# Clinical UM Guideline

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| **Subject:** | Cryosurgical, Radiofrequency, Microwave or Laser Ablation to Treat Solid Tumors Outside the Liver | | |
| **Guideline #:** | CG-SURG-61 | **Publish Date:** | 01/30/2025 |
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## Description

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

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

**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.

**Note:** This document does not address treatment for benign prostatic hypertrophy (BPH). For criteria related to BPH treatment, refer to applicable guidelines used by the plan.

**Note:** For additional information, see the following:

- CG-MED-81 Ultrasound Ablation for Oncologic Indications
- CG-SURG-78 Locoregional Techniques for Treating Primary and Metastatic Liver Malignancies
- CG-SURG-101 Ablative Techniques as a Treatment for Barrett's Esophagus
- SURG.00159 Focal Laser Ablation for the Treatment of Prostate Cancer

## Clinical Indications

**Medically Necessary:**

*Prostate Cancer*

Whole-gland cryosurgical ablation of the prostate is considered **medically necessary** as a treatment of prostate cancer.

*Non-small cell lung cancer (NSCLC)*

Thermal ablation (radiofrequency ablation, cryoablation or microwave ablation) of 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.

*Tumor(s) that have metastasized to the lung*

Thermal ablation (radiofrequency ablation, cryoablation or microwave ablation) of malignant tumor(s) that have metastasized to the lung is considered **medically necessary** when *all* of the following criteria are met:

1. Surgical or radiation treatment is considered appropriate based on stage of disease, however medical co-morbidity renders the individual unfit for those interventions; **and**
2. There is no current active extra-pulmonary metastatic disease; **and**
3. There are no more than 3 tumors per lung; **and**
4. No tumor has a maximum diameter greater than 3.0 cm; **and**
5. Tumors are located at least 1 cm from the trachea, main bronchi, esophagus, aorta, aortic arch branches, pulmonary artery and the heart.

*Osteoid osteomas*

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

*Bone metastases*

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.

*Renal malignancy*

Radiofrequency ablation or cryoablation 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.

**Not Medically Necessary:**

Focal cryosurgical ablation of prostate tumors is considered **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.

Thermal ablation (radiofrequency ablation, cryoablation, or microwave 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**

| | |
|---|---|
| 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 |
| 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 |

**HCPCS**

| | |
|---|---|
| C9751 | Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS)-guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic interventions |

**ICD-10 Procedure**

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

**ICD-10 Diagnosis**

All diagnoses

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

*Prostate:*
**When services may be Medically Necessary when criteria are met:**

**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 |

**When services not Medically Necessary:**
For the procedure and diagnosis codes listed above when criteria are not met and for the following procedure

| **CPT** | |
|---|---|
| 53850 | Transurethral destruction of prostate tissue; by microwave thermotherapy |
| 53852 | Transurethral destruction of prostate tissue; by radiofrequency thermotherapy |

| **ICD-10 Procedure** | |
|---|---|
| | For the following codes when specified as radiofrequency or microwave thermotherapy: |
| 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 |
| 19499 | Unlisted procedure, breast [when specified as radiofrequency or microwave ablation or laser ablation of breast tumor(s)] |
| 48999 | Unlisted procedure, pancreas [when specified as cryosurgical, radiofrequency, microwave or laser ablation of pancreas tumor(s)] |
| 60660 | Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency |
| 60661 | Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging guidance, radiofrequency |
| 60699 | Unlisted procedure, endocrine system [when specified as cryosurgical, laser, radiofrequency or microwave ablation of adrenal tumor(s), cryosurgical or microwave ablation of thyroid tumor(s)] |
| 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, microwave or laser ablation] |
| 0G5G0Z3-0G5H4Z3 | Destruction of thyroid gland lobe using laser interstitial thermal therapy [left or right lobe, by approach; includes codes 0G5G0Z3, 0G5G3Z3, 0G5G4Z3, 0G5H0Z3, 0G5H3Z3, 0G5H4Z3] |
| 0G5K0Z3-0G5K4Z3 | Destruction of thyroid gland using laser interstitial thermal therapy [by approach; includes codes 0G5K0Z3, 0G5K3Z3, 0G5K4Z3] |

| **ICD-10 Diagnosis** | |
|---|---|
| | All diagnoses |

**When services are also Not Medically Necessary:**

**CPT**

| | |
|---|---|
| 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 |

**ICD-10-Procedure**

| | |
|---|---|
| 00500Z3-00504Z3 | Destruction of brain using laser interstitial thermal therapy [by approach, includes 00500Z3, 00503Z3, 00504Z3] |

**ICD-10 Diagnosis**

| | |
|---|---|
| C70.0 | Malignant neoplasm of cerebral meninges |
| C71.0-C71.9 | Malignant neoplasm of brain |
| C79.31-C79.32 | Secondary malignant neoplasm of brain and cerebral meninges |
| D32.0 | Benign neoplasm of cerebral meninges |
| D33.0-D33.2 | Benign neoplasm of brain |

## Discussion/General Information

***Background/Overview***

Cryosurgery, also called cryotherapy or cryoablation, uses extreme cold to destroy abnormal tissue. When cryosurgery is used, a coolant such as liquid nitrogen or argon gas is circulated through a cryoprobe that is placed in contact with the tumor. Imaging guidance is typically used to guide placement of the cryoprobe into the tumor and to monitor therapy. During cryosurgery, a ball of ice crystals forms around the probe within the tumor, killing surrounding tissue. 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. Treatment may involve the use of more than one probe within a 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 fluid amount 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 or the focal destruction of targeted lesions.

Whole gland cryosurgical ablation is considered a safe and effective treatment for prostate cancer. Several small observational trials have shown complication rates similar 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. Cryotherapy has provided excellent cancer control when used to treat individuals with radiation-resistant/recurrent prostate cancer and in individuals with localized prostate cancer (Tan, 2022; Tan, 2023b).

The National Comprehensive Cancer Network® (NCCN) Clinical Practice Guideline® (CPG) for Prostate Cancer (V4.2024) 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.

Focal cryoablation for prostate cancer is an emerging technique proposed as a technique to target the tumor while avoiding damage to surrounding healthy tissue. This targeted approach may minimize common side effects such as urinary continence, sexual dysfunction, and bowel-related side effects. Success of the focal therapy is based on the destruction of clinically significant prostate cancer tissue. Initial results are promising, with early oncologic outcomes similar to whole gland cryoablation and complications improved over radical therapies. However, further study is needed to understand the long-term outcomes of focal cryoablation as a treatment for prostate cancer (Aker, 2023; Chin, 2022; Marra, 2022; Shah, 2019; Ward, 2012).

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

***Renal Cell Carcinoma and Other Renal Tumors***

In 2023, approximately 81,800 new cases of kidney cancer will be diagnosed and 14,890 deaths will occur from the disease (American Cancer Society, 2023). 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%. The treatment goal of RCC includes the complete resection or ablation of the lesion with a minimal decrease in renal function (Yanagisawa, 2022). For those individuals with limited disease, ablative techniques provide an alternative tissue-sparing treatment.

Yanagisawa and colleagues (2022) published a systematic review and meta-analysis comparing clinical outcomes of individuals with cT1a and cT1b renal tumors who underwent partial nephrectomy (PN) or ablative therapy (radiofrequency ablation, cryoablation or microwave ablation). A total of 27 studies were included in the meta-analysis. The meta-analysis showed no difference in the overall complication rate or the severe complication rate between PN and ablative therapy in either tumor group. The analysis found a higher combined recurrence rate for individuals with cT1a and cT1b renal tumors who underwent ablative therapy compared to PN. However, individuals with cT1a tumors who underwent ablative therapy did not have a significant difference in the recurrence rate when compared to PN. The recurrence rate in the cT1b group remained elevated compared to PN regardless of the ablative therapy approach. The authors concluded that ablative therapy was an acceptable alternative to PN in cT1 renal tumors, particularly when the percutaneous approach was used.

In a multicenter retrospective review outcomes from a national database using a 1:1 propensity-score-matched analysis, Cazalas and associates (2023) evaluated perioperative and recurrence outcomes of T1b (4.1-7.0 cm) renal cell cancer tumor treatment. The outcomes of individuals who had undergone percutaneous thermal ablation (cryoablation, RFA or microwave ablation) were compared to the outcomes of individuals who were treated with robotic-assisted partial nephrectomy (n=75 in each group). The local recurrence rate was significantly higher in the thermal ablation group compared to the surgical group (14.6% vs. 4%, p=0.02). There was no significant difference between the groups in terms of metastases, eGFR decrease, and length of hospitalization stay. Type of treatment was the only predictive factor identified. An individual in the thermal ablation group who underwent a second thermal ablation session was later diagnosed with inoperable tumor seeding along the cryo-needle tract which required systemic treatment. Additional studies would be needed to further evaluate whether thermal ablation has a role in the treatment of renal tumors greater than 4 cm.

A larger nonrandomized comparative study investigating outcomes for 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 probabilities of 5-year recurrence-free survival (RFS) were 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.

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 NCCN CPG for Kidney Cancer (V1.2025) recognizes 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 options for individuals with stage 1 (T1a) renal disease because higher rates of local recurrence or persistent disease is reported in individuals with masses greater than 3 cm who undergo ablative therapy.

A 2021 American Urological Association (AUA) guideline addressing renal masses 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 can be 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 American Society of Clinical Oncology (ASCO) (Finelli, 2017) reviewed 83 studies to develop recommendations for the management of individuals with small renal masses (SRMs; renal tumors ≤ 4 cm). ASCO notes that partial nephrectomy is considered the standard treatment for small renal masses, but also includes the following recommendation:

> Recommendation 3.2: Percutaneous thermal ablation should be considered an option for patients who possess tumors such that complete ablation will be achieved. A biopsy should be obtained before or at the time of ablation (type: evidence based; evidence quality: intermediate; strength of recommendation: moderate).

ASCO authors note that the quality of evidence is limited by its observational and retrospective nature, but thermal ablation appears to lead to improved perioperative outcomes and preserved renal function compared to surgical options. Thermal ablation should be reserved for carefully selected and counseled individuals in order to maximize clinical outcomes. ASCO summarizes by noting:

> The historical notion that ablation should be limited to unfit and vulnerable patients with SRMs who are rejected for surgical intervention should be discouraged because, as described above, those patients may be better served with active surveillance.

The available medical literature indicates that cryoablation and RFA are safe and effective for managing small, undefined peripheral renal masses (less than 4 cm). Ablative techniques are associated with better renal function preservation and a lower complication rate than surgical techniques. Ablative techniques are also associated with a higher recurrence rate and lower efficacy in larger tumors that might require multiple treatments, although some studies have not reported a similar recurrence rate in smaller renal tumors (Breen, 2013; Buy, 2013; Emara, 2014; Haramis, 2012; Panumatrassamee, 2013; Sung, 2012; Tanagho, 2013; Yanagisawa, 2022). Published studies demonstrate similar outcomes in cryosurgery and RFA therapies (Atwell, 2013; Caputo, 2016; El Dib, 2012). The risks and benefits of thermal ablation in renal tumors 4 cm or smaller need to be considered based upon individual circumstances.

***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, bone metastases pain 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 an alternative to the previously referenced therapies 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 participants who underwent 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 participants 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 CPG for cancer pain (V2.2024) 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. While cryotherapy does not appear to result in lower levels of pain, RFA does appear to provide palliation in individuals with intractable painful bone metastases.

***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 CPG (V4.2024) lists a variety of breast cancer treatment modalities, including surgery, radiotherapy, chemotherapy, endocrine therapy, biologic therapy. These treatments 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 recommended treatments for 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 common benign tumors that 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 and 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 studies with limited participants (Edwards, 2004; Golatta, 2014; Hahn, 2013; Kaufman, 2002; Kaufman, 2005; Nurko, 2005; Ward, 2019). Although cryosurgery appears to be technical feasible, 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 participants who were followed for a minimum of 18 months after RFA treatment. Participants 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 participants was 25.6 months; 14.7 months for the first-line group and 25.6 months for the second-line group. Participants 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 participants. Participants received either RFA as a primary treatment (n=47) or following another primary therapy (n=60). Median OS was reported to be 25.6 months. Median OS was significantly shorter in the primary RFA treatment group than in the secondary RFA treatment group (14.7 months versus 25.6 months). Participants who were treated with RFA, radiochemotherapy, and intra-arterial plus systemic chemotherapy (triple-approach strategy) had a median OS of 34.0 months. The authors concluded that RFA after alternative primary treatment was associated with prolonged survival.

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

The NCCN Pancreatic Cancer CPG (V2.2024) recommends surgery for resectable disease. All stages of pancreatic cancer treatment recommend systemic therapy. The NCCN CPG does not include cryosurgery, RFA or laser ablation as a recommended therapeutic modality to treat pancreatic cancer.

***Pulmonary Tumors***

Surgical resection is standard initial treatment and is the preferred local treatment for early-stage non-small cell lung cancer (NSCLC) (Lencioni, 2008; Macchi, 2017; NCCN, V7.2024). Surgical resection is an option in approximately 20% of cases (Macchi, 2017). For individuals with NSCLC who are not candidates for surgery or radiotherapy, image-guided thermal ablation therapy (IGTA) is an option (NSCLC; V7.2024). IGTA includes cryotherapy, microwave and radiofrequency therapies. IGTA is recommended for individuals with lesions less than 3 cm in size. Larger lesions are associated with higher local recurrence and complications rates. The choice of energy modality is based upon several factors including but not limited to the size and location of the target tumor, availability of equipment, and operator expertise. When tumors have metastasized to the lungs from other regions, ablative techniques can be considered when the tumors are unresectable and amenable to complete ablation (NCCN Colon Cancer, V4.2024).

*Cryoablation*

Moore and associates (2015) reported on a case series study involving 47 participants 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 participants, 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.

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.

In 2015, de Baere and colleagues evaluated cryoablation for the treatment of metastatic lung tumors in a prospective case series study involving 40 participants with 60 treated metastatic lung tumors from a variety of primary origins (ECLIPSE). The most common origin was colorectal cancer (40%). Follow-up to 12 months was reported for 35 participants (90%). At 12 months, overall local tumor control was seen in 49 of 52 metastases (94.2%) and 32 of 35 participants (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 participants (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 (AEs) 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 AEs occurred. No procedural-related delayed AEs were observed.

In 2021, de Baere and colleagues reported on the 5-year outcomes of the ECLIPSE study. At 3 years, the reported local tumor control rate per index tumor was 87.9% (29/33). At 5 years, the reported local tumor control rate per index tumor was 79.2% (19/24). At 5 years, 50% of participants (20/40) had died, with 15 cases attributed to documented lung disease progression within the lung. The OS rate at 3 years was 63.2% and 46.7% at

5 years.

*Radiofrequency Ablation*

Safi and colleagues (2015) conducted a retrospective nonrandomized controlled study of 116 participants 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 participants were younger and exhibited better performance status, and the RT participants 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 OS 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 OS rates were not different.

Another retrospective nonrandomized controlled trial was reported by Ochiai in 2015. This study involved 48 participants with a 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 OS 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 treatment related deaths 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 participants 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 participants (42.9%) died. The estimated OS rates were 95.2%, 65.0%, and 51.6% at 1, 3, and 5 years, respectively. Median OS 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 OS 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 OS.

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.

Ablation can be considered when all sites are amenable to resection or ablation (NCCN, V7.2024). 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 (V4.2024) 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.

*Microwave ablation*

Compared to radiofrequency ablation, microwave ablation has the ability to generate higher ablation temperatures over a larger heating radius in a shorter time period. This is particularly important in the lung, which is a poor conductor of heat (Tan, 2023).

In 2023, Tan and colleagues conducted a systematic review evaluating the long-term efficacy of microwave ablation to treat pulmonary metastases from colorectal cancer in those who are not candidates for pulmonary metastatectomy. A total of 8 retrospective studies with a total of 230 participants were included. Post ablation survival was reported to be 89.2% at one year was 89.2% and 40.3% at 3 years. Disease free survival at 3 years was 43.2%. The authors noted that, while radiofrequency ablation has a favorable overall survival (OS) rate and safety profile compared to microwave ablation, the techniques are comparable in terms of local recurrence rate and disease-free survival.

In a 2017 randomized, controlled trial (RCT), Macchi and colleagues evaluated the effectiveness of radiofrequency ablation and microwave ablation in treating lung tumors. Individuals with stage IV disease who were not surgical candidates were randomized to receive microwave ablation (n=24) or radiofrequency ablation (n=28). The mean baseline tumor size prior to treatment was 1.90 ± 0.89 cm. At 12 months, post treatment, the microwave ablation group showed a significant decrease in mass compared to baseline. There were no significant differences in survival times between the groups. The microwave ablation group reported less intraprocedural pain.

A number of published studies compared the outcomes of cryotherapy, radiofrequency ablation and microwave ablation therapy used in the treatment of pulmonary tumors. Microwave ablation has performed similarly in terms of complication and local control and OS rates (Bourgouin, 2022; Jiang, 2018; Kurilova, 2018; Nguyenhuy, 2022; Yuan, 2019).

The 2021 Society of Interventional Radiology (SIR) standards of practice on percutaneous ablation of NSCLC and metastatic disease of the lungs addresses IGTA as a treatment of early-stage NSCLC (stage I), recurrent lung cancer, and metastatic disease to the lungs. SIR recommendations regarding IGTA include:

1. In patients with stage IA NSCLC, image-guided thermal ablation is a safe and effective treatment with minimal complications and acceptable long-term oncological and survival outcomes that are comparable to SBRT and sublobar resection. (Level of Evidence, C; Strength of Recommendation, Moderate)
2. Image-guided thermal ablation is a safe and effective treatment option for patients with recurrent NSCLC. (Level of Evidence, C; Strength of Recommendation, Moderate)

3. Thermal ablation should be considered alongside surgical resection and SBRT in patients who require preservation of lung parenchyma function. (Level of Evidence, C; Strength of Recommendation, Moderate)
4. Image-guided thermal ablation of metastatic disease to the lungs may be appropriate in some patients, including those with a limited number of small (≤3 cm) lung metastases. (Level of Evidence, C; Strength of Recommendation, Weak)
5. RFA, CA, and MWA are all appropriate modalities for image-guided thermal ablation of primary or secondary lung tumors. The method of ablation should be determined by lesion characteristics and risk mitigation and should be left to the discretion of the operating physician. (Level of Evidence, C; Strength of Recommendation, Weak).
7. Future research in the form of comparative studies (either randomized controlled trials or well-conducted cohort studies) is required to strengthen the evidence base for image-guided thermal ablation in patients with inoperable stage I NSCLC, recurrent NSCLC, and metastatic lung disease. (Level of Evidence, E; Strength of Recommendation, Moderate).

***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 participants and provide little generalizable data. A retrospective, non-randomized, controlled study by Falk (2015) involved 281 participants with oligometastases from sarcomas. Of these, 164 participants 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 participants 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. Participants 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 participants who received local treatment (HR, 0.47; $p<0.001$). Subgroup analyses revealed similar findings in the participants 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 participants 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 CPG for soft tissue sarcoma (V1.2024) 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, V1.2024). The NCCN CPG for soft tissue sarcomas (V1.2024) 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). Studies evaluating ablative modalities to treat desmoid tumors consist of observational studies with limited participants (Cobianchi, 2014; Havez, 2014; Ilaslan, 2010; Kurtz, 2021; Redifer, 2019; Schmitz, 2016). 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 participants. 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 participants, 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%. OS at 1, 3, and 5 years was 82%, 44%, and 34%. In 16 participants with isolated adrenal metastasis, median disease-free survival was 8 months, with 4 participants 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 participants 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 participants 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 participants 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 participants 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 participants treated with RFA and in all 27 participants who had laparoscopic adrenalectomy. Hypertension was resolved less frequently after treatment with RFA compared with laparoscopic adrenalectomy; hypokalaemia was resolved in all participants. 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 participants 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.

The NCCN CPG for head and neck cancers (V4.2024) address tumors affecting the oral cavity, pharynx, larynx, mucosal melanoma, occult primary cancers, salivary gland and paranasal sinuses. Treatment generally consists of surgery, radiotherapy and systemic therapy used alone or in combination with each other. The CPG contains no recommendations for the use of locally ablative therapies in the treatment of head or neck cancers.

***Thyroid Cancer***

Ultrasound-guided RFA for the treatment of thyroid cancer was evaluated in a retrospective nonrandomized controlled study involving 23 participants 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 participants. After a mean follow-up 38.5 months, disease progression was detected in 5 out of 21 participants (23.8%) treated with PEI. One AE was reported in the RFA group, with the participants 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 CPG for thyroid cancer (V3.2024) 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. The meta-analysis was limited by 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.

The safety and efficacy of LITT in treating intracranial tumors for up to 1-year post-treatment was evaluated in a systematic review and meta-analysis (Alkazemi, 2023). A total of 45 case series and institutional experiences with 826 individuals and 829 lesions were included in the analysis of AE, PFS and OS rates. Lesions included high-grade gliomas (n=361), low-grade gliomas (n=116), metastatic brain tumors (n=337), and nonglial tumors (n=15). The overall pooled incidence of major and minor AEs was 31% for all intracranial tumors with postoperative neurologic deficits (16%), cerebral edema (14%) the most reported type of AE. The 1-year PFS and OS for individuals with high-grade gliomas was 19.6% and 43.0%, respectively, and in individuals with brain metastases 51.2% and 56.3, respectively. Reported limitations associated with the meta-analysis include the lack of experimental studies, significant clinical heterogeneity and the lack of granular information to adequately analyze the data.

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 OS 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 OS 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 OS as the primary outcome measures. The overall median EOA was 99.5% (interquartile range (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 facial palsy, all of which were transient. The median follow-up on this retrospective case series was 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.

The NCCN central nervous system cancers CPG (V2.2024) includes a 2B recommendation for MRI-guided LITT as an option to treat brain tumors. LITT may be considered in those with relapsed brain metastases, radiation necrosis, glioblastomas and other gliomas who are not surgical candidates. At this time, there is not a recognized standard LITT protocol establishing the best use of this modality (de Franca, 2020). 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, but studies have generally been limited by lack of control groups, non-randomized design 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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    - Colon Cancer (V4.2024). Revised July 3, 2024.
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    - Kidney Cancer (V1.2025). Revised July 1, 2024.
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    - Non-Small Cell Lung Cancer. (V7.2024). Revised June 26, 2024.
    - Pancreatic Adenocarcinoma (V2.2024). Revised April 30, 2024.
    - Prostate Cancer (V4.2024). Revised May 17, 2024.
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## Index



**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 |
|---|---|---|
| | 01/30/2025 | Updated Coding section with 01/01/2025 CPT changes, added 60660, 60661. |
| Reviewed | 08/08/2024 | Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion and References sections. |

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|---|---|---|
| Reviewed | 11/09/2023 | MPTAC review. Updated Discussion and References sections. |
| Revised | 08/10/2023 | MPTAC review. Retitled document to add microwave ablation to the clinical indications. Added cryoablation and microwave ablation to the MN indications for NSCLC and malignant tumors that have metastasized to the lung. Added NMN statements regarding focal cryoablation of the prostate and microwave ablation for all other indications. Revised MN indication for cryoablation of the prostate to whole gland cryoablation of the prostate. Reordered clinical indications to be based on clinical condition rather than ablative technique. Updated Coding section, including adding codes 19499, 53850, 53852, C9751, 00500Z3, 00503Z3, 00504Z3, 0G5G0Z3, 0G5G3Z3, 0G5G4Z3, 0G5H0Z3, 0G5H3Z3, 0G5H4Z3, 0G5K0Z3, 0G5K3Z3, 0G5K4Z3. |
| Revised | 05/11/2023 | MPTAC review. Removed criteria that individual must a be high renal or surgical risk from the cryoablation and radiofrequency ablation criteria for clinically localized, suspected renal malignancies. Updated Description, Discussion and References sections. |
| Revised | 05/12/2022 | 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. |

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| 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. |