Laser Interstitial Thermal Therapy

Policy Number: SURGERY 108.10
Effective Date: July 1, 2023

Instructions for Use

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Related Policy

- Intrauterine Fetal Surgery

Coverage Rationale

Laser interstitial thermal therapy is unproven and not medically necessary for treating any condition or diagnosis due to insufficient evidence of efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
19499	Unlisted procedure, breast
20999	Unlisted procedure, musculoskeletal system, general
27599	Unlisted procedure, femur or knee
32999	Unlisted procedure, lungs and pleura
53899	Unlisted procedure, urinary system
55899	Unlisted procedure, male genital system
61736	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion
61737	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)
64999	Unlisted procedure, nervous system

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Description of Services

Laser interstitial thermal therapy/thermotherapy (LITT) is an emerging treatment modality. The LITT treatment produces focal thermal ablation leading to lesion cytoreduction through tissue coagulation, necrosis, and cellular apoptosis. Historically, laser ablation techniques have been limited by an inability to assess ablation progress and parenchymal temperature during treatment. Advances in magnetic resonance imaging (MRI) capabilities have overcome these limitations, leading to the use of this technology for select conditions.

Clinical Evidence

The evidence for laser interstitial thermal therapy/thermotherapy (LITT) appears to have some promise for the future, however, overall, the evidence is lacking, low quality and needs additional robust, randomized trials with long-term results.

The National Comprehensive Cancer Network (NCCN) Practice Guidelines do not address laser thermal therapy or laser ablation as treatment in tumors of the prostate, bone, lung or breast. (2021)

Bone Tumors

In their updated Clinical Evidence Assessment on the use of LITT for treatment of osteoid osteoma, ECRI (2023) stated that the evidence regarding the safety and efficacy of LITT is inconclusive due to too few data on outcomes. The authors reviewed seven small studies (two nonrandomized comparative studies and five case series) and found that the studies included too few patients and were at too high a risk of bias to permit conclusions. The authors noted that the studies reported pain resolution in over 85% of patients with recurrence or serious complications in fewer than 11% patients. They also noted that the outcomes for patients treated with LITT were similar to those treated with surgery or radiofrequency ablation. Limitations of the studies included the small sample sizes, lack of control groups or randomization, retrospective study designs and single-center focus. The authors concluded that these findings need validation in additional studies.

Cardia et al (2023) completed a systematic review of literature to investigate the utility of using LITT for spinal lesions. The review included six studies (including the Bastos 2020 article previously included in this policy) with a total of 196 patients who had been treated with spinal LITT (sLITT) for compressive spinal metastases. The authors were not able to complete a meta-analysis of the literature as only one study met the criteria for a quantitative analysis. Most of the study participants were male (62.2%) and most of the lesions were located in the thoracic region (88.8%). The primary malignancy was renal cell carcinoma in 87 patients (36.9%), non-small-cell lung cancer in 56 patients (27.2%), hepatocellular carcinoma in 12 cases (5.8%), thyroid cancer in 18 patients (9.2%) and minor primary lesions in the last 69 patients (33.5%). in most of the studies, the patients' functional impairment has been calculated through the Karnofsky performance status scale (KPS). sLITT was done as an adjuvant treatment for 152 patients (73.8%) and as a salvage therapy in the remaining 54 patients 26.2%. The authors noted that sLITT was used as an alone treatment in 48 cases (23.3%), was followed by a spinal stereotactic radiosurgery (SSRS) in 128 patients (62.1%) and was followed by conventional external beam radiotherapy (cEBRT) in the remaining 30 patients (14.6%) and that no stabilization procedure was done following sLITT in the majority of cases (75.5%) although percutaneous stabilization was done in 45 cases (21.8%), and by a traditional open procedure in 5 patients (2.4%). All of the included studies used the epidural spinal cord compression (ESCC) scale to evaluate the compression rate. The authors noted that five of the six studies reported a statistical improvement of the compression at the last follow-up and that both of the studies that analyzed pain evolution after the procedure found a significant difference in the pain at 30 days post-procedure. The complication rate was 12.6% with most being transient conditions. Limitations of the systematic review included the small sample sizes of most of the studies (the Bastos study accounted for 110 of the 196 patients), the retrospective design of the studies, the lack of a comparison group and of any randomization. The authors concluded that sLITT was safe and provides effective local control for epidural compression from metastatic disease with a lower rate of postoperative complications when compared with traditional separation surgery. The authors indicated that sLITT should be considered as an alternative to open surgery in selected patients with spinal metastases.

The short-term and long-term treatment outcomes, complications, and patient satisfaction of MRI-guided laser ablation (LA) for the treatment of osteoid osteoma (OO) were evaluated In a single-center, retrospective, non-randomized follow-up study by Seemann, et al. (2022). The study included 29 patients (9 women and 20 men; median age 24 years) with OO in typical (long bones) and atypical (spinal column, shoulder girdle, pelvis and small bones of the hands and feet) locations who were treated with LA. The study participants completed a 3-year follow-up telephone interview (mean 31 months) that included questions

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about recurrence, residual pain or functional symptoms and satisfaction for short term follow-up. A second telephone interview for long-term follow-up at 10 years (mean 116 months) was completed with 21 of the study participants. Three of the 29 patients (10%) had recurrence, all of which were located atypically with two in the femoral neck and one in the toe. All three patients were free of symptoms afterwards undergoing a secondary procedure (one each MRI-guided LA, CT-guided radiofrequency ablation and open surgery). The authors reported a technical success rate of 100% for MRI-guided LA without major complications. The two minor complications included transient local inflammation and transient damage to the peroneal nerve. Primary success reported by the authors was 92% in typically located OO and 82% in atypically located OO. The technical success rate after repeat ablation was 100% regardless of the OO location. Limitations of the study include the small sample size, the single-center design, lack of a comparison group, the risk of bias from the data collection tools and the retrospective design of the study. The authors reported that patient satisfaction and acceptance were very good at both short-term (97%) and long-term (100%) follow-up. The authors concluded that MRI-guided LA of OO is safe and effective as a treatment option with high short-term and long-term patient satisfaction and acceptance rates.

Spinal LITT (sLITT) appears to be a promising modality for treatment of epidural metastatic spine disease in patients who are poor candidates for larger-scale procedures, and it works well with spinal stereotactic radiosurgery (SRS) to maximize local control and palliate pain. Utilizing intraoperative MRI guidance, sLITT was performed on 19 individuals with a variety of tumor types where metastatic vertebral disease was identified. The degree of epidural infiltration ranged from the tumor extending to the epidural space without displacement of the dura to epidural compression displacing the spinal cord with complete obliteration of the cerebrospinal fluid space. Median number of vertebral segments treated was 1 (range 1–3), with 80% of the involvement being the thoracic spine. Median hospital length of stay (LOS) was 2 days (range 1–14). One participant experienced post procedure transient L1 monoparesis, which resolved after 8 weeks. A second sLITT procedure was required at 16- and 33-weeks post procedure for 2 patients. One patient required salvage surgical intervention because of delayed progressive neurologic deterioration, and 1 patient developed a pathologic compression fracture 2 months post treatment requiring percutaneous stabilization. Mean preoperative Visual Analog Scale scores of 4.72 improved to 2.56 at 1 month and remained improved at 3 months postoperatively. Thirteen participants decreased their use of pain medication, whereas 3 increased medication usage (although only 1 of the 3 was a result of back pain). Preoperative mean quality of life index of 0.67, was unchanged at 1 month postoperatively, and improved to 0.83 at 3 months. MRI at 2 months post procedure showed a mean reduction in epidural tumor thickness of 22%, and the numeric scale of graded epidural compression showed an improvement from a preoperative mean of 3.8 to 2.9. The authors stated that the role of sLITT in the management of spinal metastasis needs to be compared with conventional surgery in a prospective randomized controlled trial (RCT), and that this initial evidence on the potential applicability of the technique will lay the foundation to pursue such a study. (Thomas et al., 2017)

Brain Tumors

In an Evolving Evidence Review on the use of LITT for treatment of brain radiation necrosis, Hayes (2023a) completed a full text review of three comparative studies, three single-arm studies, and two systematic reviews that they deemed were generally poor or very poor quality. Hayes concluded that there is a minimal level of support in clinical studies and in systematic reviews for using LITT for treatment of brain radiation necrosis. In their review of three full-text clinical practice guidelines, they found that two of the guidelines indicated that LITT could be considered as a treatment option for radiation necrosis but did not expressly recommend it over other therapies while the third guideline recommended another treatment over LITT for radiation necrosis but indicated that local control data for LITT was encouraging.

Hayes (2023b) published an Evolving Evidence Review on the use of LITT for the treatment of recurrent metastatic brain neoplasms in which they reviewed the full text of five clinical studies and three systematic reviews that were assessed to offer minimal support. Hayes noted that only 2 of the clinical studies were nonrandomized studies that compared LITT with other treatment modalities (craniotomy and stereotactic radiotherapy) and that reported generally consistent overall survival and progression-related results. The overall quality of the clinical studies was assessed to be of poor or very poor quality, In general, Hayes stated that most of the overall and progression-free survival rates reported in the included studies appeared to fall within expected ranges for the heterogeneous organs/tissues of cancer origination represented across studies and that the expected ranges were taken from studies of first incidence of brain metastasis and may overestimate overall survival for patients with recurrent brain metastases. In the evaluation of the systematic reviews, Hayes noted that the included studies in the systematic reviews were generally small, single-center, noncomparative and retrospective which was reflective of low-quality studies. It was also noted that the overall survival was generally similar to those reported after conventional treatments for recurrent brain metastases. Finally, the Evolving Evidence Review also assessed four full-text clinical practice guidelines and position statements and found that two guidelines recommended consideration of LITT for recurrent BMs, in patients who are poor

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surgical candidates and for surgically inaccessible lesions. The other two clinical practice guidelines provided no recommendation for the use of LITT for recurrent brain metastases due to lack of evidence and they concluded that, overall, there is weak support for LITT for the treatment of recurrent metastatic brain neoplasms.

ECRI's Clinical Evidence Assessment (2022) of the safety and efficacy of LITT for the treatment of nonglioblastoma brain cancers included a full text review of two systematic reviews (including the Chen 2021 study included in this policy below), one clinical study (not included in the systematic reviews), and one cost study with a combined 774 patients. The assessment indicated that the evidence was inconclusive due to very low quality of the studies. The authors found that the studies primarily assessed LITT in patients with recurrent brain metastases and that the results suggest that some patients who undergo LITT for brain metastases have local control at 12-month follow-up, with most discharged home within a few days. The authors noted that the studies identified that some patients developed serious complications including permanent neurologic injuries and malignant cerebral edema. Evidence for other nonglioblastoma brain cancers was scant according to the authors. Limitations included the lack of moderate- and high-quality studies comparing LITT's safety and efficacy with those of other treatment options for nonglioblastoma brain cancers, and the study designs of the originating studies (small sizes, retrospective, single-center focus and lacking control groups).The authors also noted that none of the studies reported on how LITT may improve symptoms, physical function, or quality of life, nor did they evaluate LITT's potential benefits over other treatment options. The authors concluded that the evidence was too limited in quality and scope to enable definitive conclusions regarding LITT's safety and effectiveness for nonglioblastoma cancers and recommended prospective, multicenter studies with relevant control groups that focus on specific nonglioblastoma brain cancers.

In an analysis of participants enrolled in the LAANTERN registry (an institutional review board (IRB)-approved, multisite, prospective registry) with newly diagnosed and recurrent Isocitrate dehydrogenase 1 (IDH1) wild-type glioblastoma, de Groot et al. (2022) reviewed the data of 29 newly diagnosed and 60 recurrent adult patients with IDH1 wild-type glioblastoma to determine their clinical outcomes. The authors reported that the median post-LITT overall survival (OS) was 9.73 months for newly diagnosed patients while the median post-LITT survival was 8.97 months for recurrent patients. They found that more than half (53.8%) of patients who were newly diagnosed with glioblastoma started treatment with both radiation and chemotherapy following LITT and that the median OS for this subset of patients was 16.14 months. Patients in the recurrent group had received prior LITT (6.7%), resection (88.3%), radiation (86.7%), and chemotherapy (90%). The authors reported that the factors associated with improved survival were MGMT promoter methylation, adjuvant chemotherapy within 12 weeks, and tumor volume. Limitations of the study include the variability in standard of care practices among the 28 institutions that participate in the registry, variability in the tumor volume treated with LITT, and in the timing of post-procedure imaging. There were also inconsistencies in molecular marker collection across the institutions and potential for selection bias surrounding the participating sites surrounding lesion size, functional status, and age. The authors concluded LITT offers an effective cytoreductive approach for patients with newly diagnosed and recurrent IDH wild-type glioblastoma, and that its use in newly diagnosed patients who are followed by post-LITT chemoradiotherapy produce a median OS similar to that of patients treated with conventional surgical resection which makes LITT a viable alternative for patients with inoperable tumors or those not amenable to resection.

In a single-institution, retrospective case series of patients treated with LITT for isocitrate dehydrogenase 1 and 2 (IDH1/2) mutant grade 2 or 3 gliomas, Johnson et al. (2022) collected data on patient presentation, radiographic features, tumor molecular profile, complications, and outcomes in 22 patients with a mean age of 46.6 years for the primary goal of calculating progression-free survival (PFS). Treatment prior to LITT occurred in 72.7% of patients including surgical resection (14 patients, 63.6%), chemotherapy (10 patients, 45.5%), radiation therapy (12 patients, 54.4%), biopsy (4 patients, 18.2%) and radiosurgery (1 patient, 4.5%). Three patients experienced perioperative complications after LITT including seizures, deep vein thrombosis and severe cerebral edema requiring decompressive hemicraniectomy. The authors reported an overall 22.7% (n = 5) progression of disease rate at a median follow up of 1.8 years. When the authors evaluated for factors associated with tumor progression, they considered age, extent of ablation, tumor grade, pathology, first line versus salvage, adjuvant therapy and prior extent of resection in their analysis. They found that none of these factors were independent risk factors for progression. Limitations of the study include the small sample size, the single center design, the heterogeneity in pre-LITT and adjuvant treatments, and the short follow-up period. The authors concluded that LITT is an effective alternative to open resection in patients with IDH1/2 mutant grade 2 and 3 gliomas and that the median time to progression and three- and five-year PFS estimates in the cohort were on par with those reported in other studies. The authors recommend additional multi-center studies to better characterize treatment outcomes after LITT in patients with IDH1/2 mutant grade 2 and 3 gliomas.

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Sabahi et al (2022) performed a quantitative systematic analysis of multi-institutional outcomes of LITT for the treatment of posterior fossa lesions based on demographics of the participants and their tumors to assess if LITT safe and effective in the treatment posterior fossa tumors. Their review consisted of 16 published studies involving 150 patients of which 76.1% were female with a mean age of 56.47 years. The authors extracted morbidity and mortality data on 131 of the 150 patients and found that death could be attributed to treatment failure, disease progression, recurrence or postoperative complications in 6.87% (9 of 131 participants) while procedure-related complications while occurred in 14.5% (19/131). The remaining 78.6% (103/131) of the pooled sample did not experience any complications and had progression-free survival at the time of the last follow-up. The authors' assessment of the data showed that the main determining factor in the occurrence of complications after the LITT was the proximity of the lesion to the cranial nerves and that individuals with brainstem lesions experienced higher complications while ablation of the cerebellum showed a lower risk of complications. Limitations noted by the authors included the small sample sizes in most studies (12 of the 16 studies had less than 10 patients), heterogeneous tumor types (radiation necrosis (n = 7), breast cancer (n = 34), brain lesions (n = 28), lung cancer (n = 22) renal and gastrointestinal cancer (n = 7), and metastasis from other sources (n = 13)), variability in the thinness of the MRI slices, patients lost to follow-up, lack of high-powered studies, and insufficient power to demonstrate efficacy or safety of LITT for any single diagnosis. The authors concluded that LITT for posterior fossa lesions showed promise and that clinical cohort studies are needed to further direct treatment recommendations.

Based on a Hayes Health Technology Assessment on the use of LITT for the treatment of newly diagnosed, recurrent or progressive glioblastoma (GBM) in adults, the quality of evidence continues to be assessed as very low for the use of LITT for treatment of GBM and does not allow for conclusions to be drawn regarding potential benefits and potential associated risks. Hayes reached their conclusion based on the body of evidence being composed of very-poor-quality case series that prohibited conclusions regarding the safety or efficacy of LITT for treatment of GBM, because of the small number of patients treated and because of the lack of quality-of-life (QOL) outcomes included in the studies. The assessment concluded that studies comparing LITT with standard treatment measures or with historical patient groups, as well as longer-term follow-up, are needed to ascertain the role of LITT in GBM as the current eligible studies included patients who had GBM in difficult-to-access regions or had recurrent or progressive disease and were not candidates for standard surgical resection. (Hayes 2019, updated 2022)

An ECRI evidence assessment on LITT's safety and efficacy and how LITT compares with other treatment modalities for newly diagnosed or recurrent glioblastoma (GBM) concluded that there is a very low-quality body of evidence that LITT is safe and effective. The report found three systematic reviews (two with meta-analyses), one retrospective single-center case series, one retrospective single-center cost analysis, and one cost-effectiveness study that suggest LITT is feasible and relatively safe for treating GBM with outcomes favoring LITT over surgery; however, the studies have a high risk of bias, few patients and heterogeneity which precludes their ability of reaching more definitive conclusions. The assessment concluded that there needs to be prospective, multicenter studies with parallel control groups to confirm the efficacy of LITT compared with conventional surgery and to evaluate LITT as an adjunct or alternative to stereotactic radiotherapy. It also recommends that future studies include data on overall survival, safety, quality of life and function. (ECRI 2019, updated 2021)

One of the systematic reviews included in the ECRI evidence assessment above was by Viozzi et al. (2021). They reviewed 11 studies that included a total of 114 patients to evaluate the safety and efficacy of LITT in adult patients with newly diagnosed GBM and found that 9 of the studies scored a serious risk of bias in the overall methodological quality assessment, while the remaining two scored a critical risk of bias. The authors noted that the quality of evidence was graded as very low according to the GRADE criteria because none of the studies randomized the participants, 10 were retrospective in nature, 9 were single center and only half of them reported a 95% confidence interval for the point estimates. The authors found that the studies had poor reporting of confounders and other parameters, and that they did not report any quality of life or cost-effectiveness data. The review population had a mean age of 56.6 years with a predominance of males (56.5%). Most of the tumors (61.8%) were dep-seated (thalamus, basal ganglia, corpus callosum and insula). When they analyzed the data, it showed that the median overall survival (OS) ranged from 4.1 to 32 months and progression free survival (PFS) as reported in 9 of the 11 studies ranged from 2 to 31.9 months. The data also showed a mean complication rate of 33.7%. Limitations of the systematic review that the authors noted include the heterogeneity of the studies, the low quality of the evidence, and the low number of articles included.

The authors concluded that high quality comparative studies with robust data regarding the safety and clinical effectiveness of LITT as primary treatment for patients with newly diagnosed GBM is lacking and that the real effect of LITT on survival is unclear.

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Arocho-Quinones, et al. (2020) completed a retrospective review of data collected from 17 centers to assess the safety and efficacy of MR-guided stereotactic laser ablation (SLA) therapy in the treatment of pediatric brain tumors in patients from infancy up to 21 years of age, with a diagnosis of brain tumors (primary and/or metastatic) who were treated via MR-guided SLA therapy between 2008 and 2016 and had a minimum follow-up time of 3 months. The study population included a total of 86 patients, which included 76 patients with low-grade (I or II) and 10 high-grade (III or IV) tumors. The mean age of the population was 12.2 ±4.5 years, and the mean follow-up time was 24 months. Tumor location included lobar (38.4%), deep (45.3%), and cerebellar (16.3%) compartments, where the deep compartment included basal ganglia, hypothalamus, thalamus, and periventricular locations. The authors reported that the volume of SLA-treated tumors had decreased in 80.6% of the 72 patients who had data for tumor volume at their last follow-up. For those in the low-grade tumor group, 65 had post-SLA volume data available at last follow-up which showed 83.1% had a smaller volume and 16.9% had stable or increase in tumor size. Of the 10 patients with high-grade tumors, seven had data on tumor volume at the latest follow-up that showed 57.1% had a decrease in volume and 42.9% were stable or increased in size. Progression-free survival after SLA treatment was 92% at 72 months and no subsequent surgery or adjuvant treatment was needed after SLA in 90.4% and 86.7% of patients, respectively. The authors noted that there were 29 a total of acute complications in 23 patients including malpositioned catheters (n = 3), intracranial hemorrhages (n = 2), transient neurological deficits (n = 11), permanent neurological deficits (n = 5), symptomatic perilesional edema (n = 2), hydrocephalus (n = 4), and death (n = 2) and 3 patients were reported to have worsened neuropsychological test results on long-term follow-up. Limitations of the study include the lack of a control group to compare with traditional therapies, selection bias for tumors that are sufficiently small and more difficult to access or treat with other techniques, the lack of specific histopathology for all cases that were biopsied, the retrospective design, the short-term follow up and the heterogeneity of the procedure technique and systems used. The authors concluded that SLA was an effective, minimally invasive treatment option for pediatric brain tumors and that the incidence of complications may be decreased if the volume of the generated thermal lesion is limited in volume.

Chen et al. (2021) conducted a systematic review of 14 studies with 470 patients (542 lesions) to determine the efficacy of LITT for brain metastases (BM) patients who experienced in-field recurrence (IFR) following stereotactic radiosurgery (SRS). The study population included 149 lesions in 7 studies with radiation necrosis (RN). The median age of the population was 59.6 years and there was a predominance of females (65.5%). The most common primary tumor types were lung cancer (42.5%), breast cancer (21.7%) and melanoma (14.7%). The authors determined that the local control rate (from a total of 342 lesions in ten studies) was 78.5% at 6 months (LC-6) and the 12-month local control rate (LC-12) was 69.0% overall. In a subgroup analysis of the RN population, the LC-6 was 87.4% and the LC-12 was 76.3% whereas the LC-6 for BM patients was 67.9% and 59.9% for the LC-12. The overall survival (OS) was available for analysis from 410 patients enrolled in 11 studies and was found to be 76% at 6 months (OS-6) and 63.4% at 12 months (OS-12). When the subgroups were evaluated, they were found to have an OS-6 of 83.1% for RN and 69.2% for BM, and an OS-12 of 66.8% for RN and 66.5% for BM. The authors noted that this study had a few limitations including the retrospective nature and small sizes of the studies, significant heterogeneity among the studies included due to the different pathological entities, the lack of randomization and control groups among the included studies, and a lack of standardized definition on local control across different series. The authors concluded that LITT shows a comparable local control rate and more satisfactory overall survival benefit to surgical resection for IFR and that LITT provided more satisfactory local control efficacy on RN than on BM recurrence.

Kim, et al. (2020) reported on the 12-month outcomes and quality of life (QoL) after laser ablation of intracranial tumors. Their study included 223 patients with 231 ablated tumors from 14 centers participating in the Laser Ablation of Abnormal Neurological Tissue using Robotic NeuroBlate System (LAANTERN) prospective registry. The participants included 119 females (53.4%) and 104 males (46.6%) with a median age of 54.3 years (range 3-86), of which, 72.6% had at least one baseline comorbidity. Most of the 131 patients with primary tumors had high grade gliomas (80.9%), while most of the 92 metastatic tumors were due to recurrence (50.6%) or radiation necrosis (40%) with 92.4% of them having been previously treated. The median baseline Karnofsky Performance Score (KPS) was 90 prior to LITT, declined by an average of 5.7 to 10 points immediately post-procedure and stabilized/improved for 50.5% of patients at 6 months follow-up. QoL measures were assessed at baseline and follow-up visits (1, 3, 6, and 12 months) using the Functional Assessment of Cancer Therapy-Brain (FACT-Br) questionnaire and the EuroQol 5-dimensional (EQ-5D) questionnaire. The authors reported that the study participants had an average decline of 4.5 and 4.3 points (on a scale of 200) in overall FACT-Br scores at 1 and 3 months, but that there was no significant change at 6 and 12 month compared to baseline. The authors reported that 24.9% of the tumors undergoing LITT were considered difficult to access through open surgery and 58.6% of physicians stated LITT was performed because a minimally invasive procedure was preferred by the patient. There were 24 patients (10.7%) with adverse events felt to be related to LITT with only 4 (1.8%) considered serious or resulted in rehospitalization within 30 days of the procedure. The authors also noted that steroid use increased from 40.3% to 64% within 30 days of the procedure. The estimated 1-year survival rate was

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73% with no significant difference observed between patients with metastatic or primary tumors in overall survival. There were no significant differences in KPS or QoL scores between patients with primary versus metastatic tumors. Limitations of the study include the heterogeneity of the data timepoints among the studies, the treatment protocols among the centers participating in the registry, and in the ages of the patient population included in the study. The authors concluded that the results from the ongoing LAANTERN registry demonstrated that LITT stabilizes and improves QoL from baseline levels in malignant brain tumor patients with high rates of comorbidities with an overall survival rate better than anticipated for a real-world registry and comparative to published literature.

A meta-analysis was completed by de Franca et al. (2020) which compared current stereotactic radiosurgery (SRS) therapy with LITT in brain tumors. A total of twenty-five articles were included. The total number of patients was significantly higher for the SRS studies compared with only 39 patients for LITT; despite this variable, the authors felt the studies were matched. The median overall survival (MOS) for patients receiving LITT for brain metastasis was 12.8% versus only 9.8% for SRS; the MOS for patients receiving LITT or SRS for recurrent g*lioblastoma multiforme (*rGBM) were both at 10.5%. While the data appears to be positive for LITT, the authors could not conclude if LITT was an optimal alternative treatment choice for brain tumors when compared to SRS; further randomized trials are warranted to ascertain if LITT can play an appropriate role. Limitations included inability to validate if patients or clinicians were blinded, high heterogeneity between SRS studies and only moderate heterogeneity in serious adverse events for LITT patients and lack of consistency of data amongst articles.

Hong et al. (2019) 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. Of patients with tumor, 26 underwent craniotomy and 16 had LITT. For radiation necrosis (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.

Eichberg et al. (2018) performed a pilot study on 4 individuals with recurrent cerebellar metastases who were treated with MRgLITT. The extrapolated average time for the lesion to shrink to below the initial size was 294.5 days. There was a trend toward a decrease in average edema volume from the preoperative MRI of 17.8 cm to final postoperative follow-up MRI of 3.4 cm. No postoperative hydrocephalus or complications occurred. The authors concluded that MRgLITT appears to be a safe and promising treatment for recurrent posterior fossa metastatic lesions up to 7.2 cm. Further RCTs are needed to further study the long-term efficacy of this therapy.

Kamath et al. (2017, included in the Hayes report cited above) 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 progression-free survival (PFS) and overall survival (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.

Tovar-Spinoza and Choi published the preliminary results of the first series of pediatric brain tumors treated with MRgLITT at a single pediatric center. Outcomes were evaluated retrospectively for 11 patients with 12 tumors of 6 different types, all treated with the Visualase thermal laser system (Medtronic) between February 2012 and August 2014. Medical records, radiological findings, surgical data, complications, and results of tumor volumetric analyses were reviewed. A single laser and multiple overlapping ablations were used for all procedures. The mean hospital LOS was 3.25 days, and the mean follow-up time was

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24.5 months. Tumor volume in all patients decreased in the first 3 months after surgery and continued to decrease by the 4- to 6-month follow-up. Two patients experienced transient post-ablation complications. The authors concluded that MRgLITT is an effective first- or second-line treatment for select pediatric brain tumors. Larger multi-institutional clinical trials are necessary to evaluate its use for different types of lesions to further standardize practices. (2016)

Ivan et al. (2016) conducted a meta-analysis on the use of MRgLITT in the treatment of newly diagnosed HGGs. Eighty-five articles were identified plus one that was pending publication. Four articles were accounted for in this review 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 overall survival was 14.2 months (range 0.1-23 months). The median progression-free survival was 5.1 months (range 2.4-23 months); however, these data are limited by the relatively short follow-up of the patients reviewed and small sample size. Only one participant suffered a major perioperative complication (central nervous system infection). The researchers concluded that MRgLITT is a safe and promising technology for the treatment of small, yet difficult-to-treat newly diagnosed HGG, and that future randomized studies are needed to evaluate the role of this technology. The review is limited by lack of comparison group.

Lee et al. (2016) conducted a review of the peer-reviewed literature evaluating the role of LITT in the treatment of recurrent HGGs for which current treatments have limited efficacy, and to discuss the possible role of LITT in the disruption of the blood-brain barrier to increase delivery of chemotherapy locoregionally. Six of 17 articles were thought to be most appropriate for this review. Sixty-four lesions in 63 patients with recurrent HGGs were treated with LITT. Frontal (n = 34), temporal (n = 14), and parietal (n = 16) were the most common locations. Permanent neurological deficits, vascular injuries, and wound infection were seen in 7, 2, and 1 patients, respectively. Ablation coverage of the lesions ranged from 78% to 100%. The authors concluded that although experience using LITT for recurrent HGGs is growing, current evidence is insufficient to offer a recommendation about its role in the treatment paradigm for recurrent HGGs.

Barnett et al. 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 HGGs 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 concluded that in patients presenting with HGGs in or near areas of eloquence, early results demonstrate that brain LITT may be a viable surgical alternative (2016).

Evidence-based clinical practice guidelines endorsed by the Agency for Healthcare Research and Quality (AHRQ) do not address LITT in the management of patients with diffuse low-grade glioma (Ryken et al., 2015) or progressive GBM. (Olson et al., 2014)

Clinical Practice Guidelines

American Society for Radiation Oncology (ASTRO)

ASTRO does not address LITT in an executive summary of its evidence-based clinical practice guidelines on treatment for GBM. (Cabrera et al., 2016)

American Society of Clinical Oncology (ASCO)/Society for Neuro-Oncology (SNO)/American Society for Radiation Oncology (ASTRO)

The 2022 guideline from ASCO/SNO/ASTRO on the treatment for brain metastases states that no recommendation can be made for or against LITT due to low quality of evidence. (Vogelbaum, 2022)

Congress of Neurological Surgeons (CNS)/American Association of Neurological Surgeons (AANS)

In a joint position statement on MR-guided LITT for brain tumors and radiation necrosis, the CNS and the AANS stated that there is a consensus that intracranial LITT should be considered as a potential option for patients with recurrent or progressive malignant primary or secondary tumors, lesion(s) inaccessible to surgical resection or in patients that are not surgical candidates due to medical comorbidities. (Barnett, et al. 2021)

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National Comprehensive Cancer Network (NCCN)

The NCCN guideline on central nervous system cancers includes a 2B recommendation (based on lower-level evidence with NCCN consensus that the intervention is appropriate) regarding MRI-guided LITT indicating that the procedure may be considered for patients who are poor surgical candidates (craniotomy or resection) for conditions such as relapsed brain metastases, radiation necrosis, and recurrent glioblastoma. In their 2022 update, the NCCN guideline added that LITT can be considered on a case-by-case basis for treatment of radiation necrosis in patients with a history of radiation therapy for primary brain tumor or metastatic disease. The position statement recommends consultation with an adept neurosurgeon trained in LITT when the procedure is being considered.

Breast Tumors

An ECRI report found that available evidence on LITT for early-stage breast cancer consists of small case series, some of which are synthesized in systematic reviews. Findings are at high risk of bias and are of unclear significance because of low statistical precision and because most patients underwent sequential LITT and resection, so the contribution LITT made to the outcomes cannot be discerned. Prospective studies with a parallel control group are needed to validate LITT as an alternative to surgery and to compare LITT with other minimally invasive techniques. (2019, updated 2021)

Kerbage et al. (2017) performed a systematic review to evaluate the scientific publications investigating the LITT approach in malignant and benign breast disease. Three pre-clinical studies and 8 clinical studies (2 including fibroadenomas and 6 including breast tumors) were reviewed. Although the feasibility and safety of LITT have been confirmed in a phase I trial, heterogeneous inclusion criteria and methods seem to be the main reason for LITT not being yet an extensively used treatment option. The authors concluded that further development is necessary before this technique can be used in daily practice.

Haraldsdóttir et al. (2015, included in the ECRI report above) reviewed the effect of immunological changes induced by interstitial laser thermotherapy (ILT) on long-term outcome of patients with breast tumors. Twenty-four patients with invasive breast tumors were treated with ILT followed by standard surgical excision. Immunohistological reactions on immunocompetent cells were performed on specimens obtained before and after ILT. Follow-up time ranged from 91-136 months. The authors concluded that ILT did not have any long-term adverse effects. The clinical impact should be examined in a larger patient population.

Clinical Practice Guidelines

American Society of Breast Surgeons (ASBrS)

The ASBrS 2018 Consensus Guideline on the use of transcutaneous and percutaneous ablation for treating benign and malignant breast tumors suggests that LITT is still to be investigated by the U.S. Food and Drug Administration (FDA) for breast cancer treatment and recommends additional research.

National Institute for Health and Care Excellence (NICE)

Clinical guidance from NICE states current evidence on the safety and efficacy of ILT for breast cancer does not appear adequate to support the routine use of this procedure. It is suitable for use only within good-quality research studies. (2012)

Epilepsy

Chen et al. (2023) conducted a systematic review and individual participant meta-analysis to identify independent predictors of seizure outcome and complications following magnetic resonance-guided laser interstitial thermal therapy (MRgLITT) for drug-resistant epilepsy (DRE). Their review included 46 studies (including the Jermakowicz 2017, Kang 2016, Kuo 2019, Lewis 2015, and McCracken 2015 studies previously included in this policy) that reported on 450 patients with a mean age of 29.5 ±18.1 years, and 49.6% female, who underwent MRgLITT for DRE. The studies had a median of 7 (2-42) participants. Most patients (80.6%) had lesional MRI findings most commonly attributed to mesial temporal sclerosis/atrophy (MTS/A; 33.7%), followed by hypothalamic hamartomas (HH; 16.3%), malformations of cortical development (MCD; 14.4%), cerebral cavernous malformation (CCM); 8.2%), and tuberous sclerosis complex (TSC; 5.9%). Prior to undergoing MRgLITT, 38.4% of the participants had previously undergone open epilepsy surgery, most commonly focal resection (19.4%). The authors reported that 220 (53%) of participants experienced recurrent seizures during follow-up with a median post-operative time -to-seizure freedom of 15.5 months, while 240 of 415 patients (excluding palliative corpus callosotomy) were seizure free at last follow-up. Repeat MRgLITT was performed in 22 cases where an additional 10 participants became seizure free. The individual analysis showed that generalized seizure semiology and non-lesional MRI findings independently predicted faster time-to-seizure recurrence while

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CCM and MTS/A were independently associated with greater odds of being seizure free at last follow-up. The authors noted that operative complications which occurred in 28 of 330 patients (8.5%) were independently associated with extratemporal ablations and non-lesional MRI studies and that postoperative neurological deficits were observed in 53 of 352 patients which were independently predicted by HH etiology and invasive EEG monitoring. Limitations of the study included the non-standardized reporting of data which affected data abstraction and risk of bias in meta-analyses, the small sample sizes of the included studies and the heterogeneity of the study designs. The authors concluded that MRgLITT is particularly effective in treating patients with well-circumscribed lesional DRE, such as CCM, HH and MTS/A, but less effective in non-lesional cases or lesional cases with more diffuse epileptogenic network associated with generalized seizures, and that the efficacy of MRgLITT was related to the likelihood of completely ablating the epileptogenic zone. The authors acknowledged that MRgLITT is not without its risks for neurological complications, which they stated are directly related to the target's anatomical localization and adjacent eloquent structures.

In a single-center, retrospective case series of pediatric patients with medically refractory epilepsy (MRE), Slingerland, et al. (2022) retrospectively reviewed the medical records of children who had undergone stereoelectroencephalography (SEEG) and MRgLITT or open resection/disconnection to evaluate their real-world clinical outcomes. The study include 74 SEEG patients with 27 who underwent MRgLITT ((median age 12.1 years, 63% female) and 47 underwent craniotomy (median age 12.1 years, 49% female). Age at seizure onset, age at surgery, sex, and primary seizure etiology did not significantly differ between treatment cohorts. There were 6 patients (13%) in the open cohort had previously undergone several prior resection/disconnection, vagus nerve stimulator insertion, and MRgLITT treatments while 1 of the patients in the MRgLITT cohort had undergone prior temporal resection of focal cortical dysplasia. The authors reported that complication rates did not differ between the two groups, although more subdural/epidural hematomas, infarcts, and permanent unanticipated neurological deficits were seen following craniotomy, while more temporary unanticipated neurological deficits were noted following MRgLITT. The authors stated that seizure outcomes were similar between the cohorts with 74% of MRgLITT and craniotomy patients attaining Engel class I or II outcomes at the last follow-up, and that the MRgLITT cohort tended to have shorter hospitalizations and fewer complications. The authors noted that their results should be generalized to guide treatment decisions in other practice environments with caution as their study was not a randomized comparison and that treatment modality decisions were made based on considerations for target size, location, expected efficacy and safety. Limitations included the retrospective, single-center design, the small sample size and the lack of randomization. The authors concluded that MRgLITT and open resection following SEEG were both effective treatments for MRE in pediatric patients and that MRgLITT may be best suited for focal deep-seated targets associated with relatively challenging open surgical approaches.

A systematic review and pooled analysis by Awad and Kaiser (2022) focused on the feasibility, outcomes and complications of MRgLITT treatment for corpus callosotomy in patients with epilepsy. The authors reviewed 10 retrospective studies that included 57 cases where MRgLITT was performed. The average age of the patients was 25.6 years (1-52 years) with the majority being adults (74.1%). A prior open surgery involving the corpus callosum was reported in 25.9% (15/58) of patients. All patients underwent a partial callosotomy via MRI-guided LITT except for one patient who had a complete-one-stage LITT callosotomy; 33 of the cases were anterior callosotomies and 20 were posterior callosotomies. The average clinical follow-up following LITT callosotomy was 20 months. The authors reported that complete seizure freedom and excellent seizure control were achieved in 21.1% and 49.1% of patients, respectively. For atonic seizures, the authors reported a rate of complete freedom from seizures of 52.5% and excellent control at 72.5%. Complications identified by the authors included fiber-related hemorrhage (8.6%), inaccurate placement (6.9%) followed with transient hemiparesis/hemineglect and supplementary motor area (SMA) syndrome in 5.2% of cases with a rate of disconnection syndrome of 3.4% (2 patients), which occurred in patients who underwent completion callosotomy after the ablation of the splenium. The limitations noted by the authors included the non-randomized, retrospective study design of the included studies, the heterogeneity of reporting of seizures and the variation of seizure control scales, and the inability for a head-to-head comparison to be done between the subgroups due to the lack of power in the small sample size. The authors concluded that MRgLITT for corpus callosotomy was feasible and safe with low complication rates, short hospitalization and comparable rates of seizure control to that of classic surgical callosotomy.

In a systematic review and meta-analysis of MRg-LITT for DRE, Barot et al. (2022) reviewed 28 studies that included a total of 559 patients with DRE and found that the overall prevalence of becoming free from disabling seizures (Engel class I) was 56%. Their analysis showed that patients treated for hypothalamic hamartomas had the highest seizure freedom rate of 67% while the outcome for mesial temporal lobe epilepsy (mTLE) was 56% and extratemporal epilepsy was 50%. The authors noted that the mTLE cases with mesial temporal sclerosis had better outcome compared with non-lesional cases of mTLE. Their pooled analysis also showed that the prevalence of seizure freedom decreased from 60% in the short-term (6-12 months) to 53% when the mean follow-up duration was over 24 months. Based on their analysis of 25 studies with 519 patients, the adverse event rate

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was 19% with the most common adverse event being visual field deficits with intracranial hemorrhage and motor deficits also being reported. When the authors analyzed for the reoperation rate, they evaluated 18 studies that reported the data and found the reoperation rate was 9% including repeat ablation (n = 55) and open resection (n = 18). The authors identified the small study sizes, the heterogeneity of etiologies, the retrospective approach of the studies and the lack of randomization as limitations in their review and analysis. The authors concluded that MRgLITT can be an effective and safe treatment option for DRE with different disease etiologies.

Brotis et al. (2021) performed a meta-analysis on 575 patients to evaluate the efficacy of LITT for mesial temporal lobe epilepsy (MTLE). All sixteen studies were retrospective, and the ablation performed was done so with the Visualase MRI-guided laser ablation system. Of those patients receiving LITT, approximately 55% of the patients were seizure free, however the effectiveness of the procedure seemed to diminish over time thus questioning the overall effectiveness of the procedure. While it appeared LITT may provide a viable alternative for managing patients with MTLE, the authors found additional data was required to demonstrate its efficacy. Limitations included several studies of low-quality evidence, retrospective and limited follow-up; additional high-quality studies are needed to evaluate LITT in epilepsy surgery.

A Hayes health technology assessment (2020, updated 2023) provides investigation of LITT with MRI for the treatment of refractory temporal lobe epilepsy. Based on their review of abstracts for four newly published studies, Hayes stated that there was no change to their overall rating for the use of LITT for the treatment of refractory temporal lobe epilepsy. Overall, there remains a very-low-quality body of evidence which is insufficient to draw conclusions regarding LITT for refractory mesial temporal lobe epilepsy (MTLE). The evidence primarily reflects individual study limitations such as observational rather than experimental design, a lack of comparison with control groups or baseline measures, retrospective analyses, limited follow-up duration, loss to follow-up, and small sample size. This technology assessment includes the Barot 2022, Brotis 2021, Marathe 2021 and Kerezoudis 2020 studies summarized in this policy.

Marathe et al (2021) conducted a Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) systematic review and meta-analysis to compare seizure freedom rates following open surgical procedures, radiosurgery (RS), LITT and radiofrequency ablation (RFA) for the treatment of drug resistant mesial temporal lobe epilepsy (MTLE). They included 41 studies (19 on open surgery, 11 on LITT, 4 on RFA and 7 on RS) in the quantitative analysis. For each surgery type, pooled estimates of the seizure-free rate per person-year were calculated, together with 95% confidence intervals, using a meta-analysis with inverse variance weighting. The 11 studies with LITT as the treatment methodology included the Jermakowicz (2017), Tao (2018) and Grewal (2018) studies discussed below. The authors reported that the LITT studies had a moderate degree of bias. Their analysis showed a seizure-free rate comparable with open surgical models, but they caution that long-term follow-ups and direct comparisons are needed to form a firm conclusion. Limitations noted by the authors included the varying and inconsistent duration of follow-ups, the sparsity of RCTs, the retrospective design of most studies, and the significant heterogeneity between studies. The authors concluded that there is no evidence to suggest LITT is less effective than open surgical techniques in the short term but long-term outcome data is still lacking. The authors recommend future studies to compare LITT to open surgical methods and to provide more precise data regarding timing of seizure recurrence following surgery.

A systematic review and analysis conducted by Kerezoudis et al. (2020) examined seizure freedom for patients who received LITT for temporal lobe epilepsy (TLE). A total of thirteen studies were analyzed and seizure freedom was measured with the Engel Surgical Outcome Scale. While the findings illustrated a 58% seizure freedom rate for patients with TLE, the complication rate was 17% and it was concluded that the current evidence was insufficient to support a significant correlation between seizure freedom and LITT. Limitations included retrospective design type, small sample sizes and lack of long-term follow-up.

An ECRI meta-analysis of low-quality pre-post cohort studies showed that LITT appears to be as safe and effective as stereotactic radiosurgery for patients with epilepsy, and that LITT resulted in freedom from seizures in approximately 60% of the patients with refractory epilepsy at up to two years. The report concluded that the nonrandomized studies that were reviewed suggest that LITT may be safer than open surgery; however, the report indicates prospective, multicenter studies are needed to validate the data. They also recommended additional larger studies with relevant comparison groups to define LITT's place in the epilepsy management pathway. (2019, reviewed 2021)

Hoppe and Helmstaedter conducted a systematic review on the use of LITT in pediatric epilepsy, retrieving 25 uncontrolled case series reports that included a total of 179 pediatric patients as well as 7 review papers that specifically referred to this surgical approach. Hypothalamic hamartoma (HH) represented the most frequent indication (64.2%), with therapeutic evidence

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for other more frequent etiologies underlying severe focal childhood epilepsies (e.g., focal cortical dysplasia, MTS) considered to be “scarce” (n < 20). For the published cases, the rate of severe complications was 3.4% and the overall complication rate was 23.5%. The seizure freedom rate (Engel class 1) was 57.5% (including patients with early follow-up and repeat thermoablations). None of the studies included the systematic evaluation of cognitive outcomes. The researchers found that, overall, the published evidence does not yet allow a scientific or clinical judgement on the utility of LITT for epilepsy surgery in the pediatric population. While it is a surgical option regarding deep brain lesions (e.g., HH), any therapeutic superiority of LITT over open resection in cases that are equally accessible for both approaches remains to be demonstrated. Controlled, non-randomized outcome studies are recommended. (2020)

Grewal et al. (2019) performed a systematic review and meta-analysis comparing MRgLITT and SRS in cases of medically intractable temporal lobe epilepsy (TLE). A total of 19 studies were included in the final analysis. Of those studies, 9 were on MRgLITT (n = 250), and 10 were on SRS (n = 165). They identified that the overall seizure freedom rate was comparable between the 2 procedures (MRgLITT 50% vs. SRS 42%). Similarly, among patients with lesional pathologic conditions only, the seizure freedom rate between MRgLITT and SRS was also comparable at 62% and 50%, respectively. Compared with SRS, MRgLITT was associated with lower complication rates but similar reoperation rates. The authors concluded that outcomes and complications were similar between MRgLITT and SRS. Limitations of this review include a low level of evidence, as well as varying follow-up periods between the 2 procedures. More large-scale comparative studies are required to validate findings.

In a meta-analysis of 16 published studies (including Tao (2018), Jermakowicz (2017), and Lewis (2015) (previously included in this policy)) with a total of 269 patients, Xue et al (2018) set out to assess the effectiveness of MRI-guided LITT on treatment-resistant epilepsy. The authors used the Engel Epilepsy Surgery Outcome Scale (Class I, free from disabling seizures; Class II, a rare occurrence of disabling seizures (almost seizure-free); Class III, worthwhile improvement with reduction in the frequency of seizures; Class IV, no worthwhile improvement or decrease in the frequency of seizures) to assess the post-operative outcomes. The authors determined that the meta-analysis showed the prevalence of Engel Class I was 61%, Engel Class II was 12%, Engel Class III was 16% and Engel Class IV was 15% which indicated that seizure reduction after LITT compared favorably with conventional open surgical techniques. They identified several limitations of their study including the small study population with a short follow-up period, and the potential for inappropriate patient selection. The authors concluded that MRI-guided LITT significantly reduced the frequency of seizures and reduced postoperative complications. They recommended future large-scale controlled clinical trials to address the limitations they identified.

A systematic review and analysis by Lagman et al. (2017) examined 2 commercially available MRgLITT systems used in neurosurgery: the Visualase® thermal therapy and NeuroBlate® Systems. Data extraction was performed in a blinded fashion. Twenty-two articles reflecting 223 patients were included in the analysis. Most patients (n = 154/69%) received treatment with Visualase with epilepsy being the most common indication (n = 8 studies/47%). Brain mass was the most common indication for NeuroBlate (n = 3 studies/60%). There were no significant differences, except in age, wherein the NeuroBlate group was nearly twice as old as the Visualase group (p < 0.001). Frame, total complications, and LOS were non-significant when adjusted for age and number of patients. Several limitations were cited in this analysis, including but not limited to inherent bias in selection and reporting and recognized issues of retrospective studies. The authors concluded that MRgLITT procedures have demonstrated effectiveness in the treatment of a variety of epilepsy etiologies and tumor pathologies. While laser neurosurgery has evolved over recent decades and clinical indications are currently being defined, long-term outcomes have yet to be fully elucidated. The findings are however limited by the lack of comparison group in the reviewed studies.

Kang and Sperling (2018) conducted a review of laser interstitial thermal ablation and its use in treating drug resistant epilepsy. They stated that the procedure is highly selective and targets small lesions responsible for seizures, is far less invasive than open surgery, requires a shorter hospitalization, results in less pain and allows for a rapid resumption of normal activities. Initial results in MTLE are promising, with perhaps 50% of patients becoming seizure-free after the procedure. Neuropsychological deficits appear to be reduced because of the smaller volume of ablated cortex in contrast to large resections. The authors concluded that more research with larger study groups is needed to establish optimal targeting of structures for ablation, surgical selection criteria, efficacy and adverse effect rates.

McCracken et al. (2016, included in the Lagman et al. 2017 systematic review cited above) conducted a small prospective case series of 5 consecutive patients using real-time magnetic resonance thermography (MRT)-guided stereotactic laser ablation (SLA) to treat medically refractory epilepsy secondary to cerebral cavernous malformations (CCMs). Each underwent stereotactic placement of a saline-cooled cannula containing an optical fiber to deliver 980-nm diode laser energy via twist drill craniostomy; MRI was used to evaluate targeting prior to ablation, as well as evaluation of targeting and near real-time feedback

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regarding extent of tissue thermocoagulation. Remote imaging (6 to 21 months post-ablation) was obtained in all patients, revealing no evidence of acute hemorrhage following fiber placement and confirming the desired extent of ablation. No adverse effects or neurologic deficits were identified. Four of 5 patients achieved freedom from disabling seizures after SLA alone (Engel class 1 outcome), with follow-up ranging 12 to 28 months. The authors concluded that minimally invasive MRT-guided SLA of epileptogenic CCM is a potentially safe and effective alternative to open resection. Additional studies and longer follow up are needed. The findings are limited by lack of comparison group and small sample size.

In a review of selected cases reported in the published literature, Waseem et al. (2017, included in the Hayes report cited above) evaluated several outcome measures, including seizure freedom, neuropsychological performance, complications, and other considerations on 38 patients presenting exclusively with MTLE and no other lesions (including neoplasia), who underwent MRgLITT. Eighteen (53%) had an Engel class I outcome, 10 patients had repeat procedures/operations, and 12 post-procedural complications occurred. Follow-up time ranged from 6 to 38.5 months. There was a decreased length of procedure time, hospitalization time, and analgesic requirement when compared to open surgery. In cases of well-localized MTLE, MRgLITT may offer similar (albeit slightly lower) rates of seizure freedom versus traditional surgery. The authors concluded that MRgLITT may be an alternative treatment option for high-risk surgical patients and, more importantly, could increase referrals for surgery in patients with medically refractory MTLE. However, data is limited, and long-term outcomes have not been evaluated. Further investigation is required to understand the potential of this minimally invasive technique for MTLE. This review is limited by lack of systematic method to select the literature cited and lack of concurrent comparison group.

Clinical Practice Guidelines

American Association of Neurological Surgeons (AANS)

The AANS has not taken a position on LITT for treating patients with refractory epilepsy.

American Academy of Neurology (AAN)

The AAN policies and guidelines do not address LITT for treating patients with epilepsy.

American Society for Stereotactic and Functional Neurosurgery (ASSFN)

The ASSFN acts as the joint section representing the field of stereotactic and functional neurosurgery on behalf of the Congress of Neurological Surgeons (CNS) and the American Association of Neurological Surgeons (AANS). In their position statement addressing LITT for the treatment of drug-resistant epilepsy (Wu, 2022), they provided an expert consensus opinion on evidence-based best practices that included the following indications for treatment:

- 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.

The ASSFN based their recommendations on the following:

- Multiple peer reviewed large case series regarding the safety and efficacy of MRgLITT in reducing seizure frequency in patients with drug resistant epilepsy that demonstrated that LITT was nearly comparable to data obtained from case series of open surgical procedures.
- Published literature that demonstrated that MRgLITT was a less invasive for many types of focal drug resistant epilepsy with shorter hospital stays and less surgical and neurologic morbidity compared to open surgical resection for such common epilepsy etiologies as mesial temporal epilepsy, hypothalamic hamartomas, and focal cortical dysplasia/periventricular nodular heterotopia.
- Some published studies indicated that MRgLITT may better preserve cognitive functions compared to open epilepsy surgery.
- Patient preference when offered a choice between open surgery and MRgLITT.

National Institute for Health and Care Excellence (NICE)

Clinical guidance from NICE states current evidence on the safety of MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy shows there are serious but well-recognized safety concerns and that evidence on its efficacy is limited in quality. (2020)

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Prostate Tumors

Le et al. (2022) completed a comparative study using patients with low-risk prostate cancer (PCa) from the Surveillance Epidemiology and End Results (SEER) database to compare and analyze the effects of active surveillance or watchful waiting (AS/WW) and focal laser ablation (FLA) on overall survival (OS) and cancer-specific survival (CSS) to obtain better long-term benefits. The authors conducted multivariate Cox proportional hazard analyses for OS and CSS in the two groups then applied a series of sensitivity analyses to eliminate bias. The study included data for 18, 841 men with low-risk PCa (18,611 men undergoing AS/WW and 230 men undergoing FLA) with a median of 36-month follow-up. The authors used propensity score matching (PSM) to ensure that FLA and AS/WW groups had similar baseline characteristics, and then they applied logistic regression to adjust for differences between the groups. The authors found that patients undergoing FLA were older than those undergoing AS/WW, and that patients who received FLA had a lower PSA level and longer survival rate compared with those found in patients receiving AS/WW. After adjusting for age, insurance status, year of diagnosis, race, tumor stage, and PSA level, the authors reported similarly worse OS in the FLA group than in the AS/WW and no significant difference in CSS between groups. The results of the sensitivity analysis showed that the inverse probability of the treatment weighing model indicated the same result in OS. Limitations of the study include the retrospective design, the lack of randomization (despite their attempt to randomize using statistical methods), the grouping of AS and WW together as conservative measures and the heterogeneity of the baseline data of patients in the SEER database. The authors stated that AS/WW and FLA have fewer side effects and the benefit of avoiding overtreatment when compared with standard treatment. They concluded that AS/WW provides more survival benefits for patients with low-risk PCa and they recommend further research to investigate the clinical applicability of these treatment modalities to ensure that the best treatment is available to men with low-risk PCa.

Dahm, et al. (2020) completed a comparative effectiveness review of therapies used for the treatment of clinically localized prostate cancer for the Agency for Healthcare Research and Quality (AHRQ). The authors reported that there was insufficient evidence to address laser ablation for prostate cancer.

A Clinical Evidence Assessment by ECRI (2019; updated 2022) reviewed abstracts of 12 studies (five systematic reviews, four pre-post studies, two nonrandomized comparative studies and one case series) and concluded that there was limited evidence that suggests that LITT may be safe and without negative effects on sexual and urinary function in the short term (≤ 1 year) when used to treat localized prostate cancer. The report noted that clinical trials have not yet assessed or reported on patient-oriented outcomes to demonstrate efficacy and that the available studies were at high risk of bias. The report recommended validation of the results through prospective controlled trials to compare LITT with other treatments for localized prostate cancer.

A systematic review & meta-analysis by Valerio et al. (2017) summarized the evidence regarding sources of energy employed in focal therapy for treatment of prostate tumors. Thirty-seven articles reporting on 3,230 patients undergoing focal therapy were selected, with one of the focal therapies being LITT. Four prospective Stage 1 to 2a studies evaluating LITT in 50 patients have been reported in literature. One study only included men with low-risk disease, whereas the other studies also included Gleason score ≤ 4 + 3, although risk stratification was not clearly reported. The median age was 63.5 yrs.; 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, participants underwent radical prostatectomy, whereas in the other 3 studies participants underwent MR-transrectal ultrasound (TRUS) standard 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 concluded that focal therapy seems safe and appears to offer good preservation of genito-urinary 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 effectiveness trials.

Eggener et al. (2016) 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/ml3, 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 12-month biopsy, cancer

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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 in 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.

There are multiple clinical trials studying LITT for various conditions which are in different phases of activity. Additional information is available at www.clinicaltrials.gov. (Accessed March 20 ,2023)

Clinical Practice Guidelines

American Society of Clinical Oncology (ASCO)

ASCO clinical guidelines do not address laser thermal therapy as treatment in tumors of the genitourinary system, head and neck, breast, or bone tumors.

American Urological Association (AUA)/American Society for Radiation Oncology (ASTRO)/American Society of Clinical Oncology (ASCO)/Society of Urologic Oncology (SUO)

The AUA and ASTRO formed a collaborative panel to develop a practice guideline with additional representation from the ASCO and the SUO for the evaluation and management of clinically-localized prostate cancer. The panel utilized a systematic review developed by the Agency for Healthcare Research and Quality (AHRQ) on therapies for clinically localized prostate cancer (see Dahm, 2020 above) and the primary methodology provided by the Pacific Northwest Evidence-based Practice Center of Oregon Health and Science University (OHSU). Based on the panel's review of available data, their practice guideline included the following statements:

- For patients with favorable intermediate-risk prostate cancer, clinicians should discuss active surveillance, radiation therapy, and radical prostatectomy. (Strong Recommendation; Evidence Level: Grade A)
- Clinicians should inform patients with intermediate-risk prostate cancer considering whole gland or focal ablation that there are a lack of high-quality data comparing ablation outcomes to radiation therapy, surgery, and active surveillance. (Expert Opinion)
- For patients with unfavorable intermediate- or high-risk prostate cancer and estimated life expectancy greater than 10 years, clinicians should offer a choice between radical prostatectomy or radiation therapy plus androgen deprivation therapy (ADT). (Strong Recommendation; Evidence Level: Grade A)
- Clinicians should not recommend whole gland or focal ablation for patients with high-risk prostate cancer outside of a clinical trial. (Expert Opinion)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

LITT is a procedure and, therefore, not subject to FDA regulation.

The NeuroBlate® System (Monteris Medical, MN) enables MRI-guided neurosurgical ablation, monitoring 3-D and providing real time imaging to support a surgeon's clinical decision matrix. The device was FDA approved on October 26, 2016. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K162762. (Accessed March 20, 2023)

The Visualase® Thermal Therapy System (Medtronic, MN) provides advanced MRI-guided laser ablation technology for thermal ablation markets, including neurosurgery. Delivery of laser energy results in rising temperatures in the target area, destroying the unwanted tissue. The device was FDA approved on September 10, 2008. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K081656. (Accessed March 20, 2023)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2023T0584J]

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Policy History/Revision Information

Date	Summary of Changes
07/01/2023	**Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information ● Archived previous policy version SURGERY 108.9 T2

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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