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Medicare Advantage Policy Manual **Policy ID:** M-SUR139

Magnetic Resonance (MR) Guided Focused Ultrasound (MRgFUS) and High Intensity Focused Ultrasound (HIFU) Ablation

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Magnetic resonance (MR) guided focused ultrasound (MRgFUS) and high intensity focused ultrasound (HIFU) are proposed as less invasive approaches than surgery for treatment of localized prostate cancer, uterine fibroids, and pain palliation of bone metastases.

MRgFUS is a noninvasive treatment that combines real-time MR-guidance with high-intensity focused ultrasound for the noninvasive thermal ablation of uterine fibroids. The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. This causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures.

HIFU focuses high-energy ultrasound waves on a single location, which increase the local tissue temperature to cause a discrete locus of coagulative necrosis of approximately 3×3×10 mm.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	For the ***treatment of uterine fibroids*** (***Category III CPT codes 0071T and 0072T)***: ✓ Non-Covered Services (L35008) For ***intracranial MRgFUS (Category III code 0398T):*** ✓ Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (L37738) **Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.
Medical Policy Manual	*For all other indications, Medicare coverage guidance is not available for magnetic resonance (MR) guided focused ultrasound for some indications, and no Medicare coverage guidance is available for high intensity focused ultrasound (HIFU). Therefore, the health plan's medical policy is applicable.* **Note:** The health plan's medical policy is consistent with the National Comprehensive Cancer Network (NCCN) recommendations for prostate cancer. For ***HIFU (any indication)*** *and* ***all other indications of MRgFUS not previously addressed***: ✓ Magnetic Resonance (MR) Guided Focused Ultrasound (MRgFUS) and High Intensity Focused Ultrasound (HIFU) Ablation, Surgery, Policy No. 139 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine

Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- History and Physical
- Treatment plan including treatment area
- For prostate cancer treatment, clinical documentation must also demonstrate results from transrectal ultrasound guided (TRUS) biopsy.

REGULATORY STATUS

Several devices have received U.S. Food and Drug Administration (FDA) approval via the De Novo and Premarket Application (PMA) processes:

- The ExAblate® 2000 System (InSightec, Inc.) was approved for two indications: "ablation of uterine fibroid tissue in pre- or peri- menopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure," and for palliation of pain associated with tumors metastatic to bone.
- The ExAblate® 2100 System also received approval through the PMA process. Approval remains limited to treatment of patients with metastatic bone cancer who failed or are not candidates for radiation therapy; or, in patient with symptomatic uterine fibroids with a uterine size of less than 24 weeks and those who have completed child bearing.
- In October 2012, the FDA approved the ExAblate® System, Model 2000/2100/2100 VI for pain palliation via the PMA process. For pain palliation, the intended use of the device is in adult patients with metastatic bone cancer who failed or are not candidates for radiation therapy. The device was evaluated through an expedited review process, but the FDA required a post-approval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.
- The Sonablate® 450 (SonaCare Medical) is the first high intensity ultrasound system for prostate tissue ablation to receive FDA approval, and therefore underwent the de novo application process, obtaining clearance in 2015.
- Shortly thereafter, Ablatherm Integrated Imaging® (EDAP TMS) received PMA approval.

Of note, the fact a service or procedure has been "FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary." Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered

Medicare covered services. *(Noridian LCD L35008)* The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services and New and Emerging Medical Technologies and Procedures, Medicine, Policy No. M-149

REFERENCES

None

CODING

NOTE: There are no specific CPT codes for the use of magnetic resonance–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 (eg, 23929 for the clavicle) or perhaps one of the radiation oncology unlisted codes (eg, 77299 or 77499).

Codes	Number	Description
CPT	0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume of less than 200 cc of tissue.
	0072T	; total leiomyomata volume greater or equal to 200 cc of tissue
	0398T	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed
	23929	Unlisted procedure, shoulder
	55899	Unlisted procedure, male genital system
	58578	Unlisted laparoscopy procedure, uterus
	58579	Unlisted hysteroscopy procedure, uterus
HCPCS	C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with or without magnetic resonance (MR) guidance
	C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*