Magnetoencephalography/Magnetic Source Imaging

Policy # 00082
Original Effective Date: 03/25/2002
Current Effective Date: 11/16/2015

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 are recorded externally. When this information is superimposed on an anatomic image of the brain, typically an MRI scan, the image is referred to as MSI. This technique has been studied for identifying “eloquent” areas of the brain for neurosurgical planning and for use in localization of epileptic foci.

Magnetoencephalography is a noninvasive functional imaging technique in which the weak magnetic forces associated with the electrical activity of the brain are recorded externally. Using mathematical modeling, the recorded data are then analyzed to provide an estimated location of the electrical activity. This information can be superimposed on an anatomic image of the brain, typically a MRI scan, to produce a functional/anatomic image of the brain, referred to as magnetic source imaging or MSI. The primary advantage of MSI is that while the conductivity and thus the measurement of electrical activity as recorded by the EEG is altered by surrounding brain structures, the magnetic fields are not. Therefore, MSI permits a high-resolution image.
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The technique is sophisticated. Detection of the weak magnetic fields depends on gradiometer detection coils coupled to a superconducting quantum interference device (SQUID) which requires a specialized room shielded from other magnetic sources. Mathematical modeling programs based on idealized assumptions are then used to translate the detected signals into functional images. In its early evolution, clinical applications were limited by the use of only one detection coil requiring lengthy imaging times, which, because of body movement, were also difficult to coordinate with the MRI. However, more recently the technique has evolved to multiple detection coils arranged in an array that can provide data more efficiently over a wide extracranial region.

One 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 the anatomy is distorted by underlying disease processes. In addition, the location of the eloquent functions is variable, even among healthy patients. 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 electrocorticography (ECoG). While 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, sometimes these techniques can be limited by the small surgical field. A preoperative test which is often used to localize the eloquent hemisphere is the Wada test. Magnetoencephalography/magnetic source imaging has been proposed as a substitute for the Wada test.

Another related 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 (SPECT) scanning. Anatomic imaging (i.e., MRI) is effective when epilepsy is associated with a mass lesion, such as a tumor, vascular malformation or hippocampal atrophy. If an anatomic abnormality is not detected, patients may undergo a PET scan. In a small subset of patients, extended EcoG or stereotactic electroencephalography (SEEG) with implanted electrodes is considered the gold standard for localizing epileptogenic foci. Magnetoencephalography/magnetic source imaging has principally been investigated as a supplement to or an alternative to invasive monitoring.

**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).

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
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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.”

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 September 17, 2014. 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 intra-cranial 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.

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
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The decision to proceed further in diagnostic and therapeutic endeavors is based on the results of MEG and other tests.

The American Clinical MEG Society released a position statement that supports the routine clinical use of MEG/MSI for pre-surgical evaluation of patients with medically intractable seizures. In this statement, they specifically cite a study by Sutherling et al. 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 the 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 the MEG result. Less than half of the 69 patients went on to receive IC-EEG; thus, there appears to be incomplete accounting for outcomes of all patients in the study. A similar study by De Tiege et al. also attempted to determine the number of patients in whom management decisions were altered based on MEG results. They concluded that clinical management was altered in 13% of all patients.

Section Summary
There are no clinical trials demonstrating the utility of MEG in determining location of seizure focus and no high-quality studies of diagnostic accuracy. The 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. The 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.

Localization of Eloquent and Sensorimotor Areas
In a 2003 TEC Assessment of MEG, the evidence for this particular indication concluded that the evidence was insufficient to demonstrate efficacy. At that time, the studies reviewed had relatively weak study methods and very limited numbers of subjects. There are two ways to analyze the potential utility of MEG for this indication. Magnetoencephalography 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 the laterality of the language function is important to know to determine the suitability of a patient for surgery and what types of additional functional testing might be needed prior to or during surgery. If MEG provides 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 and co-workers 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. The discordant cases occurred mostly when the Wada test indicated left dominance and the MEG indicated bilateral language function. In an alternative type of analysis where 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 gold 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, 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., MEG and the Wada test agreed in 19/20 (95%) of 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. Magnetoencephalography 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.

Conclusions
There are no clinical trials that demonstrate the utility of using MEG for localization and lateralization of eloquent and sensorimotor regions of the brain. The available evidence consists of studies that correlate results of MEG with the Wada test, which is an alternative method for localization. The evidence generally
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shows that the concordance between MEG and the Wada test is high. Since 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
An online search of ClinicalTrials.gov identified several studies of MEG/MSI for various indications (see Table 1). None are randomized. Additional ongoing studies with no completion date identified evaluate MEG/MSI in mood and anxiety disorders (NCT00024635, NCT00047853) and autism spectrum disorders (NCT01031407).

Table 1. Active Studies of MEG/MSI Listed at ClinicalTrials.gov

<table>
<thead>
<tr>
<th>NCT Number</th>
<th>Title</th>
<th>Enrollment(^a)</th>
<th>Completion Date(^b)</th>
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<tr>
<td>NCT01735032</td>
<td>Multimodal Imaging in Presurgical Evaluation of Epilepsy (EPIMAGE)</td>
<td>140</td>
<td>May 2016</td>
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<td>NCT02077504</td>
<td>Glial Tumors Electromagnetic Signature Study by Magnetoencephalography (MEG)</td>
<td>20</td>
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<td>NCT02159300</td>
<td>Brain Rhythms in Fibromyalgia: A Magnetoencephalography (MEG) Study (FMP)</td>
<td>80</td>
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<td>NCT01317121</td>
<td>Multi-site Communication Deficits in Schizophrenia</td>
<td>144</td>
<td>Jun 2015</td>
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<td>NCT02132052</td>
<td>Defining Phenotypes of Movement Disorders :Parkinson Plus Disorders (PD), Essential Tremor, (ET),Cortical Basal Degeneration, (CBD), Multiple Systems Atrophy (MSA), Magnetoencephalography (PHENO)</td>
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<td>NCT02069613</td>
<td>Multimodal Approach to Testing the Acute Effects of Mild Traumatic Brain Injury (mTBI)</td>
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<td>NCT01974427</td>
<td>Functional Brain Imaging in Healthy Volunteers to Study Cognitive Functions</td>
<td>120</td>
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\(^a\) Expected.
\(^b\) Estimated.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received from 2 physician specialty societies (5 reviewers) and 2 academic medical centers while this policy was under review in 2011. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. There was support for use of MEG/MSI for both localization of language function and as part of the preoperative evaluation of intractable seizures. Those providing clinical input indicated that use of MEG/MSI
in the preoperative evaluation leads to identification of additional people whose epilepsy may be cured using a surgical approach.

**Summary**

Published evidence on MEG is suboptimal, with no clinical trials demonstrating clinical utility. Literature on diagnostic accuracy has methodologic limitations, primarily selection bias and ascertainment bias. 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 in management lead to improved outcomes. Clinical input obtained in 2011 indicated consensus for use of MEG as a substitute for the Wada test in determining the laterality of language function in patients being considered for surgery to treat epilepsy, brain tumors, and other structural brain lesions. Clinical input also demonstrated consensus on use of MEG as part of the preoperative evaluation of patients with intractable epilepsy when standard techniques, such as magnetic resonance imaging (MRI), are inconclusive.

Based on available scientific literature, results of clinical input, and a strong indirect chain of evidence that outcomes are improved, MEG/MSI may be considered medically necessary as a substitute for the Wada test for the purpose of determining laterality of language function. Magnetoencephalography also may be considered medically necessary as part of the preoperative evaluation of patients with intractable epilepsy when standard techniques such as MRI are inconclusive.

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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.

Next Scheduled Review Date: 11/2016

Coding
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Applicable FARS/DFARS apply.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<td>ICD-9 Diagnosis</td>
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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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