MEDICAL POLICY – 7.01.92
Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

<table>
<thead>
<tr>
<th>BCBSA Ref. Policy:</th>
<th>7.01.92</th>
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</thead>
<tbody>
<tr>
<td>Effective Date:</td>
<td>Jan. 3, 2020</td>
</tr>
<tr>
<td>Last Revised:</td>
<td>Jan. 1, 2020</td>
</tr>
<tr>
<td>Replaces:</td>
<td>7.01.526</td>
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</tbody>
</table>

RELATED MEDICAL POLICIES:

- 7.01.95  Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Select a hyperlink below to be directed to that section.

POLICY CRITERIA  | DOCUMENTATION REQUIREMENTS  | 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.

Policy Coverage Criteria
<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
<th>Investigational</th>
</tr>
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</table>
| 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 (i.e., 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 (i.e., resection of renal tissue) is likely to substantially worsen kidney function  
  OR  
  • Patient is not considered a surgical candidate | Cryosurgical ablation is considered investigational to treat individuals with ANY of the following:  
  • Bone cancer  
  • Lung cancer (other than defined above)  
  • Malignant or benign tumors of the breast  
  • Other solid tumors or metastases outside the liver and prostate  
  • Pancreatic cancers  
  • Renal cell carcinomas in patients who are surgical candidates |
**Documentation Requirements**

- The need to preserve the kidney because:
  - Patient has one kidney
  OR
  - Patient has renal insufficiency as defined by a glomerular filtration rate (GFR) of less than or equal to 60 mL/min/m², and standard surgical approach (ie, resection of renal tissue) is likely to substantially worsen kidney function
  OR
  - Patient is considered not a surgical candidate

- For lung cancer, documentation of:
  - 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 lesion

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td></td>
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<tr>
<td>0581T</td>
<td>Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral (new code effective 1/1/20)</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 (eg, 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</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>
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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. Cryosurgery may be performed as an open surgical technique or as a closed procedure under laparoscopic or ultrasound guidance.

Background

Breast Tumors

Early-stage primary breast tumors are treated surgically. The selection of lumpectomy, modified radical mastectomy, or another approach is balanced against 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 radiotherapy 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 lesion and combination chemotherapy.

Fibroadenomas are common benign tumors of the breast that can present as a palpable mass or a mammographic abnormality. These benign tumors have been frequently surgically excised to rule out a malignancy.
**Lung Tumors**

Early-stage lung tumors are typically treated surgically. Patients with early-stage lung cancer who are not surgical candidates may be candidates for radiotherapy with curative intent. Cryoablation is being investigated 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. Treatment is rarely curative; rather, it 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 it is largely considered incurable. 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. Treatment focuses on slowing tumor growth and palliation of symptoms.

**Renal Cell Carcinoma (RCC)**

Localized renal cell carcinoma is treated with radical nephrectomy or nephron-sparing surgery. Prognosis drops precipitously if the tumor extends outside the kidney capsule because chemotherapy is relatively ineffective against metastatic renal cell carcinoma.

**Cryosurgical Treatment**

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

**Summary of Evidence**

For individuals who have solid tumors (located in areas of the breast, lung, pancreas, kidney, or bone) who receive cryosurgical ablation, the evidence includes nonrandomized comparative studies, case series, and systematic reviews of these nonrandomized studies. The relevant
outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. There is a lack of randomized controlled trials and high-quality comparative studies to determine the efficacy and comparative effectiveness of cryoablation. The largest amount of evidence assesses renal cell carcinoma in select patients (ie, those with small tumors who are not surgical candidates, or those who have baseline renal insufficiency of such severity that standard surgical procedures would impair their kidney function). Cryoablation results in short-term tumor control and less morbidity than surgical resection, but long-term outcomes may be inferior to surgery. For other indications, there is less evidence, with single-arm series reporting high rates of local control. Due to the lack of prospective controlled trials, it is difficult to conclude that cryoablation improves outcomes for any indication better than alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished 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><strong>Ongoing</strong>&lt;br&gt;Renal cancer&lt;br&gt;<strong>NCT01957787</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Study of Cryoablation for Metastatic Lung Tumors (SOLSTICE)</td>
<td>134</td>
<td>Aug 2018 (completed)</td>
</tr>
<tr>
<td><strong>NCT02399124</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td>ICE-SECRET PROSENSE™ Cryotherapy for Renal Cell Carcinoma Trial</td>
<td>100</td>
<td>Jan 2022</td>
</tr>
<tr>
<td><strong>NCT03390413</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Robot-assisted Surgical Resection vs. Cryoablation of Localised Renal Cancer - a Randomised Trial of Functional, Oncological and Financial Aspects</td>
<td>190</td>
<td>Mar 2028</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.<sup>a</sup> Denotes industry-sponsored or cosponsored trial.
Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2017 Input

In response to requests, clinical input on use of cryosurgical ablation to manage individuals with localized renal cell cancer, use of cryosurgical ablation to manage individuals with lung cancer, and use of cryosurgical ablation to manage individuals with breast, pancreatic, or bone cancers was received from nine respondents, including two specialty society-level responses, three physician-level responses identified by specialty societies, and four physicians identified by one health system, while this policy was under review in 2017.

Based on the evidence and independent clinical input, the clinical input supports that the following indications provide a clinically meaningful improvement in the net health outcome and are consistent with generally accepted medical practice.

- Use of cryosurgical ablation to manage individuals with localized renal cell cancer when either of the following criteria is met:
  - No more than 4 cm in size when preservation of kidney function is necessary (ie, the patient has 1 kidney or renal insufficiency defined by a glomerular filtration rate <60 mL/min/m²), and standard surgical approach (ie, resection of renal tissue) is likely to worsen kidney function substantially; or
  - When the patient is not considered a surgical candidate.

- Use of cryosurgical ablation to manage individuals with lung cancer when either of the following criteria is met:
  - Poor surgical candidates with early-stage non-small-cell lung cancer; or
  - Palliation of a central airway obstructing lesion
Based on the evidence and independent clinical input, the clinical input does not support whether the following indication provides a clinically meaningful improvement in the net health outcome or is consistent with generally accepted medical practice.

- Use of cryosurgical ablation to manage individuals with:
  - Malignant or benign tumors of the breast;
  - Pancreatic cancer; or
  - Bone cancer

**Practice Guidelines and Position Statements**

**American College of Radiology**

The American College of Radiology Appropriateness Criteria (2009) for renal cell carcinoma, updated most recently in 2014, indicated that “As an alternative to partial nephrectomy, energy-ablative therapies, such as cryoablation... are being used to treat 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 American Urological Association (2017) 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, cryoablation) are listed in Table 2.

**Table 2. Guidelines 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>Guideline statement 24</td>
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</table>
Physicians should consider thermal ablation (TA) as an alternate approach for the management of cT1a renal masses <3 cm in size. For patients who elect TA, a percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity.

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>LOR</th>
<th>LOE</th>
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<tbody>
<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>
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**Guideline statement 25**

Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation

<table>
<thead>
<tr>
<th>Guideline statement 25</th>
<th>LOR</th>
<th>LOE</th>
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<tbody>
<tr>
<td>Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation</td>
<td>Conditional</td>
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**Guideline statement 27**

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 is elected

<table>
<thead>
<tr>
<th>Guideline statement 27</th>
<th>LOR</th>
<th>LOE</th>
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<tbody>
<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 is elected</td>
<td>Strong</td>
<td>B</td>
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LOE: level of evidence; LOR: level of recommendation.

**National Comprehensive Cancer Network**

National Comprehensive Cancer Network (NCCN) guidelines on kidney cancer (v.2.20209) 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.” 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 “ablative techniques are associated with a higher local recurrence rate than conventional surgery.”

The NCCN guidelines for non-small cell lung cancer (v.6.2109) indicate surgical "resection is the preferred local treatment modality” and “other modalities include ... cryotherapy.”

**Medicare National Coverage**

There is no national coverage determination.
Regulatory Status

Several cryoablation devices have been cleared for marketing by the U.S. Food and Drug Administration 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 (Endocare)
- CryoGen Cryosurgical System (Cryosurgical)
- CryoHit® (Galil Medical) for the treatment of breast fibroadenoma
- SeedNet™ System (Galil Medical)
- Visica® System (Sanarus Medical)

Food and Drug Administration product code: GEH

References

History

<table>
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<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>10/01/19</td>
<td>New policy, approved September 10, 2019, effective January 3, 2020. This policy was previously deleted but is now being reinstated to align with the BCBSA reference policy. This policy replaces 7.01.526 (originally effective 2004). Policy created with literature review through May 2019; references added and updated. Policy statement cryosurgical ablation for benign breast fibroadenomas changed from medically necessary to investigational.</td>
</tr>
<tr>
<td>01/01/20</td>
<td>Coding update, added CPT code 0581T (new code effective 1/1/20).</td>
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</tbody>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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