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Medical Policy Manual Surgery, Policy No. 132

Cryosurgical Ablation of Miscellaneous Solid Organ, Pulmonary, and Breast Tumors

Effective: March 1, 2018

Next Review: November 2018
Last Review: February 2018

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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

MEDICAL POLICY CRITERIA

Notes:

- This policy is limited to cryosurgery for the treatment of solid organ tumors, as well as breast and pulmonary tumors.
- This policy does not address liver tumors (primary or metastatic). See Cross References.

I. Cryosurgical ablation for the treatment of kidney, and prostate tumors may be considered **medically necessary**.
II. Cryosurgical ablation for the treatment of lung cancer may be considered **medically necessary** when either of the following criteria is met:

A. 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

B. The patient requires palliation for a central airway obstructing lesion.

III. Cryosurgical ablation is considered **investigational** as a treatment of malignant or benign (fibroadenoma) breast tumors, pulmonary tumors not meeting criteria II, and all other solid organ tumors including but not limited to bone and pancreatic cancer.

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

POLICY GUIDELINES

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 for Primary and Metastatic Tumors of the Liver, Medicine, Policy No. 140
2. Radiofrequency Ablation of Tumors (RFA), 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

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;
- 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 criterion III 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 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 1 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.

NONRANDOMIZED STUDIES

The ECLIPSE trial is prospective, multicenter trial of cryoablation for metastatic disease in the lungs, interim results at 1-year follow-up were published in 2015.[68] 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 1-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).

OTHER TUMORS

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

SYSTEMATIC REVIEWS

In 2014, Keane reported on a systematic review of ablation therapies, including cryoablation, for locally advanced pancreatic cancer.[69] 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.

In 2012, Tao reported on a systematic review of cryoablation for pancreatic cancer.[70] The authors identified 29 studies from the literature search and included 5 of these studies in the review. The 5 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 3 studies), pancreatic leak (0% to 6.8% in 4 studies), biliary leak (0% to 6.8% in 3 studies), and one instance of upper gastrointestinal hemorrhage. Pain relief was reported in 3 studies and ranged from 66.7% to 100%. Median survival times reported in 3 studies ranged from 13.4 to 16 months. One-year total survival rates reported in 2 studies were 57.5% and 63.6%.

RANDOMIZED CONTROLLED TRIALS

One preliminary randomized trial studied 36 female patients with NSCLC who also had epidermal growth factor receptor gene mutations.[71] All patients received 6 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 1-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 remaining published literature is limited to case series and retrospective reviews.[72-81] 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 tumors of the kidney or prostate.[82-87]

No clinical practice guidelines or position statements based on research from U.S. professional societies were identified that recommend cryoablation for the treatment of solid tumors other than kidney and prostate tumors.[87-95]

SUMMARY

Cryosurgical ablation has become a recognized standard of care in the management of tumors of the kidney and prostate, and carefully selected patients with lung tumors. Therefore, this technique may be considered medically necessary in the treatment of these tumors.

There is not enough research to show that cryosurgical ablation for the treatment of solid organ, bone, and breast tumors other than tumors of the kidney or prostate, or lung tumors meeting criteria improves health outcomes. In addition, there are no clinical practice guidelines based on research that recommend the use of cryosurgical ablation of those tumors. Therefore, cryosurgical ablation as a treatment for solid organ, bone, and breast tumors other than those of the kidney, prostate, or lung tumors meeting criteria is considered investigational.

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CODES

Codes	Number	Description
CPT	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)
	~~0340T~~	~~Ablation, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance~~ (Deleted 1/1/2018)
HCPCS	None	

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