

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.

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National Comprehensive Cancer Network (NCCN) Breast Cancer v3.2024

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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, 7/24

CMS UM Oversight Committee Approval: 12/23, 7/24

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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