

Medical Policy

High Intensity-Focused Ultrasound

Policy Number: 098

	Commercial and Qualified Health Plans	Mass General Brigham ACO	Medicare Advantage	One Care	Senior Care Options (SCO)
Authorization Required	X (61715)		X (61715)	X (61715)	X (61715)
No Prior Authorization					
Not covered/ payable	X (55880)	X	X (55880)	X (55880)	X (55880)

Overview

This document describes the guidelines Mass General Brigham Health Plan uses to determine the medical necessity for high intensity-focused ultrasound (HIFU).

Criteria

Medical necessity for HIFU is determined through InterQual® criteria, which Mass General Brigham Health Plan has customized to remove the prostate cancer pathway. 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 \(L37790\)](#)
- [LCD - Magnetic Resonance Image Guided High Intensity Focused Ultrasound \(MRgFUS\) for Essential Tremor \(L37761\)](#)
- [LCD - Magnetic Resonance Image Guided High Intensity Focused Ultrasound \(MRgFUS\) for Tremor \(L37421\)](#)
- [LCD - Magnetic-Resonance-Guided Focused Ultrasound Surgery \(MRgFUS\) for Essential Tremor \(L38506\)](#)
- [LCD - Magnetic-Resonance-Guided Focused Ultrasound Surgery \(MRgFUS\) for Essential Tremor \(L38495\)](#)

- [LCD - Magnetic-Resonance-Guided Focused Ultrasound Surgery \(MRgFUS\) for Essential Tremor and 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 HIFU.

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 HIFU payable.**

One Care and SCO Variation

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its OneCare and SCO plan members. NCDs, LCDs, 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 uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or from MassHealth, Mass General Brigham Health Plan’s medical policies are used for medical necessity determinations.

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
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
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 magnetic resonance image-guided HIFU (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

January 2026: Ad hoc review. Updated policy for One Care and SCO members.

November 2025: Effective date.

References

Borkowetz A, Blana A, Böhmer D, et al. German S3 Evidence-Based Guidelines on Focal Therapy in Localized Prostate Cancer: The First Evidence-Based Guidelines on Focal Therapy. *Urol Int.* 2022;106(5):431-439. doi: 10.1159/000521882. Epub 2022 Feb 10. PMID: 35144260; PMCID: PMC9153342.

Ciezki JP. (2025). Overview of low- and very low-risk clinically localized prostate cancer. UpToDate. Retrieved September 11, 2025, from <https://www.uptodate.com/contents/overview-of-low-and-very-low-risk-clinically-localized-prostate-cancer>.

Cornford P, Tilki D, van den Bergh RCN, et al. EAU-EANM-ESTRO-ESUR-ISUP-SIOG Guidelines on Prostate Cancer. Retrieved from: <https://uroweb.org/guidelines/prostate-cancer>. Accessed 9/10/2025.

Duwe G, Boehm K, Haack M, et al Single-center, prospective phase 2 trial of high-intensity focused ultrasound (HIFU) in patients with unilateral localized prostate cancer: good functional results but oncologically not as safe as expected. *World J Urol.* 2023 May;41(5):1293-1299. doi: 10.1007/s00345-023-04352-9. Epub 2023 Mar 15. PMID: 36920492; PMCID: PMC10188406.

Eastham JA, Aufferberg GB, Barocas DA, et al. Clinically localized prostate cancer: AUA/ASTRO guideline, part I: introduction, risk assessment, staging, and risk-based management. *J Urol.* 2022;208(1):10-18.

Guo RQ, Guo XX, Li YM, Bie ZX, Li B, Li XG. Cryoablation, high-intensity focused ultrasound, irreversible electroporation, and vascular-targeted photodynamic therapy for prostate cancer: a systemic review and meta-analysis. *Int J Clin Oncol.* 2021 Mar;26(3):461-484. doi: 10.1007/s10147-020-01847-y. Epub 2021 Jan 2. PMID: 33387088.

Hayes Inc. Evidence analysis research brief: High-intensity focused ultrasound for salvage therapy of recurrent prostate cancer. Oct 10, 2023. Accessed 9/10/2025 from <https://evidence.hayesinc.com/report/earb.hifurecurrent3948>.

Hayes Inc. Health technology assessment: High-intensity focused ultrasound for salvage therapy of recurrent prostate cancer. Mar 30, 2017. Last updated May 6, 2021. Accessed 9/10/2025 from <https://evidence.hayesinc.com/report/dir.hifurecurrent3948>.

Hayes Inc. Health technology assessment: Ultrasound-guided high-intensity focused ultrasound (HiFU) for primary treatment of localized prostate cancer (PCa). Nov 22, 2022. Last updated Dec 5, 2024. Accessed 9/8/2025 from <https://evidence.hayesinc.com/report/dir.hifu747>.

National Comprehensive Cancer Network. Prostate Cancer. Version 1.2026 – August 29, 2025. Retrieved from https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed 9/10/2025.

National Institute for Health and Care Excellence. Focal therapy using high-intensity focused ultrasound for localised prostate cancer. 2023. NICE guideline IPG756.



Parker C, Castro E, Fizazi K, et al; ESMO Guidelines Committee. Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol*. 2020 Sep;31(9):1119-1134. doi: 10.1016/j.annonc.2020.06.011. Epub 2020 Jun 25. PMID: 32593798.

Pisters LL, Spiess PE. (2025). Cryotherapy and other ablative techniques for the initial treatment of prostate cancer. UpToDate. Retrieved September 11, 2025, from <https://www.uptodate.com/contents/cryotherapy-and-other-ablative-techniques-for-the-initial-treatment-of-prostate-cancer>.

Ploussard G, Coloby P, Chevallier T, et al; HIFI group. Whole-gland or Subtotal High-intensity Focused Ultrasound Versus Radical Prostatectomy: The Prospective, Noninferiority, Nonrandomized HIFI Trial. *Eur Urol*. 2025 May;87(5):526-533. doi: 10.1016/j.eururo.2024.11.006. Epub 2024 Dec 4. PMID: 39632125.

Richie JP. (2025). Rising serum PSA after radiation therapy for localized prostate cancer: Salvage local therapy. UpToDate. Retrieved September 11, 2025, from <https://www.uptodate.com/contents/rising-serum-psa-after-radiation-therapy-for-localized-prostate-cancer-salvage-local-therapy>.

Tay KJ, Fong KY, Stabile A, et al. Established focal therapy-HIFU, IRE, or cryotherapy-where are we now?-a systematic review and meta-analysis. *Prostate Cancer Prostatic Dis*. 2025 Sep;28(3):693-706. doi: 10.1038/s41391-024-00911-2. Epub 2024 Oct 28. PMID: 39468217; PMCID: PMC12399424.

Tempany CMC, Carroll PR, Leapman MS. (2025). The role of magnetic resonance imaging in prostate cancer. UpToDate. Retrieved September 11, 2025, from <https://www.uptodate.com/contents/the-role-of-magnetic-resonance-imaging-in-prostate-cancer>.

Westphalen AC, Lee WR. (2023). Rising serum PSA following local therapy for prostate cancer: Diagnostic evaluation. UpToDate. Retrieved September 11, 2025, from <https://www.uptodate.com/contents/rising-serum-psa-following-local-therapy-for-prostate-cancer-diagnostic-evaluation>.

