MEDICAL POLICY – 7.01.526
Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

BCBSA Ref. Policy: 7.01.92
Effective Date: Jan. 1, 2018
Last Revised: Dec. 12, 2017
Replaces: 7.01.92

RELATED MEDICAL POLICIES:
7.01.95 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors
7.01.133 Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults
8.01.24 Hematopoietic Cell Transplantation for Miscellaneous Solid Tumors in Adults

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Cryosurgical ablation uses extreme cold to destroy certain types of tumors. A probe is inserted into the tumor and an extremely cold liquid is circulated through the probe. An icy ball forms around the probe to freeze part or all of the tumor. The probe can be positioned in such a way as to maximize harm to the tumor while sparing nearby health tissue. The frozen area thaws, allowing the body to absorb the treated tissue. The policy discusses when this technique is considered medically necessary for specific breast and kidney tumors. It’s also been tried for other kinds of tumors. Because larger and longer medical studies are needed, this technique is considered investigational (unproven) for other types of tumors.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| **Cryosurgical ablation of benign breast fibroadenomas** | **Cryosurgical ablation of benign breast fibroadenomas may be considered medically necessary when ALL of the following criteria are met:**  
  - The lesion must be sonographically visible  
  **AND**  
  - The diagnosis of fibroadenoma is confirmed histologically  
  **AND**  
  - The lesion(s) is less than 3 cm in largest diameter  
  **AND**  
  - There are none of the following contraindications in existence:  
    - Large core biopsy diagnosis suggestive of cystosarcoma phyllodes tumor or other malignancy  
    - Poor visualization of lesion by ultrasound  
    - Large core biopsy diagnosis of fibroadenoma where diagnosis is thought to be non-concordant with findings on imaging or physical examination |
| **Cryosurgical ablation, localized renal cell carcinoma** | **Cryosurgical ablation may be considered medically necessary to treat localized renal cell carcinoma that is no more than 4 cm in size when either of the following criteria is met:**  
  - Preservation of kidney function is necessary (ie, the patient has one kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min per m²) and standard surgical approach (ie, resection of renal tissue) is likely to substantially worsen kidney function  
  **OR**  
  - Patient is not considered a surgical candidate |
| **Lung cancer**                              | **Cryosurgical ablation may be considered medically necessary to treat lung cancer when either of the following criteria is met:**  
  - The patient has early-stage non-small cell lung cancer and is a poor surgical candidate  
  **OR**  
  - The patient requires palliation for a central airway obstructing |
<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>lesion.</td>
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</table>

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryosurgical ablation, malignant tumors</td>
<td>Cryosurgical ablation is considered investigational as a treatment of malignant tumors of the breast, pancreas, or other solid tumors or metastases outside the liver and to treat renal cell carcinomas in patients who are surgical candidates.</td>
</tr>
</tbody>
</table>

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td></td>
<td><strong>CPT</strong></td>
</tr>
<tr>
<td>0340T</td>
<td>Ablation, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance (code terminated 1/1/18, replaced by 32994)</td>
</tr>
<tr>
<td>19105</td>
<td>Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma</td>
</tr>
<tr>
<td>20983</td>
<td>Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g. metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation</td>
</tr>
<tr>
<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 (new code effective 1/1/18)</td>
</tr>
<tr>
<td>50250</td>
<td>Ablation, open, one or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed</td>
</tr>
<tr>
<td>50542</td>
<td>Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed</td>
</tr>
<tr>
<td>50593</td>
<td>Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy</td>
</tr>
</tbody>
</table>

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Description

Cryosurgical ablation (hereafter referred to as cryosurgery or cryoablation) involves freezing of target tissues. This is most often performed by inserting a coolant-carrying probe into the tumor that is used to circulate coolant through. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

Background

Cryosurgical Treatment

The hypothesized advantages of cryosurgery include improved local control and benefits common to any minimally invasive procedure (eg, preserving normal organ tissue, decreasing morbidity, decreasing length of hospitalization). Potential complications of cryosurgery include those caused by hypothermic damage to normal tissue adjacent to the tumor, structural damage along the probe track, and secondary tumors, if cancerous cells are seeded during probe removal.

Cryosurgical treatment of various tumors including renal cell carcinomas, malignant and benign breast disease, pancreatic cancer, and lung cancer has been reported in the literature.

Breast Tumors

Early-stage primary breast tumors are treated surgically. The selection of lumpectomy, modified radical mastectomy, or another approach balances the patient’s desire for breast conservation, the need for tumor-free margins in resected tissue, and the patient’s age, hormone receptor
status, and other factors. Adjuvant radiation therapy decreases local recurrences, particularly for those who select lumpectomy. Adjuvant hormonal therapy and/or chemotherapy are added, depending on presence and number of involved nodes, hormone receptor status, and other factors. Treatment of metastatic disease includes surgery to remove the primary lesion and combination chemotherapy.

Fibroadenomas are common, benign tumors of the breast that can either present as a palpable mass or a mammographic abnormality. These benign tumors have been frequently surgically excised to rule out a malignancy. More recently, cryosurgical ablation has been proposed as a nonsurgical alternative to surgical excision of benign breast fibroadenomas. The demand for nonsurgical options for the management of these lesions is growing because less invasive strategies such as cryoablation to obliterate a palpable abnormality have evolved.

**Lung Tumors**

Early stage lung tumors are typically treated with surgery, radiation or a combination of these. Patients with early stage lung cancer who are not surgical candidates may be candidates for radiation treatment with curative intent. Cryoablation is being utilized in patients who are medically inoperable, with small primary lung cancers or lung metastases. Patients with more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. This is rarely curative but rather seeks to retard tumor growth or palliate symptoms.

**Pancreatic Cancer**

Pancreatic cancer is a relatively rare solid tumor that occurs almost exclusively in adults and is almost always fatal. Surgical resection of tumors contained entirely within the pancreas is currently the only potentially curative treatment. However the nature of the cancer is such that few tumors are found at such an early and potentially curable stage. Patients with more advanced local disease or metastatic disease may undergo chemotherapy with radiation following resection. This is rarely curative but rather seeks to retard tumor growth or palliate symptoms.
**Renal Cell Carcinoma (RCC)**

Localized RCC is treated by radical nephrectomy or nephron-sparing surgery. Prognosis drops precipitously if the tumor extends outside the kidney capsule or has distant metastases.

**Summary of Evidence**

Cryosurgical ablation involves freezing of target tissues, most often by inserting into the tumor a probe through which coolant is circulated. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

Evidence is accumulating that cryoablation provides short-term tumor control and perhaps survival benefit for carefully selected patients with small renal cell carcinomas. Based on the scientific data (large numbers of patients treated with follow-up), cryoablation of small (4 cm or less) renal cancers may be considered medically necessary in those patients who are not surgical candidates due to comorbid conditions or who have baseline renal insufficiency such that standard surgical procedures would impair their kidney function.

The current evidence on cryoablation for other indications consists largely of noncomparative, case series and is insufficient to permit conclusions concerning the effect of cryoablation on health outcomes except for selected cases of malignant kidney, liver or lung tumors. Therefore, cryoablation is considered investigational for all other malignant indications stated in the policy. Comparative studies with larger numbers of subjects and longer follow-up are needed.

**Ongoing and Unpublished Clinical Trials**

Some trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02440334</td>
<td>Two and Three Dimensional Contrast-enhanced Ultrasound</td>
<td>100</td>
<td>May 2017</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------------------------------------------------</td>
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<td>-------------------</td>
</tr>
<tr>
<td>NCT02399124*</td>
<td>ICE-SECRET PROSENSE™ Cryotherapy for Renal Cell Carcinoma Trial</td>
<td>50</td>
<td>Jan 2022</td>
</tr>
<tr>
<td>NCT03189186</td>
<td>Phase-I Trial of Pembrolizumab and Percutaneous Cryoablation Combination Followed by Nephron-Sparing Surgery or Cytoreductive Nephrectomy in Locally Advanced and Metastatic Renal Cell Carcinomas</td>
<td>21</td>
<td>Jul 2022</td>
</tr>
<tr>
<td><em>Unpublished</em></td>
<td>A Feasibility Study for a Multicentre Randomised Controlled Trial to Compare Surgery with Needle Ablation Techniques in People with Small Renal Masses</td>
<td>17</td>
<td>Jan 2015 (completed)</td>
</tr>
<tr>
<td><strong>Lung Cancer</strong></td>
<td>Study of Cryoablation for Metastatic Lung Tumors (SOLSTICE)</td>
<td>134</td>
<td>Dec 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

### Practice Guidelines and Position Statements

**The American Society of Breast Surgeons**

The American Society of Breast Surgeons 2008 consensus statement on management of fibroadenomas of the breast indicated cryoablation is appropriate for histologically confirmed fibroadenoma lesions that are less than 4 cm in largest diameter and sonographically visible. Cryoablation of fibroadenoma of the breast is contraindicated when ultrasound visualization is poor or core biopsy suggests a diagnosis of cystosarcoma phyllodes tumor or other malignancy or if physical examination or imaging is discordant with a biopsy diagnosis of fibroadenoma.

**American College of Radiology (ACR)**

The 2009 ACR Appropriateness Criteria for renal cell carcinoma, updated most recently in 2014, indicated that “As an alternative to partial nephrectomy, Emerging ablative therapies, such as cryoablation..., are being used in treating small renal cell carcinomas. These therapies have been
shown to be effective and safe." These recommendations are based on review of the data and consensus.

**American Urological Association (AUA)**

The 2009 guidelines from the AUA on stage 1 renal masses indicate percutaneous or laparoscopic cryoablation “is an available treatment option for the patient at high surgical risk who wants active treatment and accepts the need for long-term radiographic surveillance after treatment.” The guidelines also indicate cryoablation “should be discussed as a less-invasive treatment option” in healthy patients with a renal mass equal to or less than 4.0 cm and clinical stage T1a. Patients should be informed that “local tumor recurrence is more likely than with surgical excision, measures of success are not well defined, and surgical salvage may be difficult.” These recommendations are based on review of the data and “appreciable” majority consensus.

In 2017, the American Urological Association updated its guidelines on evaluation and management of clinically localized sporadic renal masses suspicious for renal cell carcinoma. The guideline statements on thermal ablation (radiofrequency ablation and cryoablation) are listed in **Table 2**.

**Table 2. Guideline Statements on Localized Masses Suspicious for Renal Cell Carcinoma**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>LOR</th>
<th>LOE</th>
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<tbody>
<tr>
<td><strong>Guideline statement 24</strong></td>
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<tr>
<td>Physicians should consider thermal ablation (TA) as an alternate approach for the management of cT1a renal masses &lt;3 cm in size. For patients who elect TA, a percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity.</td>
<td>Conditional</td>
<td>C</td>
</tr>
<tr>
<td><strong>Guideline statement 25</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation</td>
<td>Conditional</td>
<td>C</td>
</tr>
<tr>
<td><strong>Guideline statement 27</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical extirpation, which may be addressed with repeat ablation if further intervention</td>
<td>Strong</td>
<td>B</td>
</tr>
</tbody>
</table>
National Comprehensive Cancer Network (NCCN)

The NCCN practice guidelines for kidney cancer (v.2.2017) state that based on lower level evidence and uniform NCCN consensus, cryosurgery “can be considered for patients with clinical stage T1 renal lesions who are not surgical candidates. Biopsy of small lesions may be considered to obtain or confirm a diagnosis of malignancy and guide surveillance, cryosurgery ... [and] ablation strategies.” The NCCN guidelines also note that “Randomized phase III comparison with surgical resection (ie, radical or partial nephrectomy by open or laparoscopic techniques) has not been done” and that “ablative techniques are associated with a higher local recurrence rate than conventional surgery.”

The NCCN guidelines for non-small cell lung cancer (v.7.2107) indicate surgical “resection is the preferred local treatment modality” and “other modalities include ... cryotherapy.”

U.S. Preventive Services Task Force Recommendations

Cryoablation/cryosurgery is not a preventive service.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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 (Irvine, CA)
- CryoGen Cryosurgical System by Cryosurgical, Inc.
- CryoHit® by Galil Medical (Arden Hills, MN) for the treatment of breast fibroadenoma
- SeedNet™ System by Galil Medical
- Visica® System by Sanarus Medical (Pleasanton, CA)

FDA product code: GEH

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/30/04</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>10/11/05</td>
<td>Replace Policy BC.7.01.92 - Policy statement revised to indicate that benign breast fibroadenomas may be considered medically necessary if certain criteria are met. References added regarding cryoablation of breast cancer, benign fibroadenomas and renal tumors.</td>
</tr>
<tr>
<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
</tr>
<tr>
<td>06/06/09</td>
<td>Disclaimer and Scope update - No other changes.</td>
</tr>
<tr>
<td>10/10/06</td>
<td>Replace Policy - Policy updated with literature search; reference added. No change to policy statement</td>
</tr>
<tr>
<td>04/10/07</td>
<td>Replace Policy - Policy updated with literature review; no change in policy statement. Policy reviewed and recommended by OAP on February 22, 2007. Codes updated.</td>
</tr>
<tr>
<td>03/11/08</td>
<td>Replace Policy - Policy updated with literature search; no change to policy statement. References added.</td>
</tr>
<tr>
<td>10/14/08</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>03/10/09</td>
<td>Replace Policy - Policy updated with literature review; no change in policy statement. References added. OAP reviewed on February 19, 2009 and recommended that BCBSA statement of medical necessity for renal cell carcinoma not be adopted.</td>
</tr>
<tr>
<td>08/11/09</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>03/09/10</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>09/14/10</td>
<td>Replace Policy - Policy updated with literature review. Policy statement changed: Renal cell carcinoma, previously considered investigational, may now be considered medically necessary when criteria are met.</td>
</tr>
<tr>
<td>08/09/11</td>
<td>Replace Policy – Policy updated with literature search; no change in policy statement. References added.</td>
</tr>
<tr>
<td>02/27/12</td>
<td>Related Policies updated; 7.01.133 added.</td>
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<tr>
<td>03/23/12</td>
<td>Replace Policy – Policy updated with literature search; no change in policy statement. References added. Reviewed and recommended by OAP on February 16, 2012.</td>
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<tr>
<td>09/27/12</td>
<td>Update Related Policy – 8.01.516 as it was archived.</td>
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<tr>
<td>12/20/12</td>
<td>Update Related Policies; policy number 7.01.540 was replaced with 7.01.95.</td>
</tr>
<tr>
<td>09/27/13</td>
<td>Replace policy. Description section, policy guidelines, and rationale section updated. No change to policy statement. References added.</td>
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<tr>
<td>12/03/13</td>
<td>Coding Update. Add ICD-10 codes.</td>
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<tr>
<td>Date</td>
<td>Comments</td>
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</tr>
<tr>
<td>01/12/15</td>
<td>Coding update. New CPT codes 20983 and 47383, effective 1/1/15, added to the policy.</td>
</tr>
<tr>
<td>09/08/15</td>
<td>Annual Review. Minor edits for readability. Policy updated with literature review through June 7, 2015; reference 24 added. Removed CPT codes 47383 and 0304T (replaced with 0340T, the correct code) as not related to this policy. CPT code 50542 in the policy guidelines added to coding table at end of policy. Policy statements unchanged.</td>
</tr>
<tr>
<td>09/01/16</td>
<td>Interim Review, approved August 9, 2016. Update Related Policies. Remove 8.01.27 as it was archived. Removed coding table at end of policy.</td>
</tr>
<tr>
<td>11/01/16</td>
<td>Annual Review, approved October 11, 2016. No changes made to the Policy Statement.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Annual Review, approved December 12, 2017. Coverage has been increased by addition of lung cancer as medically necessary indication; harmonized with prostate and liver local therapy policies. References and Clinical Trials section updated. Added CPT code 32994 (new code effective 1/1/18).</td>
</tr>
</tbody>
</table>

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PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-537-7697 (TDD)

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Office for Civil Rights Complaint Portal, available at
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201

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