MEDICAL POLICY

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POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, cryosurgical ablation of **renal** tumors is considered a **medically appropriate** treatment option when tumor size is three cm or less in diameter. The documentation should reflect that an informed decision has been made between the surgeon and the patient and that the patient is willing to accept a possible lower oncological efficacy and higher chance of local recurrence.

II. Based upon our criteria and assessment of the peer reviewed literature, cryosurgical tumor ablation may be considered a **medically appropriate** treatment option for patients with non-small cell lung cancer (NSCLC), when:
   A. Individual is not receiving stereotactic radiotherapy (SABR) or definitive radiation therapy (RT); **and**
   B. Individual is considered "high risk", whose tumors would be considered surgically resectable but rendered inoperable due to comorbidities; **and**
      1. Forced expiratory volume (FEV1) or diffusing capacity of the lung for carbon monoxide (DLCO) ≤ 50%; **or**
      2. **TWO** of the following:
         a. FEV1 or DLCO between 51-60%;
         b. Age ≥ 75 years;
         c. Pulmonary hypertension;
         d. Left ventricular ejection fraction (LVEF) ≤ 40%;
         e. Resting or exercise partial pressure of oxygen (Pa02) < 55mmHg;
         f. Partial pressure of carbon dioxide (pC02) > 45mmHg.

III. Based upon our criteria and assessment of the peer-reviewed literature, cryosurgical tumor ablation has not been medically proven to be effective and, therefore, is considered **investigational** as a treatment method for any other tumor, including but not limited to, primary/metastatic liver malignancies, breast tumors (benign and malignant), pulmonary tumors (primary and malignant) and pancreatic cancer.

Refer to Corporate Medical Policy #7.01.01 Focal Therapies for Prostate Cancer Treatment

Refer to Corporate Medical Policy #7.01.32 Radiofrequency Tumor Ablation

Refer to Corporate Medical Policy #7.01.69 Selective Internal Radiation Therapy (SIRT) for Hepatic Tumors

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

Cryosurgical ablation is the oldest of the local thermal ablation techniques. Cryosurgical ablation is a method of in situ tumor ablation in which subfreezing temperatures are delivered through penetrating or surface cryoprobes in which a cryogen is circulated. Cell death is caused by direct freezing, denaturation of cellular proteins, cell membrane rupture, cell dehydration and ischemic hypoxia. Cryosurgical ablation may be used for the destruction of metastatic tumors in situ or for the destruction of microscopic residual carcinoma in the case of close surgical margins. It may be performed as an open surgical technique or as a closed procedure either under laparoscopic or percutaneous ultrasound/MRI guidance.

Cryosurgery has been proposed as a treatment for unresectable liver tumors, bronchogenic/lung cancer, and renal cell carcinoma (RCC) as a nephron-sparing procedure, as a nonsurgical alternative to surgical excision of breast fibroadenomas and breast cancer and as a treatment for pancreatic cancer.

RATIONALE

Renal Cancer:

Renal ablation traditionally has been reserved for patients who are poor candidates for surgery or in whom renal preservation is paramount. However, with some reports on oncologic efficacy approaching that of partial nephrectomy (PN), some centers are now considering renal ablation as a first-line option for young, healthy patients with small tumors.

The 2021 American Urological Association guidelines on stage one renal masses indicate that cryoablation may be offered as an option for the management of cT1a solid renal masses < 3cm in size, with the percutaneous technique being preferred over a surgical approach wherever feasible to minimize morbidity (Moderate Recommendation; Evidence Level: Grade C). Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical excision, which may be addressed with repeat ablation if further intervention is elected. (Strong Recommendation; Evidence Level: Grade B).

Georgiades and Rodriguez (2014) presented the five-year oncologic outcomes of a prospective trial evaluating percutaneous cryoablation as a treatment option for RCC. Over a five-year period, 134 consecutive patients with biopsy-proven RCC were treated with CT-guided percutaneous cryoablation. All were treated while under conscious sedation. The technical objective was for the ice ball to cover the lesion plus a five-mm margin. Hydro- or air dissection was utilized to aid in technical success as needed. Efficacy was defined as the lack of enhancement and/or enlargement of a previously enhancing lesion on follow-up imaging. Safety was assessed by the common terminology criteria for adverse events (CTCAE), version 4.0. The one-, two-, three-, four-, and five-year efficacy of percutaneous cryoablation for RCC was 99.2, 99.2, 98.9, 98.5, and 97.0 %, respectively. Median tumor size was 2.8 ± 1.4 cm. All-cause mortality during the study period was three (none from RCC), yielding an overall five-year survival of 97.8 %. The cancer-specific five-year survival was 100 %. No patient developed metastatic disease during the follow-up period. The overall significant CTCAE version 4.0 complication rate was 6 %, with the most frequent being transfusion-requiring hemorrhage, at 1.6 %. There was one 30-day mortality unrelated to the procedure. Investigators concluded that CT-guided percutaneous cryoablation for renal cancer offers very high efficacy, approaching that of the gold standard, with a more favorable safety profile.

Johnson, et al., (2014) reported on the long-term oncologic outcomes of laparoscopic cryoablation for clinical stage T1 renal masses at the Medical College of Wisconsin via a retrospective chart review. A total of 171 renal masses in 144 patients were treated by laparoscopic cryoablation from February 2000 through October 2009. After excluding patients with less than five years of follow-up and those with greater than clinical stage I disease, 112 renal masses treated in 92 patients remained for analysis. Mean patient age was 59.6 years (standard deviation (SD), 12.5 years). Mean lesion size was 2.3 cm (SD, 0.94 cm). Mean age adjusted Charlson comorbidity index was 4.55 (SD, 1.69). Mean follow-up was 97.9 months (SD, 24.8 months). Overall survival among all patients was 80.9%. Lesions were biopsy proven to be malignant in 70 patients (76.3%). Of those with biopsy-proven malignancy, there were six recurrences, 14 non-cancer-related deaths, and one cancer-related death, leading to overall survival of 77.6%, progression-free survival of 91.0%, and cancer-specific survival of 98.5%. The authors concluded that laparoscopic cryoablation is an efficacious treatment for clinical stage T1 renal masses and provides excellent long-term oncologic outcomes.

Thompson, et al., (2014) compared oncologic outcomes among patients treated with partial nephrectomy (PN), percutaneous radiofrequency ablation (RFA) and percutaneous cryoablation. A total of 1803 patients with primary cT1N0M0 renal masses treated between 2000 and 2011 were identified from the prospectively maintained Mayo Clinic Renal Tumor Registry. Of the 1424 cT1a patients, 1057 underwent PN, 180 underwent RFA, and 187 underwent cryoablation. Outcome measures included local recurrence-free survival, metastases-free survival, and overall survival, with rates estimated using the Kaplan-Meier method and compared with log-rank tests. In this cohort, local recurrence-free survival was similar among the three treatments (p=0.49), whereas metastases-free survival was significantly better after PN (p=0.005) and cryoablation (p=0.021) when compared with RFA. Of the 379 cT1b patients, 326 patients underwent PN, and 53 patients were managed with cryoablation (eight RFA patients were excluded). In this cohort, local recurrence-free survival (p=0.81) and metastases-free survival (p=0.45) were similar between PN and cryoablation. In both the cT1a and cT1b groups, PN patients were significantly younger, with lower Charlson scores and had superior overall survival (p<0.001 for all). The authors concluded that recurrence-free survival was similar for PN and percutaneous ablation patients. Metastases-free survival was superior for PN and cryoablation patients when compared with RFA for cT1a patients. Overall survival was superior after PN, likely because of selection bias. If these results were validated, an update to clinical guidelines would be warranted. Limitations include retrospective review and selection bias.

Larcher, et al., (2015) conducted a single center, retrospective analysis to determine whether laparoscopic renal cryoablation (LRC) could provide an effective long-term cancer control in 174 consecutive patients with a single cT1 a small renal mass (SRM) and no previous history of RCC. Median patient age was 66 years with median tumor size 20 mm. Median follow-up was 48 months. Treatment failure was evaluated one day after surgery. Local recurrence, metachronous SRM, systemic progression, disease relapse, cancer-specific mortality, and all-cause mortality were evaluated 10 years after surgery. Kaplan-Meier plots were used to depict outcome-free survival rate. Among patients with biopsy-proven RCC (63%, n = 109), the treatment failure-free rate was 98%. The 10-year recurrence-free survival rate was 95% and the 10-year metachronous SRM-free survival rate was 87%. The 10-year systemic progression-free survival rate was 100% and the 10-year disease relapse-free survival rate was 81%. The cancer-specific mortality-free survival rate was 100%, and the all-cause mortality-free survival rate was 61%. The authors concluded that LRC provides safe long-term cancer control in patients newly diagnosed with a single cT1a SRM. Treatment failure and local recurrence are uncommon. Systemic progression-free e survival and cancer-specific-free survival are optimal.

Lim et al., (2020) completed a study to evaluate the immediate and 3- and 5-year outcomes of patients with clinical stage T1 (cT1) biopsy-proven renal cell carcinoma (RCC) treated by image-guided percutaneous cryoablation at a regional interventional oncology center. A prospectively maintained local interventional radiology database identified patients with cT1 RCC lesions that were treated by percutaneous cryoablation. A total of 180 patients with 185 separate cT1 RCC lesions were identified. Mean patient age was 68.4 years (range, 34.1–88.9 years) and 52 patients (28.9%) were women. There were 168 (90.8%) and 17 (9.2%) cT1a and cT1b lesions, respectively, with a mean lesion size of 28.5 mm (range, 11–58 mm). Technical success was achieved in 98.9% of patients. The major complication rate (Clavien-Dindo classification ≥ grade III) was 2.2% (four out of 185). Residual unablated tumor on the first follow-up scan was identified in four of 183 tumors (2.2%). Estimated local tumor progression-free survival at 3 and 5 years was 98.3% and 94.9%, respectively. No distant metastases or deaths attributable to RCC occurred. Mean estimated glomerular filtration rate (eGFR) before the procedure was 72.4 ± 18.5 (SD) mL/min/1.73 m^2 and this was not statistically significantly different after the procedure (69.7 ± 18.8 mL/min/1.73 m^2), at 1 year (70.7 ± 16.4 mL/min/1.73 m^2), or at 2 years (69.8 ± 18.9

mL/min/1.73 m_2 ($p > 0.05$). The conclusion was that this data adds to the accumulating evidence that image-guided cryoablation is an efficacious treatment for selected cT1 RCC with a low complication rate and robust 3- and 5-year outcomes.

The current evidence on cryoablation for all other indications consists largely of non-comparative, case series and is insufficient to permit conclusions concerning the effect of cryoablation on health outcomes. The outcomes of these case series are inconclusive due to heterogeneity of the patient populations studied and to the lack of long-term data on the effectiveness of cryosurgical ablation on overall survival. Most case series report only short-term outcomes such as tumor response in terms of shrinkage and tumor recurrence. Comparative studies with already established treatments, larger numbers of subjects, and longer follow-up are needed.

<u>Breast:</u>

While the use of cryoablation for the treatment of breast fibroadenoma has gained in popularity, there is insufficient published literature to demonstrate the efficacy of this procedure. Kaufman, et al. (2002, 2004, 2005) reported on the outcomes of cryoablation in patients with breast fibroadenomas. Though outcome data have been reported at a mean of 2.6 years, there are several limitations to the studies, including that the studies came from a single investigator group, and did not include a direct comparison to surgical excision. Also, in their 2005 case series, Kaufman et al. reported on only 29 patients in their efficacy data. Although this procedure may offer a less invasive method of treating breast fibroadenomas, the long-term outcome of this procedure is unknown. Studies of cryoablation of breast carcinomas have been limited to preliminary evaluation studies. There are no studies directly comparing the effectiveness of cryoablation to surgical incision in the treatment of breast carcinomas. Although cryoablation is less invasive than surgical incision, a key disadvantage of cryoablation is the lack of a tissue sample to examine histologically to ensure adequate surgical margins and complete removal of the tumor.

Pfleiderer, et al. (2005) investigated the use of cryoablation in 30 women with confirmed breast cancer. No viable tumor cells were found in excised specimens at six-week follow-up in 24 patients. In five patients with larger lesions (greater than 23 mm), remnant ductal carcinoma in situ was detectable histologically beyond the margin of the cryosite in the specimens after open surgery. This feasibility study demonstrates promising results in small lesions but is limited in its sample size and extremely short follow-up. Zhao and Wu conducted a systematic review (2010) of minimally invasive ablative techniques in the treatment of early-stage breast cancer. The review noted that studies on cryoablation for breast cancer are primarily limited to pilot and feasibility studies in the research setting. Complete ablation of tumors was found to be reported within a wide range of 36-83%. As there are many outstanding issues, including patient selection criteria and the ability to precisely determine the size of tumors to achieve 100% tumor cell death, the reviewers noted minimally-invasive thermal ablation techniques for breast cancer treatment, including cryoablation, should be limited until results from prospective, randomized clinical trials become available.

The use of cryosurgical tumor ablation for the treatment of breast cancer is not included within the V. 4.2023 NCCN Clinical practice guidelines in oncology Breast Cancer.

<u>Pancreatic</u>:

Li, et al. (2011) reported on a retrospective study of 142 patients with unresectable pancreatic cancer treated with palliative bypass with (n=68) or without cryoablation (n=74) from 1995 to 2002. Median dominant tumor sizes were decreased from 4.3 cm to 2.4 cm in 36 of 55 patients (65%) at three months after cryoablation. Survival rates were not significantly different between groups, with the cryoablation group surviving a median of 350 days versus 257 days in the group that did not receive cryoablation. Complications overall were not significantly different between the two groups. However, a higher percentage of delayed gastric emptying occurred in the cryoablation group compared to the group that did not receive cryoablation (36.8% vs. 16.2%, respectively).

<u>Pulmonary</u>:

An Agency for Healthcare Research and Quality comparative effectiveness review on local nonsurgical therapies for stage I and symptomatic obstructive non-small cell lung cancer (NSCLC) was published in 2013. Cryoablation was included as a potential therapy for airway obstruction due to an endoluminal NSCLC. Reviewers were unable to draw any conclusions on local nonsurgical therapies, including cryoablation, due to a lack of quality evidence.

Cryosurgical ablation for the treatment of NSCLC has been studied in a limited number of small studies. The largest study currently available was a case series involving 47 subjects with NSCLC followed for a minimum of five years after treatment with cryoablation (Moore, 2015). The authors reported that the five-year survival rate was 67.8% ± 15.3, the cancer-specific survival rate at five years was 56.6% ± 16.5, and the five-year progression-free survival rate was 87.9%. The combined local and regional recurrence rate was 36.2%. Major complications were reported in 6.4% of subjects, with two cases of hemoptysis and a prolonged placement of a chest tube requiring mechanical sclerosis in one subject. No deaths occurred in the first 30 days after treatment. These results are promising, but results from a large, controlled, comparative trial are needed for a better understanding of the safety and efficacy of cryoablation for NSCLC.

The use of cryosurgical ablation has also been studied to treat metastatic disease of the lungs. At this time, the published literature includes case reports, case series and reviews. However, there is a paucity of comparative effectiveness data to determine whether cryosurgical ablation of pulmonary metastases is as beneficial as the available alternatives.

The largest published peer-reviewed study currently addressing the use of cryoablation for the treatment of metastatic lung tumors was published by de Baere, et al. (2015). This prospective case series study involved 40 subjects with 60 treated metastatic lung tumors from a variety of primary origins. The most common origin was colorectal cancer (40%). Follow-up to 12 months was reported, involving 35 subjects (90%). At 12 months, overall local tumor control, including stable disease, partial response, and complete response, was seen in 49 of 52 metastases (94.2%) and 32 of 35 subjects (91.4%). Local failure was observed in three of 52 metastases (5.8%) at six and 12 months with increasing size of the ablation zone. Tumor diameter was not found to be a significant factor in the rate of tumor progression (p=0.41). Additional new treatments were administered to 15 of the 40 subjects (38%) including systemic treatment (chemotherapy: n=7 and immunotherapy: n=1) and other focal therapies for new metastatic disease (n=10), including six cryoablation procedures. One-year disease-specific survival and overall survival rates were 100% and 97.5% respectively. Pneumothorax requiring chest tube placement occurred in nine of the 48 procedures (18.8%), and chest tubes were removed after one day (n=8) or two days (n=1). Common Terminology Criteria for Adverse Events (CTCAE) grade 3 adverse events within 30 days of the procedure occurred in three of 48 (6%) procedures including a delayed pneumothorax requiring pleurodesis, a thrombosis of a pre-existing hemodialysis access arterio-venous fistula requiring thrombectomy, and a non-cardiac chest pain that spontaneously resolved. No grade 4 or 5 procedure-related adverse events occurred. No procedural-related delayed adverse events were observed. The safety and efficacy of cryoablation for NSCLC has not yet been shown to be equivalent or better that other available treatment options.

NCCN Guidelines for NSCLC version 4.2023 notes that the use of image-guided thermal ablation (IGTA), which includes radiofrequency ablation, microwave ablation, and cryoablation, may be a treatment option for NSCLC. IGTA may be an option for select patients who are deemed “high risk”-those patients with tumors that are for the most part surgically resectable but rendered medically inoperable due to comorbidities. IGTA has been successfully accomplished in patients considered “high risk”, objectively defined with a single major and/or two or more minor criteria. Major criteria included an FEV1 or DCLO ≤ 50 percent and minor criteria included less depressed FEV1 or DCLO between 51-60 percent, advanced age ≥ 75 years, pulmonary hypertension, VEF ≤ 40 percent, resting or exercise paO2 <55mmHg, and PCO2>45 mmHg.

Duan, et al., (2020) notes that Global Cancer Statistics from 2018 reveal that lung cancer is the most frequent cancer in both men and women and is the leading cause of cancer-related mortalities. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer which accounts for ~86 percent of cases. Approximately 75 percent of patients diagnosed with NSCLC were found to be at an advanced stage and surgery was not a suitable therapeutic option. In 1998, a new device for ultra-low temperature interventional cryoablation, Endocare CryoCare Surgical System, was approved by the Food and Drug Administration (FDA). Argon mixed with helium became the new preferred freezing medium. Two years later, a similar device, Galil Medical, generated in Israel was also approved by the FDA. After the generation of these novel devices, cryoablation was more commonly used to treat malignant tumors, including lung cancer. Presently, cryoablation has been recommended to be used in the treatment of medically operable NSCLC when resection is not suitable. Cryoablation, compared to traditional surgery, results in lower trauma, mild adverse reactions, shorter hospital stays, and quicker recovery times. A phase II multicenter, prospective, single-arm study revealed that the local tumor control rates after receiving Endocare cryoablation were 96.6 percent and 94.2 percent at 6 and 12 months, respectively. The 1-year overall survival (OS) rate was 97.5 percent with no changes in patient quality of life. The authors note there are three systematic reviews discussing cryoablation for advanced NSCLC combined with chemotherapy, radiotherapy or chemoradiotherapy. However, all reviews are written in Chinese and consist of different methodologies, and all these reviews are not adequate in respect to systematic reviewing according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. Another shortcoming of the review was using a single cryoablation method as the control group. Another review, which included five studies (published in 2004–2007) control groups included both cryoablation and chemoradiotherapy. Thus, the study design was not completely similar to this protocol. Lastly, the latest review, included 16 studies between 2003 and 2014, where 10 of these studies were not randomized controlled trials (RCTs) but simple controlled trials. Based on these shortcomings, the effect of cryoablation for advanced NSCLC has not been fully assessed. The authors propose a systematic review which will be the first to evaluate the effectiveness and safety of cryoablation for advanced NSCLC using the PRISMA and GRADE approaches. Although an extensive and unbiased search will be conducted, it is difficult to obtain raw data for RCTs and unpublished RCTs that reveal negative results which will not be included. However, this review could provide objective evidence for the use of cryoablation in the treatment of advanced NSCLC.

Neuroendocrine and Adrenal Tumors

NCCNs Guidelines version 2.2022 states that "Cryoreductive surgery or ablative therapies such as radiofrequency (RFA) or cryoablation may be considered if near-complete treatment of tumor burden can be achieved." However, this was only a category 2B recommendation. NCCN further states "Ablative therapy in this setting is non-curative. Data on the use of these interventions is emerging."

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
19105 **(E/I)**	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma
20983 **(E/I)**	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
32994 **(E/I)**	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
47371 **(E/I)**	Laparoscopy, surgical ablation of one or more liver tumor(s); cryosurgical
47381 **(E/I)**	Ablation, open, of one or more liver tumor(s); cryosurgical
47383 **(E/I)**	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation
50250	Ablation, open, one or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
76940	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation
77013	Computed tomography guidance for, and monitoring of, parenchymal tissue ablation

Code	Description
77022	Magnetic resonance imaging guidance for, and monitoring of, parenchymal tissue ablation
0581T **(E/I)**	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral
0600T **(E/I)**	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous
0601T **(E/I)**	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, open

HCPCS Codes

Code	Description
C2618	Probe/needle, cryoablation

ICD10 Codes

Code	Description
Multiple diagnosis codes	

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*Key Article

KEY WORDS

Cryoablation, Cryosurgery, Liver neoplasms, image-guided thermal ablation

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, there is no specific regional or national coverage determination addressing cryosurgical tumor ablation other than the national coverage determination for cryosurgery of the prostate which is highlighted in a separate medical policy.