Medica Central Coverage Policy

Title: **High Intensity Focused Ultrasound (HIFU) and Magnetic Resonance Guided Focused Ultrasound (MRgFUS) MP9708**

Effective Date: **06/01/2024**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

High intensity focused ultrasound (HIFU) and Magnetic Resonance Guided Focused Ultrasound (MRgFUS) is investigative and unproven, and therefore **NOT COVERED** for uterine fibroids, prostate cancer, bone metastases and essential tremor. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

HIFU and MRgFUS is investigative and unproven and therefore **NOT COVERED** for all other indications. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

Note: This determination does not apply to devices that have been granted a Humanitarian Device Exemption (HDE) by the FDA. The Health Plan considers an FDA-approved humanitarian device exemption (HDE) device medically necessary when all of the FDA-required criteria are met.

- The Sonalleve MR-HIFU System (H190003) has FDA HDE approval for the treatment of osteoid osteomas in the extremities.

For a current list of HDE-approved devices, refer to the FDA HDE Database at: https://www.fda.gov/medical-devices/hde-approvals/listing-cdrh-humanitarian-device-exemptions

Note: See also related coverage policy, *Surgical and Minimally Invasive Treatments for Benign Prostatic Hypertrophy/Hyperplasia (BPH)*.

Medica Central Coverage Policy

Description

HIFU focuses high-energy ultrasound waves on a single location, resulting in an increase of local tissue temperature to over 80°C. This pinpoints the locus of coagulative tissue necrosis to a small area of approximately 3×3×10 mm.

MRgFUS combines focused ultrasound and magnetic resonance imaging (MRI) to target and treat affected tissue. The ultrasound beam penetrates through the soft tissues and uses MRI for guidance and monitoring. The beam is then focused on targeted sites, resulting in coagulation necrosis, while sparing the surrounding normal structures. In addition to providing guidance, the MRI provides thermometric imaging that produces a temperature mapping to confirm therapeutic effect and to facilitate real-time adjustment of the treatment parameters.

HIFU and MRgFUS have been proposed as an alternative to surgery or minimally invasive procedures (e.g., hysterectomy, myomectomy, uterine artery embolization) for treatment of uterine fibroids. Uterine fibroids (leiomyomata) are benign growths of muscle and connective tissue which form from the smooth muscle tissue of the uterus. Fibroids are estimated to occur in 20–50% of women of childbearing age. Symptoms develop in a high proportion of these women and include, but are not limited to, heavy menstrual bleeding, anemia, pelvic pressure, reproductive disorders, or urinary frequency. HIFU is purported to alleviate symptoms while retaining uterine function.

HIFU and MRgFUS have also been proposed as an alternative to surgery for treatment of cancer and other tumor types, including but not limited to prostate, breast, brain, hepatocellular, and renal cancer. It is also being studied for palliation of pain (e.g., tumors metastasis to bone). Currently, the most robust area of study is for use in the treatment of prostate cancer as either (1) primary treatment of localized prostate cancer, (2) therapy adjunctive to transurethral resection of the prostate, or (3) salvage therapy following prostatectomy or external beam radiation therapy.

FDA Approval

HIFU treatment is a procedure and, therefore, not subject to FDA approval. However, any medical devices and equipment used as part of this procedure may be subject to FDA approval, including:

ExAblate:

1. The ExAblate 2000 system received initial Premarket Approval (PMA) in October 2004 for ablation of uterine fibroid tissue in pre-or peri-menopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure.
2. The ExAblate 2001, which features enhanced sonication and several other modifications, received FDA approval in June 2009 for treatment of symptomatic fibroids in women with a uterine size of less than 24 weeks and for those who have completed child bearing. In August 2015, the Exablate 2100 approval was modified to remove the restriction of treatment of women who had completed childbearing.
3. In October 2012, the ExAblate System, Models 2000, 2100, and 2100 V1, received PMA approval for use in palliative treatment of pain due to bone metastases.

Sonablate®:

The Sonablate 450 was approved by the FDA in October 2015, for the indication of transrectal HIFU ablation of prostatic tissue; the device was not cleared specifically for prostate cancer therapy.

Ablatherm®

The FDA granted 510(k) marketing clearance for the Ablatherm for ablation of prostate tissue in November 2015. This device also did not receive clearance specifically for the indication of prostate cancer.

TULSA-PRO

Medica Central Coverage Policy

The FDA granted 510(k) approval for the TULSA-PRO System in August 2019. It is indicated for transurethral ultrasound ablation (TULSA) ablation of prostate tissue.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

- **0071T** - Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume of 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
- **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
- **55880** - Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
- **55899** – Unlisted procedure, male genital system
- **58999** – Unlisted procedure, female genital system
- **76999** - Unlisted ultrasound procedure (e.g., diagnostic, interventional)

HCPC Codes:

- **C9734** - Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with or without magnetic resonance (MR) guidance

	Committee/Source	Date(s)
Document Created:	Medical Policy Committee/Health Services Division	December 20, 2023
Revised:	Medical Policy Committee/Health Services Division	February 21, 2024
	Medical Policy Committee/Health Services Division	May 15, 2024
Reviewed:	Medical Policy Committee/Health Services Division	February 21, 2024
	Medical Policy Committee/Health Services Division	May 15, 2024

Published: 06/01/2024

Effective: 06/01/2024