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Medicare Advantage Policy Manual

Ablation of Primary and Metastatic Liver Tumors

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Medicare Link(s) Revised: 09/01/2018

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

Ablation is a method of locoregional therapy used to treat cancerous lesions, including hepatocellular carcinoma and hepatic metastases from other primary cancers.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy addresses locoregional therapies, specifically, percutaneous alcohol injection, cryoablation, radiofrequency and microwave ablation for primary and metastatic liver tumors. Please see Cross References for other ablative techniques and indications.

<table>
<thead>
<tr>
<th>CMS Coverage Manuals*</th>
<th>None</th>
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<tr>
<td>National Coverage Determinations (NCDs)*</td>
<td>None</td>
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Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*

For **pulsed radiofrequency** for the treatment of liver tumors:
- ✓ Non-Covered Services ([L35008](#))

**Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.**

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**Medical Policy Manual**

*Medicare coverage guidance is not available by the local Medicare contractor for ablative treatments of the liver. Therefore, the health plan’s medical policy is applicable.*

For **all other locoregional ablation therapies (e.g., radiofrequency, cryosurgical, microwave, percutaneous ethanol injections [PEI], etc.)** for the treatment of liver tumors:
- ✓ Ablation of Primary and Metastatic Liver Tumors, [Policy No. 204](#) (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).

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**POLICY GUIDELINES**

**REQUIRED DOCUMENTATION**

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Type of ablation therapy requested (e.g., radiofrequency, microwave, cryosurgical, etc.);
- All medical records and clinical documentation relevant to the medical condition being treated.

**REGULATORY STATUS**

There are several devices cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for MWA. Covidien’s (a subsidiary of Tyco Healthcare) Evident Microwave Ablation System has 510(k) clearance for soft tissue ablation, including partial or complete ablation of non-resectable liver tumors. The following devices have 510(k) clearance for MWA of (unspecified) soft tissue:
• BSD Medical Corporation’s MicroThermX® Microwave Ablation System (MTX-180);
• Valleylab’s (a subsidiary of Covidien) VivaWave® Microwave Ablation System;
• Vivant’s (acquired by Valleylab in 2005) Tri-Loop™ Microwave Ablation Probe;
• MicroSurgeon Microwave Soft Tissue Ablation Device;
• Microsulis Medical’s Acculis Accu2i; and
• NeuWave Medical’s Certus 140™

FDA determined that these devices were substantially equivalent to existing radiofrequency and MWA devices.

There are several cryoablation devices cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for use in open, minimally invasive or endoscopic surgical procedures in the areas of general surgery, urology, gynecology, oncology, neurology, dermatology, proctology, thoracic surgery and ear, nose and throat. Examples include:

• Cryocare® Surgical System by Endocare;
• CryoGen Cryosurgical System by Cryosurgical, Inc.;
• CryoHit® by Galil Medical;
• IceRod® CX, IcePearl® 2.1 CX and IceFORCE® 2.1 CX Cryoablation Needles by Galil Medical;
• SeedNet™ System by Galil Medical;
• Visica® System by Sanarus Medical;
• Visual-ICE® Cryoablation System by Galil;
• ERBECRYO 2® Cryosurgical Unit, ERBE USA Incorporated

CROSS REFERENCES

Radioembolization for Primary and Metastatic Tumors of the Liver, Medicine, Policy No. M-140

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

Radiofrequency Ablation (RFA) of Tumors, Surgery, Policy No. M-92

Cryosurgical Ablation of Miscellaneous Solid Organ, Pulmonary and Breast Tumors, Surgery, Policy No. M-132

Magnetic Resonance (MR) Guided Focused Ultrasound (MRgFUS) and High Intensity Focused Ultrasound (HIFU) Ablation, Surgery, Policy No. M-139

Microwave Tumor Ablation, Surgery, Policy No. M-189

REFERENCES

None

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<td><strong>IMPORTANT NOTE:</strong> 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.</td>
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