functions</td>
<td>120</td>
<td>Apr 2023</td>
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NCT: national clinical trial.

Summary of Evidence
The evidence for magnetoencephalography (MEG)/magnetic source imaging (MSI) in patients who have intractable seizures and are being evaluated for possible resective surgery includes various types of case series. Relevant outcomes are test accuracy and functional outcomes. Published evidence on MEG is suboptimal, with no clinical trials demonstrating clinical utility. 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 are not fully accounted for in the studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for MEG/MSI in patients who have planned brain resection and require localization of eloquent function areas includes studies correlating MEG with other methods of localization. Relevant outcomes include test accuracy and functional outcomes. Available studies report that this test has high concordance with the Wada test, which is currently the main alternative for localizing eloquent functions. Management is changed in some patients based on MEG testing, but 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.

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.
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
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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
01/01/2017  Coding update: Removing ICD-9 Diagnosis Codes

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2015 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Applicable FARS/DFARS apply.

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*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 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. 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 the Blue Cross and Blue Shield Association TEC or other nonaffiliated 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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