

FEP 7.01.92 Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors

Effective Date: April 15, 2018

Related Policies:

- 7.01.75 Cryosurgical Ablation of Primary or Metastatic Liver Tumors
- 7.01.79 Cryoablation of Prostate Cancer
- 7.01.91 Radiofrequency Ablation of Primary or Metastatic Liver Tumors
- 7.01.95 Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

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

Description

Cryosurgical ablation (hereafter referred to as cryosurgery or cryoablation) 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.

FDA REGULATORY STATUS

Several cryoablation devices have been cleared for marketing by the U.S. Food and Drug Administration 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 (Endocare [Irvine, CA]);
- CryoGen Cryosurgical System (Cryosurgical);
- CryoHit® (Galil Medical [Arden Hills, MN]) for the treatment of breast fibroadenoma;
- SeedNet™ System (Galil Medical); and
- Visica® System (Sanarus Medical [Pleasanton, CA]).

Food and Drug Administration product code: GEH.

POLICY STATEMENT

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 of <60 mL/min/m²), and standard surgical approach (ie, resection of renal tissue) is likely to worsen kidney function substantially; or
- The patient is not considered a surgical candidate.

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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, 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

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

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Society of Breast Surgeons

The American Society of Breast Surgeons 2008 consensus statement on management of fibroadenomas of the breast indicated cryoablation would be appropriate for histologically confirmed fibroadenoma lesions that are less than 4 cm in largest diameter and sonographically visible.⁵⁰ Cryoablation of fibroadenoma of the breast would be contraindicated when ultrasound visualization is poor, or when core biopsy suggests a diagnosis of cystosarcoma phyllodes tumor or other malignancy or if physical examination or imaging is discordant with a biopsy diagnosis of fibroadenoma.

American College of Radiology

The 2009 American College of Radiology Appropriateness Criteria for renal cell carcinoma, updated most recently in 2014, indicated that "As an alternative to partial nephrectomy, energy-ablative therapies, such as cryoablation... are being used to treat small renal cell carcinomas. These therapies have been shown to be effective and safe."⁵¹ These recommendations are based on a review of the data and consensus.

American Urological Association

The 2009 guidelines from the American Urological Association on stage I renal masses indicated percutaneous or laparoscopic cryoablation "is an available treatment option for the patient at high surgical

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risk who wants active treatment and accepts the need for long-term radiographic surveillance after treatment.”⁵² The guidelines also indicated cryoablation “should be discussed as a less-invasive treatment option” in *healthy* patients with a renal mass equal to or less than 4.0 cm and clinical stage T1a. Patients should be informed that “local tumor recurrence is more likely than with surgical excision, measures of success are not well defined, and surgical salvage may be difficult.” These recommendations were based on a review of the data and “appreciable” majority consensus.

In 2017, the American Urological Association updated its guidelines on evaluation and management of clinically localized sporadic renal masses suspicious for renal cell carcinoma.⁵³ The guideline statements on thermal ablation (radiofrequency ablation and cryoablation) are listed in Table 1.

Table 1 Guideline Statements on Localized Masses Suspicious for Renal Cell Carcinoma

Recommendations	LOR	LOE
Guideline statement 24 Physicians should consider thermal ablation (TA) as an alternate approach for the management of cT1a renal masses <3 cm in size. For patients who elect TA, a percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity.	Conditional	C
Guideline statement 25 Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation	Conditional	C
Guideline statement 27 Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical extirpation, which may be addressed with repeat ablation if further intervention is elected	Strong	B

LOE: level of evidence; LOR: level of recommendation.

National Comprehensive Cancer Network

National Comprehensive Cancer Network (NCCN) guidelines on kidney cancer (v.2.2017) state that, based on lower level evidence and uniform NCCN consensus, cryosurgery: “Can be considered for patients with clinical stage T1 renal lesions who are not surgical candidates. Biopsy of small lesions may be considered to obtain or confirm a diagnosis of malignancy and guide surveillance, cryosurgery ... [and] ablation strategies.”⁵⁴ NCCN guidelines also note that “Randomized phase III comparison with surgical resection (ie, radical or partial nephrectomy by open or laparoscopic techniques) has not been done” and “Ablative techniques are associated with a higher local recurrence rate than conventional surgery.”

NCCN guidelines for non-small-cell lung cancer (v.7.2017) indicate surgical “resection is the preferred local treatment modality” and “other modalities include ... cryotherapy.”⁵⁵

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
September 2012	Update Policy	Policy updated with literature review; lung cancer added to investigational policy statement. References 8, 15-16, 23-25 and 38 added.
September 2013	Update Policy	Policy updated with literature review; metastases added to not medically necessary statement; other policy statements unchanged. References 3, 17 and 36 added; 40 updated.
September 2014	Update Policy	Policy updated with literature review. References 18, 20, 24-25, and 29 added. Policy statements unchanged.
September 2015	Update Policy	Policy updated with literature review; reference 24 added. Policy statements unchanged.
March 2018	Update Policy	Policy updated with additional references to October 30, 2017. Medically necessary policy statements for lung cancer and the statement related to cryosurgical ablation to treat breast, lung tumors qualified with "other than defined above, or other solid tumors.." corrected from "not medically necessary" to "investigational" due to FDA 510k approval status; references 21-23, 29 and 41 were added, and reference list updated

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