Clinical Policy Bulletin: Cryoablation

Number: 0100

Policy

I. Aetna considers cryoablation of the prostate medically necessary for any of the following conditions:

   A. Members with Stage A prostate cancer (see appendix); or
   B. Members with Stage B prostate cancer; or
   C. Members with Stage C prostate cancer when the regional lymph nodes have been evaluated and are negative for cancer; or
   D. As a salvage therapy only for those members with localized prostate cancer who failed a course of radiation therapy as their primary treatment (see Note below), and have a prostate-specific antigen of less than 8 ng/ml, a Gleason score less than 9, or a disease stage of T2B or below.

Note: Cryoablation as salvage therapy is considered experimental and investigational after failure of other therapies as the primary treatment. Cryoablation as salvage is only considered medically necessary after the failure of a trial of radiation therapy.

II. Aetna considers cryoablation of the prostate experimental and investigational for any of the following groups:

   A. Members with benign prostatic hypertrophy (see CPB 0079 - Benign Prostatic Hypertrophy (BPH) Treatments); or
   B. Members with a prior cryoablation procedure; or
   C. Members with Stage C prostate cancer whose regional lymph nodes have not been evaluated; or
   D. Members with Stage D prostate cancer.

III. Aetna considers cryoablation for malignant endobronchial obstruction medically necessary.
IV. Aetna considers cryoablation of renal cell carcinoma, up to 4-cm in size, medically necessary when any of the following criteria is met:

A. Persons who are considered high-risk surgical candidates; or
B. Persons with renal insufficiency, as defined by a glomerular filtration rate of less than or equal to 60 ml/min/m$^2$; or
C. Persons with a solitary kidney.

V. Aetna considers cryoablation medically necessary for the treatment of atrial fibrillation in association with other cardiac surgery.

VI. Aetna considers cryoablation of breast carcinoma and fibroadenoma experimental and investigational.

VII. Aetna considers cryoablation medically necessary for the treatment of low-risk superficial basal cell carcinoma, and squamous cell carcinoma in situ (Bowen disease), where surgery or radiation is contraindicated or impractical.

VIII. Aetna considers cryoablation medically necessary for the treatment of low-risk superficial basal cell carcinoma, and squamous cell carcinoma in situ (Bowen disease), where surgery or radiation is contraindicated or impractical.

IX. Aetna considers cryoablation of abdominal wall endometriosis, Barrett's esophagus, esophageal cancer, extra-abdominal desmoid tumors, facet or sacroiliac joint pain, idiopathic ventricular tachycardia (VT), leiomyosarcoma, lipoma/neuroma, non-small cell lung cancer (other than malignant endobronchial obstruction), pancreatic cancer, plantar fibroma, post-infarction VT, retinopathy of prematurity, and tuberous sclerosis-associated renal angiomyolipoma experimental and investigational because its effectiveness for these indications has not been established.

X. Aetna considers cryoablation medically necessary for cervical intraepithelial neoplasia.

XI. Aetna considers endoluminal cryoablation for the treatment of symptomatic varicose veins experimental and investigational because of insufficient evidence of its effectiveness.

XII. For cryoablation of hepatic lesions, see CPB 0274 - Ablation of Hepatic Lesions.

XIII. For cryoablation of the endometrium, see CPB 0091 - Endometrial Ablation.

XIV. For cryosurgery of the skin, see CPB 0567 - Actinic Keratosis Treatments, and CPB 0633 - Benign Skin Lesion Removal.

XV. For cryosurgery of plantar fasciitis, see CPB 0235 - Plantar Fasciitis Treatments.

See also CPB 0016 - Back Pain - Invasive Procedures, and CPB 0728 - Barrett's Esophagus.
Background

Cryosurgical ablation is an established method of treating localized prostate cancer. In 1996, the American Urological Association revised their policy statement regarding cryosurgical ablation of the prostate to state that they believe that cryosurgical treatment of the prostate should be accepted as one of the methods of management of adenocarcinoma of the prostate. They indicated that because the long-term curative efficacy of this treatment modality has not been established, when used, appropriate disclosure of facts regarding all other treatments for prostate cancer should be made to the patient.

Cryosurgical ablation has been shown to be an effective method for palliation of symptoms from malignant endobronchial obstruction. The National Institute for Clinical Excellence (NICE, 2005) assessed cryotherapy for malignant endobronchial obstruction, and concluded that "[c]urrent evidence on the safety and efficacy of cryotherapy for malignant endobronchial obstruction appears adequate to support the use of the procedure provided that the normal arrangements are in place for consent, audit and clinical governance." The assessment noted that the main aim of the procedure is palliation of symptoms such as cough, dyspnea and hemoptysis. In 1 case series of 521 patients, 86% had improvement in one or more symptoms and quality of life scores were significantly improved. Dyspnea improved in 59% of patients. In 2 further studies, dyspnea improved in 71% and 81% of patients. The assessment also noted that cryotherapy does not provide immediate relief of bronchial obstruction and is therefore not suitable for the emergency treatment of acute respiratory distress.

Cryotherapy may be used as an alternative to nephrectomy for renal carcinoma in persons who are not surgical candidates. Incidental detection of solid renal masses during abdominal imaging is increasing in older patients. Although these masses often are malignant histologically, many are indolent clinically. A therapeutic option for patients who are poor surgical candidates is cryoablation, in which cryoprobes are inserted percutaneously into the mass, creating an "ice ball" that destroys the tumor. According to the peer-reviewed medical literature, cryotherapy for ablation of renal cell carcinoma is a promising alternative for persons who are not candidates for total or partial nephrectomy. Although it is potentially an attractive addition to available nephron-sparing surgical techniques, refinement of MR image guidance and percutaneous techniques for introducing cryogenic probes into the kidneys and other deep abdominal organs must be developed, and long-term data on the effectiveness of cryoablation of renal cell carcinoma are limited.

Cestari et al (2004) reported their experience with laparoscopic renal cryoablation in select cases of small renal neoplasms (n = 37). They concluded that laparoscopic renal cryoablation for small renal masses appears 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. This is in agreement with the findings of Johnson et al (2004) as well as Moon et al (2004).
associates stated that ablation technologies (cryoablation and radiofrequency ablation) appear to have a low complication profile when used to treat small renal tumors. The majority of complications are minor and require observation only. Further study and follow-up are needed to determine their long-term effectiveness. Moon and colleagues concluded that longer follow-up is required to fully define the role of laparoscopic cryoablation for the treatment of small renal tumors.

Desai et al (2005) compared peri-operative and short-term outcomes of laparoscopic partial nephrectomy versus laparoscopic cryoablation in patients with peripheral small renal tumors and concluded that, "[a]lthough the technical simplicity, decreased blood loss, and somewhat lower complication rate are attractive features of renal cryotherapy, this must be balanced against the current lack of long-term follow-up data that are needed to confirm the oncologic adequacy of this developmental procedure." These findings are consistent with a review by Aron and Gill (2005) on renal tumor ablation methods that stated, "Although the initial outcomes of cryoablation and radiofrequency ablation are encouraging, long-term studies are necessary to confirm their lasting efficacy. The optimal modality for tumor targeting, monitoring therapy, and follow-up remains to be determined."

Kaouk et al (2006) examined the experimental and clinical evolution of cryotherapy for small renal masses. The authors stated that the major criticism of this and other ablative techniques is the associated lack of histological confirmation of complete tumor ablation. They noted that long-term, diligently performed clinical trials that provide detailed, meticulous, sequential 5-year radiological and histological data are needed to confirm lasting effectiveness. Furthermore, these data must be compared with those related to partial nephrectomy, which remains the reference standard.

Littrup and colleagues (2007) evaluated the results of initial and current techniques for percutaneous renal cryotherapy, including long-term imaging outcomes. Computed tomography (CT)-guided percutaneous cryotherapy was performed on 49 masses in 48 out-patients and procedure comfort noted for each. These 49 masses included 36 primary renal cell carcinomas (RCCs), 3 oncocytomas, 1 angiomylipoma, 6 renal inflammatory lesions, 2 benign parenchymal changes, and 1 colon cancer metastasis. All complications were graded according to standardized criteria. Patients received only local anesthesia and moderate sedation during the procedure and were discharged with minimal discomfort within 4 to 6 hours. All cryotherapy zones were well defined by CT during ablation as hypodense ice with an average diameter of 5.3 cm, covering an average tumor size of 3.3 cm. Average ablation zone diameters showed significant reduction over time (p < 0.001), becoming significantly less than the original tumor size by 12 months (p < 0.05). Major and minor complications were seen in 3 (6 %) and 11 (22 %) procedures, respectively. At a mean follow-up of 1.6 years (range of 1 week to 3.8 years) for primary RCC patients, 4 failures (11.1 %) by imaging criteria were noted, but 1 proved to be inflammatory tissue at re-biopsy (estimated neoplastic failure rate = 3/36 [8.3 %]). The authors concluded that percutaneous renal cryotherapy is a well-tolerated out-patient procedure that allows safe, CT monitoring of ice formation beyond visible tumor margins. With appropriate
cryoprobe placements, a low failure rate appears less dependent on tumor size or location. Ablation volume involution was greater than 80% after 6 months.

Atwell et al (2008) determined technical feasibility, safety and short-term outcomes following percutaneous renal cryoablation. These investigators performed a retrospective review of 115 renal tumors in 110 elderly patients (mean age 72 years) treated with percutaneous cryoablation. For most patients, cryoablation was recommended instead of surgery because of substantial medical comorbidities or prior contralateral nephrectomy. Mean tumor size was 3.3 cm (range of 1.5 to 7.3 cm), including 29 tumors 4.0 cm or larger and 21 tumors in the anterior kidney. Of 90 renal mass biopsies performed, 52 (58%) showed renal cell carcinoma. All patients were admitted to the hospital following cryoablation and most (87%) were discharged home the next day (range of 1 to 12 days). There were 7 major complications associated with the 113 cryoablation procedures (6%), including pulmonary embolism, urosepsis, and large hematomas. Technical success (defined as extension of the ice ball beyond tumor margins and no post-ablation contrast enhancement of tumor parenchyma) was achieved in 112 of the 115 (97%) treated tumors and 3 residual tumors were seen on 3-month follow-up imaging. There has been no local progression in 80 tumors (100% treatment success) followed 3 months or longer (mean of 13.3 months). Commenting on this study, Brett (2008) stated that cryoablation is a technically feasible approach for patients with incidentally discovered renal masses who are not good surgical candidates. Brett observed however, that follow-up was relatively brief, and the complication rate was not trivial. Brett noted that because many small renal tumors in older patients progress slowly or not at all, simple observation without intervention is another reasonable option.

Hinshaw and colleagues (2008) compared the outcome, complications, and charges of percutaneous renal cryoablation and laparoscopic cryoablation of solid renal masses. A total of 30 percutaneous renal cryoablations (mean tumor size of 2.1 cm) in 30 patients (mean age of 67.0 years) and 60 laparoscopic renal cryoablations (mean tumor size of 2.5 cm) in 46 patients (mean age of 67.4 years) were compared. The size of the tumor, procedural complications, hospital charges, length of hospital stay, and tumor follow-up parameters were recorded. Monitoring after ablation was performed every 3 months using contrast-enhanced MRI or CT. Both percutaneous cryoablation and laparoscopic cryoablation of solid renal masses had a high technical success rate (30/30 [100%] and 59/60 [98.3%]). There was no significant difference in the rate of residual disease (3/30 [10%] and 4/60 [6.7%], p = 0.68), and the secondary effectiveness rate is 100% for both groups to date. One renal mass treated using laparoscopic cryoablation had a local recurrence, but none of the masses treated using percutaneous cryoablation had a recurrence. The disease-specific survival is 100% in both groups with no significant difference in the mean follow-up time (14.5 versus 14.6 months, p = 1.0) or major complication rate (0/30 [0%] versus 3/60 [5.0%), p = 0.55). For the treatment of solid renal masses, percutaneous cryoablation was associated with 40% lower hospital charges (mean of $14,175 versus $23,618, p < 0.00001) and a shorter hospital stay (mean +/- SD, 1.1 +/- 0.3 versus 2.4 +/- 2.1 days; p < 0.0001) than laparoscopic cryoablation. The authors concluded that although certain tumors require laparoscopic intervention because of the location or size of the tumor, percutaneous renal cryoablation is safe and effective and is associated with lower charges when used for the treatment of small renal tumors.
Finley et al (2008) reviewed their 4-year experience with percutaneous cryoablation and laparoscopy for treating small renal masses. An in-depth analysis was performed concerning demographics, hospital course and short-term outcome with respect to percutaneous versus laparoscopic cryoablation. A total of 37 patients underwent treatment for 43 renal masses. Of the 37 patients 19 underwent laparoscopic cryoablation (24 tumors) and 18 underwent percutaneous cryoablation (19 tumors) using computerized tomography fluoroscopy. For percutaneous cryoablation a saline instillation was used in 58% of cases to move non-renal vital structures away from the targeted renal mass. There were 5 cases of hemorrhage requiring transfusion, all of which were associated with the use of multiple cryoprobes. The transfusion rate in the percutaneous and laparoscopic cryoablation groups was 11.1% and 27.8%, respectively. Operative time was significantly longer in the laparoscopic cryoablation group compared to the percutaneous cryoablation group at 147 minutes (range of 89 to 209) versus 250.2 (range of 151 to 360) minutes, respectively. The overall complication rate (including transfusion) was lower in the percutaneous cryoablation group compared to the laparoscopic cryoablation group (4 of 18 [22.2%] versus 8 of 20 [40%], respectively). Hospital stay was significantly shorter in the percutaneous versus laparoscopic cryoablation group at 1.3 versus 3.1 days, p < 0.0001, respectively. Narcotic use in the percutaneous cryoablation group was more than half that used by the laparoscopic cryoablation group (5.1 versus 17.8 mg, p = 0.03, respectively). Among patients with biopsy proven renal cell carcinoma during a median follow-up of 11.4 and 13.4 months in the percutaneous and laparoscopic cryoablation groups, cancer specific survival was 100% and 100%, respectively, and the treatment failure rate was 5.3% and 4.2%, respectively. The authors concluded that percutaneous cryoablation is an efficient, minimally morbid method for the treatment of small renal masses and it appears to be superior to the laparoscopic approach. Short-term follow-up has shown no difference in tumor recurrence or need for re-treatment. Of note, hemorrhage was solely associated with the use of multiple probes.

Weight et al (2008) stated that follow-up after radiofrequency ablation and cryotherapy for small renal lesions lacks pathological analysis. The definition of successful tumor ablation has been the absence of contrast enhancement on post-treatment magnetic resonance imaging or computerized tomography. These researchers hypothesized that adding post-ablation kidney biopsy would help confirm treatment success. From April 2002 to March 2006, a total of 109 renal lesions in 88 patients were ablated with percutaneous radiofrequency ablation and from September 1997 to January 2006 a total of 192 lesions in 176 patients were treated with laparoscopic cryoablation. Patients were followed with radiographic imaging and post-ablation biopsy at 6 months. Radiographic success at 6 months was 85% (62 cases) and 90% (125) for radiofrequency ablation and cryoablation, respectively. At 6 months 134 lesions (45%) were biopsied and success in the radiofrequency ablation cohort decreased to 64.8% (24 cases), while cryoablation success remained high at 93.8% (91). Six of 13 patients (46.2%) with a 6-month positive biopsy after radiofrequency ablation demonstrated no enhancement on post-treatment magnetic resonance imaging or computerized tomography. In patients treated with cryoablation all positive biopsies revealed post-treatment enhancement on imaging just before biopsy. The authors recommend post-radiofrequency ablation follow-up biopsy due to the significant risk of residual renal
cell cancer without radiographic evidence, although to their knowledge the clinical significance of these viable cells remains to be determined. In contrast, radiographic images of renal lesions treated with cryotherapy appeared to correlate adequately with corresponding histopathological findings in our series.

The National Comprehensive Cancer Network’s clinical practice guideline for kidney cancer (2008) stated that patients in satisfactory medical condition should undergo surgical excision of stage I through III tumors. However, a small set of elderly or infirm patients with small tumors may be offered surveillance alone or energy ablative techniques, such as radiofrequency ablation or cryoablation.

An assessment by the National Institute for Health and Clinical Excellence (NICE, 2007) concluded: “Current evidence suggests that cryotherapy for renal cancer ablates tumour tissue and that its safety is adequate. However, the evidence about its effect on long-term local control and survival is not yet adequate to support the use of this procedure without special arrangements for consent and for audit or research.” The NICE assessment noted that its specialist advisors commented that, because only a small number of patients have been treated with this procedure, long-term efficacy has yet to be established. The specialist advisors to NICE also noted that the lack of histological data makes it difficult to determine whether total ablation of tumors has been achieved.

There is little evidence for use of cryoablation for large renal masses; larger tumors are more likely to be metastatic. The NICE guidance on “Percutaneous cryotherapy for renal cancer” (2011) found that the maximum renal tumor size for which cryotherapy is recommended is approximately 4 cm (small, stage I tumors).

Cryoablation has been proposed as an alternative method for management of breast fibroadenomas. A fibroadenoma is a benign solid lump of breast tissue, which is thought to result from an increased sensitivity to estrogen. Fibroadenomas are very common and it is not unusual to have more than one. They are mostly found in young women but can occur in women of any age. Most fibroadenomas do not enlarge after diagnosis. Some get smaller and some eventually disappear over time. Fibroadenomas are usually managed conservatively, with periodic ultrasound evaluation. Women who are very anxious about the presence of a tumor or who have enlarging masses are often referred for excisional biopsy. The excised material can be submitted to pathology to confirm the benign diagnosis.

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) reported on the outcomes of cryoablation in 57 patients with breast fibroadenomas. This study was limited to 12-month follow-up from a single investigator group, and did not include a direct comparison to surgical excision. Kaufman et al (2005) reported outcomes for cryoablation in 37 treated fibroadenomas with a longer follow-up period of 2.6 years on average. Of the original 84 % palpable fibroadenomas prior to treatment, 16 % remained palpable to the patient. Of those fibroadenomas that were initially less than or equal to 2.0 cm in size, 6 % remained palpable. A median volume reduction of 99 % was observed with ultrasound. Although this procedure may offer a less invasive method of treating breast fibroadenomas, long-term data on the clinical effectiveness of this procedure versus surgical excision are needed.
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.

Edwards et al (2004) provided a retrospective summary from a nationwide group of the early experience of cryoablation for the percutaneous treatment of breast fibroadenomas. The authors concluded that an early community experience with office-based cryoablation of breast fibroadenomas is encouraging and comparable to the initial experience of high-volume tertiary centers. More follow-up is necessary to determine long-term results and residual mammographic changes.

In a review of ablative approaches and breast cancer, Agnese and Burak (2005) stated that, "[a]blative therapies, including laser ablation, focused ultrasound, microwave ablation, radiofrequency ablation, and cryoablation, have been described. All of these techniques have shown promise in the treatment of small cancers of the breast; however, additional research is needed to determine the efficacy of these techniques when they are used as the sole therapy and to determine the long-term local recurrence rates and survival associated with these treatment strategies."

An assessment on cryoablation for the treatment of breast fibroadenomas by the California Technology Assessment Forum (CTAF, 2006) concluded that this technology does not meet CTAF's criteria. The assessment expressed concerns about the limitations in studies with long-term follow-up, and the lack of studies directly comparing cryoablation with other methods of management of breast fibroadenomas. The CTAF assessment documents serious methodological problems with these studies. The CTAF assessment states: "The largest series [Nurko et al, 2005] reported on 444 lesions, but follow-up was incomplete with fewer than 20 % of lesions evaluated at 12 months. None of the case-series document the systematic use of any validated instrument to establish patient satisfaction, adverse events or to evaluate any other outcomes. Follow-up was grossly inadequate to report intermediate length follow-up."

Atrial fibrillation (AF) is the most common sustained arrhythmia, and is present in approximately 35 % of patients presenting for mitral valve surgery and in 1 to 6 % of adult patients undergoing other forms of cardiac surgery. If left untreated, atrial fibrillation is associated with increased morbidity, and, in some subgroups, increased mortality. Thus, concomitant management of the arrhythmia is indicated in most cardiac surgery patients with pre-existing AF. Although the cut-and-sew Cox-maze III procedure is extremely effective, the advent of ablative energy sources such as radiofrequency and cryoablation has simplified the surgical treatment of atrial AF during concomitant cardiac procedures (Gillinov and Saltman, 2007).

A number of studies have examined the efficacy of cryoablation for atrial fibrillation. Doll and associates (2003) described their early experience in treatment of patients with chronic or paroxysmal AF with a tool for left atrial cryoablation. A total of 28 patients underwent left atrial cryoablation with the Surgifrost CryoCath. Patients underwent cryotherapy as an isolated procedure (n
Cryoablation

= 1), in combination with mitral valve surgery (n = 13), or with other surgical procedures (n = 14). In all patients contiguous lesion lines to the orifices of the pulmonary veins (PVs) connected to the mitral annulus and the atriotomy were created. Surgery was performed through a conventional sternotomy in 8 patients (29 %) and a right lateral mini-thoracotomy using video-assistance in 20 patients (71 %). Post-operatively sinus rhythm (SR) was restored in 27 patients (96 %). At discharge 82 % (23/28) of patients were in SR and 18 % (5/28) were in AF. Four patients (14 %) required pace-maker implantation. There was no in-hospital mortality. At 6-month follow-up (19/28 patients) all were alive and 74 % were in stable SR, New York Heart Association functional class was 1.2 +/- 0.4. The authors concluded that left atrial cryoablation with the Surgifrost argon cryocatheter is effective for the treatment of AF. This new device is technically easy to handle, it can be applied through a median sternotomy or lateral mini-thoracotomy. They stated that long-term follow-up is necessary to evaluate further rhythm outcome.

In a feasibility study, Hoyt and colleagues (2005) reported the findings of PV isolation (PVI) with cryoablation in 31 patients with paroxysmal AF. Event monitors were used to measure the AF episode burden. Serial spiral CT scans were obtained to monitor PV stenosis pre- and post-cryoablation. Cryoablation was immediately successful for PVI in 29 of 31 patients (94 %), with 5.9 +/- 1.2 months of follow-up. Additional RF ablation was performed for AF recurrences in 7 patients. The remaining 22 patients with a single cryoablation procedure demonstrated a time-dependent, long-term reduction in the frequency of AF episodes. At 6-month follow-up, 18 of 22 of cryo-treated only patients (82 %) were free of symptomatic AF episodes, and anti-arrhythmic drugs (AADs) were discontinued in 12 of 22 patients. Serial spiral CT scans demonstrated no change in the cryo-treated PV ostial diameter. The authors concluded that PV cryoablation was effective to control paroxysmal AF in most patients. Early recurrences of AF post-cryoablation were common, though tended to resolve within 6 months post-ablation, consistent with a process of reverse atrial remodeling. Cryoablation of the PVs did not cause PV stenosis or other serious adverse events.

Gaita and co-workers (2005) examined the role of PVI alone versus left atrial linear lesions in the treatment of permanent AF in patients with left atrial dilatation and valvular disease. The primary end point was to assess the persistence of SR off AADs at 2-year follow-up and to correlate clinical outcome with surgical results validated with electro-anatomical mapping (EAM). A total of 105 patients with permanent AF undergoing valve surgery were assigned to 3 different groups: in groups "U" and "7," left atrial linear cryoablation was performed, whereas in group "PV" patients, anatomical cryoisolation of pulmonary veins only was performed. In groups U and 7, SR was achieved in 57 % of patients, whereas it was achieved in 20 % of PV patients during 2-year follow-up. In the first 51 patients, the ablation schemes were validated with EAM. The EAM showed that the U lesion was never obtained: in 59 % of these patients, a complete 7 lesion was achieved instead; in the 7 group, a complete 7 lesion was present in 65 % of patients, whereas a complete PVI was obtained in 71 % of patients. Considering patients in whom a complete 7 lesion was demonstrated with the EAM, SR without AADs was achieved in 86 % of patients, whereas only 25 % of patients with complete PVI were in SR without AADs. The authors concluded that in patients with permanent
AF, left atrial dilatation and valvular heart disease linear lesions in the posterior region of the left atrium are more effective than PVI alone. With cryoablation, the surgical intent is fulfilled in only approximately 65% of the cases.

Mack et al (2005) reported their findings of using argon-based endocardial cryoablation for the treatment of AF in patients undergoing concomitant cardiac procedures. A total of 63 patients with AF who were undergoing concomitant cardiac procedures had the same left atrial endocardial lesion set using a flexible argon-based cryoablative device. Mean age was 65.1 +/- 1.3 years. Sixty-two percent had permanent AF, whereas 38% had paroxysmal AF. Mean duration of AF was 30.5 +/- 4.8 months. Mean left atrial diameter was 5.5 +/- 0.1 cm. Mean ejection fraction was 45 +/- 1.4%. All endocardial lesions were performed for 1 minute once tissue temperature reached -40 degrees C. Follow-up echocardiograms were obtained to determine freedom from AF. Kaplan-Meier analysis demonstrated an 88.5% freedom from AF rate at 12 months. Ablation time was 16.8 +/- 0.6 minutes. There were no in-hospital deaths and no strokes. Twelve patients (19%) required post-operative permanent pace-maker placement. The authors concluded that cryoablation using this flexible argon-based device for the treatment of AF during concomitant cardiac procedures was safe and effective, with 88.5% of patients free from AF at 12 months.

Neuwirth et al (2007) evaluated effectiveness of surgical cryoMAZE ablation for chronic AF in patients undergoing mitral valve surgical intervention. A total of 47 patients (31 females), aged 67.3 +/- 7.3 years who underwent surgical intervention for severe mitral regurgitation were studied. Mitral valvuloplasty was performed in 21 patients, and mitral valve replacement in 26 patients. Combined procedure was employed in 35 patients; simultaneous aorto-coronary bypass was performed in 16 patients, tricuspid valvuloplasty (TVP) in 5 patients, and aortic valve replacement (AVR) in 5 patients. The mean follow-up time was 19 +/- 10 months. After 6 or 12 months, 36 or 32 patients were seen and 23 (64%) or 22 (69%) of them were in stable SR, respectively. In the subset of 24 patients with simultaneous intervention on a different valve (TVP or AVR), after 6 or 12 months, 14 (74%) or 15 (83%) patients had stable SR, respectively. In the follow-up period, 2 patients underwent successful catheter ablation for type I atrial flutter or for a residual left atrial atypical flutter. The authors concluded that cryoMAZE ablation for chronic AF performed during the mitral valve surgical intervention resulted in a long-term stable SR in a high proportion of patients, particularly in patients with simultaneous intervention on two or three different valves.

Blomström-Lundqvist et al (2007) examined the effectiveness of epicardial left atrial (LA) cryoablation in eliminating AF in patients undergoing mitral valve surgery (MVS). These researchers hypothesized that MVS combined with LA cryoablation is superior to MVS alone. A total of 69 patients with permanent AF, included at four centers, underwent MVS with or without epicardial LA cryoablation. The primary endpoint was regained SR. Risk factors for failed AF cryoablation were elucidated. Sixty-five out of 69 patients reached the primary endpoint. At 6- and 12-month follow-up, 73.3% of patients who underwent cryoablation had regained SR at both follow-ups, compared with 45.7% and 42.9% of patients, respectively, who underwent MVS alone (group differences, at 6-month p = 0.024, at 12-month p = 0.013). The in-hospital complication rate was 11.4% in the MVS group and 26.5% in the cryoablation group (p = 0.110). Risk
Factors for failed elimination of AF by cryoablation were duration of permanent AF \( (p = 0.012) \) and presence of coronary artery disease \( (p = 0.047) \), according to multiple logistic regression analysis. The authors concluded that this prospective randomized study showed that combining MVS with epicardial LA cryoablation is significantly better in eliminating pre-operative permanent AF than MVS alone.

The National Institute for Clinical Excellence (2005) concluded that current evidence on the safety and effectiveness of cryoablation for AF in association with other cardiac surgery appears adequate to support the use of this procedure.

Guidelines on basal cell skin cancer from the National Comprehensive Cancer Network (NCCN, 2009) provide a limited role of cryotherapy in the treatment of skin cancers. The NCCN guidelines state that, in patients with low-risk, superficial basal cell skin cancer or low-risk squamous cell carcinoma in situ (Bowen's disease), vigorous cryotherapy may be considered where surgery or radiation is contraindicated or impractical, even though the cure rate may be lower. The British Association of Dermatologists’ guidelines for the management of basal cell carcinoma (Telfer et al, 2008) stated that cryosurgery is a good treatment for low-risk basal cell carcinoma.

Guidelines from the National Comprehensive Cancer Network (NCCN, 2009) on soft tissue sarcoma have included cryoablation as an option for symptomatic persons with disseminated metastatic soft tissue sarcoma of the trunk and extremities.

There is a lack of evidence regarding the use of cryoablation for the treatment of plantar fibroma. In the absence of peer-reviewed data, the use of cryoablation is not recommended for this condition.

Birkenmaier and colleagues (2007) stated that facet joint pain is an important aspect of degenerative lumbar spine disease, and radiofrequency medial branch neurotomy remains an established therapy, while cryodenervation has still been poorly examined. In a prospective clinical case series, these researchers examined the effects of medial branch cryodenervation in the treatment of lumbar facet joint pain. Patient selection was based on medical history, physical examination and positive medial branch blocks. Percutaneous medial branch cryodenervation was performed using a Lloyd Neurostat 2000. Target parameters were LBP (by means of visual analog scale [VAS], limitation of activity [McNab]) and overall satisfaction. A total of 50 patients were recruited, and 46 completed the study. The follow-up time was 1 year. At 6 weeks, 33 patients (72%) were pain-free or had major improvement of LBP; 13 (28%) had no or little improvement. Including failures, mean LBP decreased significantly from 7.7 pre-operatively to 3.2 at 6 weeks, 3.3 at 3 months, 3.0 at 6 months and 4.2 at 12 months \( (p < 0.0001) \). Limitation of the activities of daily living improved parallel to reduced pain. The authors cited (i) other sources of LBP, (ii) false-positive diagnostic blocks, and (iii) inadequate technique as possible explanations for cryodenervation failure in some of the study subjects.

Kujak and colleagues (2010) described their early experiences with using percutaneous cryoablation for local control of extra-abdominal desmoid (EAD) tumors in patients whose tumors had failed to respond to standard therapy. A total of 5 patients (2 males and 3 females) were included in this study. Three of these
patients had been referred for cryoablation for local tumor control, and 2 had been referred for palliation of inoperable tumors. The age range of the patients at the time of cryoablation was 9 to 41 years. Treated EAD tumors were located in the neck, shoulders and trunk and ranged in size from 3.0 cm to 10.0 cm. Medical records were reviewed for short-term and long-term follow-up, and patients were contacted for additional follow-up. Patients were asked to rate their pain as absent, mild, moderate or severe, and to compare it with their levels before cryoablation, describing it as improved, unchanged or worsened. Radiology records were reviewed to follow the size of the EAD tumors before and after cryotherapy. For the 3 patients referred for local control of EAD tumors, complete tumor coverage with the ablation zones was achieved. Two of these patients, with masses 3.0 cm and 4.9 cm in diameter, reported complete absence of pain at both short-term and long-term follow-up at 13 months and 49 months. Their tumors had completely resolved on long-term imaging follow-up at 19 months and 43 months. The third patient, with a 6.1 cm mass, reported improved mild pain at 6 months, and imaging showed a moderate decrease of tumor size. For the 2 patients referred for palliative therapy, initial partial pain relief was felt 2 weeks after the procedure. At long-term (58 months) follow-up of 1 patient with a 9.1 cm mass, the tumor was still present although reduced in size, and local pain had returned to its former moderate level. In the other patient who underwent only partial treatment of a 10.0 cm mass, at long-term follow-up (36 months) the mass had enlarged and pain had returned to the pre-treatment, moderate level. The authors concluded that cryoablation appears to be an effective alternative treatment for local control of small and moderately sized EAD tumors, but it is likely of limited use in patients with larger tumors that have untreated regions due to involvement of vital structures. They stated that continued research evaluating cryoablation for the treatment of EAD tumors is needed.

In a multi-center, retrospective, cohort study, Greenwald et al (2010) evaluated the safety and effectiveness of cryotherapy in esophageal carcinoma. Subjects with esophageal carcinoma in whom conventional therapy failed and those who refused or were ineligible for conventional therapy were included in this study; and they received cryotherapy with follow-up biopsies. Treatment was complete when tumor eradication was confirmed by biopsy or when treatment was halted because of tumor progression, patient preference, or co-morbid condition. Main outcome measures were complete eradication of luminal cancer and adverse events. A total of 79 subjects (median age of 76 years, 81 % male, 94 % with adenocarcinoma) were treated. Tumor stage included T1-60, T2-16, and T3/4-3. Mean tumor length was 4.0 cm (range of 1 to 15 cm). Previous treatment including endoscopic resection, photodynamic therapy, esophagectomy, chemotherapy, and radiation therapy failed in 53 subjects (67 %). Only 49 patients completed treatment. Complete response of intraluminal disease was seen in 31 of 49 subjects (61.2 %), including 18 of 24 (75 %) with mucosal cancer. Mean (standard deviation) length of follow-up after treatment was 10.6 (8.4) months overall and 11.5 (2.8) months for T1 disease. No serious adverse events were reported. Benign stricture developed in 10 (13 %), with esophageal narrowing from previous endoscopic resection, radiotherapy, or photodynamic therapy noted in 9 of 10 subjects. The authors concluded that spray cryotherapy is safe and well-tolerated for esophageal cancer. They noted that short-term results suggested that it is effective in those who could not receive conventional
treatment, especially for those with mucosal cancer. Limitations of this study included its retrospective study design, short-term follow-up, and that only 49 of the 79 subjects (62%) completed treatment, which could have skewed the findings of this study.

Timmermans et al (2010) reported the feasibility and safety of catheter-based cryoablation for the treatment of post-infarction and idiopathic ventricular tachycardia (VT). Catheter-based cryoablation was performed in 17 patients (15 men, 58 +/- 18 years). Ventricular tachycardia occurred after a prior myocardial infarction in 10 and was idiopathic in 7 patients. Cryoablation was performed with a 10-F, 6.5-mm tipped catheter. The ablation site was selected using entrainment mapping techniques for post-infarction VT. The site of the earliest activation time with optimal pace mapping was used for ablation of idiopathic VT. All targeted VTs (12 post-infarction and 7 idiopathic) were acute successfully ablated after a median number of 2 applications of 5 mins with an average temperature of -82 +/- 4 degrees C. Mean procedure and fluoroscopy times were 204 +/- 52 and 52 +/- 20 mins for post-infarction VT and 203 +/- 24 and 38 +/- 15 mins for idiopathic VT. No cryocatheter or cryoenergy complications were observed. After a follow-up of 6 months, 4 of the 10 patients with post-infarction VT had a recurrence. In 1 of the 7 patients with idiopathic VT the index arrhythmia recurred. The authors concluded that in this small patient population, catheter-based cryoablation of VT was safe and effective. They stated that future studies are needed to evaluate the effect of cryothermy in a larger group of patients, especially those with post-infarction VT.

Yamauchi and colleagues (2012) evaluated the mid-term results of percutaneous cryoablation for medically inoperable stage I non-small cell lung cancer. Between January 2004 and June 2010, a total of 160 patients underwent computer tomography-guided percutaneous cryoablation for lung tumors at the authors' institution. Of these patients, histologically proven stage I lung cancer patients with more than 1 year of follow-up, were retrospectively reviewed. All of these patients were considered to be medically inoperable with Charlson co-morbidity index of 3 or greater. Follow-up was based primarily on computed tomography. There were 22 patients with 34 tumors who underwent 25 sessions of cryoablation treatment. Complications were pneumothoraces in 7 treatments (28%, chest tube required in 1 treatment), and pleural effusions in 8 treatments (31%). The observation period ranged from 12 to 68 months, average 29 +/- 19 months, median 23 months. Local tumor progression was observed in 1 tumor (3%). Mean local tumor progression-free interval was 69 +/- 2 months. One patient died of lung cancer progression at 68 months. Two patients died of acute exacerbations of idiopathic pulmonary fibrosis which were not considered to be directly associated with cryoablation, at 12 and 18 months, respectively. The overall 2- and 3-year survivals were 88% and 88%, respectively. Mean overall survival was 62 +/- 4 months. Median overall survival was 68 months. The disease-free 2- and 3-year survivals were 78% and 67%, respectively. Mean disease-free survival was 46 +/- 6 months. Pulmonary function tests were done in 16 patients (18 treatments) before and after cryoablation. Percentage of predicted vital capacity, and percentage of predicted forced expiratory volume in 1 second, did not differ significantly before and after cryoablation (93 +/- 23 versus 90 +/- 21, and 70 +/- 11 versus 70 +/- 12, respectively). The authors concluded that
although further accumulation of data is necessary regarding efficacy, cryoablation may be a feasible option in medically inoperable stage I lung cancer patients.

In a report by the American Academy of Ophthalmology, Simpson and associates (2012) evaluated the role of cryotherapy in the current treatment of retinopathy of prematurity (ROP). Literature searches of PubMed and the Cochrane Library were conducted on December 2, 2009, for articles published after 1984. The searches included all languages and retrieved 187 relevant citations; 13 articles were deemed relevant to the assessment question and were rated according to the strength of evidence. Four articles reported results from 2 large multi-center randomized clinical trials, and the remaining 9 articles reported results of 3 small randomized trials that directly compared cryotherapy and laser. Neither of the multi-center randomized clinical trials was a direct comparison of cryotherapy with laser. These studies were used to evaluate the comparative trials based on treatment criteria, study populations, and clinical results. Higher percentages of poor structural and functional outcomes generally were seen in eyes treated with cryotherapy compared with eyes undergoing laser treatment. Higher rates of systemic complications and myopia also were identified after treatment with cryotherapy. No clinical studies are available to support treatment with cryotherapy for type 1 ROP as defined by the Early Treatment for ROP [ETROP] Study, especially given practical factors such as the need to treat posteriorly in younger patients who may be more susceptible to systemic complications from treatment. The authors concluded that despite a relative paucity of level I evidence directly comparing cryotherapy and laser treatment for threshold ROP, the literature suggests that neonatal facilities should gain access to laser technology and laser-trained ophthalmic staff to achieve better outcomes for treatment of the disease. Advantages of laser photocoagulation, including easier administration, lower rates of complications, and efficacy that is at least equivalent to cryotherapy, reduce the necessity for further study and make further randomized clinical trials comparing these 2 treatment methods unlikely. Any future trials are likely to sue a pharmacologic approach such as bevacizumab alone or bevacizumab either in combination with or in comparison with laser as the preferred method for ablative therapy.

Martin-Hirsch et al (2010) stated that cervical intraepithelial neoplasia (CIN) is the most common pre-malignant lesion. Atypical squamous changes occur in the transformation zone of the cervix with mild, moderate or severe changes described by their depth (CIN 1, 2 or 3). Cervical intraepithelial neoplasia is treated by local ablation or lower morbidity excision techniques. Choice of treatment depends on the grade and extent of the disease. In a Cochrane review, these investigators evaluated the effectiveness and safety of alternative surgical treatments for CIN. They searched the Cochrane Gynaecological Cancer Group Trials Register, Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library), MEDLINE and EMBASE (up to April 2009). They also searched registers of clinical trials, abstracts of scientific meetings and reference lists of included studies. Randomized controlled trials (RCTs) of alternative surgical treatments in women with CIN were selected for analysis. Two review authors independently abstracted data and assessed risks of bias. Risk ratios that compared residual disease after the follow-up examination and adverse events in women who received laser ablation, laser conisation, large loop excision of the transformation zone (LLETZ), knife conisation, or cryotherapy were pooled in random-effects
model meta-analyses. A total of 29 trials were included; 7 surgical techniques were tested in various comparisons. No significant differences in treatment failures were demonstrated in terms of persistent disease after treatment. Large loop excision of the transformation zone appeared to provide the most reliable specimens for histology with the least morbidity. Morbidity was lower than with laser conisation, although the trials did not provide data for every outcome measure. There were not enough data to assess the effect on morbidity when compared with laser ablation. The authors concluded that the evidence suggested that there is no obvious superior surgical technique for treating CIN in terms of treatment failures or operative morbidity.

Lewis et al (2011) noted that in low-resource settings, cryotherapy can be cost-effective, affordable, and a first-line treatment for CIN of any grade. These investigators reported the acceptability, safety and effectiveness of cryotherapy for women with CIN in Western Kenya. Visual inspection with acetic acid (VIA)-positive women and those suspected of having cervical cancer based on an initial evaluation at a primary health facility were referred to the district hospital for colposcopy and additional evaluation using visual inspection with Lugol's iodine (VILI) and/or visual inspection with acetic acid and magnification (VIAM). Cryotherapy was offered immediately to women diagnosed with appropriate CIN lesions based on colposcopy or after waiting for a confirmatory cervical biopsy and a follow-up visit occurred 1 year later. A total of 91 women (aged 30 to 39 years) had CIN appropriate for cryotherapy. Approximately 36% (24/67) were due for their 1 year follow-up visit and 20 of 24 (83.3%) attended. Complete data were available for 18 of 20 (90%) and 13 (72.2%) had no sign of CIN. No serious adverse events were reported 1 to 3 months after cryotherapy. All respondents reported that the treatment experience was acceptable. The authors concluded that cryotherapy was acceptable, safe and effective.

Sauvaget et al (2013) provided an updated and comprehensive estimate of the efficacy of cryotherapy for CIN. A literature search identified original studies (RCTs and clinical reports). Studies reporting cure rates, acceptability, and safety of cryotherapy were included in the analysis. Number of persistent or recurrent lesions at follow-up, adverse events, and complications were recorded. Quality of the methodology was also assessed. Meta-analyses were performed according to CIN thresholds, geographic region, study year, setting, study design, presence of endocervical involvement, freezing method, duration of follow-up, and status of the cryotherapy provider. A total of 146 articles were retrieved; 77 papers -- equivalent to 28,827 cases of treated CIN -- were included in the meta-analysis. Cryotherapy achieved cure rates of 94.0% (CIN1), 92.0% (CIN2), and 85.0% (CIN3). Use of the double-freeze method and absence of endocervical involvement significantly increased cure rates. Minimal complications were reported as adverse effects. The authors concluded that cryotherapy is an effective, safe, and acceptable treatment for CIN. It has been shown to be successful in low-resource settings, enabling availability and accessibility of early detection services.

In a multi-center RCT, Klem et al (2009) compared cryo-stripping of the great saphenous vein (GSV) with conventional stripping. The study randomized 494 patients with symptomatic (CEAP) clinical severity class 2 to 4 to cryo-stripping (n = 249) or conventional stripping (n = 245). The primary outcome was residual
GSV 6 months after surgery measured by venous duplex ultrasound imaging. Secondary outcomes were quality of life, operation time, and post-operative neural damage. Duration of follow-up was 6 months. Quality of life was measured at 6 and 26 weeks post-operatively with the Aberdeen Varicose Vein Questionnaire (AVVQ) and Medical Outcomes Study Short-Form 36 (SF-36) Health Survey. The 2 groups were well-matched at baseline. The percentage of patients with residual GSV at 6 months (primary outcome) was 44 % (102 of 230) in the cryo-stripping group and 15 % (33 of 215) in the conventional group (difference 29 %; 95 % confidence interval [CI]: 21 % to 37 %, p < 0.001). Median operation time was significantly shorter in the cryo-stripping group (30 minutes) compared with the conventional group (39 minutes). Neural damage was 12 % in both groups, and thus not significantly different. Scores on the subdomains of the SF-36 showed no significant change between the groups. The AVVQ after conventional stripping was 8.0, which was a better result than the 11.7 result after cryo-stripping (difference of 2.6 points; 95 % CI: 1.0 to 4.2; p = 0.001, repeated measurements analysis of variance with adjustment for baseline scores). The authors concluded that cryo-stripping accounts for numerous procedural failures and hence residual GSV in patients. The AVVQ showed small but significantly better results for patients after a conventional stripping. Thus, cryo-stripping has no benefits over conventional stripping.

Krummel et al (2014) stated that renal angiomyolipomas (AMLS) are frequent in tuberous sclerosis and are responsible for a significant proportion of the morbidity in adulthood, mainly from bleeding complications, which are correlated to the size of the AMLs. These researchers described the case of a 19-year old female with multiple bilateral renal AMLs. The renal AMLs measured up to 6-cm in size. She was first treated with a low-dose of the mammalian target of rapamycin (mTOR) inhibitor sirolimus (up to 3 mg/day over a 12-month period) and following significant AML size reduction, percutaneous cryoablation was performed. No side-effects of either treatment were reported. At 12 months post-cryoablation, no recurrence of the AML was noted. The authors concluded that this was the first report of this treatment strategy and the case study revealed that combining a low-dose of an mTOR inhibitor with percutaneous cryoablation to treat small tumors mitigates the side-effects while providing a good clinical outcome. They stated that this therapeutic approach is a novel tool for the clinician involved in the management of patients with tuberous sclerosis.

Song et al (2014) examined the safety and effectiveness of palliative bypass surgery combined with cryoablation to treat patients with advanced pancreatic cancer and compared them with those of palliative bypass surgery alone. Medical records of 118 patients with advanced pancreatic cancer who received palliative bypass surgery combined with cryoablation (the combination treatment group) or bypass surgery alone (the bypass surgery group) from June 30, 2008 to December 31, 2010 were retrospectively reviewed. Their baseline and post-operative parameters were collected and compared. In both groups, abdominal distension and pain was significantly improved after treatment. Pre-operative jaundice was more common in the bypass surgery group. Backache was more frequent in the combination treatment group, which were both relieved. Pre-operative serum bilirubin level was higher in the bypass surgery group that was decreased significantly after treatment. However, significant reductions in tumor size as well as serum carbohydrate antigen 19-9 (CA19-9) level were only found in
the combination treatment group. There was no significant difference in the incidence of post-operative complications and prognosis between the 2 groups. The authors concluded that cryoablation can reduce the tumor size and relieve the patients’ symptoms and signs such as abdominal discomfort and backache, although it could not improve the patients’ prognosis significantly.

In a preliminary study, Cornelis et al (2014) reported the short-term local control of percutaneous image-guided cryoablation of localized symptomatic abdominal scar endometrioma. A total of 4 consecutive patients (mean age of 34.5 years) with a total of 10 lesions were included, with mean pre-operative pain of 7 (range of 5 to 9) on the VAS. Cryoablation was performed in a single session under general anesthesia. Post-operative superficial edema disappeared within 2 weeks for all patients. No severe complications (greater than grade 2 according to the CTCAE classification) were reported. Mean post-operative pain was 1.7 at 6 months (range of 0 to 5) and magnetic resonance imaging demonstrated a significant volume decrease for all patients (range of 72.2 to 100 %; p = 0.028). The authors concluded that percutaneous cryoablation showed promising local control in patients with symptomatic abdominal wall endometriosis. These preliminary findings need to be validated by well-designed studies.

Appendix

Stages of prostate cancer

Stage I (A)

Prostate cancer can not be felt by digital rectal exam, causes no symptoms, and is only in the prostate, usually found incidentally in a prostatectomy specimen when surgery is done for benign prostatic hyperplasia.

Stage II (B)

Cancer confined to the prostate gland found by a needle biopsy done for an elevated PSA level or after rectal examination reveals a mass in the prostate.

Stage III (C)

Cancer cells have spread outside the capsule of the prostate to tissues around the prostate, e.g., seminal vesicles.

Stage IV (D)

Cancer cells have metastasized to lymph nodes or to organs and tissues such as the bone, liver, or lungs.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

0340T Ablation, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance
20982  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; radiofrequency

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); with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser therapy, cryotherapy)

+ 33257  Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, modified maze procedure) (List separately in addition to code for primary procedure)

+ 33259  Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), with cardiopulmonary bypass (List separately in addition to code for primary procedure)

50250  Ablation, open, 1 or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed

50593  Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy

55873  Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)

57511  Cautery of cervix; cryocautery, initial or repeat

**CPT codes not covered for indications listed in the CPB:**

19105  Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma

32998  Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral [cryoablation for nonobstructive non-small cell lung cancer]

43229  Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed) [not covered for cryoablation of Barrett's esophagus or malignant neoplasm of esophagus]
Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed) [not covered for cryoablation of Barrett's esophagus or malignant neoplasm of esophagus]

Other CPT codes related to the CPB:

17000 - 17286 Destruction, benign or premalignant lesions, or malignant lesions, any method
47371 Laparoscopy, surgical, ablation of one or more liver tumor(s); cryosurgical
47381 Ablation, open, of one or more liver tumor(s); cryosurgical
58353 Endometrial ablation, thermal, without hysteroscopic guidance
58356 Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed
58563 Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)
77013 Computed tomography guidance for, and monitoring of, parenchymal tissue ablation
77022 Magnetic resonance guidance for, and monitoring of, parenchymal tissue ablation

Other HCPCS codes related to the CPB:

C1886 Catheter, extravascular tissue ablation, any modality (insertable)
C2618 Probe/needle, cryoablation

ICD-9 codes covered if selection criteria are met:

162.2 - 162.8 Malignant neoplasm of bronchus and lung [malignant endobronchial obstruction]
171.2 - 171.7 Malignant neoplasm of connective and other soft tissue [soft tissue sarcoma of extremities and trunk in symptomatic persons with disseminated metastases] [not covered for leiomyosarcoma]
173.0 - 173.9 Other malignant neoplasm of skin [covered for low risk, superficial basal cell carcinoma where surgery or radiation is contraindicated or impractical]
185 Malignant neoplasm of prostate
<table>
<thead>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>189.0</td>
<td>Malignant neoplasm of kidney, except pelvis [renal cell carcinoma - see criteria]</td>
</tr>
<tr>
<td>197.0</td>
<td>Secondary malignant neoplasm of lung</td>
</tr>
<tr>
<td>198.82</td>
<td>Secondary malignant neoplasm of genital organs [prostate]</td>
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<tr>
<td>231.2</td>
<td>Carcinoma in situ of bronchus and lung</td>
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<tr>
<td>232.0 - 232.9</td>
<td>Carcinoma in situ of skin [covered for squamous cell - Bowen’s disease where surgery or radiation is contraindicated or impractical]</td>
</tr>
<tr>
<td>233.1</td>
<td>Cervix uteri (cervical intraepithelial neoplasia III [CIN III])</td>
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<tr>
<td>233.4</td>
<td>Carcinoma in situ of prostate</td>
</tr>
<tr>
<td>427.31</td>
<td>Atrial fibrillation [in association with other cardiac surgery]</td>
</tr>
<tr>
<td>622.11 - 622.12</td>
<td>Mild and moderate dysplasia of cervix (cervical intraepithelial neoplasia I and II [CIN I and CIN II])</td>
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</table>

ICD-9 codes not covered for indications listed in the CPB:

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<thead>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>150.0 - 150.9</td>
<td>Malignant neoplasm of esophagus</td>
</tr>
<tr>
<td>171.0</td>
<td>Malignant neoplasm of connective and other soft tissue</td>
</tr>
<tr>
<td>171.8 - 171.9</td>
<td>[leiomyosarcoma, lipoma/nuroma]</td>
</tr>
<tr>
<td>174.0 - 175.9</td>
<td>Malignant neoplasm of breast</td>
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<tr>
<td>214.0 - 214.9</td>
<td>Lipoma</td>
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<tr>
<td>215.0 - 215.9</td>
<td>Other benign neoplasm of connective and other soft tissue [plantar fibroma] [neuroma]</td>
</tr>
<tr>
<td>217</td>
<td>Benign neoplasm of breast</td>
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<tr>
<td>225.1</td>
<td>Benign neoplasm of cranial nerves [acoustic neuroma]</td>
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<tr>
<td>233.0</td>
<td>Carcinoma in situ of breast</td>
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<tr>
<td>237.70 - 237.9</td>
<td>Neurofibromatosis [multiple neuroma]</td>
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<tr>
<td>238.1</td>
<td>Neoplasm of uncertain behavior of connective and other soft tissue [extra-abdominal desmoid tumor]</td>
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<tr>
<td>239.2</td>
<td>Neoplasm of unspecified nature of bone, soft tissue, and skin [extra-abdominal desmoid tumor]</td>
</tr>
<tr>
<td>354.0 - 355.9</td>
<td>Mononeuritis [neuroma]</td>
</tr>
<tr>
<td>362.20 - 362.29</td>
<td>Other proliferative retinopathy [retinopathy of prematurity]</td>
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</tbody>
</table>
427.1 Paroxysmal ventricular tachycardia [post-infarction, idiopathic]
530.85 Barrett's esophagus
600.00 - 600.91 Hyperplasia of prostate
720.0 - 724.6 Dorsopathies [facet or sacroiliac joint pain]
728.71 Plantar fascial fibromatosis [plantar fibroma]
997.61 Neuroma of amputation stump

The above policy is based on the following references:

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Cryoablation of the Breast

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Cryoablation for Skin Cancers:


Cryoablation for Cervical Intraepithelial Neoplasia


Cryoablation for Other Indications:


