Cryosurgical Ablation of Miscellaneous Solid Organ, Pulmonary, and Breast Tumors

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IM PORTANT REM INDER

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 healthcare 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

Cryosurgical ablation (also called cryosurgery, cryotherapy, or cryoablation) kills cells (cancerous and normal) by freezing target tissues, most often by inserting a probe into the tumor through which coolant is circulated. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

MEDICARE ADVANTAGE POLICY CRITERIA

Notes:
- This policy is limited to cryosurgery for the treatment of solid organ tumors, as well as breast and pulmonary tumors.
- This policy does not address cryosurgical ablation of liver tumors. See Cross References for the applicable Medicare Advantage medical policy.
### CMS Coverage Manuals*
None

### National Coverage Determinations (NCDs)*
For cryosurgical ablation of the **prostate as a primary treatment of patients with clinically localized prostate cancer or for salvage therapy**\(^1\) (CPT code 55873):
- Cryosurgery of Prostate (230.9)

### Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*
None

### Medical Policy Manual
Medicare coverage guidance is not available for several types of ablation techniques for the treatment of liver tumors. Therefore, the health plan's medical policy is applicable.

For cryosurgical ablation of all solid organ tumors **other than liver or prostate** (*i.e.*, kidney, lung/pulmonary, etc.) as well as breast (malignant or benign), bone, and pancreatic tumors:
- Cryosurgical Ablation of Miscellaneous Solid Organ and Breast Tumors, Surgery, **Policy No. 132** *(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

### 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:

- Medical documentation and records, including the history and physical;
- Treatment plan, including the treatment area.

### REGULATORY STATUS
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
- **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
- **Ablation of Primary and Metastatic Liver Tumors**, Surgery, Policy No. M-204

### REFERENCES

1. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, §180.1 - Coverage Requirements

### CODING

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<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<td>19105</td>
<td>Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma</td>
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<td>20983</td>
<td>Ablation, therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation</td>
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<tr>
<td>Codes</td>
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<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)</td>
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<td>32994</td>
<td>Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation</td>
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</tbody>
</table>

**HCPCS**  None

*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.*