MEDICAL POLICY

Excellus

SUBJECT: CRYOSURGICAL TUMOR ABLATION POLICY NUMBER: 7.01.03 CATEGORY: Technology Assessment	EFFECTIVE DATE: 10/25/99 REVISED DATE: 06/20/01, 06/20/02, 05/21/03, 05/19/04, 03/17/05, 02/16/06, 12/21/06, 12/20/07, 12/18/08, 11/19/09, 11/18/10, 10/20/11, 10/18/12, 08/15/13, 08/21/14, 05/28/15, 05/25/16, 05/18/17, 04/19/18 PAGE: 1 OF:14

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, cryosurgical ablation of renal tumors is a **medically appropriate** treatment option when tumor size is 4 cm or less in diameter. There MUST be documentation that there has been an informed decision making process between the surgeon and the patient and 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 peer-reviewed literature, cryosurgical tumor ablation has not been medically proven to be effective and 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 regarding Cryosurgery for Prostate Cancer.

Refer to Corporate Medical Policy #7.02.32 regarding Radiofrequency Tumor Ablation.

Refer to Corporate Medical Policy # 7.01.69 regarding Selective Internal Radiation Therapy (SIRT).

Refer to Corporate Medical Policy # 7.01.78 regarding Peptide Receptor Radionuclide Therapy.

Refer to Corporate Medical Policy # 11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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 of unresectable liver tumors, of bronchogenic/lung cancer, of renal cell carcinoma 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 2009 guidelines from the American Urological Association on stage 1 renal masses indicate percutaneous or laparoscopic cryoablation "is an available treatment option for the patient at high surgical risk who wants active treatment and accepts the need for long-term radiographic surveillance after treatment". The guidelines also indicate 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."

Georgiades and Rodriguez (2014) presented the 5-year oncologic outcomes of a prospective trial evaluating percutaneous cryoablation as a treatment option for renal cell carcinoma (RCC). Over a 5-year period, 134 consecutive patients with biopsy-proven RCC were treated with CT-guided percutaneous cryoablation. All were treated while under conscious sedation. Technical objective was for the ice ball to cover the lesion plus a 5-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 1-, 2-, 3-, 4-, and 5-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 3 (none from RCC), yielding an overall 5-year survival of 97.8 %. The cancer-specific 5-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 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 cyroablation 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- October 2009. After excluding patients with <5 years follow-up and those with >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 6 recurrences, 14 non-cancer-related deaths, and 1 cancer-related death, leading to an 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 both an efficacious treatment for clinical stage T1 renal masses and provides excellent long-term oncologic outcomes.

RH Thompson and colleagues (2014) compared oncologic outcomes among patients treated with partial nephrectomy (PN), percutaneous 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, metastases-free, and overall survival rates were 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 (8 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 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.

A Larcher, et al. (2015) conducted a single center, retrospective analysis to determine if 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 20mm. Median follow-up was 48 months. Treatment failure was evaluated 1 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 survival and cancer-specific-free survival are optimal.

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 being 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>Liver:</u>
A 2000 BlueCross BlueShield TEC Assessment found insufficient data to permit conclusions regarding the effect of cryosurgical ablation on the health outcomes of patients with unresectable HCC or metastatic liver disease. This conclusion applied to performing cryosurgery alone, as an adjunct to surgical resection or combined with other ablative therapies. Peer-reviewed literature published since the 2000 TEC Assessment consist mainly of uncontrolled case series with heterogeneity in the sample population and still do not provide conclusive evidence on the overall survival benefit of cryosurgical ablation (e.g., Gurusamy, et al. 2009; Zhou, et al. 2009; NICE Dec 2010). Awad et al, (2010) conducted a systematic review to evaluate the potential benefits and harms of cryotherapy for the treatment of hepatic carcinoma. No randomized or quazi-randomized trials were identified. However, they found 2 cohort studies (2 prospective and 2 retrospective). Only one of the studies could be included for the assessment of benefit. The authors concluded that at present, there is no evidence to recommend or refute cryotherapy for patients with hepatocellular carcinoma. Large, well-designed randomized clinical trials are feasible and necessary to define the role of cryotherapy in the treatment of HCC.

<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 has 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, the 2005 case series of 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 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 tumor.

Pfleiderer SO., 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 6 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 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%. Since there are many outstanding issues, including patient selection criteria and the ability to precisely determine the size of tumors and 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.

<u>Pancreatic</u>:
Li and colleagues (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 decreased from 4.3 cm to 2.4 cm in 36 of 55 patients (65%) 3 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 2 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 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 lack of quality evidence.

Cryosurgical ablation for the treatment of non-small cell lung cancer (NSCLC) has been studied in a limited number of small studies. The largest currently available was a case series study involving 47 subjects with NSCLC followed for a minimum of 5 years after treatment with cryoablation (Moore, 2015). The authors reported that the 5-year survival rate was 67.8% ± 15.3, the cancer-specific survival rate at 5 years was 56.6% ± 16.5, and the 5-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 1 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 to 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 if 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 and colleagues in 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, the overall local tumor control, including stable disease, partial, and complete response, was seen in 49 of 52 metastases (94.2%) and 32 of 35 subjects (91.4%). Local failure was observed in 3 of 52 metastases (5.8%) at 6 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 OS rates were 100% and 97.5% respectively. Pneumothorax requiring chest tube placement occurred in 9 of the 48 procedures (18.8%), and chest tubes were removed after 1 day (n=8) or 2 days (n=1). Common Terminology Criteria for Adverse Events (CTCAE) grade 3 adverse events within 30 days of the procedure occurred in 3 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 which 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.

CODES: Number Description

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:	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, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance
	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, if performed
	50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
	76940	Ultrasound guidance for, and monitoring of, tissue ablation
	77013	Computed tomography guidance for, and monitoring of, parenchymal tissue ablation
	77022	Magnetic resonance guidance for, and monitoring of, parenchymal tissue ablation

HCPCS:	C2618	Probe/needle, cryoablation
ICD10:	Multiple diagnosis codes	

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KEY WORDS:

Cryoablation, Cryosurgery, Liver neoplasms.

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.