MEDICAL POLICY

Excellus

SUBJECT: CRYOSURGICAL TUMOR ABLATION	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
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- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, cryosurgical ablation of renal tumors is considered a **medically appropriate** treatment option in the following circumstances:
   A. Patients with a solitary kidney or renal insufficiency; defined by a glomerular filtration rate (GFR) of less than 60 mL/m^2; OR
   B. Patients with a contraindication to surgery (e.g., significant comorbidities, location or number of tumors preclude surgical intervention); AND
   C. Tumor size is equal to or less than 4 cm.

   The comorbidities of patients unable to undergo surgery should not be so severe as to limit their life expectancy to less than one year.

II. Based on our criteria and assessment of peer-reviewed literature, cryosurgical ablation is considered **investigational** as a primary treatment in patients with renal tumors who are surgical candidates.

III. 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, and pancreatic cancer.

Refer to Corporate Medical Policy # 7.01.01 regarding Cryosurgery for Prostate Cancer.

Refer to Corporate Medical Policy #7.01.49 regarding Transcatheter Arterial Chemoembolization of Hepatic Tumors.

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:

The literature on the use of cryosurgical ablation of tumors consists primarily of reports of single-center case series; however, evidence is accumulating that cryoablation provides acceptable tumor control and a survival benefit for carefully selected patients with small renal cell carcinomas. Based on the current evidence (large numbers of patients treated with follow-up), cryoablation of small (4 cm or less) renal cancers appears to be an effective treatment in those patients who are not surgical candidates due to comorbid conditions or who have baseline renal insufficiency such that standard surgical procedures would impair their kidney function.

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.

Renal cancer:
In a 2010 Cochrane review, Nabi and colleagues review the evidence on the management of localized renal cell carcinoma (RCC). No randomized trials comparing cryoablation to open radical or partial nephrectomy were identified. One nonrandomized study compared laparoscopic partial nephrectomy with laparoscopic cryoablation using a matched paired-analysis and 3 retrospective studies. The review notes percutaneous cryoablation can successfully destroy small RCC and may be considered a treatment option in patients with serious comorbidities that pose surgical risks. The review concluded that high quality, randomized controlled trials (RCTs) are required in the management of localized RCC and that one area of emphasis should be the role of renal surgery compared to minimally invasive techniques for small tumors (less than 4 cm).

T Klatte, et al. performed a systematic review and cumulative analysis of oncological outcomes and perioperative complications of studies comparing laparoscopic cryoablation and partial nephrectomy. The authors concluded that both procedures are viable options for the management of patients with small renal masses. Compared to partial nephrectomy, laparoscopic cryoablation results in a higher risk of local tumor progression but a lower risk of perioperative complications. However this difference is strongly influenced by selection bias, and thus limited conclusions can be made regarding true differences in complications. Therefore, partial nephrectomy is the gold standard for small renal masses, but laparoscopic cryoablation may be indicated in selected patients with significant comorbidity.

Kunkle and Uzzo (2008) conducted a comparative meta-analysis evaluating cryoablation and radiofrequency ablation (RFA) as primary treatment for small renal masses. Forty-seven case series representing 1,375 renal tumors were analyzed. Of 600 lesions treated with cryoablation, 494 were biopsied before treatment versus 482 of 775 treated with RFA. The incidence of RCC with known pathology was 72% in the cryoablation group and 90% in the RFA group. The mean duration of follow-up after cryoablation was 22.5 months. Most studies used contrast enhanced imaging to determine treatment effect. Local tumor progression was reported in 31 of 600 (5%) lesions after cryoablation and in 100 of 775 (13%) lesions after RFA. Progression to metastatic disease was described in 6 of 600 (1%) lesions after cryoablation versus 19 of 775 (2.5%) after RFA. The authors caution that minimally invasive ablation generally has been performed selectively on older patients with smaller tumors, possibly resulting in selection bias; series of ablated lesions tend to have shorter post-treatment follow-up compared with tumors managed by surgical excision or active surveillance, and treatment efficacy may be overestimated in series that include tumors with unknown pathology.

Cestari et al (2004) reported their experience with laparoscopic renal cryoablation in select cases of small renal neoplasms (n = 37). Of the 35 patients with at least 6 months of followup, CT guided biopsy was performed in 25, who were negative for neoplasm. They concluded that laparoscopic renal cryoablation for small renal masses appear to be a safe,

reproducible, minimally invasive technique. Medium term follow-up is encouraging, although further studies and prolonged follow-up are needed to access properly the role of this surgical technique. Gill et al (2005) came to similar conclusions in their case series of 56 patients with small renal tumors. At 3 year follow-up, 17 cryolesions (38%) had completely disappeared on MRI. Postoperative needle biopsy identified locally persistent/recurrent renal tumor in 2 patients, but only 39 pts (70%) were available for needle biopsy. The authors concluded that the 3-year outcomes following renal cryoablation were encouraging. Longer- term (5-year) data are necessary to determine the proper place of renal cryotherapy among minimally invasive, nephron sparing options.

Liver:

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.

Breast:

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.

Pancreatic:

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).

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
	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
	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
	0340T **(E/I)**	Ablation, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance

HCPCS:	C2618	Probe/needle, cryoablation
ICD9:	Multiple diagnosis codes	
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.