

# Medical Policy Magnetic Resonance Image-Guided Focused Ultrasound

**Policy Number: 098** 

	Commercial and Qualified Health Plans	Mass General Brigham ACO	Medicare Advantage
Authorization Required	Х		Х
No Prior Authorization			
Not payable		Х	

## Overview

This document describes the guidelines Mass General Brigham Health Plan uses to determine the medical necessity for Magnetic Resonance Image-guided Focused Ultrasound (MRgFUS).

## Criteria

Medical necessity for MRgFUS is determined through InterQual® criteria, which Mass General Brigham Health Plan has customized to remove high-intensity focused ultrasound (HIFU) as a treatment for prostate cancer. To access the criteria, log into Mass General Brigham Health Plan's provider website at MassGeneralBrighamHealthPlan.org and click the InterQual® Criteria Lookup link under the Resources Menu.

# **Medicare Variation**

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. At the time of Mass General Brigham Health Plan's most recent policy review, CMS includes the following coverage guidelines:

- LCD Magnetic Resonance Guided Focused Ultrasound Surgery System (MRgFUS) for the treatment of neurologic conditions (L37790)
- <u>LCD Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential</u>
   Tremor (L37761)
- LCD Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Tremor (L37421)
- <u>LCD Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor</u> (<u>L38506</u>)
- LCD Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (L38495)
- <u>LCD Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor and</u> Tremor Dominant Parkinson's Disease (L37729)



When NCDs are not available, and LCDs are not available for the states in which Mass General Brigham Health Plan members seek care, Mass General Brigham Health Plan applies additional coverage criteria to clarify medical necessity of the requested service. For some services, Mass General Brigham Health Plan utilizes coverage criteria from InterQual® which align with the latest clinical evidence and accepted standards of practice, without contradicting existing determinations, and enhance the clarity of medical necessity criteria, documentation requirements, and clinical indications. For members who do not seek care in the states covered by the LCDs above, Mass General Brigham Health Plan uses the InterQual® criteria described in this policy to review requests for MRgFUS.

#### **MassHealth Variation**

Mass General Brigham Health Plan uses guidance from MassHealth for medical necessity determinations for Mass General Brigham ACO members. When there is no guidance from MassHealth for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. At the time of Mass General Brigham Health Plan's most recent policy review, MassHealth did not consider MRgFUS payable.

## **Codes**

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

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

# **Summary of Evidence**

Please see InterQual® guidelines for literature in support of MRgFUS as a treatment for essential tremor and Parkinson's disease.

HIFU as an effective treatment for prostate cancer is considered investigational due to limited high-quality, long-term evidence supporting its oncologic efficacy and safety compared to established treatments. Multiple guidelines, including those from the German S3, the European Association of Urology, and the National Comprehensive Cancer Network (NCCN), emphasize that while HIFU offers promising focal therapy options with potentially better functional outcomes, its oncological control remains less certain. Of note, NCCN's guidelines highlight that while the US Food and Drug Administration (FDA) has approved HIFU for the destruction of prostate tissue, it has not explicitly approved it for prostate cancer. Prospective trials have shown that although HIFU can yield good functional results, it may not be as oncologically safe as expected, with concerns about cancer recurrence and incomplete treatment. Systematic reviews and health technology assessments highlight variability in outcomes and a lack of consensus on patient selection, standardized protocols, and long-term follow-up data. Consequently, leading clinical guidelines and expert consensus reserve HIFU primarily for investigational use or salvage therapy in recurrent disease, rather than as a frontline standard of care for localized prostate cancer. The limited evidence, lack of support from professional societies, and lack of approval from the FDA are why Mass General Brigham Health Plan maintains that HIFU as a treatment for prostate cancer is experimental and investigational for all lines of business.

# **Effective Dates**

November 2025: Effective date.

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