Medical Policy Manual Medicine, Policy No. 178

Histotripsy for Hepatic or Renal Tumor Treatment

Effective: June 1, 2025

Next Review: April 2026
Last Review: April 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Histotripsy is a non-invasive treatment that uses focused ultrasound pulses to mechanically break down targeted tissue through the creation and collapse of microscopic bubbles. Histotripsy is proposed for the treatment malignant lesions including in liver and kidney.

MEDICAL POLICY CRITERIA

The use of histotripsy is considered **investigational** for any indication.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Radiofrequency Ablation (RFA) of Tumors Other than Liver, Surgery, Policy No. 92
2. Cryosurgical Ablation of Miscellaneous Solid Tumors, Surgery, Policy No. 132
3. Magnetic Resonance (MR) Guided Focused Ultrasound (MRgFUS) and High Intensity Focused Ultrasound (HIFU) Ablation, Surgery, Policy No. 139
4. Microwave Tumor Ablation, Surgery, Policy No. 189
5. Ablation of Primary and Metastatic Liver Tumors, Surgery, Policy No. 204

BACKGROUND

Histotripsy is a non-invasive medical treatment that uses focused ultrasound technology to precisely destroy targeted tissue. The technique works by delivering rapid, high-intensity ultrasound pulses that create tiny bubbles in the tissue. These bubbles quickly expand and collapse in a process called cavitation, which mechanically breaks down the targeted tissue into a liquid-like state without using heat or causing significant damage to surrounding healthy tissue.

The Edison® System (HistoSonics, Inc) operates by delivering high-amplitude, microsecond ultrasound pulses that create controlled acoustic cavitation, forming "bubble clouds" at targeted locations. These bubble clouds, consisting of microbubbles that rapidly expand and collapse, exert mechanical stress on the liver tissue, ultimately destroying it and creating an acellular lysate. The system is integrated with a GE LOGIQ E10s ultrasound system allowing for precise targeting and treatment delivery through system software that controls the treatment arm's movement through the planned treatment volume.[1]

REGULATORY STATUS

The Edison® System (HistoSonics®, Ann Arbor, MI)

- In October 2023 the Food and Drug Administration issued de novo marketing authorization for the Edison System for focused ultrasound system for non-thermal, mechanical tissue ablation. This device uses focused ultrasound to mechanically ablate soft tissue. The device is not intended to thermally ablate tissue. (DEN220087)
- In October 2024 the Edison® System was granted 510 (k) premarket approval for non-invasive destruction of liver tumors, using a non-thermal, mechanical process of focused ultrasound. This approval was based on the predicate Edison System. (K241902)[1]

EVIDENCE SUMMARY

SYSTEMATIC REVIEWS

There are no systematic reviews for this indication.

Nonrandomized Studies

Mendiratta-Lala (2024) published the results of a prospective multicenter, single arm trial (#HOPE4LIVER).[2] A total of 44 participants with up to three 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). All participants underwent a single session of histotripsy. Technical efficacy at 30 days was 83%. A total of 101 adverse events were reported within 30 days postoperative, with 94 (93.1%) categorized as nonserious. Three of the serious adverse events were classified as primary safety end-point failures (Sepsis, pleuritic pain and hepatic failure leading to death 37 days post procedure). The remaining four serious adverse events were splenic hematoma, melena, procedural pain, and progression of metastatic colorectal cancer. Limitations include outcomes focused only on early performance metrics rather than long-term clinical outcomes, the patient cohort primarily consisted of stage IV metastatic disease cases, which may not represent typical ablation

treatment candidates and the absence of a control group limits the ability to compare histotripsy's effectiveness against established ablative technologies.

Vidal-Jove (2022) published a first-in-human phase I trial evaluating histotripsy, a noninvasive focused ultrasound therapy, for treating liver tumors.[3] The study, known as the Theresa Study, included 8 of 14 recruited patients (median age 60.4 years) with unresectable end-stage multifocal liver tumors, targeting eleven tumors total with an average diameter of 1.4 cm. The distribution of cases included 5 patients with colorectal liver metastases (7 tumors), 1 patient with breast cancer metastases (1 tumor), 1 with cholangiocarcinoma metastases (2 tumors), and 1 with hepatocellular carcinoma (1 tumor). Using a prototype system from HistoSonics, Inc., the study achieved its primary endpoint of creating planned tissue destruction zones in 100% of procedures, as verified by MRI one day post-procedure. The treatment demonstrated a favorable safety profile with zero device-related adverse events during the eight-week follow-up period, and 2 of 8 patients showed continuous decline in tumor markers. Limitations include small sample size and the non-randomized design.Trial Registration: Study to Evaluate VORTX Rx (Theresa). NCT03741088.

PRACTICE GUIDELINE SUMMARY

National Comprehensive Cancer Network (NCCN)

- The NCCN Practice guidelines for Hepatocellular Carcinoma (V1. 2025) do not address Histotripsy.[4]
- The NCCN practice guidelines for Kidney Cancer (V3. 2025) do not address Histotripsy.[5]

SUMMARY

There is not enough research to show that histotripsy is a safe and effective treatment for renal or hepatic malignant tumors. No U.S. evidence based clinical practice guidelines recommend the use of histotripsy for any indication. Therefore, the use of histotripsy for any indication is considered investigational.

REFERENCES

1. FDA 510(k) premarket notification for Edison System Secondary FDA 510(k) premarket notification for Edison System [cited. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241902.pdf.
2. 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. PMID: 39225612
3. 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):1115-23. PMID: 36002243
4. Network NCC. NCCN Guidelines for Hepatocellular Carcinoma (V1. 2025). Secondary NCCN Guidelines for Hepatocellular Carcinoma (V1. 2025) [cited 3/25/2025]. 'Available from:' https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf.

5. Network NCC. NCCN Guidelines for Kidney Cancer (V3. 2025). Secondary NCCN Guidelines for Kidney Cancer (V3. 2025) [cited 3/25/2025]. 'Available from:' https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.

CODES

Codes	Number	Description
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
HCPCS	None	

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