

Medical Coverage Policy | Magnetic Resonance Imaging-Guided Focused Ultrasound



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OVERVIEW

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

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary when the medical criteria in the online authorization tool for participating providers is met for the following procedure codes:

- 61715
- C9734

PRIOR AUTHORIZATION

Prior authorization for magnetic resonance -guided high-intensity ultrasound ablation (CPT code 61715 and HCPCS code C9734) is required for Medicare Advantage Plans and recommended for Commercial Products and is obtained via the online portal for participating providers.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary when the medical criteria in the online authorization tool for participating providers is met for the following procedure codes:

- 61715
- C9734

Medicare Advantage Plans

Magnetic resonance-guided high-intensity ultrasound ablation is considered not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes in all other situations including but not limited to:

- treatment of uterine fibroids (0071T, 0072T)

Commercial Products

Magnetic resonance-guided high-intensity ultrasound ablation is considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes in all other situations including but not limited to:

- treatment of uterine fibroids (0071T, 0072T)

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for the applicable surgery services and not medically necessary benefits/coverage.

BACKGROUND

Uterine fibroids are one of the most common conditions affecting women in the reproductive years. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain.

Several approaches currently available to treat symptomatic uterine fibroids include 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 treatments.

Magnetic Resonance-Guided Focused Ultrasound

MRgFUS is a noninvasive treatment that combines 2 technologies: focused ultrasound and magnetic resonance imaging (MRI). The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. Ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. Ultrasound waves from each sonication are directed at a focal point that has a maximum focal volume of 20 mm in diameter and 15 mm in height/length. This causes a rapid rise in temperature (ie, to 65°C-85°C), which is sufficient to ablate tissue at the focal point. In addition to providing guidance, the associated MRI can provide online thermometric imaging, a temperature "map", to 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) approved the ExAblate MRgFUS system (InSightec) for 2 indications: treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone. The ultrasound equipment is specifically designed to be compatible with magnetic resonance magnets, and it is integrated into standard clinical MRI units; it also includes a patient table, which has a cradle that houses the focused ultrasound transducer in water or a light oil bath. Some models have a detachable cradle; only certain cradle types can be used for palliation of pain associated with metastatic bone cancer. For treating pain associated with bone metastases, the aim of MRgFUS is to destroy nerves in the bone surface surrounding the tumor.

Regulatory Status

In October 2004, the ExAblate® 2000 System (InSightec) was approved by the FDA through 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 fewer than 24 weeks who have completed childbearing.

For individuals who have uterine fibroids who receive MRgFUS, the evidence includes 2 small randomized controlled trials (RCTs), nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. One RCT (n=20) has 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. This trial did not have an active comparator, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. The second RCT (n=49) is ongoing; preliminary results at 6 weeks posttreatment, comparing MRgFUS with uterine artery embolization have shown that the 2 groups are comparable in medication use and symptom improvement following treatments. Patients in the MRgFUS group reported recovering significantly faster than patients in the uterine artery embolization group, as measured by time to return to work and time to normal activities. In a separate 2013 comparative study, outcomes appeared to be better with uterine artery embolization than with MRgFUS. Long-term data on the treatment effects, recurrence rates, and impact on future fertility and pregnancy are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) may be medically necessary for Medicare Advantage Plans and Commercial Products when the medical criteria in the online authorization tool for participating providers is met:

61715 Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed

C9734 Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

0071T Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue

0072T Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue

RELATED POLICIES

Prior Authorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, January/November 2025

Provider Update, December 2024

Provider Update, October 2023

Provider Update, November 2022

Provider Update, September 2021

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3. Barnard EP, AbdElmagied AM, Vaughan LE, et al. Periprocedural outcomes comparing fibroid embolization and focused ultrasound: a randomized controlled trial and comprehensive cohort analysis. *Am J Obstet Gynecol.* May 2017; 216(5): 500.e1-500.e11. PMID 28063909
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