



## Kaiser Foundation Health Plan of Washington

### Clinical Review Criteria Cryosurgery

- Cryosurgical Ablation (CSA) for Breast Cancer and Benign Lesions
- Cryosurgical Ablation (CSA) for Liver Tumors
- Cryosurgical Ablation (CSA) for Prostate Cancer
- Cryosurgical Ablation (CSA) for Renal Tumors
- Cryosurgical Ablation (CSA) for Lung Cancer

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### Criteria For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Cryosurgery of Prostate (230.9)</a>
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	<b>For Breast Cancer and Benign Lesions:</b> Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, <b>"Cryosurgery"</b> for medical necessity determinations. Use the Non-Medicare criteria below.

### For Non-Medicare Members

Indication	Criteria Used
Breast Cancer and Benign Lesions	<p><b>Effective until January 1, 2024</b></p> <p>There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.</p> <p><b>Effective January 1, 2024</b></p> <p>Please see Medically Necessary Services page <a href="#">here</a></p>
Cryosurgical Ablation (CSA) for Liver Tumors Cryosurgical Ablation (CSA) for Lung Cancer Cryosurgical Ablation (CSA) for Prostate Cancer Cryosurgical Ablation (CSA) for Renal Tumors	Medical necessity review no longer required.

**If requesting review for these services, please send the following documentation:**

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Cryosurgery has been known for years, but the recent changes in the technology and the development of improved cryosurgery units are permitting its clinical use. Cryoablation is a technique that uses liquid nitrogen or argon gas to freeze and ablate tissues. Cryoablation is mainly performed laparoscopically under real time ultrasound guidance.

It is reported that the critical temperature that leads to cancer cell destruction is approximately  $-40^{\circ}\text{C}$ . Normal and neoplastic tissues are ablated and rendered necrotic at temperatures of  $-20^{\circ}\text{C}$  (Chosy, 1996). During cryosurgery, the temperature is lowest at the center of the iceball with an incremental increase towards the periphery. Thus, with a cryoprobe tip temperature of  $-185^{\circ}$  to  $-195^{\circ}\text{C}$ , the temperature will be approximately  $0^{\circ}\text{C}$  at outer edge of the ice ball,  $-20^{\circ}\text{C}$  at a distance of 4mm, and  $-40^{\circ}\text{C}$  at a distance of 6mm towards the center of the iceball. It is important that the edge of the cryolesion be 1 cm beyond the margin of the tumor to make sure that a lethal temperature of  $-40^{\circ}\text{C}$  or less was achieved throughout the tumor. The effect of cryosurgery occurs in two phases, freezing and thawing. The freezing phase is performed rapidly, and passive thawing is performed more slowly for a maximum effect. A double freeze-thaw cycle is usually performed to ensure the extension of the iceball to approximately 1 cm beyond the tumor edge.

The size of the cryolesion depends on several factors, including the temperature at the tip of the cryoprobe, area of tissue contacts, freeze time, and tissue vascularity. The response of a tumor to cryoablation depends on its biological characteristics e.g. density, specific heat, thermal conductivity, and rate of blood flow (Gage 1992).

## Evidence/ Source Documents

[Breast Cancer/Lesions](#)

## Medical Technology Assessment Committee

### *Cryoablation for Breast Cancer or Benign Fibroadenomas of the Breast*

#### **BACKGROUND**

Cryoablation has been used to treat liver and prostate tumors. It is also proposed a treatment for small breast cancers and benign fibroadenomas of the breast. Cryoablation kills tumor cells by alternately freezing and thawing a target tissue. Freezing injures individual cells at the time of treatment. In addition, the tissue as a whole is affected because microcirculation is damaged. Cell necrosis during cytoablation depends on the lowest temperature achieved and the hold time at subzero temperatures. It is believed that uniform ablation can be achieved when tissue is exposed to at least  $-40^{\circ}\text{C}$  during two consecutive freeze thaw cycles (Whitworth & Rewcastle, 2005). The procedure for using cryoablation to treat breast tumors is as follows: Using ultrasound guidance, a cryoprobe is inserted through a 3mm skin incision into the center of the tumor. Ultrasound is used to guide the cryoprobe, and also to monitor the treatment. Once appropriate placement of the cryoprobe is confirmed, the machine is turned on "high." When set to "high," argon gas, the cooling agent, is allowed to flow continuously through the cryoprobe. The probe is cooled to  $-160^{\circ}\text{C}$  which freezes the tumor, forming an "ice ball" around it. After the iceball is formed, the cryoablation unit is set on "low" setting which allows argon gas to flow intermittently into the cryoprobe for 1 of every 10 seconds to preserve freezing temperatures. Generally, two freeze-thaw cycles are used. Helium is used as the warming agent between freezing cycles (Nurko et al., 2005; Visica, manufacturer's Web site). Benign breast fibroadenomas are common, especially among young women. Approximately 10% of women will experience a breast fibroadenoma during their lifetime. Currently accepted treatments include excisional biopsy and conservative management. Conservative management may be a reasonable choice for this benign condition, particularly smaller fibroadenomas. Moreover, women may choose to avoid immediate intervention since an estimated 30% of breast fibroadenomas resolve spontaneously within several years. Excisional biopsy provides a definitive diagnosis, but a disadvantage is morbidity including possible cosmetic and/or ductal damage. Cryoablation is less invasive than excisional biopsy and is done on breast fibroadenomas after confirmation that the tumor is benign, generally with needle biopsy (Whitworth & Rewcastle, 2005; Houssami et al. 2001). A minimally invasive procedure, such as cryoablation, may also be useful for treating early breast cancers treated with breast-conserving therapy rather than mastectomy. Other thermal methods have been used to treat breast tumors. These include radiofrequency ablation, interstitial laser therapy and highly intensive focused ultrasound (Pfleider et al., 2005).

## 08/07/2006: MTAC REVIEW

### Cryosurgery – Breast Cancer

**Evidence Conclusion:** There is insufficient evidence to permit conclusions the efficacy of cryoablation for treating benign breast tumors including fibroadenomas. No studies were identified that compared cryoablation to conservative management, an accepted approach for managing fibroadenomas. The available studies were case series. A limitation of the published series was that there was likely overlap among patients in the studies. The degree of overlap could not be determined. In addition, two of the three studies reviewed (not the registry) were funded by the manufacturer of the cryoablation system. The Kaufman et al. and Caleffi et al. studies found that a higher proportion of larger (>2.5cm) fibroadenomas than smaller fibroadenomas were palpable at 12 months. This suggests that the usefulness of cryoablation may be limited because there is likely more demand for intervention, rather than conservative management, with larger fibroadenomas. There is insufficient evidence to permit conclusions on the efficacy of cryoablation for treating early breast cancer. No studies were identified comparing cryoablation to other treatments such as radiofrequency ablation or interstitial laser therapy. The available studies were relatively small case series with sample sizes of 30 or fewer patients. In the series, cryoablation was followed by surgery 1-4 weeks later, at which time the tumor cells were evaluated. In one study, there was residual DCIS in 5 out of 30 patients and in the other study, there was residual invasive cancer or DCIS in 6 out of 27 patients. In the latter study, cryoablation was successful in all of the 10 patients with tumors <1.5 cm and with ductal or medullary cancer and no extensive intraductal component. Number of patients were too small to draw conclusions about sub-groups that might benefit from cryoablation for early breast cancer. Cryoablation appears to be safe, although data on adverse effects are limited. No major complications were reported in any of the series that were reviewed.

**Articles:** No randomized controlled trials or other controlled trials were identified. Empirical studies were all case series. Three series on benign breast tumors, including fibroadenomas, were identified. Findings from one of the series, written by Kaufman and colleagues, were reported in three articles. Sample sizes were 63 patients in the Kaufman study and 102 and 29 in the other series. In addition, a registry of fibroadenomas treated by cryoablation was identified. The registry included 444 fibroadenomas (the number of patients was not reported, some patients contributed more than one fibroadenoma). The registry study and the two largest case series were critically appraised. All of the Kaufman et al. studies were included in the same evidence table. Four studies on cryoablation for breast cancer were identified. All included patients with small breast tumors  $\leq 2.0$  cm. Sample sizes in the studies were n=30, n=29, n=15 and n=9. The two larger case series were critically appraised. The series with n=15 appeared to report preliminary data for one of the larger studies. The studies reviewed were as follows: Kaufman CS, Bachman B, Littrup PJ et al. Cryoablation treatment of benign breast lesions with 12-month follow-up. *Am J Surg* 2004; 188: 340-348. (Kaufman CS, Littrup PJ, Freeman-Gibb LA et al. Office-based cryoablation of breast fibroadenomas with long-term follow-up. *Breast J* 2005; 11: 344-350. Kaufman CS, Littrup PJ, Freeman-Gibbs LA et al. Office-based cryoablation of breast fibroadenomas: 12-month follow-up, *J Am Coll Surg* 2004; 198: 914-923) v See [Evidence Table](#). Caleffi M, Filho DD, Borghetti K et al. Cryoablation of benign breast tumors: Evolution of technique and technology. *The Breast* 2004; 13: 397-407. See [Evidence Table](#). Nurko J, Mabry CD, Whitworth P et al. Interim results from the FibroAdenoma Cryoablation Treatment Registry. *Am J Surg* 2005; 190: 647-652. See [Evidence Table](#). Pfliegerer SOR, Marx C, Camara O et al. Ultrasound-guided, percutaneous cryotherapy of small ( $\leq 15$ mm) breast cancers. *Invest Radiol* 2005; 40: 472-477. See [Evidence Table](#)

Sabel MS, Kaufman CS, Whitworth P et al. Cryoablation of early-stage breast cancer: Work-in-progress report of a multi-institutional trial. *Ann Surg Oncol* 2004 11: 542-549. See [Evidence Table](#).

The use of Cryoablation in the treatment of breast cancer or benign fibroadenomas of the breast does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### Cryosurgical Ablation (CSA) for Liver Tumors

#### BACKGROUND

The liver is a common site for primary and secondary malignancies. Hepatocellular carcinoma (HCC), the most common primary tumor, is the fifth most common cancer in the world, and the third most common cause of cancer-related mortality. It is responsible for more than half a million deaths across the globe each year. Treatment options for patients diagnosed with primary and secondary malignancies are limited. Less than 15% are candidates for surgical resection at presentation because of inadequate liver functional reserve, extrahepatic disease, anatomic constraints of the tumor, or medical co morbidities. The use of external beam radiation is limited due to the intolerance of normal liver parenchyma to tumoricidal radiation doses (the dose required to destroy solid tumors (>70 Gy) is much higher than the liver tolerance dose of 35 Gy). In addition, systematic chemotherapy was found to have little impact on survival, and negative impact on the health-related quality of life due to the toxicity to other organs and systems. These limitations have led to the emergence of other therapies, such as radiofrequency ablation (RFA), cryosurgical ablation (CSA), percutaneous ethanol injections (PEI), hepatic arterial infusion chemotherapy, transarterial chemo-embolization (TACE), and selective intraarterial

radioembolization therapy (Steel 2003, Salem 2005, Ibrahim 2008, Bult 2009, Riaz 2009, Bhardwaj 2010). Ablative techniques, such as RFA and CSA, improve the ability to treat patients with unresectable hepatic tumors. Thermal ablative techniques destroy tumors via a source that changes temperature to levels that are associated with cell death while causing minimal damage to adjacent, normal tissue. The choice of technique depends on equipment availability and physician preference. The most commonly used ablative technique in the United States is RFA. RFA causes tumor destruction through the use of alternating high-frequency electric current in the radiofrequency range (460-500 kHz). This current is delivered through an electrode placed in the center of a lesion. Ions within the cell follow the alternating current creating frictional heat producing local tissue temperatures that can exceed 100°C. This ionic agitation leads to tissue destruction via tissue boiling and creation of water vapors. Once temperatures greater than 60°C are reached, protein denaturation, tissue coagulation, and vascular thrombosis result in a zone of complete ablation. Partial tissue destruction can occur up to 8 mm in diameter from the zone of complete ablation. RFA can be delivered either percutaneously, laparoscopically, or through open approaches (laparotomy). Complications from RFA include: pleural effusion, hepatic abscess, biliary injury, liver failure, intra-abdominal hemorrhage, pneumothorax, and hypoxemia. The most troubling complications arise when a probe is placed too close to the diaphragm or intra-abdominal organ, resulting in ablation of the surrounding viscera with the accompanying complications of perforation, diaphragmatic injury, or pulmonary damage. Limitations of RFA include: treating lesions in perihilar areas or near large vascular structures, and real time monitoring of the ablative zone is difficult due to air released during heating (Yamane 2009, Arciero 2006). CSA is another ablative technique. CSA uses repetitive freezing and thawing to produce irreversible tissue destruction. One or more cryoprobes are inserted at the site of the diseased tissue and liquid nitrogen or argon gas is delivered through the probe to freeze the tissue. Rapid freezing of the tissue results in the formation of intercellular ice crystals. At temperatures of about -40°C lethal ice crystals begin to form in the cell. Ice crystals also form in the fluid outside the cell leading to cell dehydration. The combination cause tumor cells to burst. Additionally, ice crystals form in small vessels and block blood supply to the tumor. Normally, two freeze-thaw cycles are used. CSA is easy to monitor, and the area treated can be accurately visualized with ultrasound. This allows for accurate real-time visualization; however, it does not guarantee that there has been cell death. Two devastating complications that are associated with CSA are cryoshock, a complex of severe coagulopathy and multi-organ failure, and intra-operative hypothermia. Other complications include: hemorrhage from cracking of the frozen liver, subphrenic abscesses, bilomas, and biliary fistulae (Bhardwaj 2010, Arciero 2006). The cryoprobe that is used in CSA has received FDA approval for ablation of cancerous or malignant tumors, benign tumors, and as a palliative intervention. RFA has received FDA approval for generic tissue ablation and the ablation of unresectable colorectal cancer metastases. This technology is being reviewed based on a request from gastroenterology.

## 06/21/2010: MTAC REVIEW

### Cryosurgery – Liver Tumors

**Evidence Conclusion:** It is difficult to compare the results of CSA with surgery or other ablative techniques, as most authors report data from studies where a variety of different treatment modalities were used in conjunction with CSA. Differences in patient selection, follow-up duration, types of tumors, and treatment approaches also make studies difficult to compare.

**CSA vs. RFA:** The empirical evidence comparing CSA to RFA consists of nonrandomized, case series, and cohort studies that examined multimodal therapies rather than CSA alone. The Pearson study was selected for critical appraisal as it was the largest prospective study (N=146). The objective of this study was to compare complication and local recurrence rates in patients treated with RFA or CSA. Patients with either primary or secondary hepatic malignancies were included in the study. Compared to patients treated with RFA, patients treated with CSA appeared to have higher local recurrence rates (22% vs. 3%). However, data was not adjusted for confounding factors that may influence the rate of recurrence. With regard to complications, a total of 27 complications occurred in 22 CSA patients, while a total of 3 complications occurred in 3 RFA patients. Patients treated with CSA had a higher incidence of intrahepatic abscess and symptomatic pleural effusion than patients treated with RFA. It is not clear who these results are generalizable to as only very limited demographic information is presented. There is a high probability of selection bias in the study, as it is not stated how patients were recruited for the study and treatment choice was based on preference and training of the individual surgeon. Additionally, a subset of patients underwent resection in combination with CSA or RFA.

**CSA vs. CSA + resection:** The Niu study was selected for critical appraisal as it was a large prospective study (N=315) that compared long-term results of resection combined with CSA with resection alone in patients with colorectal liver metastases. The study found that the combined treatment group (CSA + resection) had higher recurrence rate, but survival rates were not statistically different between the two groups. Results from this study should be interpreted with caution as treatment groups were not comparable at baseline, more patients in the combined treatment group were treated with chemotherapy, and results were not controlled for confounding factors. It is not clear who these results are generalizable to as only very limited demographic information is presented. **Conclusion:** There is insufficient evidence to determine the relative safety and efficacy of CSA

compared to RFA. There is insufficient evidence to determine whether CSA combined with hepatic resection will improve recurrence and survival rates compared to resection alone in patients with liver metastases from colorectal carcinomas.

**Articles:** No published randomized controlled trials or meta-analyses were found pertaining to the use of cryosurgical ablation for liver cancer. The literature consisted mainly of case series and cohort studies. Two prospective cohort studies were selected for critical appraisal. One study (Pearson 1999) assessed the relative safety and efficacy of CSA versus RFA and one study (Niu 2007) evaluated recurrence and survival rates of CSA combined with resection versus resection alone in patient with liver metastases from colorectal carcinomas. The following studies were critically appraised:

Pearson SA, Izzo FI, Declan RY, Delrio P et al. Intraoperative radiofrequency ablation or cryoablation for hepatic malignancies. *Am J Surg* 1999; 178:592-599. See [Evidence Table](#). Niu R, Yan TD, Zhu JC et al. Recurrence and survival outcomes after hepatic resection with or without cryotherapy for liver metastases from colorectal carcinoma. *Ann Surg Oncol* 2007; 14:2078-2087. See [Evidence Table](#).

## **Cryosurgery for Prostate Cancer**

### **BACKGROUND**

Radical prostatectomy and external beam radiation therapy are considered standard treatments for localized prostate cancer. Both can result in significant morbidity such as incontinence and impotence. There is interest in other treatments that are of similar or greater effectiveness and have less morbidity. Cryosurgery (also known as cryoablation) was first used to treat prostate cancer in the last 1960s. Originally, clinicians used an open perineal approach that had high morbidity. The procedure was re-introduced in 1993 by Onik and colleagues using transrectal ultrasound (Onik, 1993). The technique continued to evolve and is now performed with modifications to the procedure introduced by Onik. In the basic modern technique, six to eight 3.4 mm diameter cryoprobes are inserted transperineally into the prostate guided by transrectal ultrasound. Temperature probes are placed in the right and left neurovascular bundles and the apex of the prostate gland to ensure that temperatures reach optimal levels in the margins of the gland. In addition, temperature probes are placed in the Denonvilliers' fascia and the external sphincter and are used to make sure that sensitive areas adjacent to the prostate are not frozen. A urethral warming catheter is used to prevent the urethra from being frozen. Patients are treated with one or two freeze-thaw cycles (two is used more often in recent procedures) using a target temperature of  $-40^{\circ}\text{C}$ . When the target temperature is attained, the ice ball is maintained at a static size for up to 10 minutes if this is possible without endangering the rectal wall (Bahn et al., 2002). Cryosurgery is also used as salvage therapy to treat recurrent prostate cancer after radiation therapy. Salvage prostatectomy is the standard treatment, but about half of patients have positive surgical margins and there is significant associated morbidity (Cespedes et al., 1997).

### **06/11/2003: MTAC REVIEW**

#### **Cryosurgery – Prostate Cancer**

**Evidence Conclusion:** Primary treatment of clinically localized prostate cancer - Only case series data were available, the lowest grade of evidence because there is no control or comparison group. In addition, the case series did not evaluate a standard intervention; instead, the procedure changed over time. Both case series reported an intermediate outcome, biochemical success, as their primary health outcome. Conclusions about the effectiveness of cryosurgery compared to standard treatments for prostate cancer (e.g. radical prostatectomy, external beam radiation therapy) or no treatment can be drawn. Randomized controlled trials testing cryotherapy as primary treatment for prostate cancer should be feasible. The case series data suggest that cryosurgery is associated with a high-rate of impotence. Among men potent before surgery, in Bahn, 95% became impotent after cryosurgery and 90% remained so at follow-up (a mean of 5.4 years) and in Donnelly, 100% became impotent after cryosurgery and 53% remained so at 3 years, even with the use of sildenafil.

Salvage treatment for recurrent prostate cancer- Only case series data were available, the lowest grade of evidence because there is no control or comparison group. In addition, the procedure was inconsistent and changed over time. In a series of 131 patients (Izawa), 5-year disease-specific survival was 79% and 5-year disease-free survival was 40%. The long-term post-cryosurgery incontinence rate was 29%. Conclusions about the effectiveness of cryosurgery as salvage therapy after radiation treatment for patients with recurrent prostate cancer, or associated morbidity, compared to an alternate treatment such as salvage prostatectomy cannot be drawn.

**Articles:** *Primary treatment of clinically localized prostate cancer:* There were no randomized or non-randomized controlled trials. The only empirical data were from case series. The two largest case series that had data both on outcomes and adverse effects were critically appraised: Bahn DK, Lee F, Badalament R et al. Targeted cryoablation of the prostate: 7-year outcomes in the primary treatment of prostate cancer. *Urology* 2002 (Suppl 2A): 3-11. See [Evidence Table](#). Donnelly BJ, Saliken JC, Ernst S et al. Prospective trial of cryosurgical ablation of the prostate: Five-year results. *Urology* 2002; 60: 645-649. See [Evidence Table](#).

*Salvage treatment for recurrent prostate cancer:* Three case series were identified. Two were from the same institution and reported different outcomes on virtually the same group of patients. These studies were critically

appraised. The other case series, which had a smaller sample size and a shorter follow-up, was excluded. Cespedes RD, Pisters LL, von Eschenbach AC et al. Long-term follow-up of incontinence and obstruction after salvage cryosurgical ablation of the prostate: Results in 143 patients. *J Urol* 1997; 157: 237-240. See [Evidence Table](#). Izawa JI, Madsen LT, Scott SM et al. Salvage cryotherapy for recurrent prostate cancer after radiotherapy: Variables affecting patient outcome. *J Clin Oncol* 2002; 20: 2664-2671. See [Evidence Table](#).

The use of cryosurgery in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **Cryoablation of Renal Tumors**

### **BACKGROUND**

With the widespread use of body imaging techniques as magnetic resonance imaging (MRI) and computed tomography (CT), there is an increasing number of incidentally detected small renal masses or lesions with unclear clinical significance. The standard treatment for renal masses is radical nephrectomy. Other available treatment options include watchful waiting or partial nephrectomy. Recently, with the current trend of minimally invasive surgery, nephron-sparing approaches have gained more acceptance. Open, percutaneous, and laparoscopic renal cryoablation, radiofrequency ablation, and high intensity focused ultrasonography (HIFU) have been performed but are still under development. These techniques only target selected, small renal tumors with a diameter of 4 cm or less. Cryosurgery has been known for years, but the recent changes in the technology and the development of improved cryosurgery units are permitting its clinical use. Cryoablation is a technique that uses liquid nitrogen or argon gas to freeze and ablate tissues. Cryoablation is mainly performed laparoscopically under real time ultrasound guidance. It is reported that the critical temperature that leads to cancer cell destruction is approximately  $-40^{\circ}\text{C}$ . Normal and neoplastic renal tissues are ablated and rendered necrotic at temperatures of  $-20^{\circ}\text{C}$  (Chosy, 1996). During cryosurgery, the temperature is lowest at the center of the iceball with an incremental increase towards the periphery. Thus, with a cryoprobe tip temperature of  $-185^{\circ}\text{C}$  to  $-195^{\circ}\text{C}$ , the temperature will be approximately  $0^{\circ}\text{C}$  at outer edge of the ice ball,  $-20^{\circ}\text{C}$  at a distance of 4mm, and  $-40^{\circ}\text{C}$  at a distance of 6mm towards the center of the iceball. It is important that the edge of the cryolesion be 1 cm beyond the margin of the tumor to make sure that a lethal temperature of  $-40^{\circ}\text{C}$  or less was achieved throughout the tumor. The effect of cryosurgery occurs in two phases, freezing and thawing. The freezing phase is performed rapidly, and passive thawing is performed more slowly for a maximum effect. A double freeze-thaw cycle is usually performed to ensure the extension of the iceball to approximately 1 cm beyond the tumor edge. The size of the cryolesion depends on several factors including the temperature at the tip of the cryoprobe, area of tissue contact, freeze time, and tissue vascularity. The response of a tumor to cryoablation depends on its biological characteristics e.g. density, specific heat, thermal conductivity, and rate of blood flow (Gage 1992). Potential complications of renal cryosurgery include post-thaw hemorrhage, urine leakage due to caliceal cryoinjury, and fistula formation.

### **04/09/2003: MTAC REVIEW**

#### **Cryosurgery – Renal Tumors**

**Evidence Conclusion:** There is insufficient published evidence to determine the efficacy, safety, and long-term outcome of cryoablation for the treatment of renal tumors. No randomized controlled trials or non-randomized comparative studies were conducted to compare the procedure to surgery or other alternatives and assess its long-term benefits. All studies were either case reports or case series with very small sample sizes. The case series reviewed included small numbers of patients, were subject to selection and observation biases, and had short follow-up durations. These series showed that after a mean follow-up of 9 months in Shingleton's study, 14 months in Lee's study and 16 months in Gill's study the ablated renal tumor was no longer detectable in 25-40% or reduced in size in 20-75% of the patients with available follow-up data. Large randomized controlled studies with long-term follow up duration will be needed to compare cryoablation to other alternatives, and to determine its efficacy, safety, and long-term benefits.

**Articles:** The search yielded 48 articles. Many were reviews or tutorials that dealt with the technical aspects of the procedure. There were no meta-analyses or randomized controlled trials. There were 13 case reports (with 1-9 patients), and 9 case series with a small number of patients (10 to 32 patients). The 3 largest series were selected for critical appraisal: Gill IS, Novick AC, Meraney AM, et al. Laparoscopic renal cryoablation in 32 patients. *Urology* 2000; 56:748-753. See [Evidence Table](#). Lee DI, McGinnis DE, Feld R, et al. Retroperitoneal laparoscopic cryoablation of small renal tumors: intermediate results. *Urology* 2003;61: 83-88. See [Evidence Table](#). Shingleton WB and Sewell PE. Percutaneous renal tumor cryoablation with magnetic resonance imaging guidance. *J Urol* 2001; 165:773-776. See [Evidence Table](#).

The use of cryoablation in the treatment of renal tumors does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## Applicable Codes

### Breast Cancer and Benign Lesions - Considered Not Medically Necessary:

CPT® Codes	Description
19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma

### Prostate Cancer –

**Medicare** - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

**Non-Medicare** - Medical Necessity Review not required

CPT® Codes	Description
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)

### Renal Tumors - Medical Necessity Review not required:

CPT® Codes	Description
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

### Liver Tumors - Medical Necessity Review not required:

CPT® Codes	Description
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
47381	Ablation, open, of 1 or more liver tumor(s); cryosurgical

### Lung Cancer - Medical Necessity Review not required:

CPT® Codes	Description
32994	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
06/30/2003	08/03/2010 <sup>MDCRPC</sup> , 03/01/2011 <sup>MDCRPC</sup> , 01/03/2012 <sup>MDCRPC</sup> , 11/06/2012 <sup>MDCRPC</sup> , 09/03/2013 <sup>MPC</sup> , 07/01/2014 <sup>MPC</sup> , 02/02/2016 <sup>MPC</sup> , 12/06/2016 <sup>MPC</sup> , 10/03/2017 <sup>MPC</sup> , 08/07/2018 <sup>MPC</sup> , 08/06/2019 <sup>MPC</sup> , 08/04/2020 <sup>MPC</sup> , 08/03/2021 <sup>MPC</sup> , 08/02/2022 <sup>MPC</sup> , 08/01/2023 <sup>MPC</sup>	08/01/2023

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee

Revision History	Description
08/04/2020	Added Kaiser Permanente Medical Policy statement under Medicare for Breast Cancer and Benign Lesions.
08/01/2023	MPC approved to retire Cryosurgery-Breast as it meets clinical retirement parameters. Requires 60-day notice; effective January 1, 2024.