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Clinical UM Guideline

Subject:	Cryosurgical, Radiofrequency or Laser Ablation to Treat Solid Tumors Outside the Liver		
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Description

This document focuses on the use of cryosurgical (also known as cryosurgery or cryoablation), radiofrequency or laser ablation as a treatment of:

- Primary or secondary malignancies outside the liver; and
- Benign tumors outside the liver.

Cryosurgery involves freezing of target tissues, most often by inserting into the tumor a probe through which coolant is circulated. Radiofrequency ablation involves the use of heat to destroy tissue via high-energy radio waves passing through a probe inserted into the tumor. Laser ablation uses heat generated by light energy to destroy tissue or shrink tumors.

Note: This document does not address the treatment of epithelial or endothelial lesions, including basal and squamous cell carcinoma, Barrett's esophagus, polyps of the esophagus or condylomata. This document also does not address laser treatments for benign prostatic hypertrophy.

Note: For additional information, see the following:

- CG-MED-81 Ultrasound Ablation for Oncologic Indications
- CG-SURG-78 Locoregional and Surgical Techniques for Treating Primary and Metastatic Liver Malignancies
- CG-SURG-101 Ablative Techniques as a Treatment for Barrett's Esophagus
- CG-SURG-107 surgical and Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH)
- SURG.00159 Focal Laser Ablation for the Treatment of Prostate Cancer

Clinical Indications

Medically Necessary:

Cryosurgical Ablation

Cryosurgical ablation of the prostate is considered **medically necessary** as a treatment of prostate cancer.

Cryosurgical ablation for clinically localized, suspected renal malignancy is considered **medically necessary** for individuals with peripheral lesions that are less than or equal to 4 cm in diameter when one or more of the following criteria are met:

- Individual has a single kidney; **or**
- Individual has renal insufficiency; **or**
- Individual is considered a high-risk surgical candidate.

Radiofrequency Ablation

A. Radiofrequency ablation of osteoid osteomas is considered **medically necessary**.

B. Radiofrequency ablation of painful bony metastases is considered **medically necessary** in individuals who have failed or who are considered poor candidates for standard treatments such as opioids or radiation therapy.

C. Radiofrequency ablation for clinically localized, suspected renal malignancy is considered **medically necessary** for individuals with peripheral lesions that are less than or equal to 4 cm in diameter and when *one or more* of the following criteria are met:
   1. Individual has a single kidney; **or**
   2. Individual has renal insufficiency; **or**
   3. Individual is considered a high-risk surgical candidate.

D. Radiofrequency ablation of biopsy-proven non-small cell lung cancer (NSCLC) is considered **medically necessary** when *all* of the following criteria are met:
   1. Surgical or radiation treatment with curative intent is considered appropriate based on stage of disease, however medical co-morbidity renders the individual unfit for those interventions; **and**
   2. No tumor has a maximum diameter of greater than 3.0 cm; **and**
   3. Tumors are located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

E. Radiofrequency ablation of *metastatic* malignant tumor(s) to the lung is considered **medically necessary** when *all* of the following criteria are met:
   1. Biopsy-proven lung metastasis(es) from an extra-pulmonary primary site; **and**
   2. Surgical or radiation treatment is considered appropriate based on stage of disease, however medical co-morbidity renders the individual unfit for those interventions; **and**
   3. There is no current active extra-pulmonary metastatic disease; **and**
   4. There are no more than 3 tumors per lung; **and**
   5. No tumor has a maximum diameter greater than 3.0 cm; **and**
   6. Tumors are located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart; **and**
   7. If a repeat procedure, at least 12 months have elapsed since the prior ablation.

Not Medically Necessary:

Laser ablation, or laser interstitial thermal therapy is considered **not medically necessary** as a therapy to treat solid tumors outside the liver.

Cryosurgical ablation of tumors outside the liver is considered **not medically necessary** when the above criteria are not met and for all other indications.

Radiofrequency ablation of tumors outside the liver is considered **not medically necessary** when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Bone:
When services may be Medically Necessary when criteria are met:

CPT	
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

ICD-10 Diagnosis	
C79.51	Secondary malignant neoplasm of bone
D16.00-D16.9	Benign neoplasm of bone and articular cartilage

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for all other diagnoses not listed

When services are also Not Medically Necessary:

CPT	
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

ICD-10 Diagnosis	
	All diagnoses

Lung:
When services may be Medically Necessary when criteria are met:

CPT

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, including imaging guidance when performed, unilateral; radiofrequency

ICD-10 Procedure

0B5K3ZZ-0B5M3ZZ	Destruction of lung, percutaneous approach [right, left, bilateral; includes codes 0B5K3ZZ, 0B5L3ZZ, 0B5M3ZZ; when specified as radiofrequency ablation]

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

When services are also Not Medically Necessary:

CPT

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

ICD-10 Procedure

0B5K3ZZ-0B5M3ZZ	Destruction of lung, percutaneous approach [right, left, bilateral; includes codes 0B5K3ZZ, 0B5L3ZZ, 0B5M3ZZ; when specified as cryosurgical ablation]

ICD-10 Diagnosis

All diagnoses

Prostate:
When services are Medically Necessary:

CPT

55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)

ICD-10 Procedure

	For the following codes when specified as cryosurgical ablation:
0V500ZZ-0V504ZZ	Destruction of prostate [by approach; includes codes 0V500ZZ, 0V503ZZ, 0V504ZZ]

ICD-10 Diagnosis

C61	Malignant neoplasm of prostate
C79.82	Secondary malignant neoplasm of genital organs
D07.5	Carcinoma in situ of prostate

Renal:
When services may be Medically Necessary when criteria are met:

CPT

50250	Ablation, open, 1 or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed [when specified as cryosurgical or radiofrequency ablation]
50592	Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy

ICD-10 Procedure

	For the following codes when specified as cryosurgical or radiofrequency ablation:
0T500ZZ-0T514ZZ	Destruction of kidney [left or right, by approach; includes codes 0T500ZZ, 0T503ZZ, 0T504ZZ, 0T510ZZ, 0T513ZZ, 0T514ZZ]
0T530ZZ-0T544ZZ	Destruction of kidney pelvis [left or right, by approach; includes codes 0T530ZZ, 0T533ZZ, 0T534ZZ, 0T540ZZ, 0T543ZZ, 0T544ZZ]

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

Other tumors:
When services are Not Medically Necessary:

CPT

19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma
48999	Unlisted procedure, pancreas [when specified as cryosurgical, radiofrequency or laser ablation of pancreas tumor(s)]
60699	Unlisted procedure, endocrine system [when specified as cryosurgical or radiofrequency ablation of thyroid or adrenal tumor(s)]

61736	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion
61737	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesions
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral
0673T	Ablation, benign thyroid nodule(s), percutaneous, laser, including imaging guidance

ICD-10 Procedure

0H5T0ZZ-0H5V3ZZ	Destruction of breast [right or left or bilateral, by approach; includes codes 0H5T0ZZ, 0H5T3ZZ, 0H5U0ZZ, 0H5U3ZZ, 0H5V0ZZ, 0H5V3ZZ] [when specified as cryosurgical, radiofrequency or laser ablation]

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

Background/Overview

Cryosurgery, also called cryotherapy or cryosurgical ablation, uses extreme cold to destroy abnormal tissue. Cryosurgery may be used to treat skin tumors such as basal cell carcinoma or tumors inside the body such as prostatic or renal tumors.

When cryosurgery is used to treat tumors inside the body, a coolant such as liquid nitrogen or argon gas is circulated through a hollow instrument called a cryoprobe that is placed in contact with the tumor. Imaging procedures such as ultrasound or MRI are used to guide the cryoprobe to the tumor location and monitor the freezing process. The cryoprobe may be inserted into the tumor during an open or laparoscopic surgical procedure or may be inserted through the skin and guided to the tumor using an imaging technique. During cryosurgery, a ball of ice crystals forms around the probe within the tumor. This freezes and kills nearby cells. Treatment is monitored to limit the amount of damage to nearby healthy tissue. The probe is removed after treatment and the frozen tissue thaws. The dead tissue is then naturally absorbed by the body. Sometimes more than one probe is used to treat different parts of the tumor.

Radiofrequency ablation (RFA) can also be used to treat inoperable tumors or to treat individuals ineligible for surgery due to age or comorbidities. Goals of RFA may include control of local tumor growth, prevention of recurrence, palliation of symptoms, and extending survival. The procedure kills cells with heat generated by rapidly alternating current delivered through probes inserted into the tumor. The effective volume of RFA depends on the frequency and duration of applied current, local tissue characteristics, and probe configuration (for example, single versus multiple tips). The overall effectiveness of RFA can be affected by perfusion mediated tissue cooling caused by an adjacent blood flow (heat sink effect) and by target tissue heterogeneity such as calcifications, fibrosis, or the amount of fluids in the area (Orloff, 2022). RFA can be performed as an open surgical procedure, laparoscopically, or percutaneously with ultrasound or computed tomography (CT) guidance.

In laser ablation, the probe is inserted into the target tissue. Once it is triggered, light energy delivers thermal energy and causes protein denaturation, melting of membrane lipids, vessel sclerosis, and coagulation necrosis (Mirza, 2020). The amount of tissue destroyed is monitored using real-time MR thermometry. The procedure results in 3 zones: an inner zone of coagulation necrosis, a middle zone which contains non-viable tissue which has increased interstitial fluid and an outer zone which consists of edematous, viable tissue (Mirza, 2020).

Cryosurgery, RFA and laser may offer advantages over other methods of cancer treatment. They may be an option for treating cancers that are otherwise inoperable, do not respond to standard treatments or for individuals who are not good candidates for conventional surgery because of their age or other medical conditions. They can be less invasive than surgery, involving only a small incision to insert the probe through the skin. Destruction of nearby healthy tissue is minimized. Consequently, complications of surgery such as pain and bleeding may be minimized. These procedures may require a shorter recovery time and a shorter hospital stay, or no hospital stay at all. They can sometimes be done using only local anesthesia. In addition, these treatments may often be safely repeated. They are often used as adjuncts to surgery, chemotherapy, hormone therapy, or radiation.

Cryosurgery and RFA can result in adverse effects; however, these may be less severe than those associated with conventional surgery or radiation therapy. Adverse effects depend on the location of the tumor but may include bleeding, damage to tissues adjacent to the tumor, and structural damage along the route of access to the tumor. Incontinence or urinary retention can occur following treatment for prostate cancer. Post-operative infection can occur. Secondary tumors can occur if tumor cells are seeded along the access tract when the probe is removed. In rare cases, cryosurgery may interact adversely with certain types of chemotherapy.

Prostate Cancer

Treatment options for prostate cancer include watchful waiting, surgical prostatectomy, various forms of radiation therapy and cryosurgery. The goal of prostate cryoablation is the destruction of the entire gland.

Cryosurgical ablation for treatment of prostate cancer is considered a safe and effective treatment. Several small observational trials have shown similar complication rates to external beam radiation therapy (EBRT) or brachytherapy in terms of erectile dysfunction, obstruction, incontinence, and urethral stricture (Abufaraj, 2021; Valle, 2020). Post-operative biopsy results and recurrence rates are also similar to EBRT. A guideline published in 2017 by the American Urological Association (AUA) in conjunction with the American Society for Radiation Oncology (ASTRO) and the Society of Urologic Oncology (SUO) provides broad support for the use of cryotherapy in prostate cancer.

The National Comprehensive Cancer Network® (NCCN) Clinical Practice Guideline® for Prostate Cancer (V3.2022) recommends cryosurgery as a minimally invasive local option for individuals with prostate cancer. The guideline also notes that cryosurgery may be used as salvage therapy after failed radiation.

Cryosurgical ablation continues to be studied in combination with other treatments for prostate cancer. However, the current body of evidence supports that cryotherapy is a recognized and established treatment of prostate cancer.

Renal Cell Carcinoma and Other Renal Tumors

Localized renal cell carcinoma (RCC) is usually treated by radical nephrectomy or nephron-sparing surgery. Surgical excision of small renal masses remains the standard of care with 5-year survival approaching 97%. However, for those individuals with limited disease who are not candidates for surgery, ablative techniques provide an alternative treatment.

Tanagho (2013) compared cryoablation to robotically assisted partial nephrectomy in subjects with contrast enhancing renal masses that were concerning for renal cell carcinoma (RCC). This retrospective nonrandomized controlled study involved 267 subjects who underwent either laparoscopic (n=149) or percutaneous (n=118) cryoablation compared to 233 subjects who received treatment with robotically assisted partial nephrectomy. The authors reported no significant differences between the cryoablation and nephrectomy groups with regard to perioperative complication rates (8.6% versus 9.4%). Biopsy results were reported in only 153 (57%) of the 267 subjects in the cryoablation group, with confirmed RCC in 52.3% (80/153) of subjects. Five-year Kaplan-Meier estimated disease-free survival (DFS) was 93.1%, cancer-specific survival (CSS) was 96.4%, and overall survival (OS) was 77.1%. In the nephrectomy group, all subjects had biopsy results and RCC was confirmed in 79.4%. In this group, DFS was 100%, CSS was 100%, and OS was 91.7%. Unfortunately, no intergroup comparative statistical data were provided for these data points. The intraoperative complication rate for the nephrectomy group was significantly better than the rate for the cryoablation group (1.3% versus 7.2%). This finding was reversed for postoperative complications (7.7% versus 2.2%, respectively; $p<0.01$). Cancer recurrence was also significantly better after nephrectomy, with 12.7% of the cryoablation group experiencing recurrence versus 0% in the nephrectomy group. It should be noted that there were significant differences between groups preoperatively with regard to several factors including mean tumor size (2.5 cm for the cryoablation versus 2.9 cm for the nephrectomy group), the Charleston Comorbidity Index (6.5 versus 2.1, respectively), and mean nephrectomy score (6.4 versus 7.3, respectively).

Several nonrandomized retrospective studies comparing nephrectomy with cryoablation have demonstrated similar outcomes with regard to operative times, blood loss, and complication rates (Emara, 2014; Haramis, 2012; Panumatrassamee, 2013). Two of these studies (Emara, 2014; Panumatrassamee, 2013) reported significantly better post-operative renal function following cryoablation. Breen (2013) and Buy (2013) reported on cryosurgical studies with follow-up of 20 months. The Breen study prospectively enrolled 147 subjects and reported that only tumor location in the upper pole was a predictive factor for complications. Only one case of recurrence was reported in the subset of 62 subjects with biopsy proven RCC. The Buy study prospectively enrolled 95 subjects and reported a technical success rate of 94%. The 12-month OS rate was 96.7% and disease-free survival (DFS) rate was 96.4%.

Atwell (2013) published findings of a large retrospective review comparing RFA and cryoablation for tumors < 3 cm. RFA was used to treat 256 tumors in 222 subjects and cryoablation was used for 189 tumors in 163 subjects. In the RFA group, 59% (152/256) of tumors were biopsied and 54% of these (82/152) were identified as RCC. For the cryoablation group, 74% (140/189) of tumors were biopsied and 56% of these (79/140) were RCC. Significant baseline differences between groups were identified. RFA subjects more likely to have had previous history of RCC and more likely to have larger tumors than cryoablation subjects (2.3 cm versus 1.9 cm). There was 1 technical failure in the RFA group compared to 4 in the cryoablation group. No significant differences were noted with regard to rates of major complications. Follow-up of at least 3 months occurred in 60% of RFA tumors and only 40% of cryoablation tumors. For biopsy-proven RCC, estimated local recurrence-free survival rates at 1, 3, and 5 years after RFA were 100%, 98.1%, and 98.1%, respectively, compared with cryoablation: 97.3%, 90.6%, and 90.6%, respectively.

A larger nonrandomized comparative study investigating the outcomes between laparoscopic (n=275) and percutaneous (n=137) cryoablation of single renal masses was published by Zargar in 2015. The overall and major complication rates were similar (7.27% versus 7.29% and 0.7% versus 3.6%, respectively). The median follow-up time for the laparoscopic group was significantly longer than the percutaneous group (mean 4.41 years versus 3.15 years). Estimated probabilities of 5-year OS for laparoscopic and percutaneous cryoablation were 89% and 82%, respectively. The estimated probability of the 5-year recurrence-free survival (RFS) was 79% and 80%, respectively. There was no significant difference in OS or RFS at 5 years between the two groups. Heart disease and history of disease recurrence were predictors of death. Tumor size and anterior location affected local recurrence rates. The authors recommended that these factors be considered when choosing treatment plans.

Caputo and colleagues published the results of a retrospective case series in 2016. The study focused on the long-term outcomes of cryoablation for renal tumors. It followed 138 subjects with 142 renal tumors treated with laparoscopic cryoablation. Of the 142 tumors, 100 were diagnosed as RCC. In the subjects with renal carcinoma, at 3, 5 and 10-year follow-up time points, the estimated RFS was 91.4%, 86.5% and 86.5%, respectively. Estimated cancer specific survival was 96.8%, 96.8% and 92.6%, respectively. Estimated OS was 88.7%, 79.1% and 53.8%, respectively. The mean follow-up was 98.8 ± 54.2 months in subjects diagnosed with RCC. The mean time to recurrence was reported as 2.3 years; the last experienced recurrence occurred 4.4 years after the intervention. In the 3 subjects that experienced incomplete ablation, 1 subject underwent repeat cryoablation and 2 subjects underwent radical nephrectomy. There was a postoperative complication rate of 10.6% with a total of 15 complications. The most common complications were ileus (n=3), hypoxia (n=2), and hemorrhage (n=2). The authors concluded that laparoscopic cryoablation achieved good long-term oncologic outcomes for localized small renal masses.

A meta-analysis by El Dib and colleagues (2012) evaluated cryoablation compared to RFA as a treatment of small (less than 4 cm) RCC. Cryoablation had a pooled clinical efficacy rate of 89% in 457 cases versus 90% in 426 cases with RFA. The observed difference in the rate of complications was not statistically significant between the ablation techniques. The authors concluded that both cryoablation and RFA were promising therapies to treat small renal tumors in individuals who were considered poor candidates for more involved surgery.

A small number of controlled studies address the use of RFA for RCC. The largest was a retrospective nonrandomized comparative study involving 385 subjects with renal masses ≤ 3.0 cm who underwent treatment with either RFA (n=256 tumors in 222 subjects) or cryoablation (n=189 tumors in 163 subjects) (Atwell, 2013). Subjects were selected for percutaneous ablation due to either high surgical risk or prior renal surgery. A total of

152 out of 256 tumors were biopsied prior to treatment with RFA. Of these, 102 were confirmed malignancies, 27 were benign, and 23 were unclassified. For the 189 tumors in the cryoablation group, 91 were malignant, 28 were benign, and 21 were unclassified. Subjects treated with RFA were more likely to have no prior renal cancer history (p=0.043) and were significantly more likely to have been followed for at least 3 months (p=0.023). Mean tumor size was significantly greater in the cryoablation group (p<0.001), and cryoablation was conducted more frequently for centrally located tumors (p<0.001). Thirteen subjects underwent treatment with both modalities. Treatment failures were reported in 1 RFA case and 4 cryoablation cases. Major complications were reported in 10 (4.3%) RFA cases and 9 (5.1%) cryoablation cases. Out of the 363 subjects followed for at least 3 months, 218 were in the RFA group and 145 were in the cryoablation group. Recurrence was reported to have occurred in 7 (3.2%) of RFA subjects at a mean of 2.8 years and in 4 (2.8%) of cryoablation subjects at a mean of 0.9 years. Estimated 1-, 3- and 5-year survival rates for the RFA group were 100%. 97.2% and 93%, respectively compared to the cryoablation group rates: 98.3%, 95.6%, and 95.6%, respectively. A significant difference was noted in favor of the cryoablation group. Only one RFA-treated tumor had a recurrence versus three in the cryoablation group. Estimated 1-, 3-, and 5-year RFS for the RFA group was 100%, 98.1%, and 98.1% respectively. For the cryoablation group, these rates were 97.3%, 90.6%, and 90.6%, respectively. No significant differences were noted between groups. The authors noted that both RFA and cryoablation are effective in the treatment of renal masses less than or equal to 3 cm, with low complication rates.

A nonrandomized controlled comparative trial reported by Sung and colleagues in 2012 included 150 subjects with renal masses undergoing either RFA (n=40) or open partial nephrectomy (OPN, n=110). Tumor size and location were matched between the two groups. There were no significant demographic or other clinical differences between groups. The mean reduction in estimated glomerular filtration rates (eGFR) was similar in the RFA (2.3 ± 8.6 mL/min/1.73m^2) and OPN groups (7.4 ± 10.9 mL/min/1.73m^2). The 3-year recurrence-free survival rates in the RFA and OPN groups were 94.7% and 98.9%. The authors summarized that while both RFA and OPN therapy will result in reduced renal function, RFA can preserve more normal renal tissue than OPN. In terms of mid-term survival rates, RFA and OPN are equivalent.

In 2016, Yin and colleagues reported the results of a meta-analysis comparing data for radiofrequency ablation used to treat small renal tumors to data for partial nephrectomy (PN). Twelve retrospective studies met the selection criterion. The pooled results indicated that the local recurrence rate (4.14% versus 4.10%) and distant metastases rate (2.76% versus 1.89%) were not significantly different. RFA was reported to be associated with a significantly shorter length of stay and a non-significant lower eGFR decline after treatment. No significant differences were noted between groups for the perioperative complication rate (7.5% versus 6.2%) or the major complication rate (3.7% versus 4.4%+. The authors concluded that RFA achieved an equal oncological outcome for small renal tumors compared to partial nephrectomy.

The National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guideline® for Kidney Cancer (V4.2022) includes surgical resection as an effective therapy for clinically localized RCC. Recommended options include radical nephrectomy and nephron-sparing surgery. Individuals with stage I through III tumors who are in satisfactory medical condition are recommended to undergo surgical excision. Active surveillance or ablative techniques, such as cryoablation or radiofrequency ablation are alternative strategies for individuals with T1 renal lesions who are not surgical candidates.

A 2021 AUA guideline addressing renal mass and localized renal cancer noted that while radical nephrectomy is associated with excellent cancer-specific survival, nephron-sparing techniques such as partial nephrectomy or thermal ablation are recommended. Thermal ablation is a means of preserving function while increasing procedure tolerance and reducing the potential complications associated with partial nephrectomy. The AUA addresses specific thermal ablation techniques noting:

> A multitude of techniques/technologies have been investigated to ablate renal tumors, however radiofrequency ablation (RFA) and cryoablation have been most widely investigated and integrated into clinical practice. While the superiority of RFA or cryoablation remains controversial, it is generally accepted that oncologic outcomes are similar for both approaches.

The AUA makes the following recommendations regarding thermal ablation:

> Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation. (Conditional Recommendation; Evidence Level: Grade C)
>
> Physicians should consider thermal ablation (TA) as an alternate approach for the management of cT1a renal masses <3 cm in size. For patients who elect TA, a percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity. (Conditional Recommendation; Evidence Level: Grade C)

In 2020, the Society of Interventional Radiology published a position statement on the role of percutaneous ablation in RCC, focusing on small renal masses and oligometastatic disease. For individuals with small renal tumors (stage T1a) percutaneous is recommended as a safe and effective treatment which has acceptable long-term oncological and survival outcomes and fewer complications than nephrectomy. For those with suspected stage T1a RCC, percutaneous thermal ablation is recommended over active surveillance. (Level of Evidence: C; Strength of Recommendation: Moderate). The position statement also recommends that percutaneous thermal ablation may be offered to those with T1b RCC who are not surgical candidates or in those with oligometastatic RCC with surgically resectable primary RCC who are not candidates for metastasectomy (Level of Evidence D; Strength of Recommendation: Weak).

The available medical literature indicates that cryoablation and RFA are safe and effective for: managing small, undefined peripheral renal masses (less than 4 cm); treating solitary kidneys or situations where the contra-lateral kidney is functioning poorly; and treating individuals who have significant comorbidities and cannot tolerate nephrectomy.

Renal Insufficiency

Chronic kidney disease can be detected by the presence of a marker of kidney damage or a decreased glomerular filtration rate (GFR) for 3 or more months. The GFR has been considered to be the leading indicator of kidney function. A GFR level below 60 mL per minute per $1.73m^2$ was considered to represent loss of half or more of normal kidney function (Johnson, 2004). GFR can be directly measured, but the process is time consuming and involves continuous intravenous infusions, bladder catheterization, and multiple blood samples. As a practical matter, GFR is often estimated using serum markers such as creatinine or serum cystatin C. Hsu and colleagues reported results of a large cross-sectional population analysis of 1248 individuals (2021). The analysis found that use of estimating equations based on creatinine levels, age, and sex without consideration of race systematically underestimated GFR for individuals who self-identify as black. Several authors have called for transition to methods of GFR estimation that avoid promotion of race-based disparities (Williams, 2021).

Recently, the American Society of Nephrology and the National Kidney Foundation created a task force to assess the value of including race in the estimated GFR (eGFR) formula and the associated implications to diagnosis and management and notes the following:

> The Task Force recommends for US adults (>85% of whom have normal kidney function) that the CKD-EPIcr_R equation that was developed without the use of the race variable be implemented immediately, including in all laboratories. In addition to not including race in the calculation and reporting, it included diversity in its development, is immediately available to all laboratories in the United States, and has acceptable performance characteristics and potential consequences that do not disproportionately affect any one group of individuals
>
> The Task Force recommends national efforts to facilitate increased, routine, and timely use of cystatin C, especially to confirm eGFR in adults who are at risk for or have CKD. Combining filtration markers (creatinine and cystatin C) is more accurate and would support better clinical decisions than either marker alone.

Bone Cancer and Bone Metastases

After lung and liver, bone is the third most common metastatic site. Bone metastases are relatively frequent among individuals with primary malignancies of the breast, prostate, and lung. Approximately 60-84% of metastatic cancer has osseous involvement (Mehta, 2020). Cancer-related bone pain is thought to be related to "tumor- and osteoclast-related changes to the osseous metastatic microenvironment resulting in a variety of neuropathic effects" (Mehta, 2020). These metastases often cause osteolysis resulting in pain, fractures, decreased mobility, and reduced quality of life. External beam irradiation is often the initial palliative therapy used for osteolytic bone metastases. However, pain from bone metastases is refractory to radiation therapy in 20% to 30% of individuals. Recurrent pain at previously irradiated sites may be ineligible for additional radiation due to risks of normal tissue damage. Alternatives include hormonal therapy, radiopharmaceuticals such as strontium-89, and bisphosphonates. Less often, surgery or chemotherapy may be used for palliation. Intractable pain may require opioid medications. RFA has been investigated as alternatives for palliating pain from bone metastases. RFA is thought to provide relief by the following mechanism:

> RF ablation is able to directly affect osteoclast- and tumor cell–mediated sensory fiber activation by inhibition of osteoclast activity, reduction in overall tumor volume, and destruction of tumor

cells producing nerve-stimulating cytokines as well as inhibiting transmission of painful signals by destruction of sensory nerve fibers in the bone (Mehta, 2020).

Callstrom and colleagues (2012) reported results from a prospective case series of 61 subjects investigating percutaneous cryoablation to treat painful bone metastases. The primary endpoints were worst pain and average pain scores on a visual analog scale. Participants completed questionnaires prior to therapy, a day after cryoablation, and thereafter via telephone interview on day 4 and then every 2 weeks for up to 6 months. During the 24-week follow-up period, 45 participants (74%) dropped out of the study. There was no significant change in the worst-pain score from baseline (7.1/10) to the interview at day 1 (7.0/10). The worst pain dropped significantly at week 1 to 5.1/10 (p<0.0001). Out of the 35 participants who were followed for a minimum of 8 weeks, 5 participants (14%) had recurrent worst pain that was equal to or greater than the baseline pain level prior to cryoablation. Of note, study participants were a subset of individuals included in multiple radiation treatment trials.

In a small case series, Meftah (2013) evaluated the outcomes of curettage and cryosurgery of low-grade chondrosarcoma of the bone in 42 subjects comparing a cryoprobe to a modified Marcove pour technique. There were no differences between the cryoprobe and Marcove techniques with respect to the Musculoskeletal Tumor Society score, fracture, or local recurrence rate. A significant correlation between tumor recurrence and soft-tissue extension was found (r=0.79). Kaplan-Meier survivorship with freedom from recurrence as the endpoint was 90.7%.

Mehta and associates (2020) performed a meta-analysis to evaluate the efficacy, durability and response time of RFA for pain relief from osseous metastases. The analysis included 14 studies comprised of 426 individuals. A majority of the studies were limited to those with cancer-related bone pain unresponsive to other pain control treatments. At the post-procedure median follow-up of 24 weeks, the median pain reduction from baseline was 67% (range, 17%–90%). At 1 week post-procedure, individuals reported an average 44% reduction in baseline pain.

The NCCN clinical practice guidelines for cancer pain (V1.2022) notes that RFA may be used to reduce pain and prevent skeletal-related events. The guidelines do not include cryoablation therapy as a technique to treat painful bone metastases or skeletal-related events.

Breast Cancer

Early-stage primary breast tumors are typically treated surgically. The selection of lumpectomy, modified radical mastectomy, or another approach balances the individual's desire for breast conservation, the need for tumor-free margins in resected tissue, and age, hormone receptor status, and other factors. Adjuvant radiation therapy decreases local recurrences, particularly for those who select lumpectomy. Adjuvant hormonal therapy and/or chemotherapy are added, depending on presence and number of involved nodes, hormone receptor status, and other factors.

Studies on minimally invasive techniques to treat breast cancer published before 2010 consist of small uncontrolled observational reports or reviews. These papers do not demonstrate that these techniques provide health benefits comparable to other established treatments (Izzo, 2001; Pfleiderer, 2002; Hayashi, 2003; Singletary, 2003; Fornage, 2004; Oura, 2007; Littrup, 2009; Zhao, 2010). More recent studies continue to consist of small populations with limited follow-up (García-Tejedor, 2018; Klimberg, 2014).

In a 2021 meta-analysis, van de Voort and colleagues examine whether thermal ablation is an effective method to treat early-stage breast cancer (tumors 2 cm or smaller). A total of 37 studies and 1266 participants were included in the analysis. The overall complete ablation rate was 86%. While these rates were similar to re-excision rates following breast-conserving surgery, thermal ablation does not allow evaluation of complete ablation when no subsequent resection is performed. The authors note that a method to confirm complete ablation needs to be sufficiently sensitive to maintain the current low local recurrence rates which are associated with breast-conserving surgery in this population. While the results show promise, the studies were largely noncomparative and small with great heterogeneity. The authors note "the results of this review should not lead to firm conclusions, but rather serve as a basis for larger phase 2 and 3 clinical trials".

The NCCN Breast Cancer Clinical Practice Guidelines (V2.2022) lists a variety of treatment modalities breast cancer, including surgery, radiotherapy, chemotherapy, endocrine therapy, biologic therapy. These modalities are typically used in combination with each other. The choice of modality is based upon prognostic and predictive factors. The guidelines do not include cryoablation or RFA as a modality to treat breast cancer.

The American Society of Breast Surgeons (ASBS, 2018) has provided recommendations for RFA and cryoablation of malignant tumors of the breast. Specifically, they state:

> Percutaneous and/or transcutaneous treatments of malignant tumors of the breast are not specifically approved by the FDA, though some ablative technologies are approved for treatment of benign and malignant soft tissue tumors. Therefore, ablative and percutaneous excisional treatments for breast cancer are considered investigational and should not be performed outside the realm of a clinical trial.

Breast Fibroadenomas

Fibroadenomas of the breast are a common benign tumor, which may be palpated or discovered by imaging techniques. Fibroadenomas are often observed or may be surgically excised if causing concern or discomfort. Cryosurgery has been proposed as a surgical alternative.

The American Society of Breast Surgeons (ASBS, 2018) recommendations for cryoablation or percutaneous excision of fibroadenoma state that the lesion should be sonographically visible, histologically confirmed to be a fibroadenoma, the diagnosis of fibroadenoma must be concordant with the imaging findings, patient history, and physical exam, and the lesions should less than 4 cm in size.

The use of cryosurgery as a treatment for breast fibroadenomas has been reported in small studies (Edwards, 2004; Golatta, 2014; Kaufman, 2002; Kaufman, 2005; Nurko, 2005). Although technical feasibility appears promising, cryoablation has not been conclusively shown to produce health benefits comparable to alternative treatment options.

Pancreatic Cancer

The use of RFA to treat locally advanced pancreatic carcinoma was reported by Giardino and others (2012). This retrospective case series study involved 107 consecutive subjects who were followed for a minimum of 18 months following RFA treatment. Subjects were stratified by whether they received RFA as a first-line treatment (n=47) or as a second-line treatment (n=60). The overall postoperative mortality rate was 1.8%. The overall morbidity rate was 28.0%, of which the abdominal complication rate was 26.1%. Among these, 17.7% were considered RFA-related complications caused by thermal injuries. A temperature > 90°C applied to the tumor was found to be the only independent factor related to complications. The authors reported that the median OS for all subjects was 25.6 months, and 14.7 months for the first-line group and 25.6 months for the second-line group 2. Subjects who received the multimodal treatment had an OS of 34.0 months.

Two additional case series reported on the use of RFA for pancreatic cancers. Cantore (2012) reported RFA treatment of advanced pancreatic carcinoma in 107 subjects. Subjects received either RFA as a primary treatment (n=47) or following another primary therapy (n=60). Median overall survival was reported to be 25.6 months. Median overall survival was significantly shorter in the primary RFA treatment group than in the secondary RFA treatment group (14.7 months versus 25.6 months). Subjects who were treated with RFA, radiochemotherapy, and intra-arterial plus systemic chemotherapy (triple-approach strategy) had a median overall survival of 34.0 months. The authors concluded that RFA after alternative primary treatment was associated with prolonged survival.

Girelli (2013) reported on 100 consecutive subjects with Stage III pancreatic ductal adenocarcinoma who received RFA combined with chemoradiotherapy. RFA treatment was initially given to 48 subjects; 52 subjects had associated palliative surgery. Abdominal complications occurred in 24 subjects, which were RFA related in 15 cases. The reported mortality rate was 3%. At a median follow-up of 12 months, 55 subjects had died of disease and 4 had died due to unknown causes. Another 19 subjects were alive with disease progression, and 22 were alive and progression-free.

The NCCN Pancreatic Cancer Clinical Practice Guideline (V1.2022) recommends surgery for resectable disease. All stages of pancreatic cancer treatment recommend systemic therapy. The NCCN CPG does not include cryosurgical, RFA or laser ablation as a recommended therapeutic modality to treat pancreatic cancer.

Pulmonary Tumors

Cryoablation

Surgical resection is standard initial treatment and is the preferred local treatment for early stage, non-small cell lung cancer (NSCLC) (Lencioni, 2008; NCCN, V3.2022). The choice of surgical procedure depends on the extent of the disease, presence of comorbid conditions, and the individual's cardiopulmonary reserves.

Cryosurgical ablation for the treatment of NSCLC has been studied in a limited number of small studies. Moore and associates (2015) reported on a case series study involving 47 subjects with NSCLC followed for a minimum of 5 years. The 5-year survival rate was 67.8% ± 15.3, the cancer-specific survival rate at 5 years was 56.6% ± 16.5, and the 5-year progression-free survival rate was 87.9%. The combined local and regional recurrence rate was 36.2%. Major complications were reported in 6.4% of subjects, with two cases of hemoptysis and a prolonged placement of a chest tube requiring mechanical sclerosis in 1 subject. No deaths occurred in the first 30 days after treatment. These results are promising, but results from a large, controlled, comparative trials are needed to compare the risks and benefits of cryoablation for NSCLC compared to surgical resection.

The use of cryoablation has also been studied to treat metastatic disease to the lungs. In 2020, Callstrom and associates reported on a prospective, single arm phase 2 study evaluating the safety and local recurrence-free survival of individuals with pulmonary metastases who were treated with cryoablation (n=128). The majority of participants had primary colon cancer (49%, 63/128) or renal cell cancer (12%, 16/128). Individuals could participate with up to 6 tumors and a maximum 3.5 cm size of the targeted index tumor. The majority of participants had 3 or fewer treated tumors (91%, 117/128). Follow-up was performed during the first week post-procedure then at 1, 3, 6, 12, 18 and 24 months. At 12 months follow-up, 89% (114/128) individuals and 90% (202/224) tumors were evaluated. The initial local tumor efficacy was 85.1% (172/202). After initial treatment, a complete response was observed in 14% (16/114) of individuals, 9% (10/114) showed a partial response, 55% (63/114) showed stable disease, and 22% (25/114) showed local treatment failure. A subset of individuals with local treatment failure (11/25) were retreated with cryoablation and reassessed 12 months later. The secondary local tumor efficacy was 91.1% (184/202). At 24 months follow-up on 77.3% (99/128) of the individuals and 80.3% (180/224) of tumors in the group, the initial local tumor efficacy was achieved in 77.2% (139/180; 95% CI: 70.4–83.1). Following retreatment of 3 individuals, the secondary local tumor efficacy was 84.4% (152/180). There were 4.7% (8/169) grade 3 complication events and 0.6% (1/169) grade 4 events. Approximately 26% (44/169) of procedures were associated with pneumothorax that required pleural catheter placement. The single-arm study design does not permit conclusions to be drawn about the relative effectiveness of cryoablation compared to more established treatments.

In 2015, de Baere and colleagues evaluated cryoablation for the treatment of metastatic lung tumors in a prospective case series study involving 40 subjects with 60 treated metastatic lung tumors from a variety of primary origins. The most common origin was colorectal cancer (40%). Follow-up to 12 months was reported for 35 subjects (90%). At 12 months, overall local tumor control was seen in 49 of 52 metastases (94.2%) and 32 of 35 subjects (91.4%). Tumor diameter was not found to be a significant factor in the rate of tumor progression (p=0.41). Additional new treatments were administered to 15 of the 40 subjects (38%). These included systemic treatment (chemotherapy: n=7 and immunotherapy: n=1) and other focal therapies for new metastatic disease (n=10), including six cryoablation procedures. One-year disease-specific survival and OS rates were 100% and 97.5% respectively. Pneumothorax requiring chest tube placement occurred in 9 of the 48 procedures (18.8%). Common Terminology Criteria for Adverse Events (CTCAE) grade 3 adverse events within 30 days of the procedure occurred in 3 of 48 (6%) procedures including a delayed pneumothorax requiring pleurodesis, a thrombosis of a pre-existing hemodialysis access arterio-venous fistula requiring thrombectomy, and a non-cardiac chest pain which spontaneously resolved. No grade 4 or 5 procedure-related adverse events (AEs) occurred. No procedural-related delayed AEs were observed. The design of this study does not allow for conclusions to be drawn about the effectiveness.

The American College of Chest Physicians (ACCP) stated in their 2012 consensus statement on the treatment of stage 1 NSCLC that cryoablation has limited efficacy compared to lobectomy (Donington, 2012). The NCCN Guidelines for NSCLC (V3.2022) discuss thermal ablation as an option for select individuals who do not receive radiotherapy or surgery. In 2022, the NCCN guideline for colon cancer (V.1.2022) added a notation that while resection is preferred over locally ablative procedures, local techniques can be considered for lung oligometastases when all sites are amenable to resection or ablation..

Radiofrequency Ablation

Safi and colleagues (2015) conducted a retrospective nonrandomized controlled study of 116 subjects with histologically proven clinical stage I NSCLC who were treated with sublobar resection (SLR; n=42), RFA (n=25), or radiotherapy (RT; n=49). The SLR subjects were younger and exhibited better performance status, and the RT subjects had larger tumors. After adjusting for age and tumor size, there were differences between the treatments in terms of the primary recurrence rate, but no differences were observed in overall survival or disease-free survival. The hazard ratio (HR) for primary recurrence comparing SLR versus RT adjusted for age and tumor size was 2.73 (95% confidence interval [CI], 0.72-10.27) and for SLR versus RFA was 7.57 (95% CI, 1.94-29.47). The authors concluded that SLR was associated with a higher primary tumor control rate compared to RFA or RT, although the overall survival rates were not different.

Another retrospective nonrandomized controlled trial was reported by Ochiai in 2015. This study involved 48 subjects with single, NSCLC lung tumor treated with RFA versus 47 treated with stereotactic body radiotherapy (SBRT). The mean maximum tumor diameter was 2.0 cm (range 0.6-3.9 cm) in the RFA group, and 2.1 cm (range 0.8-4.7 cm) in the SBRT group. The RFA and SBRT groups showed similar 3-year local tumor progression (9.6%, versus 7.0%) and overall survival rates (86.4% versus 79.6%). No factor significantly affected local tumor progression. A maximum tumor size of 2 cm was identified as a prognostic factor in both univariate and multivariate analyses. There were no deaths related to treatment procedures reported. The rate of Grade 3 AEs was 10.4% (5/48) for the RFA group and 8.5% (4/47) for the SBRT group. The authors concluded that for individuals with lung tumors, lung RFA provided local tumor control and survival that were similar to those achieved using SBRT, with equal safety.

Matsui (2015) reported the results of a retrospective case series of 84 subjects with 172 colorectal lung metastases who underwent RFA. Participants included individuals without (n=71) and with (n=13) viable extrapulmonary recurrences at the time of ablation. During a median follow-up of 37.5 months, 36 subjects (42.9%) died. The estimated overall survival rates were 95.2%, 65.0%, and 51.6% at 1, 3, and 5 years, respectively. Median overall survival time was 67.0 months. Multivariate analysis revealed that a carcinoembryonic antigen (CEA) level of at least 5 ng/mL before RFA and the presence of viable extrapulmonary recurrences at the time of RFA were independent negative prognostic factors. The local tumor progression rate was 14.0% (24/172). Grade 3 AEs were observed after two sessions (1.8%), and no grade 4/5 AEs were observed. The paper concluded that RFA of colorectal lung metastases provided favorable long-term survival with a low incidence of severe AEs. Independent prognostic factors were a high CEA level before RFA and the presence of viable extrapulmonary recurrences at the time of RFA.

Li and associates (2021) published a retrospective analysis of individuals with stage IA NSCLC listed in the Surveillance, Epidemiology, and End Results (SEER) registry. The OS and CSS were compared in individuals treated with SBRT (n=6004) or RFA (n=191) who had not undergone neo-adjuvant chemotherapy. The median OS for RFA was 36 months compared to 35 months for SBRT. The 1-, 3-, and 5-year OS rates were also similar (RFA: 83.3%, 48.5% and 29.1%; SBRT: 83.8%, 48.3% and 27.4%). The RFA median CSS was 62 months compared to SBRT median CSS of 58 months. While the RFA group reported better OS compared to the SBRT group, it was not statistically significant.

A retrospective study completed by Tselikas and colleagues (2021) compared the efficacy of tolerability of RFA and surgery for the treatment of oligometastatic lung disease. The surgical group (n=78) underwent a variety of procedures, including wedge resection (single and multiple), segmentectomy, lobectomy and thoracotomy. The majority of those in the RFA group (n=126) had a single session. The local tumor progression rate in the surgery group compared to the RFA group at 1 year was 5.4% versus 14.8% and 2 years was 10.6% versus 18.6% respectively. A tumor size > 2 cm and number of tumors >3 were independently associated with increased local tumor progression. The pulmonary-progression-free rate for the surgical group compared to the RFA group at 1 year were 60.9% versus 58.1%, at 3 years 43.9% versus 34.7% respectively. The overall survival rate for the surgical group compared to the RFA group at 1 year were 94.8% versus 94.0%, at 3 years 67.2% versus 72% respectively. While the RFA group was older, had more comorbidities and more bilateral lung and extra-pulmonary metastases, there were no differences in overall survival.

Tetta and colleagues (2021) analyzed the median OS and local control of SBRT and RFA in the treatment of lung metastases from soft tissue sarcoma. A total of seven studies were selected for each modality, with approximately equal participants for RFA (n=206) and SBRT (n=218). The median gross tumor volume ranged from 3.0 cm^3 to 5.0 cm^3 in the SBRT group. The RFA group lesion size ranged from 3 mm to 70 mm. The SBRT group median OS was reported in four studies and ranged from 25.2 to 69 months. The RFA group median OS was also only reported in 4 studies varied from 19 to 62 months. The 2-year local control rate in the SBRT studies ranged from 84% to 96.2% compared to 85.6% to 94.5% in the RFA studies. Successful outcomes are associated with the following individual characteristics:

> 1) long DFI (>36 months) between the treatment of the primary tumor and the appearance of metastases; 2) oligometastatic disease (i.e. <3-5 metastases); 3) disease involving only the lung (or small number of extra-thoracic locations); 4) small size nodules (up to 2-3 cm of larger diameter); 5) lesions far away from large vessels.

Surgical resection is still standard of care when the individual is a candidate. For individuals who are not surgical candidates, RFA may be an option in high-risk individuals with lesions less than 3 cm. Treatment in lesions greater than 3 cm may be associated with increased risk of local recurrence and complications.

Ablation can be considered when all sites are amenable to resection or ablation (NCCN, V1.2022). There appears to be no adverse impact on overall or recurrence-free survival in individuals with a history of previously treated extra-pulmonary lesions (Gillams, 2013; Petre, 2012). The presence of active extrapulmonary metastasis is an independent negative prognostic factor (Akhan, 2016; de Baère, 2015; Hiyoshi, 2019; Matsui, 2015; Tetta, 2021;

Tselikas, 2021; Wang, 2015). Matsui and associates (2015) note that viable extrapulmonary disease represents systemic disease and RFA is considered a local treatment. The NCCN CPG for Colon Cancer (V1.2022) notes:

> Resection or ablation (either alone or in combination with resection) should be reserved for patients with metastatic disease that is entirely amendable to local therapy with adequate margins. Use of surgery, ablation, or the combination of both modalities, with the goal of less-than-complete eradication of all known sites of disease is not recommended other than in the scope of a clinical trial.

Soft Tissue Sarcoma

Studies of soft tissue sarcoma RFA treatment include a few small case series (Menendez, 1999; Nakamura, 2009; Palussière, 2011; Saumet, 2015; Tappero, 1991). These studies involved 16 to 29 subjects and provide little generalizable data. A retrospective, non-randomized, controlled study by Falk (2015) involved 281 subjects with oligometastases from sarcomas. Of these, 164 subjects were treated with local ablation therapy and 117 were not. Local therapy was defined as an ablative treatment used with the aim of removing all metastases via surgery, RFA, or radiotherapy. It is unclear how many subjects received RFA, but it was some number less than 35. The purpose was to assess the efficacy of local ablative treatment on the survival of patients with oligometastases from sarcomas. Subjects had one to five lesions at any metastatic site and any grade/histology. Median follow-up was 25.7 months, with 129 (45.9%) deaths observed by the end of the study. Median OS was 45.3 months for the local treatment group and 12.6 for the non-local group. Survival was better among subjects who received local treatment (HR, 0.47; $p<0.001$). Subgroup analyses revealed similar findings in the subjects with single oligometastases (HR, 0.48; $p=0.007$). A significant benefit was observed for grade 3 tumors, and a trend was observed for grade 2 tumors. No survival or other data was provided for the subset of subjects who received RFA, allowing no opportunity to assess the benefit of this approach on its own.

The evidence addressing the use of cryoablation or RFA for the treatment of soft tissue sarcoma is very limited. While the NCCN guideline for soft tissue sarcoma (V1.2022) includes recommendations for RFA or cryoablation, they do not provide citations or a rationale to support this position. Available evidence has not shown the use of RFA or cryoablation for soft tissue sarcoma to be as good as or better than alternative treatment options.

Desmoid Tumor

Desmoid tumors, also known as aggressive fibromatoses, are comprised of well-circumscribed, locally invasive, differentiated fibrous tissue. These tumors rarely metastasize but can invade locally and cause functional morbidity. Although desmoid tumors do not have histopathologic features of true sarcomas, their invasiveness and tendency to recur are similar to the behavior of low-grade sarcomas (NCCN, V1.2022). The NCCN guidelines for soft tissue sarcomas (V1.2022) consider surgery, systemic therapy, ablation or definitive radiotherapy as options to treat desmoid tumors but does not provide citations to support this recommendation. The discussion section of the guidelines does not discuss the use of ablative procedures for desmoid tumors.

In 2020, Vora and colleagues performed a systemic review and meta-analysis of evidence regarding the safety and efficacy of cryotherapy in the treatment of extra-abdominal desmoid tumors. The analysis included nine studies that involved 214 individuals and 234 desmoid tumors treated with 282 cryoablation procedures. The reported minor and major complication rates varied widely among the studies (4.8% - 23.3% and 2.4% - 14.2%; respectively). The progression-free survival was estimated to be 84.5% at 1 year and 78.0% at 3 years. The authors concluded that cryoablation is an appropriate treatment option based on the low complication rate and the durable short to medium term tumor response and symptom relief rate. There were multiple limitations in this meta-analysis including the non-randomized nature of the studies (eight retrospective studies and one phase 2 prospective study), lack of comparison to more established treatments, significant heterogeneity, lack of standardization in reporting outcomes and missing data within studies.

In a retrospective analysis, Mandel and associates (2022) compared treatment of extra-abdominal desmoid tumors with cryoablation (n=22) and surgery (n=33). The purpose of the study was to determine outcomes and prognostic factors in those with primary and recurrent desmoid tumors. The primary comparison endpoints were the local recurrence-free survival (LRFS) after the initial treatment, and disease control after one or more treatments. The median follow-up time was 16.3 months in the cryoablation group and 14.9 months in the surgical group. The median LFRS was 26.6 months in the cryoablation group, the median LFRS was not reached in the surgical group. The 2-year LFRS was 59% (37-94%) in the cryoablation group and 71% (55-90%) in the surgical group. Median disease control was not reached in either group. A total of 2 individuals in the cryoablation group and 7 individuals in the surgical group had uncontrollable local recurrence during follow-up. Repeat cryoablation was performed in 7/22 individuals. There are a number of limitations associated with this retrospective study. The study was small and participant characteristics were limited, reducing the generalizability of the data. The participants did not represent consecutive individuals treated for desmoid tumors during that time. There were differences in therapeutic algorithms and in follow-up protocols within the institution during the study period. Studies with longer follow-up are needed to better evaluate durability.

Surgery was once considered the gold standard treatment of desmoid tumors. More recently, active observation and medical therapy have been used as first line therapy (Mandel, 2022). Data regarding the treatment of desmoid tumors is challenging based upon the unpredictable behavior of these tumors and the high rate of recurrence (Mandel, 2022). Further studies comparing cryoablation to other desmoid tumor treatments with long-term follow-up are needed.

Adrenal Neoplasms or metastases

In 2018, Frenk published the results of a retrospective case series study of image-guided ablations of adrenal metastases measuring less than 5 cm. The study did not include matched controls. The study reported on 51 procedures performed on 46 tumors in 38 subjects. The tumors included renal cell carcinoma (n= 17), metastatic non-small cell lung cancer (n=10), and metastases from other primary malignancies (n=11). Cryoablation was done in 30 subjects, radiofrequency ablation in 12, and microwave ablation in 9. The mean follow-up was 37 months (range, 2-128 months). The authors reported technical success, primary efficacy, and secondary efficacy were 96%, 72%, and 76%. The local progression rate during all follow-up time was 25%. Local tumor progression-free survival at 1, 3, and 5 years was 82%, 69%, and 55%. Overall survival at 1, 3, and 5 years was 82%, 44%, and

34%. In 16 subjects with isolated adrenal metastasis, median disease-free survival was 8 months, with 4 subjects had no evidence of disease during follow-up. The authors noted that lung cancer metastases were associated with decreased survival (HR, 4.41, p=0.002). While the results of this study are promising, the lack of controls and small number of subjects receiving RFA provide insufficient evidence to show that RFA for of adrenal metastases provides benefits similar to or better than other treatments.

Mendiratta and colleagues (2011) evaluated the use of RFA as a primary treatment for symptomatic primary functional adrenal neoplasms. The authors evaluated images and medical records from 13 consecutive individuals with symptomatic functional tumors smaller than 3.2 cm in diameter who underwent RFA over a 7-year period. All participants demonstrated resolution of abnormal biochemical markers after ablation (mean biochemical follow-up, 21.2 months). In addition, all participants experienced resolution of clinical symptoms or syndromes, including hypertension and hypokalemia (in those with aldosteronoma), Cushing syndrome (in the participant with cortisol-secreting tumor), virilizing symptoms (in the participant with testosterone-secreting tumor), and hypertension (in the participant with pheochromocytoma). For those with aldosteronoma, improvements in hypertension management were noted. The study is limited by its retrospective observational design and its small size. Larger studies that include subjects with adenomas and carcinomas are needed further determine the value of RFA in the treatment of functional adrenal tumors.

Yang and colleagues (2016) retrospectively evaluated the safety and efficacy of RFA in 7 individuals with aldosterone-producing adenoma (APA) of the adrenal gland compared to 18 subjects with unilateral adrenal APA treated by laparoscopic adrenalectomy (LA). Tumors in both groups were all smaller than 25 mm in diameter. After 3-6 months of follow-up, complete tumor ablation on follow-up CT scan and normalization of serum aldosterone-to-renin ratio was seen in 100% of the RFA group compared to 94.4% in the LA group. The normalization of the aldosterone-to-renin ratio was statistically equivalent in the RFA and the LA groups. Compared to the LA group, the RFA group demonstrated significantly less post-operative pain (visual analog scale, 2.0 versus 4.22) and shorter operative time (105 min versus 194 min). The authors concluded that CT-guided percutaneous RFA is effective, safe and is a justifiable alternative for individuals who are reluctant or unfit for laparoscopic surgery for the treatment of APA. Larger, prospective, controlled trials are needed to confirm this finding.

In a retrospective study of 63 subjects with APA, Liu and colleagues (2016) evaluated the effectiveness of laparoscopic adrenalectomy (n=27) versus CT-guided percutaneous RFA (n=36). They reported that RFA was associated with significantly shorter duration of operation, shorter hospital stays, lower analgesic requirements, and earlier resumption of work. Morbidity rates were similar in the two groups after a median follow-up of 5-7 years (range 1.9-10.6 years). Resolution of primary aldosteronism was seen in 33 of 36 subjects treated with RFA and in all 27 subjects who had laparoscopic adrenalectomy. Hypertension was resolved less frequently after treatment with RFA compared with laparoscopic adrenalectomy; hypokalaemia was resolved in all subjects. The authors concluded that in this study, RFA was slightly inferior to LA as a treatment of APA.

Overall, the evidence addressing the use of radiofrequency ablation or cryoablation for the treatment of primary and metastatic adrenal tumors is insufficient to show that this approach is equivalent or superior to adrenalectomy. To date, the evidence consists of a limited number of small retrospective studies, only two of which were comparative trials. Additional data regarding these approaches are needed to establish safety and efficacy.

Osteoid Osteoma

Osteomas are benign tumors of the bone typically seen in children and young adults. They cause inflammation, local effects on normal tissue from tumor expansion, and secondary effects and complications (for example, scoliosis or osteoarthritis). Complete removal of the osteoid bone, which forms the nidus of the tumor, must be done in order to provide symptomatic relief and decrease the chance of recurrence (Noordin, 2018). Open excision is the accepted treatment and is generally successful, with the success rate reported at 88-100% and a recurrence rate of 4.5-25% (Tanrıverdi, 2020). However, it is associated with increased risk of fracture, recurrence of larger tumors, and incomplete resection of anatomically inaccessible tumors. RFA has been used as a minimally invasive alternative to the surgical excision. The rate of recurrence of RFA is approximately 5-12% (Tanrıverdi, 2020).

The use of radiofrequency ablation (RFA) has been demonstrated in several case series to be an effective treatment of osteoid osteoma. In the largest case series,126 individuals treated over an 11-year period received complete pain relief in 89% of participants (Rosenthal, 1998). In another study, Rimondi and colleagues (2005) were able to demonstrate an 85% primary success in 82 out of 97 participants. Secondary success was achieved in 15 individuals (15%). There were no treatment related complications. A smaller study by Martel (2005) reported a 97% primary success rate with RFA in 38 individuals. The secondary success rate was 100% in this study. Knudsen and colleagues (2015) reported the results of a case series study involving 52 subjects who underwent CT-guided RFA of osteoid osteomas in the extremities. The response rate after two treatments was 98%, with no major AEs.

Flanigan (2014) reported results of a case series of 28 individuals with osteoid osteoma treated with intraoperative RFA performed by one surgeon. Technical success was reported for all procedures with no intraoperative or post-operative complications. One individual was lost to follow-up and 27 individuals were evaluable at the end of the study period. At the mean follow-up of 31.1 months (range, 5.2-55.8 months), 26 individuals (92.8%) reported complete relief from pain and no evidence of recurrence. There were two recurrences after RFA recorded. One individual had repeat RFA 2 months after the initial treatment, and no recurrence was evident at the close of the study. The second individual was also treated with repeat RFA treatment but was lost to follow-up.

Head and Neck Cancer (HNC)

Owen and colleagues (2011) studied RFA for local control in 21 individuals with recurrent and/or unresectable HNC who failed treatment with surgery, radiation, and/or chemotherapy. Eight of 13 participants had stable disease after intervention. Median survival was 127 days. They concluded that RFA may be a promising palliative treatment alternative for local control and quality of life in those with incurable HNC who have failed standard curative treatment. Further prospective controlled study is needed to confirm this finding.

Thyroid Cancer

Ultrasound-guided RFA for the treatment of thyroid cancer was evaluated in a retrospective nonrandomized controlled study involving 23 subjects with 42 locoregional well-differentiated thyroid carcinomas (Guenette, 2013). Half of the tumors were treated with RFA and the other half with percutaneous ethanol injection (PEI). The use of RFA versus PEI was based on tumor size and location. Technical failure was reported in 1 case in each treatment group, and both were excluded from the analysis. The mean tumor size was 1.5 cm, with a range of 0.5-3.7 cm. Mean follow-up was 61.3 months for the RFA-treated group. No progression was observed in the RFA-treated subjects. After a mean follow-up 38.5 months, disease progression was detected in 5 out of 21 subjects (23.8%) treated with PEI. One AE was reported in the RFA group, with the subjects having permanent vocal cord paralysis. The authors conclude that RFA is a safe and effective option for the treatment of thyroid cancer. Larger, randomized trials are needed to confirm these results.

In 2017, a meta-analysis and systematic review published by Chung and colleagues evaluated safety of RFA in treating benign thyroid nodules and recurrent thyroid cancers. The pooled proportions of overall and major complications reported in eligible studies were reported as the major indices. For the purpose of this study, a major complication is a complication which, if left untreated, might threaten life, lead to substantial morbidity or disability, or result in a lengthened hospital stay. A total of 24 studies were included, with the majority of being retrospective (n=12), but also included prospective (n=9) and an unclear study design (n=3). A total of 89 complications were reported among the 2786 thyroid nodules treated in 2421 individuals. The overall complication rate was 2.38% (95% CI: 1.42%–3.34%; I2 = 21.79%) and a major complication rate of 1.35% (95% CI: 0.89%–1.81%; I2 = 1.24%). The rate of overall complications and major complications was significantly higher in the malignant nodule group compared to the benign nodule group. There were no life-threatening treatment related complications reported. The authors concluded that RFA has an acceptable complication rate associated with the treatment of benign thyroid nodules and recurrent thyroid cancers. The study did not address the efficacy of RFA treatment for these conditions.

The 2015 American Thyroid Association (ATA) guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer notes that RFA might be most useful in high-risk individuals with recurrent thyroid cancer or in individuals who refuse additional surgery. The ATA does not recommend RFA as a standard alternative to surgical resection. The ATA includes the following recommendations regarding advanced thyroid cancer:

(A) Both stereotactic radiation and thermal ablation (RFA and cryoablation) show a high efficacy in treating individual distant metastases with relatively few side effects and may be considered as valid alternatives to surgery. (Weak recommendation, Moderate-quality evidence)
(B) Stereotactic radiation or thermal ablation should be considered prior to initiation of systemic treatment when the individual distant metastases are symptomatic or at high risk of local complications. (Strong recommendation, Moderate-quality evidence)

The 2015 ATA recommendations are based upon more robust evidence located in other solid tumor trials. The authors note that the clinical evidence is limited regarding thermal ablation to treat thyroid cancer. Randomized prospective trials comparing specific techniques are also lacking.

In 2022, The American Association of Clinical Endocrinology Clinical Practice Guidelines Oversight Committee reviewed the evidence regarding the use of minimally invasive thyroid techniques to treat thyroid nodules and well-differentiated thyroid cancers. While ablative procedures to treat thyroid benign and malignant lesions is more prevalent in Asia and Europe, these procedures are not currently endorsed by most U.S medical societies due to a paucity of quality data, particularly data regarding the rate of recurrence. The authors concluded:

> Despite the increasing use of nonsurgical procedures in the management of thyroid nodules and cancer, there continues to be a need for high-quality, large prospective studies and/or randomized controlled trials, as knowledge gaps remain.

An international multidisciplinary consensus statement by multiple societies, including the American Head and Neck Society-Endocrine Surgery section provided best practice recommendations regarding radiofrequency and related ultrasound guided ablation procedures to treat benign and malignant thyroid disease (Orloff, 2022). These guidelines note that US guided ablation procedures may be considered in individuals with suitable recurrent papillary thyroid carcinoma who are not a candidate for or decline surgery or active surveillance. These recommendations were based on international guidelines and prospective or retrospective studies with limited follow-up. The authors concluded that RFA to treat primary thyroid cancer is a developing application (Orloff, 2022).

The American Association of Clinical Endocrinologists (AACE), American College of Endocrinology (ACE), and Associazione Medici Endocrinologi (AME) guideline on the diagnosis and management of thyroid nodules (2016) recommends classifying nodules into 5 categories: nondiagnostic, benign, indeterminate, suspicious for malignancy, or malignant based upon the results of fine needle aspiration cytology. Benign asymptomatic thyroid nodules require no treatment; for nodules categorized as high-risk indeterminate lesions suspicious nodules surgery is recommended.

The NCCN guidelines for thyroid cancer (V1.2022) notes that local therapies may be considered in select individuals with limited burden nodal disease, but do not provide any clinical studies to support that recommendation.

Benign Thyroid Nodules

The increase in the diagnosis of benign thyroid nodules has been linked to an increased used of diagnostic imaging. Nodules are present in an estimated 20% to 76% of the population (Chen, 2016). More than 90% of nodules are clinically insignificant benign lesions and the vast majority of these nodules will not be associated with a significant size change (Durante, 2015). The American Thyroid Association (ATA) 2015 guidelines for the management of thyroid nodules and differentiated thyroid cancer recommends that asymptomatic nodules with no or modest growth should be monitored, but do not require intervention. The ATA recommends surgery or percutaneous ethanol injection for nodules which are greater than 4 cm, those causing compression or for individuals with structural symptoms or other clinical concerns.

The 2022 international consensus statement document (Orloff) includes a recommendation that ablation procedures may be used as a first-line alternative to surgery in individuals with benign thyroid nodules. This recommendation is based upon individual international guideline documents. The document notes that thermal ablation procedures can be a safe alternative to treat autonomously functional thyroid nodules (AFTN) in individuals with contraindications to first-line therapies. This recommendation is based upon prospective study of 30 individuals and a meta-analysis which the authors. The meta-analysis was limited the quality of the studies (prospective or retrospective with short term follow-up) and heterogeneity. The authors concluded that further studies, ideally RCTs with long follow-up, are needed to "extend the use of RFA as an option to cure patients with AFTN/toxic thyroid nodules (TTN).

Radiofrequency Ablation

In a systematic review and meta-analysis, Chen and colleagues (2016) reported on the efficacy of RFA for the treatment of benign thyroid nodules. The study included 20 articles reporting care for 1090 individuals. Several indicators of procedure success, including nodal volume, largest lesion diameter, symptom score and cosmetic score showed improvement following 1, 3, 6, and 12 months through last follow-up. The authors noted significant heterogeneity and study design, variations in diagnostic criteria, small study sample sizes, and the possibility that publication bias may have influenced the results.

Bernardi and associates (2014) retrospectively compared the efficacy and tolerability of RFA to hemithyroidectomy for the treatment of benign thyroid nodules. The clinical outcomes of individuals who underwent RFA was compared to 74 individuals who underwent thyroid surgery. RFA was noted to shrink nodules by 70% with results maintained up to 4 years following surgery. In these cases, surgery was found to be more effective in treating nodules with an initial volume of greater than 35 mil and in autonomously functions nodules. Surgery also allows for pathology testing to be done following the procedure.

Laser Ablation

Døssing and colleagues (2019) reported on the long-term efficacy of laser therapy to treat benign complex thyroid nodules. Individuals with recurrent cytologically benign cystic thyroid nodules causing local discomfort were treated with laser therapy. Follow-up was completed at 1, 3 and 6 months after treatment, then annually. Following laser therapy, 17% (19/110) underwent surgery due to dissatisfaction with the laser ablation results. The median follow-up in the nonsurgical group was 45 months (12-134 months). In the individuals who did not undergo surgery, the overall median nodule volume decreased by 85% over the course of follow-up.

In a retrospective review, Pacella and colleagues (2015) reported on the effectiveness, tolerability, and complications associated with laser ablation therapy. Consecutive individuals with solid or mixed nodules treated with laser ablation were included (n=1531). The mean nodule volume reduction was 72% ±11% (range 48%–96%) at 12 months after treatment. The authors reported 17 complications, 8 of them categorized as major and 9 categorized as minor. Larger prospective studies comparing laser ablation to standard surgery are needed to establish conclusions about the relative effects of laser treatment.

Central Nervous System

The mainstays of brain tumor treatment have been surgical resection, stereotactic radiosurgery (SRS), whole-brain radiotherapy and systemic therapies. Stereotactic laser ablation (SLA), also known as laser interstitial thermotherapy (LITT). has been proposed as an alternative for individuals with glioblastoma because it is a minimally invasive procedure with precise focal tissue destruction.

Rennert and associates (2020) reported initial data from an industry-sponsored multi-institutional international prospective observational registry. Individuals with primary intracranial tumors or brain metastases were prospectively enrolled in the Laser Ablation of Abnormal Neurological Tissue (LAANTERN) registry. Of the initial 100 registrants, 48% had primary intracranial tumors and 34% had brain metastases. The remainder of the participants were treated for other indications including epilepsy. Over 90% of the lesion was ablated in 72% of the treated lesions. There were 11 AEs reported at 1-month post-procedure, 5 AEs were related to the energy deposition from laser ablation and 4 AEs were related to surgical manipulation. Kim and associates (2020) reported 12 -month outcomes of the LAANTERN study for 92 individuals with metastatic tumors who had a total of 131 primary tumors. The estimated 1-year survival rate was 73% (95% CI: 65.3% to 79.2%). There were no observed significant differences between individuals with primary or metastatic tumors. The Karnofsky Performance Score (KPS) declined significantly between baseline and 12 months. There was no significant difference between the individuals with primary and metastatic tumors. The limited amount of currently available information does not allow for oncologic outcomes to be adequately assessed.

A common shortcoming of a prospective registry is limited data availability due to underreported or missing data. In the LAANTERN study, there were reports of cases of excessive blood loss and prolonged intensive care stays. The clinical situation of these serious complications were not explained, leaving researchers with no clinical context in which to evaluate these events (Ginalis, 2020).

The Laser Ablation After Stereotactic Radiosurgery (LAASR) study is a multicenter prospective study by Ahluwalia and colleagues (2020) that evaluated the local progression-free survival in individuals treated with LITT. Individuals with brain metastases and radiographic progression following stereotactic radiosurgery were eligible for the study (n=42). The primary outcome was local progression-free survival. Only 64% (27/42) of participants were available through the 12-week follow-up and 38% (16/42) were available through the 26-week follow-up. At 12 weeks post-procedure, 15% of the treated lesions were stable, 22% had a partial response and 37% had a complete response. A portion of the participants (26%) continued to progress throughout the follow-up. The overall survival of the 42 participants was 86.5% at 12 weeks and 72.2% at 26 weeks. During the study period, 35 (83.3%) of the 42 participants experienced an adverse event. The quality of the data reported by this study was limited by the high attrition rate and the short-term follow-up. The authors questioned whether the study group was reflective of the clinical population, citing the paucity of individuals receiving systemic chemotherapy at the time of tumor regrowth. The authors noted that "Larger studies with longer follow-up and comparison with the natural history of lesions in untreated patients are needed to elucidate which factors may best predict improved outcomes after LITT and the timing of consolidative therapy."

In a retrospective study of consecutive individuals treated with LITT, Bastos and colleagues (2020) evaluated the predictive factors related to local recurrence following ablation. The authors reviewed medical records of 61 consecutive individuals with brain metastases treated with LITT. The lesions included recurrence (n=46), radiation necrosis (n=31) and newly diagnosed tumors (n=5). The time from LITT to local recurrence or last follow-up was used as the primary outcome. The final analysis included 59 individuals and 80 lesions. The local recurrence rate at

6 months was 69.6%, 59.4% at 12 months and 54.7% at 18 and 24 months. Clinical factors affecting time to recurrence were extent of lesion ablation, size of lesion, tumor type, presence and timing of systemic treatment. The median overall survival was 29 months. The overall complication rate was 26.2%. There was one fatal complication reported.

Sujijantarat and associates (2020) reviewed the charts of individuals with brain metastasis who were previously treated with radiation, developed radiation necrosis and were subsequently treated with LITT (n=25) and bevacizumab (n=13). Several individuals who were initially treated with LITT also received bevacizumab. The outcomes for these individuals were assigned to their original treatment group. The median progression-free survival in the LITT group was 12.1 months (range 0–64.6 months) and 2.0 months (range 0–22.2 months) in the bevacizumab group. The median survival was 24.8 months in the LITT group compared to 15.2 months in the bevacizumab group. The authors theorized that the differences in progression-free survival were likely due to an uneven distribution of individuals and lesions within each group. Characteristics of individuals in the bevacizumab group suggest that these individuals were sicker. The authors concluded "Given the significant differences between the cohorts, these findings need to be confirmed in a larger and perhaps randomized study."
In 2020, de Franca and colleagues compared the clinical outcomes of SRS and LITT to treat brain metastasis or recurrent glioblastoma multiforme. The meta-analysis included 4 studies regarding LITT, and 21 studies regarding SRS. The total number of participants in each treatment group varied greatly (SRS=1787; LITT=39). The median OS was significantly longer in the LITT group compared to the SRS group (12.8 [9.3-16.3] months versus 9.8 [8.3-9.8] months; p = 0.02) respectively. Limitations of this study include high heterogeneity due to methodological and clinical diversity within the groups. The very small number of individuals in the LITT group does not allow for conclusions regarding treatment efficacy to be made.

In an exploratory cohort series, Shah and associates (2020) reported on the cases of individuals with newly diagnosed and treatment refractory brain tumors treated with LITT. Study investigators followed 91 individuals who underwent 100 procedures. The authors reported the average extent of ablation (EOA), median time to recurrence (TTR), local control rates at 1-year follow-up, and median overall survival (OS) as the primary outcome measures. The overall median EOA was 99.5% (IQR 83.5%-100.0%) and did not differ between tumor subtypes. The median TTR was 31.9 months, and the median OS was 16.9 months. Complications occurred in 4% of the cases and included superficial wound infections, seizures and transient facial palsy, all of which were transient. The median follow-up on this retrospective case series is limited to 7.2 months. The authors note that while this was adequate to detect perioperative complications and same-site recurrence, follow-up may not have been adequate to detect longer term complications and disease progression events. The study design does not permit conclusions to be drawn about the effects of LITT compared to more established treatments.

In 2021, the NCCN central nervous system cancers CPG added a 2B recommendation for MRI-guided laser interstitial thermal therapy. The guidelines note that LITT may be considered in those with relapsed brain metastases and radiation necrosis who are not surgical candidates. While the results of LITT studies are promising, there is not a recognized standard LITT protocol establishing the best use of this modality (de Franca, 2020). While laser therapy has proposed benefits, including the ability to access difficult to reach lesions with minimal damage to surrounding tissue and the ability of laser therapy to affect changes which enhance adjuvant therapies, the studies have generally been limited by lack of control groups, non-randomized design, small sample size and short follow-up periods.

Definitions

Ablation: The destruction of a body part or tissue or its function. Ablation may be achieved by surgery, hormones, drugs, radiofrequency, heat, or other methods.

Cryosurgical ablation (cryotherapy or cryoablation): A surgical procedure where cancerous or diseased cells are destroyed using extreme cold.

Metastasis: The spread of cancer from one part of the body to another. A metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Osteoid osteoma: A benign skeletal tumor of unknown etiology that can occur in any bone.

Overall survival (OS): The length of time between disease diagnosis or start of treatment for disease, that the individual is still alive.

Progression free survival (PFS): The length of time following treatment that the individual lives with the stable disease (disease does not worsen).

Radiofrequency ablation (RFA): A surgical procedure where cancerous or diseased cells are destroyed using heat produced by high-frequency radio waves.

Recurrence free survival (RFS): The length of time following the end of the primary treatment that the individual does not have any signs or symptoms of the disease. Also known as relapse-free survival or disease-free survival.

Renal insufficiency: Impaired kidney function which can be identified and monitored by laboratory testing, such as urine albumin, glomerular filtration rate and creatinine. Glomerular Filtration Rates calculators can be located at: https://www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-management/kidney-disease/laboratory-evaluation/glomerular-filtration-rate-calculators.

Solid tumors: Tumors that appear in body tissues other than blood, bone marrow, or the lymphatic system; examples include tumors of the liver, lung, or colon.

Tumor: An abnormal mass of tissue that results from excessive cell division that is uncontrolled and progressive, also called a neoplasm.

Unresectable: Refers to a tumor that cannot safely be removed surgically due to size or location.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	05/12/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised title from *Cryosurgical or Radiofrequency Ablation to Treat Solid Tumors Outside the Liver* to *Cryosurgical, Radiofrequency or Laser Ablation to Treat Solid Tumors Outside the Liver*. Removed the reference to glomerular filtration rate from the radiofrequency and cryosurgical ablation treatment of renal cancer. Added the term "metastatic" to the radiofrequency ablation treatment of metastatic lung cancer to clarify extra-pulmonary disease. Added not medically necessary statement for laser ablation therapy. Removed examples from the cryosurgical and radiofrequency ablation not medically necessary statements. Updated Description, Discussion, Definitions and References sections. Updated Coding section; added codes 61736, 61737, 0673T and 60699 NOC.
Reviewed	05/13/2021	MPTAC review. Updated Discussion, Definitions, References and Websites sections. Reformatted Coding section.
Reviewed	05/14/2020	MPTAC review. Updated Discussion, References and Websites sections.
Revised	11/07/2019	MPTAC review. Moved content from CG-SURG-62 Radiofrequency Ablation to Treat Tumors Outside the Liver into this guideline. Revised title from *Cryosurgical Ablation of Solid Tumors Outside the Liver* to *Cryosurgical or*

		Radiofrequency Ablation to Treat Solid Tumors Outside the Liver. Updated Coding section with radiofrequency ablation coding and 01/01/2020 CPT changes; added 0581T.
Reviewed	11/08/2018	MPTAC review.
Reviewed	10/31/2018	Hematology/Oncology Subcommittee review. Updated Rationale and References sections. Updated Coding section with ICD-10-PCS codes 0B5K3ZZ, 0B5L3ZZ, 0B5M3ZZ.
New	11/02/2017	MPTAC review.
New	11/01/2017	Hematology/Oncology Subcommittee review. Initial document development. Moved content of SURG.00025 Cryosurgical Ablation of Solid Tumors Outside the Liver to new clinical utilization management guideline document with the same title. Updated Rationale section. Updated Coding section with 01/01/2018 CPT changes; removed 0340T deleted 12/31/2017.