Medical Policy

Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

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Policy Number: 260
BCBSA Reference Number: 7.01.92
NCD/LCD: N/A

Related Policies
- Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors, #259
- Cryosurgical Ablation of Primary or Metastatic Liver Tumors, #633
- Radiofrequency Ablation of Primary or Metastatic Liver Tumors, #286
- Cryoablation of Prostate Cancer, #149

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

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 1 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 worsen kidney function substantially, or
- Patient is not considered a surgical candidate.

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 lesion.

Cryosurgical ablation is considered INVESTIGATIONAL as a treatment for benign or malignant tumors of the breast, lung (other than defined above), pancreas, or bone and other solid tumors or metastases outside the liver and prostate and to treat renal cell carcinomas in patients who are surgical candidates.

Prior Authorization Information

Inpatient
- For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.
Outpatient

- For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Product</th>
<th>Prior Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Not required</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Not required</td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
<td>Not required</td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
<td>Not required</td>
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</tbody>
</table>

CPT Codes / HCPCS Codes / ICD Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>32994</td>
<td>Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s)</td>
</tr>
<tr>
<td></td>
<td>including pleura or chest wall when involved by tumor extension, percutaneous,</td>
</tr>
<tr>
<td></td>
<td>including imaging guidance when performed, unilateral; cryoablation</td>
</tr>
<tr>
<td>50250</td>
<td>Ablation, open, 1 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</td>
</tr>
<tr>
<td></td>
<td>ultrasound guidance and monitoring, when performed</td>
</tr>
<tr>
<td>50593</td>
<td>Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy</td>
</tr>
<tr>
<td>76940</td>
<td>Ultrasound guidance for, and monitoring of, parenchymal tissue ablation</td>
</tr>
<tr>
<td>77013</td>
<td>Computed tomography guidance for, and monitoring of, parenchymal tissue ablation</td>
</tr>
<tr>
<td>77022</td>
<td>Magnetic resonance guidance for, and monitoring of, parenchymal tissue ablation</td>
</tr>
</tbody>
</table>

The following CPT code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>0581T</td>
<td>Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging</td>
</tr>
<tr>
<td></td>
<td>guidance when performed, unilateral</td>
</tr>
<tr>
<td>19105</td>
<td>Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each</td>
</tr>
<tr>
<td></td>
<td>fibroadenoma</td>
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</tbody>
</table>

Description

Breast Tumors

Early-stage primary breast cancers 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. Adjunctive radiotherapy decreases local recurrences, particularly for those who select lumpectomy. Adjunctive hormonal therapy and/or chemotherapy are added, depending on the 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 are 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 a 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 a 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
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
Cryosurgical ablation (hereafter referred to as cryosurgery or cryoablation [CRA]) 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.

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 CRA. 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). CRA 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 CRA improves outcomes for any indication better than alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2017 supports that the following indications provide a clinically meaningful improvement in 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:
o 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
  o 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:
  o Poor surgical candidates with early-stage non-small-cell lung cancer; or
  o Palliation of a central airway obstructing lesion.

Thus, the above indications may be considered medically necessary considering the suggestive evidence and clinical input support.

However, 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:
  o Malignant or benign tumors of the breast;
  o Pancreatic cancer; or
  o Bone cancer.

Thus, the above indication may be considered investigational.

Clinical input obtained in 2009 provided substantial support for CRA in patients with small renal cell cancers who were either poor surgical candidates or whose kidney function was likely to be impaired by surgery. Moreover, there was clinical support for CRA in patients who were either poor surgical candidates with early-stage non-small-cell lung cancer or who required palliation for a lesion obstructing the central airway. Contextual factors contributing to this support included the lack of treatment alternatives and the potential for reduced harm compared with surgery.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>1/2020</td>
<td>Clarified coding information.</td>
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<td>1/2018</td>
<td>Clarified coding information.</td>
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<tr>
<td>10/2016</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>8/2015</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>9/2014</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>10/2013</td>
<td>New references from BCBSA National medical policy.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


33. Ko...