Medical Policy

Subject:	Histotripsy		
Document#:	SURG.00165	**Publish Date:**	04/16/2025
Status:	Reviewed	**Last Review Date:**	02/20/2025

Description/Scope

This document addresses the use of histotripsy to ablate tissue. Histotripsy is an incisionless non-thermal procedure that uses ultrasound to induce mechanical cavitation resulting in the transformation of targeted tissue into acellular debris. The mechanism of action for histotripsy differs from that for high intensity focused ultrasound (HIFU). In HIFU, the heat produced by high intensity focused ultrasound directly destroys tissue. The spread of this heat can damage adjacent tissue. Histotripsy uses minimal heat to create microbubbles within tissue and it is these bubbles that destroy the tissue. Histotripsy has been proposed as a treatment for malignant tissue, including liver lesions and renal cancer. This treatment has also been proposed for treatment of nonmalignant conditions such as benign prostatic hypertrophy (BPH).

Note: For other documents related to ultrasonic ablation techniques, please see the following:

- CG-MED-81 Ultrasound Ablation for Oncologic Indications
- MED.00057 MRI Guided High Intensity Focused Ultrasound Ablation for Non-Oncologic Indications

Position Statement

Investigational and Not Medically Necessary:

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

The requirements below are specific to the Florida Medicaid Managed Care Plan and are not a part of the Medical Policy or Clinical UM guideline approved by Elevance Health's Medical Policy and Technology Assessment Committee.

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Below is a list of the materials the plans are required to submit when they deny coverage as experimental/investigational:

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I. Include a rationale for the immediacy of the review

Additional required information

A. Submit the rationale used to preliminarily indicate the service is experimental/investigational
  1. Include peer-reviewed journal articles in PDF format with links to the online articles
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Histotripsy is considered **investigational and not medically necessary** for all indications.

Rationale

Histotripsy is a focal ablative therapy that destroys tissue by acoustic cavitation. It has been proposed as an alternative treatment of tumors. The proposed benefits of low-heat focal ablative therapy include avoidance of heat sink effects, which is theorized to allow histotripsy to be used in highly vascular areas (Hendricks-Wenger, 2021).

A phase I trial provided the initial safety and efficacy data regarding the use of histotripsy in individuals with hepatocellular carcinoma and hepatic metastasis (Vidal-Jove, 2022). In this study, 8 individuals with multifocal liver tumors were followed for 8 weeks post-procedure. There were no significant procedure-related events. The study focused on technical safety and did not provide follow-up data on cancer-related outcomes.

On October 6, 2023, the Edison® System (HistoSonics®, Ann Arbor, MI) received de novo marketing authorization from the FDA for the non-thermal destruction of liver tumors. On February 14, 2024, an updated Edison system was cleared for use in the non-invasive destruction of liver tumors. The authorization was based in part on the data from two single-arm, non-randomized prospective trials evaluating primary or metastatic liver tumors (NCT04572633, NCT04573881). Interim results have been published for one of those studies (Mendiratta-Lala, 2024). Participants will be followed for 5 years post-procedure (NCT04572633, NCT04573881). On October 1, 2024, the FDA approved the updated system for the treatment of liver tumors, as "substantially equivalent to the predicate device".

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Mendiratta-Lala and colleagues (2024) published the results of a prospective multicenter, single arm trial (#HOPE4LIVER). A total of 44 participants with up to 3 tumors smaller than 3 cm in size were treated with histotripsy. Participants included individuals with hepatocellular carcinoma (n=18) or with liver metastases from non–hepatocellular carcinomas (n=26). The co-primary endpoints address technical success, tumor treatment volume being greater than or equal to the targeted volume with complete tumor coverage, and safety, and the absence of procedure-related major complications through 30-day postoperative. All participants underwent a single session of histotripsy. Technical efficacy at 30 days was 83%. A total of 101 adverse events (AEs) were reported within 30 days postoperative, with 94 AEs (93.1%) categorized as nonserious. Of the 7 serious AEs, 3 were classified as primary safety end-point failures. These end-point failures included 1 case each of sepsis, pleuritic pain requiring inpatient care, and hepatic failure leading to death 37 days after the procedure. The remaining serious AEs were identified as splenic hematoma, melena, procedural pain, and progression of metastatic colorectal cancer. The study was limited to reporting early endpoints related to performance rather than clinical outcomes. The authors noted that the cohort in this study may not be typical of individuals who receive ablative treatment because many of them had stage IV metastatic disease. Longer-term 12-month data regarding safety and efficacy is being analyzed with plans to publish in the future. The lack of a control group prevents comparing this study's results to more established ablative technologies.

Histotripsy is proposed for use to treat renal cancer; however, there are no published studies evaluating the use of histotripsy for this indication. There are two prospective, multi-center, single-arm clinical trials underway to evaluate the safety of effectiveness of the device in treating renal tumors. The CAIN trial (NCT05432232) and the pivotal #HOPE4KIDNEY trial (NCT05820087) are still recruiting participants and have a December 2024 estimated completion date. The preferred treatment of renal cancer is a partial or radical nephrectomy. For individuals with small tumors or for individuals who are not candidates for surgery, ablative therapy, such as RFA, cryoablation or stereotactic ablative body radiation therapy are considered standard alternative therapies (National

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Cancer Institute (NCI), Renal Cancer Treatment, 2024; NCCN, Kidney cancer V3.2025). Histotripsy is not mentioned as a potential treatment of renal tumors in any current guidelines.

Schuster and associates (2018) presented the results of a prospective cohort study in which 25 individuals with benign prostatic hypertrophy (BPH) were treated with histotripsy to relieve urinary obstruction. The primary study endpoint was safety as reflected by the rate of adverse events. There was 1 serious adverse event (urinary retention requiring catheterization for 8 days) and 26 other adverse events including catheter-related pain (n=8), dysuria (n=5), bladder spasm (n=5), urinary retention (n=3), minor anal abrasion (n=1), microhematuria (n=1), and local reaction at the catheter site (n=3). The authors describe this as a limited pilot study. Larger controlled studies with longer follow up are needed to evaluate outcomes of histotripsy compared to more established therapies for BPH.

Summary

Histotripsy is being investigated as a non-thermal option to ablate tissues such as kidney or hepatic malignancies. Histotripsy has demonstrated promising outcomes in preclinical and early-phase clinical trials (Sandilos, 2024). These early published studies focus on technical outcomes and there are no published studies evaluating clinical outcomes. There is insufficient evidence published in peer-reviewed medical literature to permit reasonable conclusions concerning the oncologic effects of histotripsy therapy.

Background/Overview

Histotripsy is sometimes compared to HIFU, but the treatments are fundamentally different. HIFU is a thermal treatment that uses continuous or long bursts of ultrasound to induce heat resulting in tissue destruction. In contrast, histotripsy is a non-thermal treatment that employs “short ultrasound bursts with higher peak pressure amplitudes”

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to cause mechanical cavitation and tissue destruction (Verma, 2024). The treated tissue is liquefied and reabsorbed within 1-2 months post-treatment (Xu, 2024).

Histotripsy devices consist of a treatment head and probe linked to a touchscreen interface for real-time visualization and control. Tumor margins are mapped out and the probe generates bubble clouds in specific locations within the target area to confirm margins and determine the energy needed for cavitation. During ablation, overlapping histotripsy zones cover the tumor, with changes in ultrasound transmission observed. In histotripsy, focal volumes are stacked together to treat the target volume. This has the proposed benefit of sparing surrounding tissues, unlike thermal ablation. Robotic assistance can be incorporated to ensure precise positioning of the treatment arm over the tumor.

Histotripsy works differently in solid tissues compared to tissue-fluid interfaces. In solid tissue, histotripsy transforms tissue into a liquid, entirely removing cellular structures and creating clear acellular zones. In tissue-fluid interfaces, histotripsy erodes the tissue surface, causing the shedding of micrometer-sized cell debris and progressively thinning the tissue until it completely perforates. It is theorized that histotripsy may induce immune responses, potentially aiding in tumor regression and enhancing immunotherapy.

The benefits of non-thermal focal ablative therapy over other ablative therapies include tissue destruction in the targeted area and avoidance of heat sink effects which is theorized to allow histotripsy to be used in highly vascular areas (Hendricks-Wenger, 2021). Limitations of histotripsy include decreased effectiveness with increased target depths, potential risks in gas-filled organs, and a theoretical risk of metastasis due to tissue fragmentation (Verma, 2024).

Definitions

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Ablation: The destruction of a body part or tissue or its function. Ablation may be achieved by surgery, hormones, drugs, radiofrequency, heat, or other methods.

Cavitation: Creating cavities within the body by breaking down tissue at a cellular level. A number of methods can be used to facilitate tissue destruction including heat, radiation or mechanical.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance
0888T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance
55899	Unlisted procedure, male genital system [when specified as histotripsy of prostate tissue]

ICD-10-Procedure

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XF50X08	Destruction of liver using ultrasound-guided cavitation, external approach, new technology group 8
XF51X08	Destruction of right lobe liver using ultrasound-guided cavitation, external approach, new technology group 8
XF52X08	Destruction of left lobe liver using ultrasound-guided cavitation, external approach, new technology group 8

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Hendricks-Wenger A, Weber P, Simon A, et al. Histotripsy for the treatment of cholangiocarcinoma liver tumors: in vivo feasibility and ex vivo dosimetry study. IEEE Trans Ultrason Ferroelectr Freq Control. 2021; 68(9):2953-2964.
2. Jahangiri S, Yu F. Fundamentals and applications of focused ultrasound-assisted cancer immune checkpoint inhibition for solid tumors. Pharmaceutics. 2024; 16(3):411.
3. Khokhlova VA, Fowlkes JB, Roberts WW, et al. Histotripsy methods in mechanical disintegration of tissue: towards clinical applications. Int J Hyperthermia. 2015; 31(2):145-162.
4. Mendiratta-Lala M, Wiggermann P, Pech M, et al. The #HOPE4LIVER single-arm pivotal trial for histotripsy of primary and metastatic liver tumors. Radiology. 2024; 312(3):e233051.
5. Sandilos G, Butchy MV, Koneru M, et al. Histotripsy - hype or hope? Review of innovation and future implications. J Gastrointest Surg. 2024; 28(8):1370-1375.

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6. Schuster TG, Wei JT, Hendlin K, et al. Histotripsy treatment of benign prostatic enlargement using the vortx rx system: Initial human safety and efficacy outcomes. Urology. 2018; 114:184-187.
7. Verma Y, Perera Molligoda Arachchige AS. Advances in tumor management: harnessing the potential of histotripsy. Radiol Imaging Cancer. 2024; 6(3):e230159.
8. Vidal-Jove J, Serres X, Vlaisavljevich E, et al. First-in-man histotripsy of hepatic tumors: the THERESA trial, a feasibility study. Int J Hyperthermia. 2022; 39(1):1115-1123.
9. Xu Z, Hall TL, Vlaisavljevich E, Lee FT Jr. Histotripsy: the first noninvasive, non-ionizing, non-thermal ablation technique based on ultrasound. Int J Hyperthermia. 2021; 38(1):561-575.
10. Xu Z, Khokhlova TD, Cho CS, Khokhlova VA. Histotripsy: a method for mechanical tissue ablation with ultrasound. Annu Rev Biomed Eng. 2024; 26(1):141-167.

Government Agency, Medical Society, and Other Authoritative Publications:

1. HistoSonics, Inc. The HistoSonics Edison™ System for treatment of pancreatic andenocarcinoma using histotripsy (GANNON). NLM Identifier: NCT06282809. Last updated on January 9, 2025. Available at: https://clinicaltrials.gov/study/NCT06282809?term=histosonics&aggFilters=status:rec%20act&rank=3. Accessed on February 18, 2025.
2. HistoSonics, Inc. The HistoSonics Edison™ System for Treatment of Primary Solid Renal Tumors Using Histotripsy (#HOPE4KIDNEY) (#HOPE4KIDNEY). NLM Identifier: NCT05820087. Last updated on January 17, 2025. Available at: https://clinicaltrials.gov/study/NCT05820087?term=NCT05820087&limit=10&rank=1. Accessed on February 18, 2025.
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4. National Comprehensive Cancer Network® (NCCN) Practice Guidelines in Oncology™. ©2025 National Comprehensive Cancer Network, Inc. For additional information, visit the NCCN website: http://www.nccn.org. Accessed on February 18, 2025.
    - Hepatocellular Carcinoma. V4.2024. Revised January 10, 2025.
    - Kidney Cancer. V3.2025. Revised January 9, 2025.
5. Solbiati, L. Humanitas Hospital. The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER). NCT04573881. Last updated on February 18, 2025. Available at: https://clinicaltrials.gov/ct2/show/study/NCT04573881?term=%23HOPE4LIVER&draw=1&rank=1. Accessed on February 18, 2025.
6. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. Histosonics Edison System Summary of Safety and Effectiveness. Rockville, MD: FDA. Accessed on January 7, 2025.
    - No. K233466. March 13, 2024. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233466.
    - No. K241902. October 1, 2024. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241902.pdf.
7. Ziemlewicz T, Cho C. The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER US). NCT04572633. Last updated on October 10, 2024. Available at: https://clinicaltrials.gov/ct2/show/study/NCT04572633?term=%23HOPE4LIVER&draw=1&rank=2. Accessed on February 18, 2025.

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Histotripsy

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/20/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Rationale and References sections.
New	11/14/2024	MPTAC review. Initial document development.

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