Magnetic Resonance-Guided Focused Ultrasound

Policy # 00180
Original Effective Date: 09/22/2005
Current Effective Date: 11/16/2016

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 magnetic resonance–guided high-intensity ultrasound ablation for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy 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 magnetic resonance-guided high-intensity ultrasound ablation to be investigational* in all other situations including but not limited to:
• Treatment of uterine fibroids;
• Treatment of other tumors, eg, brain cancer, prostate cancer and breast cancer.

Background/Overview
Magnetic resonance–guided focused ultrasound (MRgFUS) is a noninvasive treatment that combines 2 technologies, focused ultrasound (US) and magnetic resonance imaging (MRI). The US beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. The US causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. The US waves from each sonication are focused at a focal point that has a maximum focal volume of 20 nm in diameter and 15 nm in height/length. This causes a rapid rise in temperature (ie, to approximately 65°C-85°C), which is sufficient to achieve tissue ablation at the focal point. In addition to providing guidance, the associated MRI can provide online thermometric imaging that provides a temperature “map” that can further confirm the therapeutic effect of the ablation treatment and allow for real-time adjustment of the treatment parameters.

U.S. Food and Drug Administration (FDA) has approved the ExAblate® MRgFUS system (InSightec Inc., Haifa, Israel) for 2 indications; treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone. The US equipment is specially designed to be compatible with MR magnets and is integrated into standard clinical MRI units. It includes a patient table, which includes a cradle housing the focused US transducer in a water or light oil bath. Some models of the device have a detachable cradle; only certain cradle types can be used for palliation of pain associated with metastatic bone cancer.
As noted, FDA has approved an MRgFUS for treatment of uterine fibroids, which is one of the most common conditions affecting women in the reproductive years. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain. There are several approaches that are currently available to treat symptomatic uterine fibroids: hysterectomy; abdominal myomectomy; laparoscopic and hysteroscopic myomectomy; hormone therapy; uterine artery embolization; and watchful waiting. Hysterectomy and various myomectomy procedures are considered the criterion standard treatment.

Regarding treating pain associated with bone metastases, the other FDA approved indication, the aim of MRgFUS treatment is to destroy nerves in the bone surface surrounding the tumor. Metastatic bone disease is one of the most common causes of cancer pain. Existing treatments include conservative measures (eg, massage, exercise) and pharmacologic agents (eg, analgesics, bisphosphonates, corticosteroids). For patients who fail the above treatments, standard care is use of external beam radiotherapy. However, a substantial proportion of patients have residual pain after radiotherapy, and there is a need for alternative treatments for these patients.

MRgFUS is also being investigated for treatment of other tumors, including breast, prostate, and brain tumors.

**FDA or Other Governmental Regulatory Approval**

**FDA Approval**

In October 2004, the ExAblate 2000 System (InSightec Inc., Haifa, Israel) was FDA approved via the premarket approval process for “ablation of uterine fibroid tissue in pre- or perimenopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure.” Treatment is indicated for women with a uterine gestational size of less than 24 weeks who have completed childbearing.

In October 2012, FDA approved the ExAblate System, Model 2000/2100/2100 VI via the PMA process. The intended use of the device is for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy. The device was evaluated through an expedited review process. FDA required a postapproval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

FDA product code: NRZ.

**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**

A June 2005 TEC Assessment on MRgFUS for symptomatic uterine leiomyomata found insufficient evidence of efficacy compared with conventional therapies. The policy was updated regularly with searches of the MEDLINE database. Most recently, the literature was reviewed through December 15, 2015. Following is a summary of the literature to date.
Assessment of efficacy for therapeutic interventions such as MRgFUS involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. The technology should be compared with the best alternative treatment when available, as is the case of MRgFUS for treating uterine fibroids. In the case of subjective outcomes such as pain or quality of life (QOL), a sham comparison is also appropriate. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as selection bias (eg, noncomparability of treatment groups) and observational bias (eg, the placebo effect).

**Uterine Fibroids**

In 2015, a pilot sham-controlled RCT with 20 patients was published by Jacoby et al. The study was designed as a feasibility study evaluating MRgFUS for treatment of uterine fibroids. The study included 20 premenopausal women with symptomatic uterine fibroids. Women who were pregnant or had a desire for future fertility were excluded. Patients were randomized to MRgFUS with ExAblate 2000 system (n=13) or a sham treatment not using thermal energy (n=7). The investigators did not specify primary outcomes. The sample size was selected, not to provide sufficient statistical power, but to assess the feasibility of a larger trial. All patients assigned to the MRgFUS group and 6 of 7 in the placebo group received their allocated treatment and all treated patients completed 3 months of follow-up. (Patients were unblinded at 3 months and those in the sham group were given the option of active treatment.)

Quality of life outcomes included the Uterine Fibroid Symptom and Quality of Life Questionnaire (UFS-QOL) which has subscales including the Symptom Severity Score (SSS) and Health Related Quality of Life (HRQL) score. The 36-Item Short-Form Health Survey (SF-36), which includes the Mental Component Summary (MCS) and Physical Component Summary (PCS), was also used. At both the 4- and 12-week follow-ups, there were no statistically significant differences (at the p<0.05 level) between the MRgFUS and the sham groups in the SSS, HRQL, PCS, or MCS scores. Change in uterine and fibroid volume, however, differed significantly between groups at 12 weeks. Uterine volume decreased by 17% in the MRgFUS group and by 3% in the sham group (p=0.04). Total fibroid volume decreased by 18% in the MRgFUS group and did not change in the sham group (p=0.03). The authors concluded that women would be willing to participate in a sham-controlled RCT of MRgFUS and that larger trials were feasible.

The remaining published studies are nonrandomized; there are no RCTs comparing MRgFUS to an alternative uterine fibroid treatment. A systematic review, published by Gizzo et al in 2014, identified 38 uncontrolled studies with a total of 2500 patients who underwent MRgFUS for treatment of uterine fibroids. All published studies included women older than age 18 years with symptomatic uterine fibroids, and most excluded patients who desired future pregnancies. Authors of the systematic review did not pool study findings.

A nonrandomized, pivotal study, designed for FDA approval of the ExAblate 2000 device, included 109 women treated with MRgFUS and 83 women treated with abdominal hysterectomy. The primary outcome was change in SSS, which is part of the validated UFS-QOL. Symptom severity is measured by 8 questions relevant to bulk and bleeding symptoms; it is a 0-to-100 scale, with the higher number representing greater severity of symptoms. Outcome data were initially reported for the MRgFUS group only. At 6-month follow-
up, 71% of the MRgFUS group achieved a 10-point or greater reduction in SSS, but this decreased to 51% at 12 months. It is unclear what represents a clinically meaningful change in SSS. A threshold of more than 10 points was selected for the analysis, but this threshold is somewhat arbitrary and not substantiated by other research. Twenty-one percent of those treated by MRgFUS needed additional surgical treatment, and 4% underwent a repeat MRgFUS by 12 months.

In 2009, Taran et al reported outcomes for the hysterectomy group. The Taran article did not include the original primary outcome measure, SSS scores, and instead reported findings on a different QOL measure, the SF-36; also reported were safety data. A significantly higher proportion of women in the hysterectomy group (82/83 [99%]) reported at least 1 adverse event (AE) compared with women in the MRgFUS group (88/109 [81%]). Pain or discomfort, AEs associated with the gastrointestinal tract, dermatologic system, nervous system, and cardiovascular system, were significantly more common in the hysterectomy group. However, a similar proportion reported a serious AE, 9 of 109 (8%) in the MRgFUS group and 8 of 83 (10%) in the hysterectomy group. At 6 months, there were significantly higher scores in the hysterectomy group on 2 of 8 SF-36 subscales; scores on the remaining subscales did not differ significantly between groups. SF-36 scores were subject to a multiple comparison bias; a large number of statistical comparisons were done for secondary outcomes and p values were not adjusted.

Several other nonrandomized comparative studies have been published. In 2013, Froeling et al reported on 121 women with symptomatic uterine fibroids who were equally eligible for treatment with MRgFUS and uterine artery embolization (UAE). Forty-four (36%) women were lost to follow-up. Follow-up data at approximately 60 months were available on 77 women, 41 in the UAE group and 36 in the MRgFUS group. The primary study outcome was the rate of reintervention (eg, repeat MRgFUS, myomectomy, hysterectomy, endometrial ablation). During follow-up, 5 (12%) women in the UAE group and 24 (67%) women in the MRgFUS group experienced a reintervention (statistical comparison not reported). Healthcare QOL scores, secondary outcomes, were significantly better in the UAE group compared with the MRgFUS group at follow-up. Fennessy et al compared 2 variations on the MRgFUS procedure. Patients were either treated with the original protocol (33% of fibroid volume with a maximum treatment time of 120 min, n=96) or modified protocol (50% treatment volume, 180 min maximum treatment time, and a second treatment if within a 14-day period, n=64). In the original group, the nonperfused (effectively treated) area was calculated at 17% of fibroid volume compared with 26% of fibroid volume with the modified protocol. Overall, symptom severity was reported to have decreased from a score of 62 at baseline to 33 at 12 months, with fewer patients in the modified group choosing alternative treatment (28% vs 37%, respectively). Interpretation of these results was limited by 49% loss to follow-up; 55 patients (57%) from the original treatment protocol completed follow-up. Only 21 patients (33%) from the modified protocol group were evaluable at 12-month follow-up.

A 2007 publication reported 24-month follow-up from 3 phase 3 trials and 1 postmarketing study (total of 416 patients). The study found a relationship between the nonperfused volume ratio and the probability of undergoing additional leiomyoma treatment. For nonperfused volume ratios of 20% to 50%, there was a 25% probability of additional treatment. Patients with a nonperfused volume ratio of less than 20% of fibroid volume had a 40% probability of additional treatment. No shrinkage (and a trend toward growth) was seen with nonperfused volume ratios of 10% or less. Most women were found to have had limited treatments.
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with 57% of the patients having a nonperfused volume of 20% or less and 34% of the patients having a nonperfused volume between 30% and 70%. Fewer than 3% of women had a nonperfused volume ratio of 70% or greater. These results raise questions about the amount of nonperfusion achieved with current treatment protocols.

In addition to nonrandomized comparative studies, a number of case series have been published on MRgFUS for treating uterine fibroids. A representative case series, published in 2011, included 40 women who were treated with MRgFUS for symptomatic uterine fibroids at 1 center in the United States. The primary study end points were change from baseline in QOL and symptom severity. (Higher scores on the QOL measure and lower scores on the symptom severity measure indicated improvement.) The mean symptom severity score in the 29 (73%) of patients who completed the 3-year follow-up was 64.8 at baseline and 17.0 at 3 years; this represents a mean reduction of 47.8 points. The mean baseline QOL score was 44.1 and the mean QOL at the 3-year follow-up was 83.9, a mean increase of 39.8 points. The improvement from baseline to 3 years was statistically significant for both outcome variables. Another representative case series reported 12-month outcome data on 130 women treated with MRgFUS. Eight women had additional procedures to relieve symptoms within 1 year of MRgFUS treatment; 7 underwent hysterectomy and 1 underwent endometrial ablation. Data on symptom relief at 12 months were available for 70 of 130 (54%) of patients. Fifty-one of the 70 (73%) reported excellent symptom relief.

Fertility Following MRgFUS for Treatment of Uterine Fibroids

A prospective registry of pregnancies after MRgFUS had been maintained by the manufacturer of the ExAblate device. A 2010 article reported that there were 54 known pregnancies a mean of 8 months after treatment. They included 8 pregnancies from clinical trials designed for women who did not desire pregnancy, 26 pregnancies after commercial treatment, and 20 pregnancies in 17 patients from an ongoing study of MRgFUS in women trying to conceive. Twenty-two of the 54 pregnancies (42%) resulted in deliveries, 11 were ongoing beyond 20 weeks at the time the article was written. There were 14 miscarriages (26%) and 7 elective terminations (13%). Among the 22 live births, the mean birth weight of live births was 3.3 kg, and the vaginal delivery rate was 64%. The article provided initial information on the impact of MRgFUS for uterine fibroids on pregnancy; findings suggest that fertility may be maintained but that the number of cases is too small to draw definitive conclusions. Moreover, the study did not address the possible impact of MRgFUS treatment on the ability to become pregnant.

Section Summary

For the treatment of uterine fibroids, there is 1 pilot RCT with 20 women and several nonrandomized studies comparing MRgFUS with a different treatment. The pilot RCT determined that a larger trial is feasible. It was not powered for health outcomes, and did not find statistically significant differences in QOL between active and sham treatment; it did find lower fibroid volumes after active treatment. The pivotal FDA trial was not randomized and data on the comparison group were not published until 5 years after data on the treatment group, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. In the 2013 comparative study, outcomes appeared to be better with UAE than with MRgFUS. There is insufficient evidence on the long-term treatment effects, recurrence rates, and impact on future fertility and pregnancy.
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Palliative Treatment of Bone Metastases
An RCT evaluating the ExAblate MRgFUS system was published by Hurwitz et al in 2014. Previously, findings of this study, the pivotal trial leading to FDA approval of the device for treatment of painful bone metastases, were available on the FDA website. Data from the published version of the study are described here. The study included patients with at least 3 months of life expectancy who had bone metastases that were painful, despite radiotherapy treatment or who were unsuitable for or declined radiotherapy. Patients needed to rate tumor pain on a numeric rating scale (NRS) of at least 4 of a maximum score of 10. They could have up to 5 painful lesions; however, only 1 lesion was treated and it had to cause at least 2 points greater pain on the NRS than any other lesion. In addition, targeted tumors needed to be device accessible.

Study participants were randomized in a 3:1 ratio to active (n=122) or sham (n=39) MRgFUS treatment. Ten patients in the treatment group and 4 in the sham group did not receive the allocated treatment. An additional 26 patients in the treatment group and 23 in the sham group did not complete the 3-month follow-up. A much larger proportion of the placebo group dropped out; 17 of 35 who were treated (49%) decided to have rescue MRgFUS treatment after lack of response to placebo. A modified intention-to-treat analysis was used that included patients who had at least 1 MRgFUS or placebo sonication. Missing values were imputed using the last observation carried forward method.

The primary efficacy outcome, assessed at 3 months, was a composite outcome comprised of change in baseline in worst NRS score and morphine equivalent daily dose (MEDD) intake. Patients were considered responders if their worst NRS score decreased by at least 2 points and if their MEDD intake did not increase more than 25% from baseline to 3 months. NRS score and MEDD intake separately were reported as secondary outcomes.

Seventy-two of 112 (64.3%) patients in the MRgFUS group and 7 of 35 patients (20%) in the control group were considered responders, as previously defined. The difference between groups was statistically significant (p=0.01), favoring active treatment. When the 2 measures that made up the primary end point were analyzed separately, there was a statistically significant difference between groups in change in worst NRS score and a nonsignificant difference in change from baseline in pain medication. The NRS score decreased by a mean (SD) of 3.6 (3.1) points in the MRgFUS group and a mean of 0.7 (2.4) in the placebo group (p<0.01). Change in MEDD was only reported in a figure. Fifty-one patients (45.5%) in the MRgFUS group and 1 (2.9%) in the placebo group experienced at least 1 AE. Most AEs were transient, and the most common was sonication pain, experienced by 36 patients (32.1%) in the MRgFUS group. In 17 patients (15.2%), sonication pain was severe; 3 patients did not complete treatment due to pain. The most clinically significant AEs that lasted more than a week were third-degree skin burns in 1 patient (associated with noncompliance with the treatment protocol) and fracture in 2 patients (one of which was outside the treatment location). Potential limitations of the trial include a nonconventional primary outcome measure and, the small initial size of the sham group. Moreover, a large number of sham patients (66%) did not complete the 3-month follow-up; however, the authors stated that this low completion rate was due to lack of response to placebo treatment.

In addition to the single RCT, several manufacturer-sponsored case series on MRgFUS for pain palliation in bone metastases have been published. For example, in 2009, Liberman et al published findings of a
A multicenter prospective study conducted in Canada, Israel, and Germany. The study included 31 patients with painful bone metastases who had failed or refused other treatment options; 25 patients (81%) were available for 3-month follow-up. The mean visual analog scale score decreased from 5.9 before treatment to 1.8 three months after treatment. Thirteen of 25 patients who used nonopioid analgesics and 6 of 10 who used opioids decreased medication use after treatment. Neither group reported any treatment-related AEs.

Section Summary
The evidence base consists of a single industry-sponsored RCT which found significant improvement after MRgFUS in a composite outcome comprised of reduction in pain and morphine use, and in pain reduction as a stand-alone outcome. This study was appropriately sham-controlled. A substantial proportion of patients in the treatment group experienced AEs, but most of these were transient and not severe.

Treatment of Other Tumors
Only small case series have been published investigating the safety and/or efficacy of MRgFUS for treating other tumors, including breast cancer, brain cancer, prostate cancer, and nonspinal osteoid osteoma.

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>Ongoing</td>
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<td>NCT01827904</td>
<td>A Pivotal Study to Evaluate the Effectiveness and Safety of ExAblate Transcranial MRgFUS Thalamotomy Treatment of Medication Refractory Essential Tremor Subjects</td>
<td>72</td>
<td>Sep 2015 (ongoing)</td>
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<td>NCT01772693</td>
<td>ExAblate Transcranial MR Guided Focused Ultrasound for the Treatment of Parkinson's Disease</td>
<td>30</td>
<td>Oct 2015 (ongoing)</td>
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<td>NCT00995878</td>
<td>The FIRSTT Study: Comparing Focused Ultrasound and Uterine Artery Embolization for Uterine Fibroids</td>
<td>180</td>
<td>Dec 2016</td>
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NCT: national clinical trial.

Denotes industry-sponsored or cosponsored trial.

Summary of Evidence
The evidence for magnetic resonance-guided focused ultrasound (MRgFUS) in individuals who have uterine fibroids includes a pilot RCT, nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. The pilot RCT (N=20 patients) reported some health outcomes, but its primary purpose was to determine the feasibility of a larger trial. It did not find statistically significant differences in QOL outcomes between active and sham treatment groups, but it did find lower fibroid volumes after active treatment. The pivotal FDA trial was not randomized, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. In the 2013 comparative study, outcomes appeared to be better with uterine artery embolization than with MRgFUS. There are insufficient data on the long-term treatment effects, recurrence...
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rates, and impact on future fertility and pregnancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for MRgFUS in individuals who have metastatic bone cancer who failed or are not candidates for radiotherapy includes a sham-controlled randomized trial. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The RCT found statistically significant improvement after MRgFUS in a composite outcome comprised of reduction in pain and morphine use, and in pain reduction as a stand-alone outcome. A substantial proportion of patients in the treatment group experienced adverse events, but most of these were not severe and were transient. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for MRgFUS in individuals who have miscellaneous tumors (eg, brain cancer, prostate cancer, breast cancer) includes case series. Relevant outcomes are symptoms, health status measures, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

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09/07/2005 Medical Director review
09/20/2005 Medical Policy Committee review
09/22/2005 Quality Care Advisory Council approval
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
09/05/2007 Medical Director review
09/19/2007 Medical Policy Committee approval. Coverage eligibility unchanged.
09/03/2009 Medical Policy Committee approval
09/16/2009 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/09/2010 Medical Policy Committee review
09/15/2010 Medical Policy Implementation Committee approval. Added that magnetic resonance imaging (MRI)-guided ablation of other tumors, including but not limited to breast, brain, prostate cancer, and palliative treatment of bone metastases, is considered to be investigational.
09/01/2011 Medical Policy Committee review
09/14/2011 Medical Policy Implementation Committee approval. Title changed from “MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids” to “MRI-Guided Focused Ultrasound (MRgFUS) for the Treatment of Uterine Fibroids and Other Tumors.” Coverage eligibility unchanged.
10/11/2012 Medical Policy Committee review
10/31/2012 Medical Policy Implementation Committee approval
10/03/2013 Medical Policy Committee review
10/16/2013 Medical Policy Implementation Committee approval. Policy title changed from “MRI-Guided Focused Ultrasound (MRgFUS) for the Treatment of Uterine Fibroids and Other Tumors” to “MRI-Guided Focused Ultrasound (MRgFUS)”. Policy changed to a single investigational statement with no change to coverage eligibility.
11/06/2014 Medical Policy Committee review
11/21/2014 Medical Policy Implementation Committee approval. No change to coverage. Title changed from MRI-Guided Focused Ultrasound (MRgFUS) to Magnetic Resonance Imaging-Guided Focused Ultrasound.
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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. Added “Based on review of available data, the Company may consider magnetic resonance imaging (MRI)–guid ed high-intensity ultrasound ablation for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy to be eligible for coverage.”
11/03/2016 Medical Policy Committee review
11/16/2015 Medical Policy Implementation Committee approval. Title change, “imaging” removed from policy statements.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
Next Scheduled Review Date: 11/2017

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

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<th>Code Type</th>
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<td>ICD-10 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:
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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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