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Subject: Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Cryosurgical ablation (also known as cryosurgery or cryoablation) involves freezing of target tissues, usually 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.

Cryosurgical treatment of various tumors has been reported for malignant and benign breast disease, lung cancer, pancreatic cancer, renal cell carcinoma, and bone cancer. The purpose of cryosurgical ablation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as surgical resection, other ablative techniques, or no intervention, in patients with solid tumors (located in the breast, lung, pancreas, kidney, or bone).

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. 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 primary 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 and Lung Metastases: Early-stage lung tumors are typically treated surgically. Patients with early-stage lung cancer who are not surgical candidates may be candidates for radiation treatment

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 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. Treatment focuses on slowing tumor growth and palliation of symptoms.

Renal Tumors: Localized kidney cancer 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.

Bone Cancer and Bone Metastases: Primary bone cancers are extremely rare, accounting for less than 0.2% of all cancers. Bone metastases are more common, with clinical complications including debilitating bone pain. Treatment for bone metastases is performed to relieve local bone pain, provide stabilization, and prevent impending fracture or spinal cord compression.

Summary and Analysis of Evidence: The evidence for individuals with early stage kidney cancer who are not surgical candidates and who are treated with cryoablation includes comparative observational studies of cryoablation compared to partial nephrectomy or other ablative techniques, systematic reviews of these studies, and case series. Although oncological outcomes were better with surgery, in comparative observational studies, cryoablation was associated with less decline in kidney function. Recent case series totaling more than 400 patients showed cryoablation was associated with good oncological outcomes and preservation of renal function. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. For individuals with non-small cell lung cancer (NSCLC) who are either poor surgical candidates or who required palliation for a lesion obstructing the central airway who receive cryoablation, the evidence includes case series. A series of 521 consecutive patients reported improvement in symptoms in 86% of patients. It is reported by clinical input that the procedure is consistent with generally accepted medical practice and provides a clinically meaningful improvement in net health outcome. Evidence for the treatment of individuals with early stage kidney cancer who are surgical candidates and treated with cryoablation includes comparative observational studies and systematic reviews. Multiple comparative observational studies and systematic reviews of these studies have compared cryoablation to partial nephrectomy for early stage renal cancer. These studies have consistently found that partial nephrectomy is associated with better oncological outcomes than cryosurgery, but cryosurgery was associated with better perioperative outcomes, lower incidence of complications, and less decline in kidney function. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. For individuals with NSCLC who are not surgical candidates, the evidence includes uncontrolled observational studies and case series. Medically inoperable patients with early stage primary lung tumors were treated with cryoablation in a consecutive series of 45 patients. Five year survival was 68%; the main complications were hemoptysis in 40% of patients and pneumothorax in 51%. A prospective single arm Phase 2 study of 128 patients reported on cryoablation for treatment of metastases to the

lung. Cryoablation for metastatic lung cancer was studied in a single arm trial in 40 patients. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Solid tumors located in the breast, pancreas, or bone treated with cryoablation, the evidence includes uncontrolled observational studies and case series. Due to the lack of prospective controlled trials, it is not possible to conclude that cryoablation improves outcomes for any indication better than alternative treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POSITION STATEMENT

Note: This guideline is not applicable to cryosurgical ablation of solid tumors of the liver or prostate. Refer to section entitled Related Guidelines.

This guideline is limited to treatment in adults (age 18 years and older) and does not address pediatric populations.

Cryosurgical ablation **meets the definition of medical necessity** 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 member has 1 kidney or renal insufficiency defined by a glomerular filtration rate [GFR] of less than 60 mL/min/m^2) and standard surgical approach (ie, resection of renal tissue) is likely to substantially worsen kidney function; **OR**
- The member is not considered a surgical candidate.

Cryosurgical ablation **meets the definition of medical necessity** to treat lung cancer when either of the following criteria is met:

- The member has early-stage non-small cell lung cancer and is a poor surgical candidate; **OR**
- The member requires palliation for a central airway obstructing lesion.

Cryosurgical ablation is considered **experimental or investigational** as a treatment of benign or malignant tumors of the breast, lung (other than defined above), pancreas, or bone, and to treat renal cell carcinomas in members who are surgical candidates. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

19105	Ablation, cryosurgical, of fibroadenomas, including ultrasound guidance, each (**Investigational**)
20983	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 **(Investigational)**
32994	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

50250	Ablation, open, 1 or more renal mass lesions(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50542	Laparoscopy, surgical; ablation of renal mass lesions(s), including intraoperative ultrasound guidance and monitoring, when performed
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral (**Investigational**)

LOINC Codes:

The following information may be required documentation to support medical necessity: Physician history and physical, initial assessment, procedure notes, visit notes.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician Initial Assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician procedure note	11505-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Cryoablation of Liver Tumors, 02-40000-22
Radiofrequency and Microwave Ablation of Liver Tumors, 02-40000-23
Radiofrequency Ablation of Solid Tumors Other Than Liver Tumors, 02-99221-13
Whole Gland Cryoablation of Prostate Cancer, 02-54000-14

OTHER:

None Applicable

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3. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.92 Cryoablation of Tumors Located in the Kidney, Lung, Breast, Pancreas, or Bone, 08/24.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

GUIDELINE UPDATE INFORMATION:

02/15/04	New Medical Coverage Guideline.
03/15/05	Scheduled review; no change in coverage statement.
01/01/06	Annual HCPCS coding update (added 0120T, 0135T and 50250; deleted S2090 and S2091).
02/15/06	Scheduled review; no change in coverage statement.
01/01/07	Annual HCPCS coding update (added 19105; deleted 0120T.)
02/15/07	Scheduled review; no change in coverage statement.
04/15/07	Revision consisting of adding CPT code 50542.
06/15/07	Reformatted guideline.
10/15/07	Revision to Position Statement, changing verbiage from “breast cancer…” to “…tumors of the breast…”
01/01/08	Annual HCPCS coding update: added 50593, and deleted 0135T.
02/15/08	Scheduled review; no change in coverage statement; updated references.
09/15/08	Reviewed guideline; revised position statement to include renal cell carcinoma criteria for coverage; updated references.
09/15/09	Scheduled review; no change in position statements; updated references.
10/15/10	Scheduled review; position statement unchanged; references updated; formatting changes.
01/01/11	Annual HCPCS coding update: revised descriptors for 50250 and 50542.
09/15/11	Revision; formatting changes.
09/15/12	Annual review; position statement updated to address tumors of the lung; references updated.
10/15/13	Annual review; position statement unchanged; updated Description section with information regarding lung tumors; Program Exceptions section updated; references updated.
01/01/14	Annual HCPCS coding update: added 0340T.
10/15/14	Annual review; position statement unchanged; Program Exceptions section updated; references updated.
01/01/15	Annual coding update. Added 20983.
11/01/15	Revision: ICD-9 Codes deleted.
10/15/16	Revision; description, position statement, and references updated.
01/01/18	Annual CPT/HCPCS update. Deleted code 0340T.
02/15/18	Review; position statement section and references updated.
10/15/18	Revision; Update investigational position statement, description, and references updated.
01/01/20	Annual CPT/HCPCS coding update. Added code 0581T.
09/15/20	Review; Position statements maintained; coding and references updated.

10/15/22	Review: Title updated; note guideline does not address pediatric populations added; investigational statement updated; references updated.
08/21/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.
10/15/24	Review: Position statements maintained; description and references updated.