NO. 91649

HISTOTRIPSY

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Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This medical policy addresses histotripsy (i.e., non-thermal ablation via acoustic energy delivery) for the treatment of malignant tumors (including the Edison Histotripsy System (HistoSonics).

Related policies:

- High Intensity Focused Ultrasound # 91601

I. MEDICAL NECESSITY CRITERIA

A. INCLUSIONS: Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant liver tumors (primary or metastatic), is considered medically necessary when all the following are met:

1. Other methods have been reviewed by a multidisciplinary team and determined not to be suitable, including:

   a. Other well-established methods of ablation (i.e. microwave/radiofrequency, surgical, or percutaneous ethanol injection)
   b. Arterially-directed therapies
   c. Radiation therapy

2. Member is 18 years of age or older

3. Tumors are ≤ 3 cm

B. EXCLUSIONS:

1. Tumors other than malignant liver tumors.
2. Any of the above inclusion criteria are not met.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
Wellpoint Federal (formerly National Government Services, Inc.)	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

Histotripsy is a noninvasive, nonionizing, nonsurgical treatment option for nonresectable early-stage liver cancer (hepatocellular carcinoma [HCC]) or secondary liver metastasis that involves the use of ultrasound energy to apply mechanical acoustic cavitation to the lesion of interest. This mechanism creates microbubbles in the gas within the extracellular matrix of tissues, which expand and collapse, mechanically destroying targeted tissues.

Hepatocellular carcinoma

Health Problem

Hepatocellular carcinoma (HCC) is the most common primary liver cancer, affecting adults and children. The liver is also the most common organ for metastases from other cancer types (e.g., colorectal cancer, breast cancer, lung cancer, stomach cancer, bile duct cancers) (ACS, 2020; NCI, 2024a). HCC or liver metastases disturb normal liver functions, including bile production for fat digestion, blood filtration, and sugar (glycogen) storage (NCI, 2024a). Increases in obesity and diabetes rates are contributing to the rise in HCC cases (Asafo-Agyei and Samant, 2023).

Clinical Presentation

Symptoms of primary HCC include discomfort of the upper right abdomen, abdominal swelling, yellowing of the skin and whites of the eyes (jaundice), easy bruising or bleeding, weight loss and loss of appetite, nausea and vomiting, fever, unusual tiredness, dark urine, and pale bowel movements (NCI, 2024a). Liver metastasis symptoms are similar to primary HCC, but may also include itchiness and leg swelling (ACS, 2020).

Epidemiology and Natural History

HCC is 3 times as prevalent in men than women and is the second most common cause of cancer-related death in men (Asafo-Agyei and Samant, 2023). HCC is strongly associated with chronic liver disease. Chronic viral infection with hepatitis B or hepatitis C is responsible for > 50% of HCC cases worldwide. Other risk factors include chronic excessive alcohol consumption, cirrhosis (scarring of liver), nonalcoholic liver steatohepatitis or nonalcoholic fatty liver disease (fat buildup in liver) from obesity and/or diabetes, aflatoxin exposure (fungus), α-1 antitrypsin deficiency (genetic),and hemochromatosis (iron buildup) (Orcutt and Anaya, 2018; Llovet et al., 2021; Asafo-Agyei and Samant, 2023).

Survival rate at 5 years for HCC is 18% (Asafo-Agyei and Samant, 2023).

Diagnosis

Diagnosis of HCC may involve review of the patient's health history, physical exam, laboratory testing (liver function, α-fetoprotein tumor marker), imaging (ultrasound, computed tomography, or magnetic resonance imaging), and liver biopsy (NCI, 2024b). If cancer is identified, the stage is determined using tools such as the Barcelona Clinic Liver Cancer Staging System. Cancer stage (tumor burden), liver function, other symptoms, and the patient's overall health are considered when determining prognosis (chance of recovery) (Reig et al., 2022; NCI, 2024c).

Treatment

Available options for liver tumors are categorized by whether the tumor can be surgically removed or how advanced the cancer or metastasis is, and may include (NCI, 2024d; ACS, 2025):

The standard of care for potentially resectable or transplantable liver tumors consists of resection (preferred), transplantation if criteria are met, or locoregional therapy for patients who are not candidates for surgical curative treatments, or as a part of a strategy to bridge patients for curative treatment. (NCCN, 2025) The options for locoregional therapy include:

- Ablation (microwave, radiofrequency, surgical, or percutaneous ethanol injection)
- Arterially-directed therapies (bland transarterial embolization [TAE], chemoembolization [TACE], TACE with drug-eluting beads, and radioembolization with yttrium-90 microspheres)
- Radiation therapy (3D conformal RT, intensity-modulated RT [IMRT], or stereotactic body radiotherapy [SBRT])

Edison Histotripsy System (HistoSonics)

The **Edison System (HistoSonics)** was initially cleared through the de novo route in 2023 under product code ***QGM (focused ultrasound system for nonthermal, mechanical tissue ablation)***. According to the FDA labeling, *The Edison System is indicated for the non-invasive destruction of liver tumors, including unresectable livor tumors, using a non-thermal, mechanical process of focuses ultrasound.*

The Edison Histotripsy System (HistoSonics) provides a noninvasive, nonionizing, nonsurgical treatment option for nonresectable early-stage liver cancer (hepatocellular carcinoma [HCC]) or secondary liver metastasis. The ablation zone can be tightly focused to the three-dimensional tumor area, and the nonthermal mechanical nature of the therapy minimizes damage to surrounding tissues and vessels. Histotripsy with the Edison system may also be applied as a palliative or bridge therapy while the patient awaits surgery or transplant.

The Edison System (HistoSonics; formerly Robotically Assisted Sonic Therapy [RAST], Vortx Rx) is a histotripsy* system that provides nonthermal mechanical ablation to target and destroy malignant tissue. Applied externally, the treatment uses microsecond bursts of ultrasound energy to create microbubbles in the gas within the extracellular matrix of tissues, combining to form a steerable bubble cloud. The expansion and collapse of the microbubbles mechanically destroys targeted tissues (acoustic cavitation). Varying the ultrasound pulses, bubble cloud, and focal zone size of the ultrasound beam enables targeting of specific tissues. For example, bile ducts, blood vessels, and connective tissue within and near the ablation target area are less likely to be harmed during HCC treatment due to differing resistance thresholds to histotripsy. After the targeted tissue is reduced to acellular debris, it is absorbed by the body over the next 2 months, resulting in a small scar at the treatment.

The histotripsy procedure is performed in an interventional radiology or surgical suite with the patient under general anesthesia. The physician uses ultrasound imaging and treatment planning software to identify target area(s). The robotic arm is positioned over the patient’s abdomen, with the histotripsy transducer placed over the target area. A coupling device filled with degassed water is attached to the transducer, and positioned in contact with the patient's skin; the water-filled coupling device conforms to the patient's abdomen to facilitate transmission of the ultrasound waves into the patient's body. Inside the targeted tissue, preliminary pulses are delivered to determine the energy required to create a bubble cloud and cellular destruction (personalization). The physician activates the transducer to begin automated treatment, monitoring the bubble cloud and tissue destruction continuously in real time using ultrasound imaging.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline

National Institute for Health and Care Research (NIHR) Health Technology assessment Programme	Health Technology Assessment Ablative and non-surgical therapies for early and very early hepatocellular carcinoma: a systematic review and network meta-analysis (12/2023)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Decision date
Edison System (Histosonics, Inc.)	DEN220087 K233466 K241902	10/06/2023 03/13/2024 10/30/2024

VI. CODING

ICD-10 Codes that may support medical necessity

C22.0: Liver cell carcinoma (Hepatocellular carcinoma)
C22.1: Intrahepatic bile duct carcinoma (Cholangiocarcinoma)
C22.2: Hepatoblastoma
C22.3: Angiosarcoma of liver
C22.4: Other sarcomas of liver
C22.7: Other specified carcinomas of liver
C22.8: Malignant neoplasm of liver, primary, unspecified as to type
C22.9: Malignant neoplasm of liver, not specified as primary or secondary
C78.7 Secondary malignant neoplasm of liver and intrahepatic bile duct

CPT/HCPCS Codes

0686T Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant **hepatocellular** tissue, including image guidance (Not covered for Medicaid)

Not Covered:

0888T Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant **renal** tissue, including imaging guidance

1037T Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant pancreatic tissue, including imaging guidance

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a

request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

Guidelines and Position Statements

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Liver tumors – primary and metastatic

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Renal

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2. Hayes, Inc. Medical Code Brief. 0888T – Category III (T codes). Hayes, Inc. January 17, 2024.

3. Hayes, Inc. Medical Code Brief. C9790 – HCPCS codes. Hayes, Inc. September 8, 2023.

Pancreatic

1. Hayes, Inc. Emerging Technology Report. Edison System (HistoSonics) for Histotripsy of Pancreatic Adenocarcinoma. Hayes, Inc. May 9, 2025.
2. Hayes, Inc. Medical Code Brief. 1037T – Category III (T codes). Hayes, Inc. January 6, 2026.

SUMMARY OF CHANGES

- New policy as of February 2026

Past review dates: Not applicable

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