Cryosurgical Ablation of Miscellaneous Solid Tumors Outside of the Liver

Effective: February 1, 2024

Next Review: November 2024
Last Review: December 2023

IMPORTANT REMINDER

DESCRIPTION

Cryoablation kills cells by freezing the tissue using a coolant that is circulated via a probe inserted into the tumor.

MEDICAL POLICY CRITERIA

Note: This policy does not address liver tumors (primary or metastatic). See Cross References.

I. Cryosurgical ablation may be considered **medically necessary** for the treatment of any of the following indications:
   A. Malignant dermatologic tumors
   B. Uveal melanoma
   C. Kidney tumors
   D. Prostate tumors
   E. Cervical intraepithelial neoplasia

F. Lung cancer when either of the following criteria is met:

1. For non-small cell lung cancer when the patient has early-stage (Stage I, and selected node negative Stage IIA) non-small cell lung cancer; or
2. The patient requires palliation for a central airway obstructing lesion.

II. Cryosurgical ablation is considered **investigational** as a treatment for all solid tumors not meeting Criterion I, including desmoid tumors and malignant or benign tumors of the breast (including fibroadenoma), pancreas, and bone; and for metastases outside of the liver or prostate.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical
- Treatment plan including treatment area.

CROSS REFERENCES

1. Radioembolization, Transarterial Embolization (TAE), and Transarterial Chemoembolization (TACE), Medicine, Policy No. 140
2. Radiofrequency Ablation (RFA) of Tumors Other than Liver, Surgery, Policy No. 92
3. Magnetic Resonance (MR) Guided Focused Ultrasound (MRgFUS) and High Intensity Focused Ultrasound (HIFU) Ablation, Surgery, Policy No. 139
4. Microwave Tumor Ablation, Surgery, Policy No. 189
5. Ablation of Primary and Metastatic Liver Tumors, Surgery, Policy No. 204
6. Focal Laser Ablation of Prostate Cancer, Surgery, Policy No. 222

BACKGROUND

Cryosurgical ablation (also called cryosurgery, cryotherapy, or cryoablation) kills cells (cancerous and normal) by freezing target tissues, most often 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.

The goals of cryosurgery may include the following:

- Destruction or shrinkage of tumor tissue
- Controlling local tumor growth and preventing recurrence
- Palliating symptoms
- Extending survival duration for patients with certain tumors.

Potential complications associated with cryosurgery in any organ include the following:

- Hypothermic damage to normal tissue adjacent to the tumor (e.g., nerve damage)
- Structural damage along the probe track
- Secondary tumors if cancerous cells are seeded during probe removal.

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;
- CryoGen Cryosurgical System by Cryosurgical, Inc.;
- CryoHit® by Galil Medical;
- IceRod® CX, IcePearl® 2.1 CX and IceFORCE® 2.1 CX Cryoablation Needles by Galil Medical;
- IceSense3™, ProSense™, and MultiSense Systems (IceCure Medical);
- SeedNet™ System by Galil Medical;
- Visica® System by Sanarus Medical;
- Visual-ICE® Cryoablation System by Galil;
- ERBECRYO 2® Cryosurgical Unit, ERBE USA Incorporated

EVIDENCE SUMMARY

In order to understand the impact of cryosurgical ablation on local or distant tumor recurrence and disease-free and overall survival in patients with solid tumors, randomized trials are needed that compare this technique with current standard treatments. The standard treatment for most solid tumors is surgical resection. For unresectable solid tumors, alternatives to resection depend on the tumor type and location, and may include thermal ablation, percutaneous ethanol injection, chemoembolization, chemotherapy, and radiation therapy.

Despite the weaknesses in the published clinical evidence, cryosurgical ablation has become a recognized standard of care for tumors of the kidney, liver (addressed in Ablation of Primary and Metastatic Liver Tumors, Surgery, Policy No. 204), prostate, and carefully selected patients with tumors of the lung.[1-51]

The following literature appraisal focuses on the investigational indications noted in medical policy criteria above.

BREAST TUMORS

The standard treatment for breast cancer is surgical excision by lumpectomy or mastectomy, with or without adjuvant radiation therapy, chemotherapy, and/or hormone therapy. Fibroadenomas, benign tumors of the breast, generally do not require treatment. If treated, they are typically surgically excised.

Systematic Reviews

One systematic review, by Zhao (2010), was found that included cryoablation along with other minimally-invasive thermal ablation techniques (i.e., radiofrequency, microwave, cryoablation and high-intensity focused ultrasound) for treatment of early-stage breast cancer.[52] Zhao reported that studies on cryoablation for breast cancer were primarily limited to pilot and feasibility studies conducted in the research setting. A wide range of 36-83% was reported for complete ablation of tumors. The authors concluded that, while promising, large randomized controlled trials are needed to further evaluate patient selection criteria, techniques to ensure complete tumor ablation, and long-term outcomes compared with surgical excision of breast tumors.

Randomized Controlled Trials

There are no prospective, randomized controlled trials comparing survival and recurrence rates following cryoablation of breast tumors with surgical excision or, for unresectable tumors, with nonoperative therapies.

Nonrandomized Studies

The remaining nonrandomized evidence does not permit reliable conclusions concerning the impact of cryosurgical ablation on breast cancer survival or recurrence due to a number of methodological limitations, including: heterogeneous or unreported patient selection criteria, the use of varied cryoablation techniques, nonrandomized allocation of treatment, lack of an appropriate surgical excision control group for comparison, small subject population, and limited data on long-term outcomes.[53-66]

PULMONARY TUMORS

Systematic Reviews

Lee (2011) conducted a systematic review of endoscopic cryoablation of lung and bronchial tumors.[67] Included in the review were 15 case studies and one comparative observational study. Cryoablation was performed for inoperable, advanced lung and bronchial cancers in most studies. Some studies included patients with comorbid conditions and poor general health who would not be considered surgical candidates. Complications occurred in 11.1% of patients (10 studies) and consisted of hemorrhage, mediastinal emphysema, atrial fibrillation, and dyspnea. Within 30 days of the procedure, death from hemoptysis and respiratory failure, considered to be most likely related to disease progression, occurred in 7.1% of patients. Improvements in pulmonary function and clinical symptoms occurred in studies reporting these outcomes. One published review reported the outcomes of 15 case series and one comparative observational study for endoscopic cryotherapy of endobronchial tumors. Most studies were for inoperable, advanced lung and bronchial cancers. A critical analysis of the studies was not provided. However, the authors noted the significant limitations in the available evidence due to lack of control groups, lack of random treatment allocation, and heterogeneity in study methodologies, participants' characteristics (e.g., comorbid conditions, general health, cancer grade), treatment protocols, operative techniques, and outcome measures. Complications occurred in 11.1% of patients from ten studies and consisted of hemorrhage, mediastinal emphysema, atrial fibrillation, and dyspnea. Within 30 days of the procedure, death from hemoptysis and respiratory failure, considered to be most likely related to disease progression, occurred in 7.1% of patients. Improvements in pulmonary function and clinical symptoms occurred in studies reporting these outcomes. Because the studies in the review did not include control groups or compare outcomes of cryosurgery to alternative strategies for managing similar patients, no conclusions can be made on the net health outcomes of cryosurgery for lung cancer.

Randomized Controlled Trials

One preliminary randomized trial studied 36 female patients with NSCLC who also had epidermal growth factor receptor gene mutations.[68] All patients received six months treatment with molecular target therapy gefitinib, an epidermal growth factor receptor-tyrosine kinase inhibitor. Patients were randomized to either an experimental group and underwent cryoablation prior to receiving gefitinib, or to a control group in which cryoablation was not performed. At one-year follow-up, the survival rate in the cryoablation group was significantly higher than that of the control group. The findings of this preliminary study suggest that cryoablation may improve the effects of gefitinib in this patient population. Additional larger, long-term randomized trials are needed to validate these findings.

Nonrandomized Studies

The Study of Metastatic Lung Tumors Targeted by Interventional Cryoablation Evaluation (SOLSTICE) study assessed the safety and local recurrence-free survival after cryoablation for treatment of pulmonary metastases. Callstrom (2020) published this multicenter, prospective, single-arm, phase 2 study in 128 patients with 224 lung metastases ≤3.5 cm.[69] Median tumor size was 1.0 cm. Local recurrence-free response was 85.1% at 12 months and 77.2% at 24 months. Secondary local recurrence-free response after retreatment with cryoablation for recurrent tumors was 91.1% at 12 months and 84.4% at 24 months. Overall survival at 12 and 24 months was 97.6% and 86.6%, respectively.

The ECLIPSE trial is prospective, multicenter trial of cryoablation for metastatic disease in the lungs, interim results at one-year follow-up were published in 2015.[70] The trial enrolled 40 patients with 60 metastatic lung lesions who were treated with cryoablation and had at least 12 months of follow-up. Outcomes included survival, local tumor control, quality of life, and complications. Local tumor control was achieved in 94.2% (49/52) of treated lesions, and one-year OS was 97.5% (39/40). There were no significant changes in quality of life over the 12-month study. The most common adverse event was pneumothorax requiring chest tube insertion in 18.8% (9/48 procedures). Five-year results of the trial were published by de Baère (2021), which reported disease-specific survival rates of 74.8% at three years and 55.3% at five years.[70] Five-year overall survival was 46.7% and there was no significant difference in quality-of-life measures.

BONE TUMORS

Systematic Reviews

Khanmohammadi (2023) published a systematic review of cryoablation for the palliation of painful bone metastases.[71] The review included 15 studies (n=376): ten case series and five prospective interventional studies. Of these, six were scored as “good,” six as “fair,” and three as “poor” according to the NIH Study Quality Assessment Tools. A total of 436 metastatic lesions were treated, mostly in the spine, pelvic bone, and ribs. All of the studies reported a statistically significant reduction in pain between one day and six months following the procedure.

A systematic review by Sagoo (2022) assessed percutaneous cryoablation of spinal metastases.[72] Eight studies, seven of which were retrospective, were included in the review, with a total of 148 patients and 187 treated lesions (3 cervical, 74 thoracic, 37 lumbar, and 17 sacrococcygeal). At one-month follow-up, the pooled mean difference in pain scores (1-10 scale) was 5.03 (95% confidence interval [CI] 4.24 to 5.82). Reported tumor control rates varied from 60% to 100% and complications were reported in 12 patients, three of which were grade III-V.

Lindquester (2020) published a systematic review evaluating percutaneous thermal ablation technologies for osteoid osteoma, which included 36 case-series (total n=1,798).[73] While the authors stated that the studies were evaluated for quality, the results of such an evaluation were not included in the publication. An overall success rate of 91.9% was reported, which included both technical and clinical success of the procedure as well as freedom from recurrence during follow-up, however median length of follow-up in these studies was not reported. The overall complication rate was 2.5% (95% CI 1.9% to 3.3%). No significant differences were found between radiofrequency and cryoablation, but only three of the 36 studies included cryoablation; most (32 studies) were for radiofrequency ablation.

Nonrandomized Studies

Cazzato (2022) published a review of 74 patients with spinal metastases who underwent cryoablation treatment at two academic medical centers.[74] Of these, 21 patients underwent treatment for curative purposes while 53 were treated for palliative purposes. Cryoablation was associated with a reduction in pain among those who presented with painful lesions. Local tumor control was achieved in 21 patients undergoing cryoablation with curative intent (mean follow-up of 25.9 ± 21.2 months).

Jennings (2021) reported on a multicenter, single-arm prospective study of 66 patients with metastatic bone disease who were treated with cryoablation, all of whom were not candidates for or had not benefited from standard therapy.[75] The primary endpoint was the change in pain score from baseline to week eight and patients were followed for 24 weeks. The mean decrease in pain score from baseline to week eight was 2.61 points (95% CI 3.45 to 1.78). Pain scores decreased further after the primary endpoint and reached clinically meaningful levels (more than a two-point decrease) after week eight. This study was limited by its lack of a comparator, potential for selection bias, and lack of blinding combined with subjective outcome measures.

Callstrom (2013) reported on 61 patients treated with cryoablation for pain from 69 tumors (size 1 to 11 cm) metastatic to the bone. Before treatment, patients rated their pain with a 4+ on a 1-to-10 scale using the Brief Pain Inventory, with a mean score of 7.1 for worst pain in a 24-hour period. The mean pain score gradually decreased after cryoablation to 1.4 ($p<0.001$) at 24 weeks for worst pain in a 24-hour period. A major complication of osteomyelitis was experienced by one (2%) patient.

Meller (2008) retrospectively analyzed a single-center experience with 440 bone tumor cryosurgery procedures performed between 1988 and 2002, two-thirds of them for primary benign-aggressive and low-grade malignant lesions, and one-third for primary high-grade and metastatic bone tumors.[76] At a median follow-up of seven years (range 3 to 18 years), the overall recurrence rate was 8%. Based on their data, the authors suggested that the ideal case for cryosurgery is a young adult with involvement of long bone, a benign-aggressive or low-grade malignant bone tumor, a good cavity with greater than 75%-thick surrounding walls, no or minimal soft-tissue component, and at least ±1 cm of subchondral bone left near a joint surface after curettage and burr drilling.

OTHER TUMORS

Cryoablation for the treatment of other solid tumors has not been well-studied.

Systematic Reviews

Keane (2014) reported on a systematic review of ablation therapies, including cryoablation, for locally advanced pancreatic cancer.[77] The review noted studies have demonstrated ablative therapies, including cryoablation, are feasible but larger studies are needed. No conclusions could be made on whether ablation resulted in better oncologic outcomes than best supportive care.

Tao (2012) reported on a systematic review of cryoablation for pancreatic cancer.[78] The authors identified 29 studies from the literature search and included five of these studies in the review. The five studies were all case series and considered to be of low quality. Adverse events, when mentioned in the studies, included delayed gastric emptying (0% to 40.9% in three studies), pancreatic leak (0% to 6.8% in four studies), biliary leak (0% to 6.8% in three studies), and one instance of upper gastrointestinal hemorrhage. Pain relief was reported in three studies and ranged from 66.7% to 100%. Median survival times reported in three studies ranged from 13.4 to 16 months. One-year total survival rates reported in two studies were 57.5% and 63.6%.

Nonrandomized Studies

The remaining published literature is limited to case series and retrospective reviews.[79-89] As discussed above, these studies do not permit reliable conclusions concerning the impact of cryoablation on health outcomes.

PRACTICE GUIDELINE SUMMARY

Clinical practice guidelines from U.S. professional associations consistently list cryoablation as a treatment option for uveal melanoma, certain NSCLC tumors, and for tumors of the kidney or prostate.[90-96]

No clinical practice guidelines or position statements based on research from U.S. professional societies were identified that specifically recommend cryoablation for the treatment of solid tumors other than those listed above, though some refer more generally to ablation procedures.[97 98]

SUMMARY

Cryosurgical ablation has become a recognized standard of care in the management of tumors of the skin, kidney and prostate, uveal melanoma, cervical intraepithelial neoplasia, and carefully selected patients with lung tumors. Therefore, this technique may be considered medically necessary in the treatment of these tumors when criteria are met.

There is not enough research to show that cryosurgical ablation can improve health outcomes for patients with solid tumors that do not meet policy criteria, including malignant or benign tumors of the breast (including fibroadenoma), pancreas, and bone; and for metastases outside of the liver or prostate. Therefore, cryosurgical ablation for these indications is considered investigational.

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CODES

Codes	Number	Description
CPT	0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral
	17260-17286	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement)
	19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma
	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
	31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)
	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 lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
	50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed
	50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
	55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
	57511	Cautery of cervix; cryocautery, initial or repeat
HCPCS	None	

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