

Policy: MP316

Section: Medical Benefit Policy

Subject: High Intensity Focused Ultrasound and Laser

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: High Intensity Focused Ultrasound and Laser

II. Purpose/Objective:

To provide a policy of coverage regarding High Intensity Focused Ultrasound and Laser

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

High intensity focused ultrasound (HIFU) uses an acoustic lens to concentrate multiple intersecting beams of ultrasound on a target. High intensity ultrasound energy is focused at a specific location. At the focal point where the beams converge, HIFU destroys tissue with rapid heat elevation. HIFU is typically performed with real-time imaging via ultrasound or MRI to enable treatment targeting and monitoring. HIFU has been applied to treat a variety of solid malignant tumors, including the pancreas, liver, prostate, breast, uterine fibroids, and soft-tissue sarcomas. Magnetic Resonance Guided Focused Ultrasound (MRgFUS) combines focused ultrasound and magnetic resonance imaging to target and treat affected tissue.

Focal laser ablation (FLA) is the destruction of tissue using a beam of electromagnetic radiation emitted from a laser fiber introduced into the cancer focus. Tissue is destroyed through thermal conversion of the electromagnetic energy into heat, causing coagulative necrosis. Other terms for FLA include photothermal therapy, laser interstitial therapy, and laser interstitial photocoagulation

INDICATIONS:

MRI-guided focused ultrasound (MRgFUS) is considered medically necessary if the following are met:

Diagnosis of metastatic bone cancer if **ALL** the following are met:

- Treatment is for palliation of cancer pain
- Member is eighteen years or older

Diagnosis of medication refractory essential tremor

(Medication refractory essential tremor is defined for the purposes of this policy as being refractory to a minimum of two trials of medical therapy to include the following unless contraindicated: beta blockers, anticonvulsants and/or benzodiazepines)

High-intensity focused ultrasound (HIFU) may be considered medically necessary as a local treatment for prostate cancer when all of the following criteria are met:

- radiation therapy recurrence; and
- the member is a candidate for local therapy (e.g., life expectancy > 5y); and
- transrectal ultrasound guided (TRUS) biopsy positive; and
- there is an absence of metastatic disease

MEDICARE BUSINESS SEGMENT:

According to CMS coding updates, C9747 Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance is considered reimbursable in a hospital or ASC setting.

EXCLUSIONS:

The long-term safety and efficacy data regarding the use of high intensity focused ultrasound (HIFU) in the treatment of various conditions is insufficient to show comparable or superior efficacy when compared to standard therapies.

Therefore, unless mandated, high intensity focused ultrasound (HIFU) is considered **experimental, investigational or unproven** and **NOT COVERED** for all indications including but not limited to:

- Benign prostatic hypertrophy
- Thyroid nodules and primary hyperparathyroidism
- Breast fibroadenoma
- Breast cancer
- Primary and secondary liver cancer
- Renal cell carcinoma
- Pancreatic cancer
- Brain cancer
- Osteosarcoma
- Uterine fibroids

The long-term safety and efficacy data regarding the use of focal laser ablation to treat patients with localized prostate cancer is insufficient to show comparable or superior efficacy when compared to standard therapies. Therefore, unless mandated, focal laser ablation is considered **experimental, investigational or unproven** and **NOT COVERED** for all indications, including localized prostate cancer.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services that do not meet criteria set in the PARP may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: High Intensity Focused Ultrasound

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

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

47399 Unlisted procedure, liver

48999 Unlisted procedure, pancreas

50549 Unlisted laparoscopy procedure, renal

55880 Ablation of malignant prostate tissue, transrectal, with high intensity focused ultrasound (HIFU), including ultrasound guidance

55899 Unlisted procedure, male genital system [when specified as destruction of prostate tissue by high intensity focused ultrasound]

58999 Unlisted procedure, female genital system (nonobstetrical)

60699 Unlisted procedure, endocrine system

64999 Unlisted procedure, nervous system

76999 Unlisted ultrasound procedure (eg, diagnostic, interventional)

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

0655T Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

National Comprehensive Cancer Network Clinical (NCCN) Prostate Cancer v1.2023

UpToDate Cryotherapy and Other Ablative Techniques for the Initial Treatment of Prostate Cancer. September 12, 2016.

Dickinson L, Ahmed HU, Kirkham AP, et al. A multi-centre prospective development study evaluating focal therapy using high intensity focused ultrasound for localised prostate cancer: The INDEX study. Contemp Clin Trials. 2013;36(1):68-80

Ramsay CR, Adewuyi TE, Gray J, et al. Ablative therapy for people with localised prostate cancer: A systematic review and economic evaluation. Health Technol Assess. 2015;19(49):1-490

Malietzis G, Monzon L, Hand J, Wasan H, Leen E, Abel M, Muhammad A, et. al. High Intensity Focused Ultrasound: Advances in Technology and Experimental Trails Support Enhanced Utility of Focused Ultrasound Surgery in Oncology. Br J Radiol 2013;86:20130044

National Comprehensive Cancer Network (NCCN) Hepatobiliary Cancers, Hepatocellular v1.2022

UpToDate. Nonsurgical therapies for localized hepatocellular carcinoma: radiofrequency ablation, percutaneous ethanol injection, thermal ablation and cryoablation. October 16, 2015

Li CC, Wang YQ, Li YP, Li XL. High-intensity focused ultrasound for treatment of pancreatic cancer: A systematic review. J Evid Based Med. 2014;7(4):270-281.

National Comprehensive Cancer Network (NCCN) Kidney Cancer v1.2023

UpToDate. Radiofrequency ablation and cyroablation for renal cell carcinoma. July 1, 2015

National Comprehensive Cancer Network (NCCN) Pancreatic Adenocarcinoma v1.2022

National Comprehensive Cancer Network (NCCN) Breast Cancer v4.2022

Peek MC, Ahmed M, Napoli A, et al. Systematic review of high-intensity focused ultrasound ablation in the treatment of breast cancer. Br J Surg. 2015a;102(8):873-882

Kovatcheva R, Guglielmina J, et. al. Ultrasound Guided High Intensity Focused Ultrasound Treatment of Breast Fibroadenoma – A Multicenter Experience. Journal of Therapeutic Ultrasound 2015 3:13.2018

National Comprehensive Cancer Network (NCCN) Central Nervous System Cancers v 3.2019

National Comprehensive Cancer Network (NCCN) Soft Tissue Sarcoma-v.4.2019

Kovatcheva R, Vlahov J, Stoinov J, et al. US-guided high-intensity focused ultrasound as a promising non-invasive method for treatment of primary hyperparathyroidism. Eur Radiol. 2014;24(9):2052-2058

Golan R, Bernstein AN, McClure TD, et al. Partial gland treatment of prostate cancer using high-intensity focused ultrasound in the primary and salvage settings: A systematic review. J Urol. 2017 Apr 19.

Elias WJ, Lipsman N, Ondo WG, et al. A randomized trial of focused ultrasound thalamotomy for essential tremor. N Engl J Med. 2016;375(8):730-739

Gallay MN, Moser D, Jeanmonod D. Safety and accuracy of incisionless transcranial MR-guided focused ultrasound functional neurosurgery: Single-center experience with 253 targets in 180 treatments. J Neurosurg. 2018 May 25:1-10

Fishman PS, Elias WJ, Ghanouni P, et al. Neurological adverse event profile of magnetic resonance imaging-guided focused ultrasound thalamotomy for essential tremor. Mov Disord. 2018 33(5):843-847

Chang JW, Park CK, Lipsman N, et al. A prospective trial of magnetic resonance-guided focused ultrasound thalamotomy for essential tremor: Results at the 2-year follow-up. Ann Neurol. 2018;83(1):107-114.

American Society for Radiation Oncology. Palliative radiotherapy for bone metastases: Update of an ASTRO evidence-based guideline. Practical Radiation Oncology, 2017;4-12.

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Adult Cancer Pain Version v3.2019

Lutz S, Balboni T, Jones J, et. al. Palliative radiation therapy for bone metastases: update of an ASTRO Evidence Based Guideline. Practical Radiation Oncology 2017 7, 4-12

Lee HL, Kuo CC, Tsai JT, Chen CY, Wu MH, Chiou JF. Magnetic Resonance-Guided Focused Ultrasound Versus Conventional Radiation Therapy for Painful Bone Metastasis: A Matched-Pair Study. J Bone Joint Surg Am. 2017 Sep 20;99(18):1572-1578.

Harding D, Giles SL, Brown MRD, Ter Haar GR, van den Bosch M, Bartels LW, Kim YS, Deppe M, deSouza NM. Evaluation of Quality of Life Outcomes Following Palliative Treatment of Bone Metastases with Magnetic Resonance-

guided High Intensity Focused Ultrasound: An International Multicentre Study. *Clin Oncol (R Coll Radiol)*. 2018 Apr;30(4):233-242

Dababou S, Marrocchio C, Scipione R, Erasmus HP, Ghanouni P, Anzidei M, Catalano C, Napoli A. High-Intensity Focused Ultrasound for Pain Management in Patients with Cancer. *Radiographics*. 2018 Mar-Apr;38(2):603-623.

Duc NM, Keserci B. Emerging clinical applications of high-intensity focused ultrasound. *Diagn Interv Radiol*. 2019 Jul 9

Park YS, Jung NY, Na YC, Chang JW. Four-year follow-up results of magnetic resonance-guided focused ultrasound thalamotomy for essential tremor. *Mov Disord*. 2019;34(5):727-734

Castellani D, Branchi A, Claudini R, et al. A structured framework for optimizing high-intensity focused ultrasound ablative treatment in localized prostate cancer. *Investig Clin Urol*. 2019;60(4):312-318.

Moosa S, Martínez-Fernandez R, Elias WJ, et al. The role of high-intensity focused ultrasound as a symptomatic treatment for Parkinson's disease. *Mov Disord*. 2019 Jul 10

Lee WJ, Almalki O. Gastro Esophageal Reflux Disease after Sleeve Gastrectomy: A Real Issue and Future Perspectives. *Am J General GI Surg*. 2018; 1(1): 1001.

Soong, TC, Almalki O, et al. Revision of Sleeve Gastrectomy with Hiatal Repair with Gastropexy for Gastroesophageal Reflux Disease. *Obes Surg*. 2019 Aug;29(8):2381-2386

Lim CH, LeePC et al. Resolution of Erosive Esophagitis After Conversion from Vertical Sleeve Gastrectomy to Roux-en-Y Gastric Bypass. *Obes Surg*. 2020 Aug 15 : 1–9.

Local Coverage Determination (LCD): Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (L38495)

Stabile A, Moschini M, Montorsi F, et al. Focal therapy for prostate cancer - index lesion treatment vs. hemiablation. A matter of definition. *Int Braz J Urol*. 2019; 45(5):873-876.

Valerio M, Cerantola Y, Eggener SE, et al. New and Established Technology in Focal Ablation of the Prostate: A Systematic Review. *Eur Urol*. 2017; 71(1):17-34.

Zheng X, Jin K, Qiu S, et al. Focal Laser Ablation Versus Radical Prostatectomy for Localized Prostate Cancer: Survival Outcomes From a Matched Cohort. *Clin Genitourin Cancer*. 2019; 17(6):464-469.e3.

Zhou X, Jin K, Qiu S, et al. Comparative Effectiveness of Radiotherapy versus Focal Laser Ablation in Patients with Low and Intermediate Risk Localized Prostate Cancer. *Sci Rep*. 2020; 10(1):9112.

Dosanjh A, Harvey P, Baldwin S, Mintz H, Evison F, Gallier S, et al. High-intensity Focused Ultrasound for the Treatment of Prostate Cancer: A National Cohort Study Focusing on the Development of Stricture and Fistulae. *Eur Urol Focus*. 2021 Mar;7(2):340-346

Tsukamoto S, Kido A, Tanaka Y, Facchini G, Peta G, Rossi G, Mavrogenis AF. Current Overview of Treatment for Metastatic Bone Disease. *Curr Oncol*. 2021 Aug 29;28(5):3347-3372

He L, Zhao W, Xia Z, Su A, Li Z, Zhu J. Comparative efficacy of different ultrasound-guided ablation for the treatment of benign thyroid nodules: Systematic review and network meta-analysis of randomized controlled trials. *PLoS One*. 2021 Jan 20;16(1):e0243864.

Ghai S, Finelli A, Corr K, et al. MRI-guided Focused Ultrasound Ablation for Localized Intermediate-Risk Prostate Cancer: Early Results of a Phase II Trial. *Radiology*. Mar 2021; 298(3): 695-703

Baal JD, Chen WC, Baal U, et al. Efficacy and safety of magnetic resonance-guided focused ultrasound for the treatment of painful bone metastases: a systematic review and meta-analysis. *Skeletal Radiol*. May 21, 2021

Miller WK, Becker KN, Caras AJ, et al. Magnetic resonance-guided focused ultrasound treatment for essential tremor shows sustained efficacy: a meta-analysis. *Neurosurg Rev*. May 12, 2021.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain. Version 2.2022.

Bakavicius A, Marra G, Macek P, et al. Available evidence on HIFU for focal treatment of prostate cancer: a systematic review. Int Braz J Urol. 2022;48(2):263-74.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/18

Revised: 1/19 (added indication); 1/20 (added indication); 7/21 (revise title, add exclusion); 7/23 (add indication for HIFU)

Reviewed: 1/21, 7/22

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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