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## Medicare Advantage Policy Manual

Policy ID: M-MED178

### ***Histotripsy for Hepatic or Renal Tumor Treatment***

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**Medicare Link(s) Revised:** N/A

#### **IMPORTANT REMINDER**

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.*

*The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded 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.

## MEDICARE ADVANTAGE POLICY CRITERIA

<b>CMS Coverage Manuals*</b>	None
<b>National Coverage Determinations (NCDs)*</b>	None
<b>Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles.</b>	None

Histotripsy for Hepatic or Renal Tumor Treatment  
Medicine, [Policy No. 178](#) (see “NOTE” below)

**NOTE:** If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

## POLICY GUIDELINES

### 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.

## CROSS REFERENCES

[Investigational \(Experimental\) Services and New and Emerging Medical Technologies and Procedures](#), Medicine, Policy No. M-149

[Radiofrequency Ablation \(RFA\) of Tumors Other Than the Liver](#), Surgery, Policy No. M-92

[Magnetic Resonance \(MR\) Guided Focused Ultrasound \(MRgFUS\), and High Intensity Focused Ultrasound \(HIFU\) Ablation, and Transurethral Ultrasound Ablation \(TULSA\)](#), Surgery, Policy No. M-139

## REFERENCES

None

## CODING

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

**\*IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.