Policy

Magnetic resonance–guided high-intensity ultrasound ablation may be considered medically necessary for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy.

Magnetic resonance-guided high-intensity ultrasound ablation is considered investigational in all other situations including but not limited to:
- Treatment of uterine fibroids;
- Treatment of other tumors e.g., brain cancer, prostate cancer and breast cancer.

Related Policies

8.01.61 Focal Treatments for Prostate Cancer

Policy Guidelines

Coding

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0071T</td>
<td>Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume of less than 200 cc of tissue</td>
</tr>
<tr>
<td>0072T</td>
<td>As above, but with total leiomyomata volume greater or equal to 200 cc of tissue</td>
</tr>
<tr>
<td>19499</td>
<td>Unlisted procedure, breast</td>
</tr>
</tbody>
</table>

The CPT codes above should not be used in conjunction with:
- 51702 (insertion of temporary indwelling bladder catheter, simple) or
- 77022 (magnetic resonance imaging guidance for, and monitoring of, visceral tissue ablation).

The procedure may be performed in an MRI suite with an open MRI scanner, which may not be available at many
institutions. The procedure is performed in an outpatient setting, with the patient under conscious sedation.

There are no specific CPT codes for the use of MRI-guided high-intensity ultrasound ablation in metastatic bone cancer. An unlisted code would be used based on the anatomic location of the metastasis being treated (e.g., 23929 for the clavicle) or perhaps one of the radiation oncology unlisted codes.

**Description**

An integrated system providing magnetic resonance imaging (MRI)–guided focused ultrasound (MRgFUS) treatment is proposed as a noninvasive therapy for pain palliation of bone metastases and for uterine fibroids. MRgFUS is also being investigated for the treatment of other benign and malignant tumors.

The evidence for MRgFUS in individuals who have uterine fibroids includes a pilot randomized controlled trial (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 quality of life outcomes between active and sham treatment groups, but it did find lower fibroid volumes after active treatment. The pivotal Food and Drug Administration 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 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.

**Background**

MRgFUS is a noninvasive treatment that combines two 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 (i.e., 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.

The U.S. Food and Drug Administration (FDA) has approved the ExAblate® MRgFUS system (InSightec Inc., Haifa, Israel) for two 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 (e.g., massage, exercise) and pharmacologic agents (e.g., 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. (One option, radiofrequency ablation, is addressed in a Related Policy).

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

**Regulatory Status**

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 post-approval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

FDA product code: NRZ.

**Scope**

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

**Benefit Application**

N/A

**Rationale**

<table>
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<th>Comparators</th>
<th>Outcomes</th>
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<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
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<td>Magnetic resonance–guided focused ultrasound</td>
<td>Alternative nonsurgical treatment Surgery</td>
<td>Symptoms</td>
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<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With metastatic bone</td>
<td>Magnetic resonance–</td>
<td></td>
<td>Symptoms</td>
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</table>

**[TOP]**
cancer who failed or are not candidates for radiotherapy | guided focused ultrasound treatment | • Supportive care | • Functional outcomes
| | | • Health status measures | • Quality of life
| | | • Treatment-related morbidity

Individuals:
- With miscellaneous tumors (eg, brain cancer, prostate cancer, breast cancer) | Interventions of interest are: | Magnetic resonance–guided focused ultrasound | Comparators of interest are: | Standard care | Relevant outcomes include: | Symptoms | Health status measures | Treatment-related morbidity

This policy originally created in July 2004. A June 2005 TEC Assessment on magnetic resonance imaging–guided focused ultrasound (MRgFUS) for symptomatic uterine leiomyomata found insufficient evidence of efficacy compared with conventional therapies. (1) The policy was updated regularly with searches of the MEDLINE database. The most recent review was 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.(2) 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 the 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.)

QOL 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 2013, identified 38 uncontrolled studies with a total of 2500 patients who underwent MRgFUS for treatment of uterine fibroids.(3) 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 U.S. Food and Drug Administration (FDA) approval of the ExAblate® 2000 device, included 109 women treated with MRgFUS and 83 women treated with abdominal hysterectomy.(4,5) 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. This study did not include the original primary outcome measure, SSS; instead, it 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 (8%) of 109 in the MRgFUS group and 8 (10%) of 83 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 subscale 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.

In addition to nonrandomized comparative studies, a number of case series have been published. 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).(7) 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). Health-related QOL scores (secondary outcomes) were significantly better in the UAE group than in the MRgFUS group at follow-up. Fennessy et al compared 2 variations on the MRgFUS procedure. (8) Patients were either treated with the original protocol (33% of fibroid volume with a 120-minute maximum treatment time, n=96) or modified protocol (50% treatment volume, 180-minute 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, SSS was reported to have decreased from 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 the large loss to follow-up; 55 (57%) patients from the original treatment protocol completed follow-up. Only 21 (33%) patients 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 N=416 patients). (9) The study found a relation between the nonperfused fibroid 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% 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 had limited treatments, 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 treated with MRgFUS for symptomatic uterine fibroids at 1 center in the United States. (10) 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.) Mean SSS in the 29 (73%) patients who completed the 3-year follow-up was 64.8 at baseline and 17.0 at 3 years; this represented a mean reduction of 47.8 points. Mean QOL score at baseline was 44.1 and mean QOL at the 3-year follow-up was 83.9, a mean improvement 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. (11) 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 (54%) of 130 patients. Fifty-one (73%) of the 70 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. (12) 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.

Palliative Treatment of Bone Metastases
An RCT evaluating the ExAblate MRgFUS system was published by Hurwitz et al. in 2014. (13) 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. (14,15) For example, In 2009, Liberman et al. published findings of a multicenter prospective study conducted in Canada, Israel, and Germany. (14) 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 non-opioid 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 that 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 AEs 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, (16-19) brain cancer, (20) prostate cancer, (21) and nonspinal osteoid osteoma. (22)

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>
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<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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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 randomized controlled trial (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 quality of life outcomes between active and sham treatment groups, but it did find lower fibroid volumes after active treatment. The pivotal Food and Drug Administration 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 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 (e.g., 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.

Practice Guidelines and Position Statements

**Society of Obstetricians and Gynaecologists of Canada**

In 2015, the Society of Obstetricians and Gynaecologists of Canada published a clinical practice guideline on the management of uterine fibroids in women with otherwise unexplained infertility. (23) The guideline states that there are no studies comparing MRgFUS with myomectomy or in women with fibroids who have infertility as their primary complaint, and thus additional data are needed before the treatment is offered to this patient population.

**American Society for Radiation Oncology (ASTRO)**

In 2011, the ASTRO published a guideline on palliative radiotherapy for bone metastases, which stated that external beam radiotherapy continues to be the primary therapy for treating painful uncomplicated bone metastases. (24) The guideline does not mention MRgFUS and does not have specific recommendations for patients who fail or are not candidates for radiotherapy.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

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

**References**


Appendix

N/A

History
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<td>Replace Policy - Policy updated with June 2005 TEC Assessment; references added; policy statement unchanged.</td>
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<td>Update Scope and Disclaimer - No other changes.</td>
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<tr>
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<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<td>11/20/12</td>
<td>Code update: CPT codes 19499, 55899 and 58999 added to the policy to support policy information and tumors.</td>
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<tr>
<td>02/15/13</td>
<td>Update Related Policies, add 7.01.548.</td>
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<tr>
<td>04/08/13</td>
<td>Replace policy. Policy updated with literature review. Policy changed to single investigational statement; no change to intent of policy. Policy title changed to MRI-Guided Focused Ultrasound (MRgFUS). References 10 and 17 added; other references renumbered or removed. CPT code 58999 corrected; it previously appeared as 55899, which is not the correct code.</td>
</tr>
<tr>
<td>05/05/14</td>
<td>Annual Review. Policy updated with literature review through January 6, 2014; references 2, 6, and 14 added; other references renumbered or removed. Coding update: add CPT code 55899 and remove 55999 (wrong code); update descriptor for 58999.</td>
</tr>
<tr>
<td>04/14/15</td>
<td>Annual Review. Policy updated with literature review through January 6, 2015. Statement added that MRgFUS may be considered medically necessary for pain palliation in adult patients with metastatic bone cancer. (Previously considered Investigational). References 12, 21-22 added; others renumbered or removed. Policy statement changed as noted.</td>
</tr>
<tr>
<td>08/25/15</td>
<td>Update Related Policies. Remove 7.01.548 as it was archived and add 8.01.61.</td>
</tr>
<tr>
<td>04/12/16</td>
<td>Annual Review. Policy updated with literature review through December 15, 2015; references 2 and 23 added. Policy coverage unchanged. Global change to policy to remove &quot;imaging&quot; (e.g., title, policy statement) to standardize terminology to magnetic resonance-guided focused ultrasound (MRgFUS). Coding update; CPT codes 47999 and 55899 removed from policy; these are moving to review by AIM.</td>
</tr>
<tr>
<td>06/24/16</td>
<td>Minor update. Removed codes 77299 and 77499 from information in the coding section that discusses radiation oncology unlisted codes. Correction to 4/12/16 History note: AIM is not reviewing 47999 and 55899.</td>
</tr>
</tbody>
</table>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2016 Premera All Rights Reserved.
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Information written in other languages

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Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Français (French):


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Chiama 800-722-1471 (TTY: 800-842-5357).

037338 (07-2016)
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