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Laser Interstitial Tumor Therapy (LITT)

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Related Policies (if applicable)
None

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Coverage

Treatment of epilepsy using magnetic resonance image (MRI)-guided laser interstitial tumor therapy (LITT) **may be considered medically necessary** when the following criteria are met:

1. There is documentation of disabling seizures despite use of 2 or more antiepileptic drug regimens (i.e., medically refractory epilepsy), **AND**
2. There are well-defined epileptogenic foci accessible by LITT.

Treatment of brain tumors or radiation necrosis of the brain using MRI-guided laser interstitial tumor therapy **may be considered medically necessary** when the following criteria are met:

1. LITT is being used to treat:
    a. Recurrent or progressive malignant tumor (primary or metastatic), or
    b. Lesion(s) inaccessible to surgical resection, or
    c. The individual is unable to tolerate surgical resection due to medical comorbidities, **AND**
2. The treatment plan to use LITT has been agreed upon by a multidisciplinary team of Physicians to include at least 2 specialists (e.g., neurosurgery, oncology) and, after

considering all relevant possible treatment approaches, is determined to be the best treatment option.

NOTE 1: LITT should be performed by a neurosurgeon who has completed procedure-specific training in the use of a Food and Drug Administration (FDA) approved LITT ablation system and who has been granted hospital privileges to perform brain tumor surgery and LITT ablation procedures.

Laser interstitial thermal therapy **is considered experimental, investigational and/or unproven** when the criteria above are not met or for all other indications, including but not limited to:

- Adrenal metastases;
- Breast tumors (benign or malignant);
- Liver metastases;
- Lung cancer and lung metastasis;
- Osteoid osteomas;
- Pancreatic cancer;
- Prostate cancer;
- Spinal metastasis;
- Spinal cord compression and spinal instability;
- Thyroid nodules; or
- Tremor disorders.

Policy Guidelines

- As of 1/1/2022, the appropriate CPT code(s) to report magnetic resonance imaging (MRI)-guided laser interstitial tumor therapy (LITT), intracranial of single and/or multiple or complex lesion(s) include 61736 and 61737. All other uses for LITT are typically billed as an unlisted code.
- Transperineal/transrectal focal laser ablation of the prostate with magnetic resonance fused images or other enhanced ultrasound imaging is billed under 0655T.

Description

Laser Interstitial Thermal Therapy

Laser interstitial thermal therapy (LITT), also known as laser-induced thermal therapy/thermotherapy, interstitial laser therapy (ILT), interstitial laser photocoagulation/coagulation, magnetic resonance imaging (MRI)-guided LITT (e.g., Neuroblate, Visualase) and stereotactic laser ablation (SLA), involves the introduction of a laser fiber probe to deliver thermal energy for the targeted ablation of diseased tissue. Thermal destruction of tissue is mediated via DNA damage, necrosis, protein denaturation, membrane dissolution, vessel sclerosis, and coagulative necrosis. (1) The goal of therapy is selective thermal injury through the maintenance of a sharp thermal border, as monitored via the parallel use of real-time magnetic resonance (MR) thermography and controlled with the use of

actively cooled applicators. (2) In neurological applications, LITT involves the creation of a transcranial burr hole for the placement of the laser probe at the target brain tissue. Probe position, ablation time, and intensity are controlled under magnetic resonance imaging (MRI) guidance.

The majority of neurological LITT indications described in the literature involve the ablation of primary and metastatic brain tumors, epileptogenic foci, and radiation necrosis in surgically inaccessible or eloquent brain areas. (2) LITT may offer a minimally invasive treatment option for patients with a high risk of morbidity with traditional surgical approaches. The most common complications following LITT are transient and permanent weakness, cerebral edema, hemorrhage, seizures, and hyponatremia. (3) Delayed neurological deficits due to brain edema are temporary and typically resolve after corticosteroid therapy. Contraindications to MRI are also applicable to the administration of LITT.

Regulatory Status

In August 2007, the Visualase® MRI-Guided Laser Ablation System (Medtronic; formerly Biotex, Inc.) received initial marketing clearance by the U.S. Food and Drug Administration (FDA) through the 510(k) pathway (K071328). In January 2022 (K211269), the system (software version 3.4) was classified as a neurosurgical tool with narrowed indications for use, including "to ablate, necrotize or coagulate intracranial soft tissue including brain structures (for example, brain tumor, radiation necrosis and epileptic foci as identified by non-invasive and invasive neurodiagnostic testing, including imaging) through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 800 nm through 1064 nm lasers." The device is contraindicated for patients with medical conditions or implanted medical devices contraindicated for MRI and for patients whose physician determines that LITT or invasive surgical procedures in the brain are not acceptable. Data from compatible MRI sequences can be processed to relate imaging changes to relative changes in tissue temperature during therapy. The Visualase cooling applicator utilizes saline. FDA product code ONO. (4, 5)

In April 2013, the NeuroBlate® System (Monteris Medical) received initial clearance for marketing by the FDA through the 510(k) pathway (K120561). As of August 2020, the system is indicated for use “to ablate, necrotize, or coagulate intracranial soft tissue, including brain structures (e.g., brain tumor and epileptic foci as identified by non-invasive and invasive neurodiagnostic testing, including imaging), through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers” (K201056). The device is intended for planning and monitoring of thermal therapy under MRI guidance, providing real-time thermographic analysis of selected MRI images. The NeuroBlate system utilizes a laser probe with a sapphire capsule to promote prolonged, pulsed laser firing and a controlled cooling applicator employing pressurized CO_2. FDA product code GEX. (6, 7)

In April 2018, the FDA issued an FDA alert specific to magnetic resonance (MR)-Guided LITT which included a letter to providers stating that the FDA is evaluating data which suggests that potentially inaccurate MR thermometry information can be displayed during treatment, which may contribute to a risk of tissue overheating and potentially associated adverse events, including neurological deficits, increased intracerebral edema or pressure, intracranial bleeding,

and/or visual changes. Several risk mitigation strategies were recommended. In an updated letter released on November 8, 2018, risk mitigation recommendations specific to the Visualase® and NeuroBlate® systems were issued. (8, 9)

Laser interstitial thermal therapy typically utilizes MRI guidance. Applications of LITT currently being researched include, but are not limited to, cancer, epilepsy, osteoid osteoma, radiation necrosis and tumors using MRI guidance and/or ultrasound guidance. (10)

Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging is currently an active area of research. The Echolaser X4 system (Elasta, Calenzano, Italy), marketed as the EchoLaser SoracteLite™ received 510k clearance from the FDA in 2018. (90)

Refer to <https://fda.gov> for the current U.S. FDA approved devices with their specific indication for use.

Rationale

This policy was created in July 2014 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through October 26, 2023.

Adrenal Metastasis

In 2007, Vogl and colleagues reviewed computerized tomography (CT) guided and magnetic resonance thermometry (MRT)-controlled laser induced interstitial thermotherapy (LITT) in patients with adrenal metastases. (11) The aim of the study was to evaluate the feasibility, safety and effectiveness of this technology. This small study of 9 patients (7 male, 2 female; average age 65.0 years; range 58.7-75.0 years) with 9 unilateral adrenal metastases (mean diameter 4.3 cm) from primaries comprising colorectal carcinoma (n=5), renal cell carcinoma (n=1), esophageal carcinoma (n=1), carcinoid (n=1), and hepatocellular carcinoma (n=1) underwent CT-guided, MRT-controlled LITT using a 0.5 T MR unit. LITT was performed with an internally irrigated power laser application system with an Nd:YAG laser. A thermosensitive, fast low-angle shot 2-dimensional sequence was used for real-time monitoring. Follow-up studies were performed at 24 hours and 3 months and, thereafter, at 6-month intervals (median 14 months). All patients tolerated the procedure well under local anesthesia with no complications. Complete ablation was achieved in 7 lesions, verified by magnetic resonance imaging (MRI); progression was detected in 2 lesions in the follow up. The preliminary results suggest that CT-guided, MR-thermometry-controlled LITT is a safe, minimally invasive and promising procedure for treating adrenal metastases.

In 2020, Ierardi et al. (12) noted that surgery is the gold standard for the treatment of adrenal primary malignant tumors and metastatic involvement of the adrenal glands. Based on evaluation of the published literature (including the Vogl study noted above), the authors

stated that the technical success of LITT for adrenal metastases were not reported. The authors also stated that 2 of the 9 (22%) tumors in the Vogl study demonstrated recurrence at the treated site and 2 patients expired during the follow-up phase of the study.

Existing literature on the use of LITT in individuals with adrenal metastasis are limited therefore, additional long-term studies with a larger patient population are warranted to determine the impact on health outcomes.

Brain Tumors

In 2006, Schwarzmaier et al. researched the survival after LITT in 16 patients suffering from recurrent glioblastoma multiforme (rGBM). (13) The concept underlying the intervention is the cytoreduction of the tumor tissue by local thermocoagulation. All patients received standard chemotherapy (temozolomide). The median overall survival (OS) time after the first relapse was 9.4 months, corresponding to a median OS time after laser irradiation of 6.9 months. During the study, however, the median survival after laser coagulation increased to 11.2 months. This survival time is substantially longer than those reported for the natural history (<5 months) or after chemotherapy (temozolomide: 5.4-7.1 months). The authors concluded that cytoreduction by laser irradiation might be a promising option for patients suffering from rGBM.

In 2011, Carpentier et al. conducted a pilot clinical trial exploring the safety and feasibility of real-time MRI-guided LITT for treatment of resistant focal metastatic intracranial tumors. (14) In 7 patients with chemotherapy, whole-brain radiation, and radiosurgery resistant metastatic intracranial tumors, minimally invasive stereotaxic placement of a saline-cooled interstitial fiber optic laser applicator under local anesthesia was followed by laser irradiation during continuous MRI scanning. A total of 15 metastatic tumors were treated in 7 patients. In all cases, the procedure was well tolerated, and patients were discharged within 24 hours. Physical exam and imaging at up to 30 months showed an acute increase in apparent lesion volume followed by a gradual and steady decrease. No tumor recurrence within thermal ablation zones were noted. Kaplan-Meier analysis indicated that the median survival was 19.8 months. This small pilot study concluded that real-time MRI guidance of LITT offers a high level of control. This tool therefore enables a minimally invasive option for destruction and treatment of resistant focal metastatic intracranial tumors. MRI-guided LITT appears to provide a safe and potentially effective treatment option for recurrent focal metastatic brain disease.

In 2014, Mohammadi and Schroeder (15) noted that the treatment of brain tumors remains challenging and cytoreductive surgery is the first line treatment for most brain tumors. However, complete curative resection is not achievable in many brain tumors. The NeuroBlat® System was developed as an adjuvant treatment to chemotherapy and radiation and the initial results have shown feasibility of LITT for a variety of brain pathologies. It is believed that LITT can be considered as an alternative type of surgery for difficult to access brain tumors and for tumors in patients who are deemed high-risk to traditional surgery.

In 2015, Medvid et al. (16) noted that surgical excision constitutes as first-line therapy for various brain pathologies although it can result in irreversible neurologic deficits. In addition, many patients who may benefit from surgery do not qualify as surgical candidates due to multiple comorbidities. Advancements in LITT, mainly MRI-guidance has improved the safety and efficacy of this procedure and is currently used as a minimally invasive treatment option for brain metastases, radiation necrosis (RN), glioma, and epilepsy. MRI-guided LITT should only be used for palliative/salvage therapy in patients with gliomas. Similar to glioblastoma multiforme (GBM), no consensus exists on the treatment of recurrent metastatic brain lesions and repeat use of radiation therapy is limited due to concerns over adverse cumulative radiation effects. To date, studies have shown that MRI-guided LITT is a safe, minimally invasive alternative.

In 2016, Barnett et al. (17) conducted a systematic review and meta-analysis of the peer-reviewed literature to identify studies which examined extent of resection (EOR) or extent of ablation (EOA) and major complications (defined as neurocognitive or functional complications which last >3 months post-surgery) associated with either brain LITT or open craniotomy in high grade gliomas in or near areas of eloquence. Eight studies on brain LITT (n=79) and 12 craniotomy studies (n=1,036) were identified which examined either/both EOR/EOA and complications. Meta-analysis demonstrated an EOA/EOR of 85.4 ± 10.6% with brain LITT versus 77.0 ± 40% with craniotomy (mean difference 8%) and major complications of 5.7% and 13.8% for LITT and craniotomy, respectively. The authors noted that in patients presenting with high grade gliomas in or near areas of eloquence, results demonstrate that brain LITT may be a viable surgical alternative.

In 2016, Ivan et al. (18) conducted a meta-analysis on the use of MRI-guided LITT in the treatment of newly diagnosed high grade gliomas. Eighty-five articles were identified plus one that was pending publication. Four articles were accounted for in which 25 adults underwent LITT treatments. On average, 83% of the pre-treatment lesion volume was ablated. The average tumor volume treated was 16.5 cm, and the mean follow-up time was 7.6 months. Median OS was 14.2 months (range 0.1-23 months). The median progression-free survival (PFS) was 5.1 months (range 2.4-23 months); however, data is limited by the relatively short follow-up of the patients reviewed and the small sample size. Only one participant suffered a major perioperative complication (central nervous system [CNS] infection). The researchers concluded that MRI-guided LITT is a safe and promising technology for the treatment of small, yet difficult-to-treat newly diagnosed high grade gliomas although this study is limited by a lack of comparison group.

In 2017, Kamath et al. (19) conducted a retrospective case series of patients with challenging diagnoses who received interstitial laser ablation (ILA). The focus of the study was to evaluate safety, efficacy, and preliminary outcomes within a diverse and large series of ILA treatments, as well as report useful technical details and operative trends. A total of 133 intracranial lesions in 120 patients were treated with ILA, including GBM, other gliomas, metastases, epilepsy foci, and RN. The rate of complications or unexpected readmission was 6%, and the mortality rate was 2.2%. With high-grade tumors, tumor volumes > 3 cm in diameter trended toward a higher rate of complication ($p = 0.056$). Median PFS and OS for recurrent GBM were 7.4 and 11.6

months, respectively. As a frontline treatment for newly diagnosed GBM, median PFS and OS were 5.9 and 11.4 months, respectively. For metastases, median PFS was not yet reached, and OS was 17.2 months. The authors concluded that ILA is a safe and efficacious treatment for a variety of intracranial pathologies, can be tailored to treat difficult to access lesions, and may offer a novel alternative to open craniotomy in properly selected patients.

In 2018, Salehi and colleges (20) reviewed data specific to LITT when applied to intracranial lesions, including metastatic disease to the brain. The authors note that LITT offers a safe and satisfactory treatment option with significantly less morbidity and shorter hospital stays than traditional open craniotomy. Proper patient selection is of utmost importance in ensuring the success of LITT and to minimize complications although operative risks must be weighed against possible benefits from surgery. LITT is a treatment option for lesions that are deeply seated and for which open surgery would be difficult or at least transgress some amount of normal brain. However, LITT is also appropriate for superficial lesions in patients who are too ill for surgery, have a thin scalp due to radiation or multiple prior surgeries, or have tenuous baseline functional status. Ideally, the target lesion for LITT would be well-circumscribed such that the lesion could be treated within a 3 cm-diameter cylinder; average to low vascularity; and accessible via a safe linear trajectory that avoids inadvertent heating of eloquent structures. Additionally, the patient and laser apparatus combined must fit into the bore of the MRI scanner, which can be a limitation for obese patients. The efficacy of LITT as initial therapy, particularly in small tumors, remains to be determined and will likely require larger clinical trials. Although, LITT as a treatment option for various types of intracranial lesions including brain metastasis offers a minimally invasive option for tumors that are difficult to access or refractory to prior treatment while at the same time offering comparable survival outcome to other salvage therapies.

In 2019, Hong et al. (21) conducted a retrospective review from a single institution comparing outcomes after LITT versus craniotomy in patients with recurrent lesions who were previously treated with stereotactic radiosurgery (SRS) for brain metastases. Of 75 patients, 42 had recurrent tumor (56%) and 33 (44%) had RN. Of patients with tumors, 26 underwent craniotomy and 16 had LITT. For RN, 15 had craniotomy and 18 received LITT. There was no significant difference between LITT and craniotomy relative to neurological outcomes or in a patient's ability to taper off steroids. PFS and OS were similar for LITT versus craniotomy, respectively: PFS at 1-year = 72.2% versus 61.1%, PFS at 2-years = 60% versus 61.1%, OS at 1-year = 69% versus 69.3%, OS at 2-years = 56.6% versus 49.5%. Craniotomy resulted in higher rates of preoperative deficit improvement than LITT. On subgroup analysis, the single factor most significantly associated with OS and PFS was pathology of the lesion. About 40% of tumor lesions needed postoperative salvage with radiation after both craniotomy and LITT. The researchers concluded that LITT was as efficacious as craniotomy in achieving local control of recurrent irradiated brain metastases and facilitating steroid taper, regardless of pathology. Craniotomy appears to be more advantageous for providing symptom relief in those with preoperative symptoms.

In 2019, Holste and Orringer (22) stated LITT is becoming an increasingly popular technique for the treatment of brain lesions. More minimally invasive than open craniotomy for lesion resection, LITT may be more appropriate for lesions that are harder to access through an open approach, deeper lesions, and for patients who are unable to tolerate open surgery. Current literature on LITT for brain lesions were reviewed and updates on the radiological, pathological, and long-term outcomes after LITT for brain metastases, primary brain tumors, and RN as well as common complications were included. Larger EOA and LITT as frontline treatment were potential predictors of favorable PFS and OS for primary brain tumors. In brain metastases, larger EOA was more significantly associated with survival benefit, whereas tumor size was a possible predictor. The most common complications after LITT are transient and permanent weakness, cerebral edema, hemorrhage, seizures, and hyponatremia. Although the current literature is limited by small sample sizes and primarily retrospective studies, LITT is a safe and effective treatment for brain lesions in the correct patient population.

In 2020, Rennert et al. (23) reviewed the safety profile of stereotactic laser ablation (SLA) of intracranial lesions from the Laser Ablation of Abnormal Neurological Tissue using Robotic NeuroBlate System (LAANTERN trial) which was a multi-institutional, international prospective observational registry. Data from 100 patients were analyzed. The mean age and baseline KPS score was 51(± 17) and 83(± 15), respectively. In total, 81.2% of patients had undergone prior surgical or radiation treatment. Most patients had a single lesion (79%) ablated through 1 burr hole (1.2 ± 0.7 per patient), immediately following a lesion biopsy. In total, >90% of the lesion was ablated in 72% of treated lesions. Average total procedural time was 188.2 ± 69.6 minutes and average blood loss was 17.7 ± 55.6 ccs. The average length of intensive care unit (ICU) and hospital stays before discharge were 38.1 ± 62.7 h and 61.1 ± 87.2 h, respectively. There were 5 adverse events attributable to SLA (5/100; 5%). After the procedure, 84.8% of patients were discharged home. There was 1 mortality within 30 days of the procedure (1/100; 1%), which was not attributable to the SLA procedure. This study suggests SLA is a safe, minimally invasive procedure evidenced by favorable post-operative profiles.

In 2020, Kim et al. (24) reported on the 12-month outcomes from 14 U.S. centers which included 223 subjects enrolled with 231 ablated tumors. The cohort also included 10 pediatric patients under the age of 18. The median age was 54.3 years. In total, 73.6% of patients had baseline neurological symptoms and the median baseline Karnofsky Performance Score (KPS) was 90. LITT indications included primary brain tumor (131; 58.7%) or metastatic brain tumor (92; 41.3%). Nearly all metastatic lesions (92.4%) were previously treated, and the LITT procedure was indicated for tumor recurrence (50.6%), RN (40%), or unknown (9.4%). The median length of follow-up was 223 days. Results reported a 1 year estimated survival rate of 73%, with no significant difference observed between patients with metastatic or primary tumors in OS. A total of 50.5% had stabilized/improved KPS at 6 months. There were no significant differences in KPS or quality of life (QOL) between patients with metastatic versus primary tumors. The authors concluded that data indicates that the OS in this population of patients with brain tumors reflects similar if not improved outcomes from baseline levels. Patient-reported QOL outcomes were also stabilized and better than expected in a population

with malignant brain tumors. Enrollment is ongoing, and further sub-analyses of these data are planned.

UpToDate

In 2024, UpToDate (25) published guidance on the management of recurrent high-grade gliomas that states that randomized studies of LITT for recurrent high-grade glioma are lacking. However, available data suggest that it may be a reasonable option for patients with brain lesions that are deep seated or harder to access through craniotomy or for those who may not be good open-surgery candidates.

Professional Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The 2024 NCCN guidelines for CNS cancer (26) includes a 2B recommendation that addresses MRI-guided LITT for patients who are not surgical candidates (craniotomy or resection), and potential indications include brain metastases, RN, glioblastomas, and other gliomas.

American Society of Clinical Oncology (ASCO) and the 2021 National Institute for Health and Clinical Excellence (NICE)

The 2017 ASCO (27) and the 2021 NICE guidelines for primary brain tumors and brain metastases in adults (28) do not mention MRI-guided LITT in their guidelines.

Breast Tumors

In 2015, Haraldsdóttir et al. (29) reviewed the effect of immunological changes induced by LITT on long-term outcomes in patients with breast tumors. Twenty-four patients with invasive breast tumors were treated with LITT followed by standard surgical excision. Immunohistological reactions on cells were performed on specimens obtained prior to and after LITT. The follow-up time ranged from 91-136 months. This small study revealed that LITT did not demonstrate any long-term adverse effects but the overall clinical impact of LITT should be examined in a larger patient population.

In 2017, Kerbage et al. (30) noted that while breast specialists' debate on therapeutic de-escalation in breast cancer, the treatment of benign lesions in relation to new percutaneous ablation techniques is discussed. The purpose of these innovations is to minimize potential morbidity. LITT is an option for the ablation of targeted nodules therefore, the scientific publications investigating the LITT approach in malignant and benign breast disease was examined. Three preclinical studies and 8 clinical studies (2 studies including fibroadenomas and 6 studies including breast cancers) were included in the review of literature. Although the feasibility and safety of LITT has been confirmed in a phase I trial, heterogeneous inclusion criteria and methods seem to be the main reason for LITT not being an extensively used treatment option. In conclusion, further development is necessary before this technique can be used in daily practice.

Professional Guidelines and Position Statements

National Institute for Health and Clinical Excellence (NICE)

In 2024, NICE published clinical guidelines for the diagnosis and management of early and locally advanced breast cancer (31) that does not include LITT as a treatment modality.

American Society of Breast Surgeons (ASBS)
The 2018 ASBS guidelines suggest that LITT is being Investigated by the U.S. Food and Drug Administration (FDA) for breast cancer treatment and recommends additional clinical trials. (32)

National Comprehensive Cancer Network (NCCN®)
The 2024 NCCN Breast Cancer guideline (33) does not include LITT as a recommendation for breast cancer.

Epilepsy
For patients with medically refractory epilepsy and well-defined lesions, studies suggest treatment with LITT may lead to freedom from seizures without the morbidity of temporal lobe resection. LITT has been considered as a minimally invasive option to surgical resection in patients with foci inaccessible with conventional surgery and in patients with drug resistant epilepsy.

The Center for Disease Control and Prevention defines active epilepsy in adults and children. An adult is considered to have "active epilepsy" when the adult is diagnosed with epilepsy, or a seizure disorder and they are currently taking medicine to control it or had at least 1 seizure in the last 12 months (or both). A child has "active epilepsy" if their parent or guardian reports that a health care provider has ever told them their child has epilepsy or a seizure disorder, and their child currently has epilepsy or seizure disorder. (34) The International League against Epilepsy defines drug resistant epilepsy as "failure of adequate trials of two tolerated and appropriately chosen and used AED [antiepileptic drugs] schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom." (35)

In 2016, Kang et al. (36) described mesial temporal lobe ablated volumes, verbal memory, and surgical outcomes in patients with medically intractable mesial temporal lobe epilepsy (mTLE) treated with MRI-guided stereotactic LITT. These researchers prospectively tracked seizure outcome in 20 patients with drug-resistant mTLE who underwent MRI-guided LITT from December 2011 to December 2014. Surgical outcome was assessed at 6 months, 1 year, 2 years, and at the most recent visit. Volume-based analysis of ablated mesial temporal structures was conducted in 17 patients with mesial temporal sclerosis (MTS) and results were compared between the seizure-free and not seizure-free groups. Following LITT, proportions of patients who were free of seizures impairing consciousness (including those with auras only) are as follows: 8 of 15 patients (53%, 95% CI:30.1 to 75.2%) after 6 months, 4 of 11 patients (36.4%, 95% CI: 14.9 to 64.8%) after 1 year, 3 of 5 patients (60%, 95% CI: 22.9 to 88.4%) at 2-year follow-up. Median follow-up was 13.4 months post LITT (range of 1.3 months to 3.2 years). Seizure outcome after LITT suggested an all or none response; 4 patients had anterior temporal lobectomy (ATL) after LITT; 3 are seizure free. There were no differences in total ablated volume of the amygdalohippocampus complex or individual volumes of hippocampus,

amygdala, entorhinal cortex, para-hippocampal gyrus, and fusiform gyrus between seizure-free and non-seizure-free patients. Contextual verbal memory performance was preserved after LITT, although decline in non-contextual memory task scores were noted. The authors concluded that MRI-guided stereotactic LITT is a safe alternative to ATL in patients with medically intractable mTLE. Individualized assessment is needed to examine if the reduced odds of seizure freedom are worth the reduction in risk, discomfort, and recovery time. Additionally, they stated that larger prospective studies are needed to confirm these preliminary findings, and to define optimal ablation volume and ideal structures for ablation.

In 2016, McCracken et al. (37) noted that surgery is indicated for cerebral cavernous malformations (CCM) that cause medically refractory epilepsy. Real-time MRT-guided SLA is a minimally invasive approach to treating focal brain lesions. Researchers described MRT-guided SLA as a novel approach to treating CCM-related epilepsy, with respect to feasibility, safety, imaging, and seizure control in 5 consecutive patients. Patients with medically refractory epilepsy undergoing standard pre-surgical evaluation were found to have corresponding lesions fulfilling imaging characteristics of CCM and were prospectively enrolled. Each patient underwent stereotactic placement of a saline-cooled cannula containing an optical fiber to deliver 980-nm diode laser energy via twist drill craniostomy; MR anatomic imaging was used to evaluate targeting prior to ablation. MRI provided evaluation of targeting and near real-time feedback regarding extent of tissue thermocoagulation. Patients maintained seizure diaries, and remote imaging (6 to 21 months post-ablation) was obtained in all patients. Imaging revealed no evidence of acute hemorrhage following fiber placement within presumed CCM; MRT during treatment and immediate post-procedure imaging confirmed desired EOA. These investigators identified no adverse events or neurological deficits; 4 of 5 (80%) patients achieved freedom from disabling seizures after SLA alone (Engel class 1 outcome), with follow-up ranging 12 to 28 months. Re-imaging of all subjects (6 to 21 months) indicated lesion diminution with surrounding liquefactive necrosis, consistent with the surgical goal of extended lesionotomy. The authors concluded that minimally invasive MRT-guided SLA of epileptogenic CCM is a potentially safe and effective alternative to open resection.

In 2017, Shukla et al. (38) noted that medically intractable epilepsy is associated with increased morbidity and mortality. For those with focal epilepsy and correlated electrophysiological or radiographic features, open surgical resection can achieve high rates of seizure control but can be associated with neurologic deficits and cognitive effects. Recent innovations have allowed for more minimally invasive methods of surgical seizure control such as MRI-guided LITT, which achieves the goal of ablating seizure foci while preserving neuropsychological function and offering real-time feedback and monitoring of tissue ablation. These investigators summarized the utilization of MRI-guided LITT for mTLE and other seizure disorders. The authors concluded that MRI-guided LITT is a safe and effective therapeutic option for the management of medically intractable epilepsy in the adult and pediatric populations. The minimally invasive nature of MRI-guided LITT, enables the surgical management of patients who are not good candidates for, or are otherwise averse to, open resection. Compared to other minimally invasive procedures, MRI-guided LITT is associated with improved outcomes and better side effect profile. While open surgical procedures have demonstrated slightly higher rates of

seizure freedom, MRI-guided LITT is associated with reduced hospitalization time, decreased post-operative pain, and improved neuropsychological function. The researchers stated that it is important to note that the studies reviewed were limited by small samples sizes. Other limitations of the data include the lack of availability of long-term outcomes and a scarcity of RCTs. They stated that future studies may seek to address these gaps while also looking at questions regarding the use of the procedure for multi-focal epilepsy and the relationship between time from diagnosis and MRI-guided LITT efficacy.

In 2018, Xue and colleagues (39) conducted a meta-analysis of MRI-guided LITT to assess effectiveness in treatment-resistant epilepsy. In total, 16 studies were identified which included 269 individuals with medication-resistant epilepsy with focal onset of seizures. In the short-term, 61% of the individuals were seizure-free or disabling seizure-free (Engel Class I) following MRI-guided LITT. While approximately 24% of the individuals reported postoperative complications, the authors note that some complications resolved within six months. The authors determined that while MRI-guided LITT can achieve good outcomes, there are several factors which affect the effectiveness in the clinical setting. Good clinical outcomes depend upon accurate and precise localization of the epileptogenic zone. Inadequate resection of the epileptogenic focus, wider epileptogenic zones, and inadequate training can result in suboptimal results.

In 2020, Kerezoudis and colleagues (89) published a systematic review with meta-analysis examining the effect of ablation volume on seizure freedom rate for individuals who received MRgLITT for TLE. A total of 13 studies including 551 participants were analyzed. The seizure freedom rate at the last follow-up was 58% for the entire cohort. The overall reported complication rate was 17% with a permanent complication rate of 5%. In the overall cohort, seizure freedom was not significantly associated with total ablation volume (p=0.42). The review was limited by the retrospective design, size, and lack of long-term follow-up of the included studies.

In 2021, Barot et al. (40) published a meta-analysis evaluating the effectiveness of MRI-guided LITT in patients with drug-resistant epilepsy. In total, 28 studies were identified which included 559 individuals with treatment-resistant epilepsy. Their primary outcome of interest was seizure freedom, which is typically reported by the Engel classification with at least 6 months of follow-up. Their secondary outcomes of interest were postoperative complications and reoperation rates. The overall prevalence of Engel class I outcome (free from disabling seizures) was 56%. Individuals with hypothalamic hamartomas had the highest seizure freedom rate (67%). The outcome was overall comparable between individuals with mTLE, (56%) and extratemporal epilepsy (50%). The mTLE cases with MTS had better outcome compared with non-lesional cases of mTLE. A total of 25 studies, which included 519 individuals, reported postoperative adverse events. The prevalence of postoperative adverse events was 19% with the most common adverse event being visual field deficits which were most commonly noted in individuals with mTLE. Other relevant adverse events included intracranial hemorrhage (n=13) and motor deficits (n=27). The reoperation rate was 9% in only 18 of 28 studies with reported data. Reoperative events included repeated ablation (n=55) and resective surgery (n=18). Their

review indicates that MRI-guided LITT can be an effective and safe therapy for drug resistant epilepsy. However, a majority of the evidence is limited to retrospective studies.

In 2021, Kohlhase et al. (41) published a meta-analysis to compare the outcomes and complications between MRI-guided LITT, radiofrequency ablation (RFA), and conventional surgical approaches to the temporal lobe (e.g., ATL resection or selective amygdalohippocampectomy [sAHE]) for the treatment of drug-refractory mTLE. A total of 43 studies (13 MRI-guided LITT, 6 RFA, and 24 surgery studies) involving 554, 123, 1504, and 1326 individuals treated by MRI-guided LITT, RFA, ATL, or sAHE, respectively, were included in the analysis. Engel class I outcomes were achieved after MRI-guided LITT in 57%, RFA in 44%, ATL in 69%, and sAHE in 66% of participants. There was no significant difference in seizure outcome between MRI-guided LITT and RFA (p=0.098). The authors report that compared with MRI-guided LITT, participants that received ATL (p=0.002) or sAHE (p=0.037) had significantly better outcomes, with better outcomes at follow-up of 60 months or more. Similarly, participants who received ATL (p=0.113) and sAHE (p=0.0247) compared to RFA had significantly better outcomes. However, the authors note a large difference in the range of follow-up periods between the surgical groups (12 to 116.4 months) and the MRI-guided LITT (6 to 70 months) and RFA (12 to 62 months) groups. Comparable long-term data for MRI-guided LITT and RFA is not yet available. In a subgroup analysis for participants with follow-up less than 60 months, the difference in seizure outcomes was nonsignificant between MRI-guided LITT and ATL (p=0.057) or sAHE (p=0.28). Mesial hippocampal sclerosis was associated with significantly better outcome after MRI-guided LITT (Engel class I outcome in 64%, p=0.0035). The rate of major complications was lower for MRI-guided LITT (3.8%) and RFA (3.7%) compared to ATL (10.9%) and sAHE (7.4%). However, the differences did not show statistical significance. Regarding neuropsychological deficits, lateral functions such as naming, or object recognition may be more preserved with the use of MRI-guided LITT. Some of the limitations of the analysis include the retrospective uncontrolled design as well as lack of long-term follow-up of available MRI-guided LITT and RFA studies.

ECRI

In 2021, ECRI (42) published an updated clinical evidence assessment from 2019 which states the evidence for the use of LITT is “somewhat favorable” in patients with epilepsy not responsive to medication. Systematic reviews of meta-analysis of low-quality and pre-post cohort studies shows that LITT results in freedom from seizures at up to 2 years in about 60% of treated patients with medically refractory epilepsy; complications were reported in about one-fourth to one-fifth of LITT patients. LITT appears to be as safe and effective as SRS (e.g., Gamma Knife®). Nonrandomized studies suggest LITT may be safer than open surgery, but larger studies are needed to validate this data. At the time of the ECRI publication, epilepsy management guidelines have yet to specifically address LITT.

Professional Guidelines and Position Statements

Epilepsy Foundation of America

The Epilepsy Foundation of America website (43) includes information for professionals which addresses MRI-guided LITT. The foundation supports the use of LITT in patients with mesial

temporal lobe epilepsy (mTLE) who have persistent seizures despite adequate trials of 2 or more seizure medicines. They also state that the LITT procedure can also benefit people who have seizures from lesions, such as a small brain malformation, a blood vessel malformation, or hypothalamic hamartoma.

National Institute for Health and Clinical Excellence (NICE)
The 2022 NICE guidelines (44) state that drug resistant epilepsy is when seizures persist, and seizure freedom is very unlikely to be attained with further manipulation of antiseizure medication. Defined by the International League Against Epilepsy as 'failure of adequate trials of 2 tolerated and appropriately chosen and used antiseizure medication schedules (whether as monotherapy or in combination) to achieve sustained seizure freedom'.

American Society for Stereotactic and Functional Neurosurgery
The 2022 American Society for Stereotactic and Functional Neurosurgery (ASSFN) Position Statement include the following indications for the use of MRI-guided LITT as a treatment option for patients with Drug-Resistant Epilepsy (DRE) (45):

- Failure to respond to, or intolerance of, at least 2 appropriately chosen medications at appropriate doses for disabling, localization-related epilepsy; and
- Well-defined epileptogenic foci or critical pathways of seizure propagation accessible by MRgLITT.

Liver Cancer (Including Metastasis)
In 2004, Wietzke-Braun et al. studied LITT as a minimally invasive procedure for local tumor destruction within solid organs. (46) The aim of the study was to investigate QOL and outcomes of ultrasound guided LITT in patients with liver metastases of colorectal cancer (CRC). This was a prospective non-randomized study involving 45 patients with liver metastases from CRC and was palliatively treated by LITT. Patient survival was analyzed by the Kaplan-Meier method and the QOL by questionnaire C30 of the European Organization for Research and Treatment of Cancer before, and 1 week, 1 month, and 6 months after initiation of LITT. Median survival after initiation of LITT was 8.5 +/- 0.7 months with a range of 1.5-18 months. Body weight was constant 1 month after LITT. In the multivariate analyses, QOL symptoms and functioning scales did not deteriorate in patients alive at 6 months after initiation of LITT. Univariate analyses outlined a significant increase of the pain subscale before and at 1 week after LITT. The study determined potential benefits of LITT to include prolonged survival time by preserved QOL although this will need to be verified in a comparative study.

In 2014, Eichler and colleagues (47) studied a small sample of MRI-guided LITT patients with liver metastases of uveal melanoma. LITT was performed in 18 patients with liver metastases (n=44) from uveal malignant melanoma. All patients tolerated this intervention well. Survival rates were calculated with the Kaplan-Meier method. Indications for the procedure were defined for patients with no more than 5 metastases, none of which were larger than 5 cm in diameter. The indications for LITT treatment were recurrent liver metastases after partial liver resection (22%), locally non-resectable tumors (17%), or metastases in both liver lobes (61%). The mean survival rate for all treated patients was 3.6 years (95% CI: 2.19, 5.06). The median

survival was 1.83 years; 1-year survival, 88%; 3-year survival 47%, 5-year survival 17%. After the first LITT treatment the median survival was 2.8 years (95% CI: 1.0, 5.0). Ten patients were treated by transarterial chemoembolization before LITT. The authors concluded MRI-guided LITT shows high local tumor control and survival rates in patients with liver metastases of uveal malignant melanoma.

In 2014, Vogl et al. (48) evaluated the long-term survival and PFS post treatment of CRC liver metastases with MRI-guided LITT in 594 patients (mean age, 61.2 years). The tested prognostic factors included: sex, age, the location of primary tumor, the number of metastases, the maximal diameter and total volume of metastases and necrosis, the quotient of total volumes of metastases and necrosis, the time of appearance of liver metastases and location in the liver, the TNM (tumor, nodes, metastasis) classification of CRC, extrahepatic metastases, and neoadjuvant treatments. The 1-, 2-, 3-, 4-, and 5-year survival rates were 78%, 50.1%, 28%, 16.4%, and 7.8%, respectively. The median PFS was 13 months. The 1-, 2-, 3-, 4-, and 5-year PFS rates were 51.3%, 35.4%, 30.7%, 25.4%, and 22.3%, respectively. The number of metastases and their maximal diameter were the most important prognostic factors for both long-term survival and PFS. Long-term survival was also influenced by the initial involvement of lymph nodes. The study concluded that the number and size of metastases and the initial lymph node status are significant prognostic factors for long-term survival of patients treated with LITT for CRC liver metastases.

In 2016, Vogl et al. (49) noted that surgery is considered the treatment of choice for patients with CRC liver metastases when resectable. The researchers searched published literature to identify studies and reviews relevant to RF ablation, MW ablation, and LITT in terms of local progression, survival indexes, and major complications in patients with CRC liver metastases. Literature revealed a local progression rate between 2.8 and 29.7% in RF-ablated liver lesions at 12-49 months follow-up, 2.7-12.5% of MW ablated lesions at 5-19 months follow-up, and 5.2% of lesions treated with LITT at 6-month follow-up. Major complications were observed in 4-33% of patients treated with RF ablation, 0-19% of patients treated with MW ablation, and 0.1-3.5% of lesions treated with LITT. Although not significantly different, the mean of 1-, 3-, and 5-year survival rates for RF, MW, and laser ablated lesions was (92.6, 44.7, 31.1%), (79, 38.6, 21%) and (94.2, 61.5, 29.2%), respectively. The median survival in these methods was 33.2, 29.5 and 33.7 months. This review article stated that thermal ablation may be an appropriate alternative in patients with CRC liver metastases who have inoperable liver lesions or have operable lesions as an adjunct to resection. However, further competitive evaluation should clarify the efficacy and priority of these therapies in this patient population.

No RCTs were identified in this literature review that address MRI-guided LITT as an alternative to surgical resection. Large, multicenter studies are warranted.

ECRI

In 2021, ECRI (50) examined the use of LITT in patients with metastasis to the liver. The authors concluded the evidence is “inconclusive” based on low-quality nonrandomized studies. ECRI noted that the evidence is at a high risk of bias and are of unclear significance since available

studies involved patients with different etiologies and prognoses. ECRI recommends RCTs that focus on each tumor type to compare LITT with other treatment options (e.g., surgery, microwave, RF).

UpToDate

In 2022, UpToDate examined nonsurgical local treatment strategies for individual with CRC with liver metastases (51) and note that published experience with interstitial laser thermotherapy is limited to a few institutions and include the Vogl study (noted above). UpToDate does not include recommendations for the use of MRI-guided LITT as a treatment modality in individuals with chemotherapy-naïve or chemotherapy refractory-disease.

Professional Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

Most liver metastases originate within the colon or rectum therefore, the NCCN Clinical Practice Guideline (CPG) for colon (52) and rectal cancer (53) were examined. Guidance offers resection as the standard approach for local treatment of resectable metastatic disease. Ablative therapy, alone or in conjunction with resection, is discussed for metastatic disease when all measurable disease can be treated. NCCN does not specifically address MRI-guided LITT as an ablation technique for colon or rectal cancer.

Lung Cancer and Lung Metastasis

In 2017, Nour-Eldin et al. (54) retrospectively compared the local tumor response and survival rates in patients with non-CRC with lung metastases post-ablation therapy using LITT, RFA, and MWA. A retrospective analysis of 175 CT-guided ablation sessions were performed on 109 patients (43 men and 66 women, mean age of 56.6 years); 17 patients with 22 lesions underwent LITT treatment (tumor size: 1.2 to 4.8 cm), 29 patients with 49 lesions underwent RFA (tumor size: 0.8 to 4.5 cm), and 63 patients with 104 lesions underwent MWA treatment (tumor size: 0.6 to 5 cm) ; CT scans were performed 24-hour post-therapy and on follow-up at 3-, 6-, 12-, 18-, and 24 months. The OS rates at 1-, 2-, 3- and 4-years were 93.8, 56.3, 50.0 and 31.3% for patients treated with LITT; 81.5, 50.0, 45.5 and 24.2% for patients treated with RFA and 97.6, 79.9, 62.3 and 45.4% for patients treated with MWA, respectively. The mean survival time was 34.14 months for MWA, 34.79 months for RFA and 35.32 months for LITT. In paired comparison, a significant difference could be detected between MWA versus RFA ($p = 0.032$). The PFS showed a median of 23.49 ± 0.62 months for MWA, 19.88 ± 2.17 months for LITT, and 16.66 ± 0.66 months for RFA ($p = 0.048$). The lowest recurrence rate was detected in lesions ablated with MWA (7.7%; 8 of 104 lesions) followed by RFA (20.4%; 10 of 49 lesions) and LITT (27.3%; 6 of 22 lesions) ; p value of 0.012. Pneumothorax was detected in 22.16% of MWA ablations, 22.73% of LITT ablations, and 14.23% of RFA ablations. The authors concluded that LITT, RFA, and MWA may provide an effective therapeutic option for non-CRC lung metastases with an advantage for MWA regarding local tumor control and PFS rate. The sample size for the LITT-treated group was small ($n = 17$) and the 2- to 4-year OS rates were low to modest. This study was limited by many factors including non-randomized design, short follow-up, and selection bias specific to ablation therefore, these findings warrant further investigation.

ECRI

In 2023, ECRI (55) examined the use of LITT in patients with metastatic lung cancer. The authors concluded the evidence is "inconclusive" based on low-quality, small nonrandomized studies and case series. ECRI noted that the evidence is at a high risk of bias due to small size, lack of randomization or control groups, and/or single-center focus. Data pertains to individuals with metastases of unspecified or mixed anatomic origin and may not generalize across studies. Studies do not report on patient-oriented outcomes, such as symptoms, physical function, and QOL. In addition, studies do not assess LITT as an alternative to surgical intervention or other energy-based ablation techniques. RCTs focusing on each primary tumor type are needed to compare LITT with alternative treatments.

Professional Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The NCCN guideline for non-small cell lung cancer (56) recommends thermal ablation (radiofrequency ablation, microwave ablation, cryoablation) techniques in select individuals, but does not specifically include MRI-guided LITT among the list of thermal techniques.

The NCCN guideline for small cell lung cancer (57) does not specifically include MRI-guided LITT as a treatment option for small cell lung tumors.

Society of Interventional Radiology (SIR)

In 2021, the SIR (58) published guidance on percutaneous ablation of non–small cell lung cancer and metastatic disease to the lungs which considers LITT an investigational image-guided thermal ablation method but notes that LITT is still being investigated for safety and efficacy in lung tumors and is not well studied or documented.

Osteoid Osteoma

In 2007, Gangi et al. (59) retrospectively reported on the use of a diode laser to perform interstitial laser ablation (ILA) on 114 patients with suspected osteoid osteoma. One week following ILA, 112 patients had a pain score of zero on the visual analog scale (VAS). One week following ILA, 1 patient had persistent pain for 2 months due to reflex sympathetic dystrophy. At follow-up (mean, 58.5 months), 6 patients had recurrent pain from 6 weeks to 27 months after the initial ILA. These recurrences were successfully treated with a second ILA. Only 1 unsuccessful treatment was encountered. The authors noted that percutaneous ILA is an effective treatment for osteoid osteoma. This study is limited by a small subset of patients therefore, additional long-term studies are needed to determine the impact on health outcomes.

In 2014, Fuchs et al. (60) prospectively followed 35 osteoid osteoma patients treated with MRI-guided LITT for a mean time of 13.6 months. MRI follow-up demonstrated 28/35 patients (80%) showed a typical post-interventional target-like appearance of the ablated area, followed by a constant shrinking process along with a steady decrease in peri-ablation changes such as peripheral bone edema. The authors stated that clinical success was achieved in 32/35 (91%). Evaluation of long-term follow-up MRI after laser ablation of osteoid osteoma identified typical

postinterventional changes and thus may contribute to the interpretation of therapeutic success and residual or recurrent osteoid osteoma in suspected cases.

ECRI

In 2023, ECRI (61) examined the use of LITT in patients with osteoid osteoma and concluded the evidence is "inconclusive." This determination is based on limited evidence of 7 small studies (2 nonrandomized comparative studies and 5 case series) that suggest LITT is safe, and symptoms were reduced. However, available studies are small and are at a high risk of bias to permit conclusions. Single studies compared LITT with surgery and RFA, but their findings need independent validation. Large, multicenter studies reporting on pain and physical function measures are needed to validate findings and to assess LITT's effectiveness for osteoid osteomas. Additional studies to validate specific LITT techniques on different tumor and patient groups and to compare LITT with other ablative techniques (e.g., high-intensity focused ultrasound) would also be useful to guide care decisions.

Professional Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The 2025 NCCN CPG for Bone Cancer (62) does not include MRI-guided LITT as a treatment modality in tumors of the bone.

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS (63) website does not endorse MRI-guided LITT as a treatment option for individuals diagnosed with osteoid osteoma.

Pancreatic Cancer

In 2011, Saccomandi et al. researched LITT for pancreatic tumor ablation (64). This comparative study aimed to develop and verify a theoretical model to reproduce the thermal response of pancreatic tissue that had undergone LITT. The model provides the evaluation of ablated volumes induced by thermal ablation, tissue response time to irradiation and heat extinction time. Theoretical volume values were compared with ex vivo healthy tissue and in vivo healthy and neoplastic tissue volume values. The theoretical model considered the differences between healthy and neoplastic tissue due to blood perfusion. Mathematical model shows that ablated volume of ex vivo healthy tissue is greater than in vivo one after the same treatment. Moreover, ablated neoplastic in vivo tissue volume is greater than healthy in vivo one, because of tumor angiogenesis. Ablated volume values were compared with experimental data obtained by laser treatment of 30 ex vivo porcine pancreases. Experimental ablated volume values show a good agreement with theoretical values, with an estimated increase of 61% when power increases from 3 watts to 6 watts, versus 46% of experimental data, and an estimated increase of 14% from 6 watts to 10 watts, versus 21% of experimental values. LITT could be an alternative or a neo-adjuvant treatment to surgical resection for pancreas cancer removal, and the proposed model could be the basis to supervising the evolution of ablated volumes during tumor treatment.

No RCTS for the use of MRI-guided LITT for pancreatic cancer were identified.

Professional Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The 2024 NCCN CPG for pancreatic adenocarcinoma does not identify MRI-guided LITT as a treatment modality. (65)

Prostate Cancer

In 2012, Colin et al. (66) noted that there were current challenges related to prostate cancer management and he believed that the development of focal therapies would allow treatment to the specific cancer area (sparing the rest of the gland to minimize the potential morbidity). Focal laser ablation appears to be a potential candidate to focus energy delivery on identified targets. This study reviewed current literature regarding this new treatment option. Relevant literature was identified using the MEDLINE database to include focal therapy, LITT, prostate cancer, and focal laser ablation. The author noted that precision, real-time LITT monitoring, and MRI compatibility and low cost of the integrated system are principal advantages of focal laser ablation. Feasibility and safety of this technique have been reported in a phase I assay. Focal laser ablation might eventually prove to be a middle ground between active surveillance and radical treatment. In conclusion, focal laser ablation may have found a role in the management of prostate cancer. However, the article noted that additional trials are required to demonstrate the oncologic effectiveness in the long-term.

In 2016, Eggener et al. (67) conducted a phase II study evaluating MRI-guided focal laser ablation in 27 men with stage T1c-T2a prostate cancer. Inclusion criteria included prostate specific antigen (PSA) <15 ng/mL or PSA density <0.15 ng/mL^3, Gleason score of 7 or less in 25% or less of biopsies, and MRI with 1 or 2 lesions concordant with biopsy-detected cancer. At 3 months, all patients underwent MRI with biopsy of ablation zone(s). At 12 months, all underwent MRI and systematic biopsy. I-PSS (International Prostate Symptom Score) and SHIM (Sexual Health Inventory for Men) scores were collected pre-treatment, and at 1, 3, and 12 months. The primary end point was no cancer on the 3-month ablation zone biopsy. Secondary end points were safety, 12-month biopsy, and urinary and sexual function. At 3 months, 26 patients (96%) had no evidence of cancer on MRI-guided biopsy of the ablation zone. No significant I-PSS changes were observed. SHIM was lower at 1 month (p=0.03), marginally lower at 3 months (p = 0.05) and without a significant difference at 12 months (p = 0.38). At a 12-month biopsy, cancer was identified in 10 patients (37%) (inside the ablation zone(s) in 3 cases [11%] and outside the ablation zone(s) in 8 [30%]). Cancer was identified both inside and outside the ablation zone in 1 participant. The authors concluded that in select individuals with localized prostate cancer and visible MRI lesions, focal laser ablation has an acceptable morbidity profile and is associated with encouraging short-term oncologic outcomes. Significantly longer follow up is mandatory to fully assess this treatment. Furthermore, the study was limited by lack of comparison group.

In 2017, Valerio et al. (68) completed a systematic review and meta-analysis on the evidence regarding focal therapy for the treatment of prostate tumors. Thirty-seven articles reporting on 3230 patients undergoing focal therapy, with 1 of the focal therapies being LITT. Four

prospective stage 1-2a studies evaluating LITT in 50 patients have been reported in the literature. One study included only men with low-risk disease, whereas the other studies also included a Gleason score ≤4+3, although risk stratification was not clearly reported. The median age was 63.5 years; median PSA was 5.4 ng/mL; median follow-up was 4.5 months with all series including mandatory sampling after treatment. In the stage 1 study, all men underwent radical prostatectomy, whereas in the other 3 studies men underwent transrectal ultrasonography (TRUS) and/or targeted biopsy. Overall, the presence of significant and insignificant tumors was 4.8% and 22.2%, respectively. The probability of transition to secondary local treatment was 0%; overall and disease-specific survival, pad-free continence and potency preservation were 100% and 100%, respectively. No adverse events were reported in any study. The authors determined that focal therapy seems safe and appears to offer good preservation of genitourinary function. Tumor control in studies with intention to treat is encouraging, although this needs to be verified against standard of care in high quality comparative trials.

ECRI

In a 2019 report updated in February 2022, ECRI determined that there is limited evidence specific to the use of LITT for localized prostate cancer. (69) Available evidence consists of very small case series and systematic reviews, which suggest that LITT may be safe and without negative effects on sexual and urinary function in the short term (≤ 1 year) when used for localized prostate cancer; however, clinical trials have not yet demonstrated efficacy because studies have not assessed or reported on patient-oriented outcomes, such as 5-year OS or PFS. Available studies are at high-risk of bias, and results need confirmation in prospective controlled trials that compare LITT to other treatments for localized prostate cancer, such as radical prostatectomy, cryotherapy, and radiation therapy (external or radioactive seed implants). ECRI considers the evidence “inconclusive” for the use of LITT in individuals with localized prostate cancer.

Transperineal Focal Laser Ablation (TPLA)

Available literature for the use of ultrasound guided TPLA is limited. (70, 71) Most studies are small in size and are at a high risk of bias due to the retrospective design and/or single center focus. In addition, there is a lack of control group and randomization. Large, multicenter RCTs are warranted to establish the long-term safety and efficacy of ultrasound guided TPLA in individuals with prostate cancer and/or benign prostatic hyperplasia to order to determine the impact on health outcomes.

Professional Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The 2024 NCCN Practice Guidelines on prostate cancer (72) does not specifically address MRI-guided LITT as a treatment option for prostate cancer. NCCN acknowledges that multiple ablative therapies are actively being investigated for individuals with localized and recurrent prostate cancer. NCCN states that cryotherapy and other local therapies are not recommended as routine primary therapy in patients with localized prostate cancer due to a lack of long-term data comparing these treatments to radiation and/or radical prostatectomy. NCCN only

recommends cryosurgery and high intensity focused ultrasound (HIFU) as local therapy options for radiation therapy in the absence of metastatic disease.

Radionecrosis

Radiation necrosis (RN) in patients can be very difficult to treat. The available treatment options include prolonged high-dose corticosteroids, hyperbaric oxygen, anticoagulation, bevacizumab, ablation therapy and surgical resection. (73)

In 2014, Rao et al. (74) reported on the largest series for the use of LITT for the treatment of recurrent enhancing lesions post SRS for brain metastases. Patients with recurrent metastatic intracranial tumors or RN who had prior radiosurgery with a KPS of >70 were eligible for LITT. A total of 16 patients underwent a total of 17 procedures. The primary end-point was local control using MRI scans at intervals of greater than 4 weeks. Radiographic outcomes were followed-up prospectively until death or local recurrence (defined as >25% increase in volume compared with the 24-hour post-procedural scan). Fifteen patients, age 46 to 82 years of age, were available for follow-up. Primary tumor histology was non-small-cell lung cancer (n=12) and adenocarcinoma (n=3). On average, the lesion size measured 3.66 cm (range of 0.46 to 25.45 cm); there were 3.3 ablations per treatment (range of 2 to 6), with 7.73 cm depth to target (range of 5.5 to 14.1 cm), ablation dose of 9.85 W (range of 8.2 to 12.0 W), and total ablation time of 7.43 minutes (range of 2 to 15 minutes). At a median follow-up of 24 weeks (range of 4 to 84 weeks), local control was 75.8% (13 of 15 lesions), median PFS was 37 weeks, and OS was 57% (8 of 14 patients). Two patients experienced recurrence at 6- and 18-weeks post procedure. Five patients died of extracranial disease progression; 1 patient died of neurological progression elsewhere in the brain. The authors concluded that MRI-guided LITT is a well-tolerated procedure and may be effective in treating tumor recurrence/RN. This was a small, single-arm, non-randomized study and the authors noted “larger studies with longer follow-up that include patient QOL, decreased steroid dependence and neurological symptoms as endpoints are necessary to confirm these findings and better define the appropriate patient for this therapy.”

In a 2016 single-center, retrospective study, Smith and colleagues (75) evaluated the radiographic response and effectiveness of MRI-guided LITT for biopsy-confirmed post-radiation treatment effect (PRTE) and the QOL outcomes of patients following MRI-guided LITT. Investigators reviewed radiographic responses and clinical outcomes of 25 patients with previously treated primary or secondary brain neoplasms (World Health Organization [WHO] grades 4 [n=8], 3 [n=5], 2 [n=5]) and metastatic brain tumors (n=7); MRI-guided LITT was applied directly following stereotactic needle biopsy confirming PRTE without any evidence of tumor presence. Mean OS times (months) for grades 4 and 3 and for metastatic brain tumors were 39.2 (standard error [SE], 7.6; 95% confidence interval [CI]: 24.3 to 54.1), 29.1 (SE, 7.7; 95% CI: 14.0 to 44.2), and 55.9 (SE, 10.0; 95% CI: 36.3 to 75.4), respectively. Mean PFS times after MRI-guided LITT were 9.1 (SE, 3.6; 95% CI: 2.1 to 16.1), 8.5 (SE, 2.4; 95% CI: 3.9 to 13.2), 31/54 and 11.4 (SE, 3.9; 95% CI: 3.8 to 19.0), respectively. Mean survival times after MRI-guided LITT were 13.1 (SE, 2.3; 95% CI: 8.5 to 17.6), 12.2 (SE, 4.0; 95% CI: 4.4 to 20.0), and 19.2 (SE, 5.3; 95% CI: 8.9 to 29.6), respectively. The SF-36 indicated significant overall effects on mental

health (p= 0.029) and vitality (p= 0.005). The authors concluded that MRI-guided LITT may be a viable option for patients with symptomatic advancing PRTE and is less invasive than open craniotomy and noted that although findings suggested a positive effect for MRI-guided LITT on PRTE, additional prospective randomized trials are needed to validate the results.

In 2018, Ahluwalia et al. (76) evaluated laser ablation after SRS in a multicenter prospective study of LITT ablation in patients with radiographic progression after SRS for brain metastases. Patients with a Karnofsky Performance Scale (KPS) score ≥ 60, an age >18 years, and surgical eligibility were included in this study. The primary outcome was local PFS assessed using the Response Assessment in Neuro-Oncology Brain Metastases (RANO-BM) criteria. Secondary outcomes were OS, procedure safety, neurocognitive function, and QOL. Forty-two patients, 19 with biopsy-proven RN, 20 with recurrent tumor, and 3 with no diagnosis were enrolled. The median age was 60 years, 64% of the subjects were female, and the median baseline KPS score was 85. Mean lesion volume was 6.4 cm^3 (range 0.4–38.6 cm^3). There was no significant difference in length of stay between the recurrent tumor and RN patients (median 2.3 vs 1.7 days, respectively). PFS and OS rates were 74% (20/27) and 72%, respectively, at 26 weeks. Thirty percent of subjects were able to stop or reduce steroid usage by 12 weeks after surgery. Median KPS score, QOL, and neurocognitive results did not change significantly for either group over the duration of survival. Adverse events were also similar for the two groups, with no significant difference in the overall event rate. There was a 12-week PFS and OS advantage for the RN patients compared with the recurrent tumor or tumor progression patients. In this study, in which enrolled patients had few alternative options for salvage treatment, LITT ablation stabilized the KPS score, preserved QOL and cognition, had a steroid-sparing effect, and was performed safely in the majority of cases.

In 2018, Rammo et al. (77) noted that cerebral RN is a known complication of radiation therapy and therapeutic options are limited (steroids, bevacizumab, and surgery), therefore they sought to examine the safety of LITT in patients with for cerebral RN. Patients undergoing LITT for tumor treatment at a single center between November 2013 and January 2016 with biopsy confirmed cerebral RN were prospectively collected and retrospectively evaluated with attention to ablation volume, survival, demographic data, steroid dose, and complications. Imaging occurred at set intervals beginning pre-ablation. A total of 10 patients with 11 ablations were examined; 4 patients had a primary diagnosis of high-grade glioma, while 6 had metastatic lesions. An average of 86% of cerebral RN volume was ablated. Ablation volume increased to 430% of initial CRN volume at 1 to 2 weeks before decreasing to 69% after 6 months. No patient had a decline in their baseline neurological examination while inpatient; 4 patients developed delayed neurological deficits likely due to post-operative edema, of which 3 improved back to baseline. The 6-month survival was 77.8% and the 1-year survival was 64.8% based on Kaplan-Meier curve estimates. The authors concluded that LITT was a relatively safe treatment for cerebral RN, providing both a diagnostic and therapeutic solution for refractory patients. Significant increase in ablation volume was noted at 1 to 2 months, gradually decreasing in size to less than the original volume by 6 months. These investigators stated that further studies are needed to better-define the role of LITT in the treatment of cerebral RN.

In 2019, Hong et al. (21) conducted a retrospective review from a single institution comparing outcomes after LITT versus craniotomy in patients with recurrent lesions who were previously treated with SRS for brain metastases. Of 75 patients, 42 had recurrent tumor (56%) and 33 (44%) had RN. In the 42 patients with recurrent tumor, 26 underwent craniotomy and 16 had LITT. For RN, 15 had a craniotomy and 18 received LITT. There was no significant difference between LITT and craniotomy relative to neurological outcomes or in a patient's ability to taper off steroids. PFS and OS were similar for LITT versus craniotomy, respectively: PFS at 1-year= 72.2% versus 61.1%, PFS at 2-years = 60% versus 61.1%, OS at 1-year = 69% versus 69.3%, OS at 2-years = 56.6% versus 49.5%. Craniotomy resulted in higher rates of preoperative deficit improvement than LITT. On subgroup analysis, the single factor most significantly associated with OS and PFS was pathology of the lesion. About 40% of tumor lesions needed postoperative salvage with radiation after both craniotomy and LITT. The researchers concluded that LITT was as efficacious as craniotomy in achieving local control of recurrent irradiated brain metastases and facilitating steroid taper, regardless of pathology. Craniotomy appears to be more advantageous for providing symptom relief in those with preoperative symptoms.

In 2020, Sujijantarat et al. (78) conducted a retrospective chart review comparing outcomes for patients having previously irradiated brain metastases with biopsy-confirmed RN treated with LITT (n=25) or bevacizumab (n=13) at a single center between 2011 and 2018. The LITT group had a significantly longer OS compared to bevacizumab (median, 24.8 vs. 15.2 months; p=.003). Time to local recurrence was not statistically significant between groups (p=.091) but trended longer in the LITT cohort. Among 13 patients with pre-treatment symptoms in the LITT group, 9 (69%) achieved symptom relief. Among 11 patients with pre-treatment symptoms in the bevacizumab group, 4 (36%) achieved symptom relief. No significant difference was noted between groups for the ability to wean off concurrent steroids. Given that 50% of lesions treated with LITT were symptomatic compared to 80% of lesions treated with bevacizumab, the authors suggest that LITT treatment may be more successful before RN lesions become symptomatic. Overall, the study is limited by its retrospective design, small samples size, and population heterogeneity.

In 2022, Sankey et al. published a multicenter, retrospective study of SRS-treated patients with brain metastases who developed biopsy-proven RN who were treated with LITT (n=57) or medical management (n=15). (79) Median follow-up was 10.0 months (range, 4.2 to 25.1 months). There was no significant difference in median OS (15.2 vs. 11.6 months; p=.60) or freedom from local progression (13.6 vs. 7.06 months; p=.40) in LITT or medical management cohorts, respectively. Patients were able to discontinue steroid therapy earlier in the LITT cohort at a median of 37 versus 245 days (p<.001). The authors note that prospective trials should be designed to validate the utility of LITT for RN, including its impact on steroid-induced morbidity.

In 2023, Chan et al. noted that LITT for post-SRS RN in individuals with brain metastases has growing evidence for efficacy. (80) However, questions remain regarding hospitalization, local control, symptom control, and concurrent use of therapies. Statistical analysis included individual variable summaries, multivariable Fine and Gray analysis, and Kaplan-Meier

estimated survival. Ninety patients met the inclusion criteria. Four patients underwent 2 ablations on the same day. Median hospitalization time was 32.5 hours. The median time to corticosteroid cessation after LITT was 13.0 days (0.0, 1229.0) and cumulative incidence of lesional progression was 19% at 1 year. Median post-procedure OS was 2.55 years [1.66, infinity] and 77.1% at 1 year as estimated by Kaplan-Meier. Median KPS remained at 80 through 2-year follow-up. Seizure prevalence was 12% within 1-month post-LITT and 7.9% at 3 months; down from 34.4% within 60-day prior to procedure. The authors note that LITT for RN was noted to be safe with low patient morbidity but was also a highly effective treatment option for RN for both local control and symptom management (including seizures). In addition to averting expected neurological death, LITT facilitates ongoing systemic therapy (in particular immunotherapy) by enabling the rapid cessation of steroids, thereby facilitating maximal possible survival for these patients.

UpToDate

In 2024, UpToDate (81) published a review regarding delayed complications of cranial irradiation, which states that surgical resection of necrotic tissue in patients is sometimes required, particularly in cases in which there is diagnostic uncertainty as to whether the radiographic changes are indicative of tumor progression or treatment-induced tissue necrosis, or in patients with severe necrosis who have contraindications to bevacizumab. LITT is an option in this context, but is less preferred in patients with preoperative neurologic deficits.

Professional Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The 2024 NCCN guidelines for CNS cancer (26) includes a 2B recommendation that addresses MRI-guided LITT for patients who are not surgical candidates (craniotomy or resection), and potential indications include RN.

Spinal Metastasis, Spinal Cord Compression and Spinal Instability

In 2015, Tatsui et al. (82) stated that high-grade malignant spinal cord compression is commonly managed with a combination of surgery aimed at removing the epidural tumor, followed by spinal SRS aimed at local tumor control. The researchers introduced the use of spinal LITT as an alternative to surgery prior to spinal SRS. Eleven (n=11) patients with a high degree of epidural malignant compression due to radioresistant tumors participated in the study. VAS scores for pain and QOL were obtained before and within 30 and 60 days after treatment. A laser probe was percutaneously placed in the epidural space. Real-time thermal MRI was used to monitor tissue damage in the region of interest. All patients received postoperative spinal SRS. The maximum thickness of the epidural tumor was measured, and the degree of epidural spinal cord compression (ESCC) was scored in pre- and post-procedure MRI. The mean VAS score for pain decreased from 6.18 in the preoperative period to 4.27 within 30 days and 2.8 within 60 days after the procedure. A similar VAS interrogating the percentage of QOL demonstrated improvement from 60% preoperatively to 70% within both 30 and 60 days after treatment. Imaging follow-up 2 months after the procedure demonstrated a significant reduction in the mean thickness of the epidural tumor from 8.82 mm (95% CI; 7.38-10.25) before treatment to 6.36 mm (95% CI; 4.65-8.07) after spinal LITT and spinal SRS (p=0.0001).

The median preoperative ESCC Grade 2 was scored as 4, which was significantly higher than the score of 2 for Grade 1b (p=0.04) on imaging follow-up 2 months after the procedure. This small study (n=11) concluded that spinal LITT provided local control with low morbidity and improvement in both pain and the QOL of patients. In addition, this report represented the initial experience with LITT in which this preliminary evidence on the potential applicability of LITT can potentially lay the foundation to pursue future studies. Multiple limitations were acknowledged including the small size of the cohort, the short follow-up with lack of randomization, no direct comparison with surgery, and no standardization in the time for post procedure SRS. Further randomized prospective studies are warranted.

Tatsui et al. (2016a) assessed spinal LITT as an alternative to surgery. Patients referred for spinal metastasis without motor deficits underwent MR-guided spinal LITT, followed by SRS. (83) Clinical and radiological data were gathered prospectively. MR-guided spinal LITT was performed on 19 patients with metastatic epidural compression. No procedures were discontinued due to technical difficulties, and no permanent neurological injuries occurred. The median follow-up duration was 28 weeks (range 10-64 weeks). Systemic therapy was not interrupted to perform the procedures. The mean preoperative VAS scores of 4.72 decreased to 2.56 at 1 month and remained improved from baseline at 3.25 at 3 months post procedure. The preoperative mean EQ-5D index for QOL was 0.67 (SD ± 0.07) and remained without meaningful change at 1 month 0.79 (SD ± 0.06, P=.317) and improved at 3 months 0.83 (SD ± 0.06, P=.04) after spinal LITT. Follow-up MR imaging after 2 months revealed significant decompression of the neural component in 16 patients. However, 3 patients showed progression at follow-up; 1 was treated with surgical decompression and stabilization and 2 were treated with repeated spinal LITT. The authors concluded that MR-guided spinal LITT can be both a feasible and safe alternative to separation surgery in carefully selected cases of spinal metastatic tumor epidural compression. This was a small study (n=19) with short-term median follow-up (28 weeks). These preliminary findings will need to be validated by well-designed studies.

Tatsui et al. (2016b) noted that an emerging concept for treating patients with ESCC caused by metastatic tumors is surgical decompression and stabilization, followed by SRS. (84) In the setting of rapid progressive disease, interruption or delay in return to systemic treatment can lead to a negative impact in OS. To overcome this limitation, researchers introduced the use of spinal LITT in association with percutaneous spinal stabilization to facilitate a rapid return to oncological treatment. The authors retrospectively reviewed a consecutive series of patients with ESCC and spinal instability who were poor surgical candidates and instead were treated with spinal LITT and percutaneous spinal stabilization. Demographic data, Spine Instability Neoplastic Scale score, degree of epidural compression before and after the procedure, length of hospital stay, and time to return to oncological treatment were examined. A total of 8 patients were treated with thermal ablation and percutaneous spinal stabilization. The primary tumors included melanoma (n = 3), lung (n = 3), thyroid (n = 1), and renal cell carcinoma (n = 1). The median KPS score before and after the procedure was 60, and the median hospital stay was 5 days (range of 3 to 18 days). The median Spine Instability Neoplastic Scale score was 13 (range of 12 to 16). The mean modified post-operative ESCC score (2.75 ± 0.37) was significantly lower than the pre-operative score (4.5 ± 0.27) (Mann-Whitney test, p = 0.0044). The median

time to return to oncological treatment was 5 days (range of 3 to 10 days). The authors presented the first cohort of spinal LITT associated with a percutaneous spinal stabilization for the treatment of ESCC and spinal instability. This minimally invasive technique can allow a faster recovery without prejudice of adjuvant systemic treatment, with adequate local control and spinal stabilization. The limitations of this study included the retrospective nature, the small sample size (n = 8), the short follow-up (follow-up imaging is performed generally 6 to 12 weeks after spinal LITT), the heterogeneity of histologies, and the lack of comparison with the standard surgical technique, which may limit the interpretation of these findings. The authors noted that a randomized prospective study comparing open and percutaneous separation surgery is warranted to evaluate the role of this new concept in the management of ESCC.

A literature search failed to identify any RCTs of LITT for the treatment of spinal metastasis.

Professional Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The 2024 NCCN CPG for the CNS (26) does not identify MRI-guided LITT as a treatment modality for metastatic spine tumors.

Thyroid

In a small 2013 randomized trial, Døssing et al. (85) studied 44 patients with recurrent, benign (predominantly cystic) thyroid nodules who were randomized to a single aspiration with (n=22) or without (n=22) subsequent interstitial laser photocoagulation. A diode laser was used under ultrasound guidance. At 6 months follow-up results showed no significant difference between the group (p=0.001) in reduction of median total nodule volume. In the ILP group remission of the cystic part was obtained in 15 of 22 (68%) patients, compared with four of 22 (18%) patients treated with aspiration alone (p=0.002). The authors concluded that that ILP compared to remission rate from 18–68%. The authors concluded that ultrasound guided interstitial laser photocoagulation results in a satisfactory long-term clinical response in the majority of patients with a benign solitary solid cold thyroid nodule and additional large-scale studies should aim at optimizing selection criteria, preferably in randomized studies with surgery and/or other nonsurgical options as the comparator.

A literature search failed to identify any RCTs or systematic reviews for the use of LITT for the treatment of thyroid nodules.

Professional Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The 2024 NCCN CPG for thyroid carcinoma does not identify MRI-guided LITT as a treatment option for the treatment of thyroid tumors. (86)

American Thyroid Association

The 2015 American Thyroid Association Guidelines on Medullary Thyroid Carcinoma (87) states surgical resection should be considered in patients with large solitary lung metastases. RFA should be considered when the metastases are peripheral and small. Systemic therapy should

be considered in patients with multiple metastases that are progressively increasing in size. (Grade C Recommendation)

Tremor Disorders

In 2019, Harris et al. (88) stated that medically intractable tremors are a common, difficult clinical situation. Deep brain stimulation decreases Parkinson's disease (PD) resting tremor and essential tremor, but not all patients are candidates from a diagnostic, medical, or social standpoint, prompting the need for alternative surgical strategies. These researchers described the findings of 13 patients with medically intractable tremor treated with laser interstitial thermal thalamotomy performed under general anesthesia using live MRI-guidance and the Clearpoint stereotactic system. All patients had a dramatic decrease in tremor immediately post-operatively, which has been sustained through follow-up (3 to 17 months) in all but 1 patient (mean tremor score reduction of 62%; 10.33 ± 2.69 to 3.89 ± 3.1). Objective side effects were transient and included imbalance and paresthesia. The authors concluded that medically intractable tremor treated with laser interstitial thermal thalamotomy may be a useful addition to the treatment armamentarium for medically intractable tremor disorders although these preliminary findings need to be validated by well-designed studies in larger patient population.

Professional Guidelines and Position Statements

Unable to locate any guidelines or position statements that address the use of MRI-guided LITT for individuals with tremors.

Summary of Evidence

For individuals with adrenal metastases there are no large randomized controlled trials (RCTs) that demonstrate the long-term safety and efficacy of laser interstitial tumor therapy (LITT) in terms of local progression and survival, compared with surgical removal. Available literature are small studies therefore, additional long-term studies with a larger patient population are warranted to determine the impact on health outcomes. Based on available published literature, the use of MRI-guided LITT for individuals with adrenal metastasis is considered experimental, investigational, and/or unproven.

For individuals with recurrent or malignant brain tumors which are inaccessible to surgical resection or who are unable to tolerate surgical resection due to medical comorbidities, the evidence is mainly small case series with small sample sizes and retrospective studies. MRI-guided LITT is a minimally invasive alternative for recurrent or malignant brain tumors and can be tailored to treat difficult to access brain tumors and offers an alternative to open craniotomy in properly selected patients. MRI-guided LITT should only be used for palliative/salvage therapy by a physician as repeat use of radiation therapy is limited due to concerns over adverse cumulative radiation effects. To date, published literature has shown that MRI-guided LITT is a safe, minimally invasive alternative when the above criteria are met.

For individuals with breast tumors, there are no RCTs that address the use of LITT for the treatment of breast tumors. Most published literature is review articles, small case series and meta-analysis. Additional long-term studies with a larger patient population are warranted to

determine the impact on health outcomes and to validate LITT as an alternative to surgery and other minimally invasive techniques. Based on available published literature, the use of LITT for individuals with breast tumors is considered experimental, investigational, and/or unproven.

For individuals with medically refractory epilepsy (failure of 2 or more antiepileptic drug regimens), the evidence is limited to case reviews, case series, and prospective/retrospective studies. While RCTs comparing minimally invasive procedures to the gold standard of anterior temporal lobectomy (ATL) provides a high level of evidence, this type of study is not feasible for LITT in the current setting. The current evidence suggests that the efficacy of MRI-guided LITT is comparable to open procedures and has improved patient outcomes in select patients. To date, published literature has shown that MRI-guided LITT is a safe, minimally invasive alternative for carefully selected patients when criteria are met.

For individuals with liver metastases, the evidence includes nonrandomized studies that address LITT for liver metastases that are of low quality. Findings are at high risk of bias and are of unclear significance due to some studies involving patients with different etiologies and prognoses. RCTs focusing on each specific tumor types are needed to compare LITT with other treatment modalities (e.g., surgery, microwave, radiofrequency). Larger studies are warranted to establish the long-term safety and efficacy of LITT for this indication and to determine the impact on health outcomes. Based on available published literature, the use of LITT for individuals with liver metastasis is considered experimental, investigational, and/or unproven.

For individuals with lung cancer and lung metastasis, the evidence consists mainly of low-quality nonrandomized studies and case series with a high risk of bias. Larger studies are warranted to establish the long-term safety and efficacy of LITT for this indication and to determine the impact on health outcomes. Based on available published literature, the use of LITT for individuals with lung cancer is considered experimental, investigational, and/or unproven.

For individuals with osteoid osteoma, there is limited evidence from nonrandomized comparative studies and case series that suggest LITT is safe and reduced patients' symptoms. However, available studies are small and are at a high risk of bias for one or more of the following reasons: small sample size, lack of control groups and randomization, single-center focus, and/or heterogeneous patient populations (ages and tumor sites varied widely). Studies also reported relatively short follow-ups (1 to 13.6 months). A single study compared LITT with conventional surgery and had heterogeneity among individuals regarding tumor location, which may affect pain levels and physical function. Large, multicenter studies reporting on pain and physical function measures are needed to validate findings and to assess LITT's effectiveness for osteoid osteomas. Additional studies to validate specific LITT techniques on different tumor and patient groups and to compare LITT with other ablative techniques (e.g., high-intensity focused ultrasound) would also be useful to guide care decisions. Larger RCTs are warranted to establish the long-term safety and efficacy of LITT for this indication and to determine the impact on health outcomes. Based on available published literature, the use of LITT for individuals with osteoid osteoma is considered experimental, investigational, and/or unproven.

For individuals with pancreatic cancer, the evidence includes a comparative study. No RCTS and/or professional guidelines were identified that support the use of LITT in individuals with pancreatic cancer. Larger RCTs are warranted to establish the long-term safety and efficacy of LITT for this indication and to determine the impact on health outcomes. Based on available published literature, the use of LITT for individuals with pancreatic cancer is considered experimental, investigational, and/or unproven.

For individuals with prostate cancer, the evidence for LITT includes small case series and systematic reviews of small case series. This would suggest that LITT may be safe and without negative effects on sexual and urinary function in the short term when used for localized prostate cancer. However, studies have not yet demonstrated efficacy. Available literature for the use of ultrasound guided transperineal focal laser ablation are small nonrandomized studies with only short-term oncological follow-up. Large RCTs are warranted to establish the long-term safety and efficacy of LITT and ultrasound guided transperineal focal laser ablation in patients with prostate cancer, and to determine the impact on health outcomes. Based on available published literature, the use of MRI-guided LITT and ultrasound guided transperineal focal laser ablation for individuals with prostate cancer is considered experimental, investigational, and/or unproven.

For individuals with radiation necrosis (RN) of the brain that is inaccessible to surgical resection, or in patients who are unable to tolerate surgical resection due to medical comorbidities, the evidence includes meta-analyses, nonrandomized comparative studies, and a single-arm study. MRI-guided LITT is a minimally invasive alternative for RN and is a relatively safe treatment option providing both a diagnostic and therapeutic solution in refractory patients who cannot safety undergo a craniotomy. MRI-guided LITT has reported to be efficacious in managing symptoms in this small subset of patients when the above criteria are met. In addition, relevant society guidelines support the use of LITT in properly selected patients with radiation necrosis. Therefore, MRI-guided LITT may be considered medically necessary in individuals with radiation necrosis of the brain when the policy criteria have been met.

For individuals with spinal metastasis and/or spinal cord compression, the evidence is mainly comprised of case reports and review articles. No RCTS and/or professional guidelines were identified that support the use of LITT in individuals with spinal metastasis and/or spinal compression. Larger RCTs are warranted to establish the long-term safety and efficacy of LITT for this indication and to determine the impact on health outcomes. Based on available published literature, the use of LITT for individuals with spinal metastasis and/or spinal compression is considered experimental, investigational, and/or unproven.

For individuals with thyroid nodules, the evidence is mainly comprised of case reports, small studies, and review articles. No RCTS and/or professional guidelines were identified that support the use of LITT in individuals with thyroid nodules. Larger RCTs are warranted to establish the long-term safety and efficacy of LITT for this indication, and to determine the

impact on health outcomes. Based on available published literature, the use of LITT for individuals with thyroid nodules is considered experimental, investigational, and/or unproven.

For individuals with tremor disorders, there are no RCTS and/or professional guidelines that support the use of LITT. Large RCTs are warranted to establish the long-term safety and efficacy of LITT for this indication, and to determine the impact on health outcomes. Based on available published literature, the use of LITT for individuals with tremors is considered experimental, investigational, and/or unproven.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	19499, 20999, 27599, 32999, 47399, 48999, 53899, 55899, 60699, 61736, 61737, 64999, 0655T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change

10/15/2024	Document updated with literature review. No change in coverage. Added references 1-3, 5, 7, 9, 58, 71, 78-80; others updated, some removed.
05/01/2023	Reviewed. No changes.
12/15/2022	Document updated with literature review. The following changes were made in Coverage: 1) Added lung metastasis, spinal instability and tremor disorders to the existing "including but not limited to" experimental, investigational and/or unproven statement. 2) Removed "MRI-guided" from the existing experimental, investigational and/or unproven statement. 3) Title changed from "Magnetic Resonance Image Guided Laser Interstitial Tumor Therapy (LITT)" 4) Added references 3, 5, 19, 40, 41, 44, 69, 78, 82-85; others updated.
09/15/2021	Reviewed. No changes.
01/01/2021	Document updated with literature review. The following change was made to Coverage: Added conditionally medically necessary coverage for epilepsy, brain tumors, and radiation necrosis of the brain. Expanded experimental, investigational and/or unproven statement to include lung cancer and osteoid osteomas; Added references 5, 10-20, 22, 33-35, 37, 38, 40, 50, 55, 61, 65, 71-74, 79; some removed/updated. Title changed from Laser Interstitial Tumor Therapy (LITT/ILT) and Laser Ablation.
12/15/2019	Document updated with literature review. Added "epilepsy" to the current experimental, investigational and/or unproven coverage statement. Added references 11, 12, 14, 20, 25-43, 48, 51-58, and 66. Some references removed. Title changed from Laser Induced Interstitial Tumor Therapy (LITT/ILT) and Laser Ablation of Tumors.
12/18/2018	Document updated with literature review. Added "spinal compression" to the current experimental, investigational and/or unproven coverage statement. Added references 5, 10, 11, 13, 15-17, 21, 25-28, 35, 37, 39, 40. Some references removed.
11/01/2017	Reviewed. No changes.
01/01/2017	Document updated with literature review. Added spinal metastasis as an example under the experimental, investigational and/or unproven coverage statement.
07/15/2015	Reviewed. No changes.
07/01/2014	New Medical Document. Laser Interstitial Tumor Therapy (LITT/ILT) and Interstitial Laser Ablation (ILA) of Tumors are considered experimental, investigational and/or unproven: for any indication, including but not limited to: Adrenal metastases; brain tumors; breast tumors (benign or malignant); liver metastases; pancreatic cancer; prostate cancer; radionecrosis; thyroid nodules.