Medical Coverage Policy

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Laser Interstitial Thermal Therapy

Table of Contents

Related Coverage Resources

[Ablative Treatments for Malignant Breast Tumors](#)
[Benign Prostatic Hyperplasia (BPH) Treatments](#)
[eviCore-Cigna cobranded Radiation Therapy Clinical Guidelines](#)
[High Intensity Focused Ultrasound (HIFU)](#)
[Peripheral Nerve Destruction for Pain Conditions](#)

Overview

This Coverage Policy (CP) addresses brain laser interstitial thermal therapy, also known as magnetic resonance-guided laser interstitial thermal therapy (MRgLITT). At this time, this technology is specific to the Monteris NeuroBlate® System and the Medtronic Visualase™ Thermal Therapy System.

For interstitial laser coagulation of the prostate, see CP 0159 Benign Prostatic Hyperplasia (BPH) Treatments.

Coverage Policy

Epilepsy

Laser Interstitial Thermal Therapy (LITT) is considered medically necessary in the treatment of refractory epilepsy when ALL of the following criteria are met:

- there is documentation of disabling seizures despite use of two or more antiepileptic drug regimens (i.e., medically-refractory epilepsy)

- there is a well-defined epileptogenic focus in the temporal lobe or hypothalamus accessible by LITT
- the treatment plan to use LITT has been agreed upon by a multidisciplinary team of physicians to include at least two specialists (e.g., neurosurgery, neurology) and, after considering all relevant possible treatment approaches, LITT is determined to be the best treatment option

Malignant Brain Neoplasms

LITT is considered medically necessary in the treatment of symptomatic, recurrent metastatic malignant brain neoplasms when ALL of the following criteria are met:

- the recurrent neoplasm measures up to 30 cubic centimeters (cc) in volume
- the individual is not considered a suitable candidate for craniotomy
- the treatment plan to use LITT has been agreed upon by a multidisciplinary team of physicians to include at least two specialists (e.g., neurosurgery, oncology) and, after considering all relevant possible treatment approaches, LITT is determined to be the best treatment option

Radiation Necrosis

LITT is considered medically necessary in the treatment of symptomatic radiation necrosis in the brain when ALL of the following criteria are met:

- the radiation necrosis measures up to 30 cc in volume
- the individual is not considered a suitable candidate for craniotomy
- the treatment plan to use LITT has been agreed upon by a multidisciplinary team of physicians to include at least two specialists (e.g., neurosurgery, oncology) and, after considering all relevant possible treatment approaches, is determined to be the best treatment option

Other

LITT is considered experimental, investigational or unproven for all other indications.

General Background

Laser interstitial thermal therapy (LITT) uses thermal energy to induce cell death by damaging DNA and causing protein denaturation. The goal of LITT is to achieve selective thermal injury of pathological tissue while maintaining a sharp thermal border between the tumor and normal brain tissues. LITT is one of several energy delivery methods using interstitial high heat to destroy tissue; another example is radiofrequency ablation (RFA). LITT has been explored since the late 1970s, but recent advances in probe design, cooling mechanisms, and real-time magnetic resonance (MR) thermography have increased interest in LITT.

LITT is also referred to as magnetic resonance-guided laser interstitial thermal therapy (MRgLITT), laser induced thermal therapy/thermotherapy, interstitial laser photocoagulation/coagulation, interstitial laser ablation, MRI-guided laser surgery, and MRI-guided percutaneous laser ablation.

LITT involves the creation of a small cranial bur hole, through which a thin laser fiber is introduced into the brain until the tip reaches the targeted location. After the probe is inserted in the operating room, the thermal ablation procedure is performed in the MRI suite. Thereafter, the patient is moved back into the operating room for probe removal. In real time, laser-induced temperature change is monitored by MR thermometry and correlated with predicted cell death by computer models. The workstation is located in the MRI control room. The surgeon controls the probe position inside the MRI and regulates ablation time and intensity on the workstation. Alternatively, the whole procedure could be performed under intraoperative MRI monitoring.

Alternate procedures that may be performed depend on the diagnosis/location. For example, alternate treatments for brain tumors may include but are not limited to craniotomy or stereotactic radiosurgery (SRS).

Alternate treatment examples for intractable epilepsy may include anterior temporal lobectomy or vagus nerve stimulation.

Indications
The clinical indications for LITT are currently being defined. Ablation of deep-seated, eloquently situated primary and metastatic brain tumors, epileptogenic foci, and radiation necrosis are the majority of indications described in the literature.

Benefits and Risks
Proposed benefits include providing a minimally invasive option for 1) treating surgically challenging tumors in locations that would otherwise have represented an intrinsic comorbidity by the approach itself, and 2) those with comorbidities that preclude open surgical procedures because of potentially high risks of morbidity and mortality. Surgical site infections, bleeding, anesthesia-related risks, and inpatient length of stay are considered lower in LITT than those in open craniotomy.

Specific risks of LITT include damage to the cerebral vasculature by the laser probe which could result in hemorrhage or pseudoaneurysm that may require subsequent open or endovascular surgery. Although MR thermometry allows precise control of the ablated tissue, the risk of damage to the critical cortex areas and white matter tracts by the probe or thermal energy remains. Delayed transitory neurologic deficits due to increasing brain edema usually resolve after steroid therapy. Nonspecific adverse effects include balance disorder, dizziness, and headache. Brain abscess, seizures, and wound infection have also been reported. Risks and contraindications for MRI are also applicable to LITT. Other potential risks include variable skill level/technology learning curve. 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 LITT ablation procedures. The exact rates of complications vary among patient populations and facilities. Neurosurgeons considering LITT balance the potential benefits of surgical treatment with the risks of surgery in patients with comorbidities (Belykh, et al., 2017; Lagman, et al., 2017; Shukla, et al., 2017; Riordan, et al., 2014).

U.S. Food and Drug Administration (FDA)
The NeuroBlate® System (Monteris Medical, Plymouth, MN) and the Visualase® Thermal Therapy System (Medtronic Inc., Dublin, Ireland) are FDA-approved devices that are being used in LITT. Both systems can be used with intraoperative MRI, navigation or stereotactic systems, and provide predictive thermal dosage lines to estimate ablation volume.

- Monteris NeuroBlate System: The NeuroBlate System is a collection of MRI-compatible laser devices and accessories that create an MRI guided delivery of precision thermal therapy in the practice of neurosurgery. Indications for use include:
  - to ablate, necrotize, or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers
  - for planning and monitoring thermal therapies under MRI visualization. It provides MRI based trajectory planning assistance for the stereotaxic placement of MRI compatible (conditional) NeuroBlate™ Laser Delivery Probes. It also provides real time thermographic analysis of selected MRI images

- Visualase™ Thermal Therapy System: The Visualase Thermal Therapy System comprises four devices: a laser energy source, a cooled laser applicator, a pump for circulating coolant through the applicator, and a computer workstation with magnetic resonance imaging (MRI) analysis software for determination and visualization of relative changes in tissue temperature during therapy. Indications for use include:
  - to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, for wavelengths 80Onm through 1064nm
  - when therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the Visualase system can process images to determine relative changes in tissue

temperature during therapy. The image data may be manipulated and viewed in a number of different ways and the values of data at certain selected points may be monitored and/or displayed over time

Literature Review

The use of MR-guided LITT for treatment of epilepsy and brain tumors continues to expand in the US. Although the majority of studies are small, retrospective case series, numerous published studies and meta-analysis in the peer-reviewed literature demonstrate the safety and efficacy of MR-guided LITT in the treatment of:

- refractory epilepsy
- symptomatic, recurrent metastatic malignant brain neoplasms
- symptomatic radiation necrosis in the brain.

The Laser Ablation of Abnormal Neurological Tissue using Robotic NeuroBlate System (LAANTERN) trial is an ongoing multicenter, non-randomized, prospective NeuroBlate LITT study.

Kim et al. (2020) has reported 12 month outcomes from 223 subjects enrolled at 14 US centers with 231 ablated tumors. The cohort included 10 pediatric patients (<18 yr of age). The median age was 54.3 years. In total, 73.6% of patients had baseline neurological symptoms. 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%), radiation necrosis (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 overall survival. A total of 50.5% had stabilized/improved KPS at six months. There were no significant differences in KPS or QoL between patients with metastatic vs primary tumors. The authors concluded that data in this first outcome analysis of the LAANTERN registry show that the overall survival in this population of patients with brain tumors reflects similar if not improved outcomes to those previously reported for a population of patients with mostly recurrent disease. Patient-reported QoL outcomes were also stabilized and better than expected in a population with malignant brain tumors. Enrollment is ongoing, and further subanalyses of these data are planned and are likely to yield additional learning regarding patient selection and management.

Landazuri et al. (2020) reported of 60 patients enrolled into LAANTERN specifically for epilepsy treatment, 42 reached one year follow up. Patients with mesial temporal lobe epilepsy (MTLE) comprised 56.7 % of this cohort of multiple epilepsy types. Thirty-one out of 42 patients were considered responders (Engel I or II outcome). Engel I outcome was achieved in 27/42 patients (64.3 %). At last follow-up, median quality of life scores increased 14.1 points with 72.4 % (21/29) reporting an improvement in quality of life; however, total score change was not statistically significant. The authors concluded that initial reporting of an ongoing prospective multicenter study presents further data in support of LITT as a surgical treatment for drug-resistant epilepsy.

In a recent retrospective review by Hong et al. (2019), 75 patients with lesions regrowing after SRS were compared. Forty-two had recurrent tumor (56%) and 33 (44%) had radiation necrosis (RN) (75 total, 34 underwent NeuroBlate LITT). Of patients with tumor, 26 underwent craniotomy and 16 LITT. For RN, 15 had craniotomy and 18 LITT. Results demonstrated progression-free survival (PFS) and overall survival (OS) were similar for LITT versus craniotomy, respectively: %PFS-survival at 1 year = 72.2% versus 61.1%, %PFS-survival at 2 years = 60.0% versus 61.1%, p = 0.72; %OS-survival at 1 year = 69.0% versus 69.3%, %OS-survival at 2 years = 56.6% versus 49.5%, p = 0.90. Overall, craniotomy was shown to be more effective for providing relief of preoperative neurological symptoms but a larger number of the craniotomy patients with symptoms had lesions >3 cm diameter. Subset analysis of patient with tumors <3 cm in diameter eliminated the symptom relief advantage of craniotomy and further exhibited equivalent 12-month PFS rates (72.2% for LITT vs. 61.1% for craniotomy) and 12-month OS rates (69.0% vs. 69.3%). The authors propose that while craniotomy remains better for the management of larger lesions, MRgLITT may be a viable equivalent alternative in patients with lesions with diameters <3 cm (Hong, et al., 2020; Hong, et al., 2019).

The Canadian Agency for Drugs and Technologies in Health (CADTH) Technology Assessment on Laser Interstitial Thermal Therapy for Epilepsy and/or Brain Tumours (Williams, et al., 2019) notes that no comparative evidence on disease progression, overall survival, hospitalization, or quality of life was found. The evidence, drawn primarily from retrospective chart reviews, case series, and case reports, suggested that magnetic resonance-guided LITT proffers no advantage over stereotactic radiosurgery in reducing seizures in patients with drug-resistant, medically-intractable temporal lobe epilepsy (TLE). Also, relative to patients treated with SRS for medically-intractable TLE and craniotomy for high grade tumours in areas of eloquence, patients treated with LITT appeared to experience fewer adverse events and complications. None of the studies reported on the incidence of epileptic episodes, post-operative pain, use of medication, or hospital readmissions.

Epilepsy Meta-analysis

Diagnosis	Number of patients	Type of laser	Author / year	Key Points
drug-resistant epilepsy	559 28 studies	Not specified (only Visualase mentioned in background)	Barot 2021	✓ Seizure freedom rate: ➢ Hypothalamic hamartomas (HH) 67% ➢ Mesial temporal lobe epilepsy (mTLE) (56%) ➢ Extratemporal epilepsy (50%) (Outcome was overall comparable) ✓ Pooled prevalence of seizure freedom decreases from 60% with short follow-up duration (6–12 months) to 53% when mean follow-up duration was above 24 months. ✓ The mTLE cases with mesial temporal sclerosis had better outcome vs non-lesional cases of mTLE. ✓ The prevalence of postoperative adverse events was 19% and the most common adverse event was visual field deficits. ✓ The reoperation rate was 9%, which included repeat ablation and open resection.
drug-refractory mesial temporal lobe epilepsy (mTLE).	554 13 studies	Not specified	Kohlhase 2021	✓ Compared MRgLITT, RFA, and conventional surgical approaches to the temporal lobe (i.e., anterior temporal lobe resection [ATL] or selective amygdalohippocampectomy [sAHE]). ✓ 43 studies (13 MRgLITT, 6 RFA, and 24 surgery studies) involved 554, 123, 1504, and 1326 patients treated by MRgLITT, RFA, ATL, or sAHE, respectively. ✓ MRgLITT and RFA were both inferior relative to conventional surgical approaches (ATL and sAHE) in terms of seizure outcome (Engel Class I). Engel-I outcomes were achieved after: ➢ MRgLITT in 57% (315/554, range = 33.3%–67.4%), ➢ RFA in 44% (54/123, range = 0%–67.2%), ➢ ATL in 69% (1032/1504, range = 40%–92.9%), and ➢ sAHE in 66% (887/1326, range = 21.4%–93.3%). ✓ Meta-analysis revealed no significant difference in seizure outcome between MRgLITT and RFA ($p = .098$), whereas ATL and sAHE were both superior to MRgLITT (ATL: $p = .002$; sAHE: $p = .037$) and RFA (ATL: $p = .0113$; sAHE: $p = .0247$), with better outcome in patients at follow-up of 60 months or more. ✓ The rate of major complications was 3.8% for MRgLITT, 3.7% for RFA, 10.9% for ATL, and 7.4% for

Diagnosis	Number of patients	Type of laser	Author / year	Key Points
				sAHE; the differences did not show statistical significance. ✓ Cognitive outcome might be more favorable after MRgLITT compared to ATL and sAHE. Lateral functions such as naming or object recognition may be more preserved in MRgLITT.
temporal lobe epilepsy	551	Not specified	Kerezoudis 2020	✓ The mean follow-up ranged from 6 to 42.9 months. ✓ The pooled mean epilepsy duration was 24.4 years. ✓ A total of 384 patients had MTS (70% of overall cohort). ✓ Overall seizure freedom rate was 58% and was not significantly associated with total ablation volume (p=0.42). ✓ Pooled seizure freedom rate of 58% for all patients with TLE and 66% for patients with MTS (in contrast to 73% and 67% for open anterior temporal lobectomy and selective amygdalohippocampectomy, respectively). ✓ Total ablation volume as well as hippocampal or amygdala ablation were not significantly associated with seizure freedom. ✓ Overall complication rate was 17%. The permanent complication rate was 5%, the temporary complication rate was 10%.
Mesial temporal lobe epilepsy (mTLE).	434	Not stated	R. Wang 2021	✓ Literature review (not meta-analysis) ✓ 1094 patients (LITT: 434, SRS: 81, RF-TC: 402, Cortico-amygdalohippocampectomy (CAH): 153, and selective amygdalohippocampectomy (SelAH): 24). ✓ Seizure freedom was similar between all LITT studies and to rates achieved by cortico-amygdalohippocampectomy (CAH) and selective amygdalohippocampectomy (SelAH) however, direct comparisons were lacking. ✓ Although ablation volume was not associated with seizure outcomes, targeting more of the mesial, anterior, and inferior temporal structures was associated with increased rates of Engel I. ✓ Common complications included transient postprocedure headaches (LITT: 0.4%-27%, SRS: 15%-70%, and RF-TC: 23%) and visual field deficits (VFDs) (LITT: 3%-40%, SRS: 34%-50%, and RF-TC: 2%-5%) Cranial nerve (CN) palsies were unique to LITT with 7%of patients experiencing this complication.
drug-resistant epilepsies (DRE)	414	Not specified	Y. Wang 2020	✓ 16 studies with MRgLiTT (414 patients) ✓ 10 studies with stereoelectroencephalography-guided radiofrequency thermocoagulation (SEEG-RFTC) (390 patients) ✓ Follow-up minimum 6 months ✓ Overall complication rate across all samples was low in the two approaches (5%). ✓ In this analysis, authors included those who received repeated ablations and became seizure free into the seizure-free group.

Diagnosis	Number of patients	Type of laser	Author / year	Key Points
				✓ Authors propose that the underlying mechanism of the significant difference in postoperative rates of seizure-free outcomes between MRgLiTT and SEEG-RFTC (65 % vs. 23 % respectively, p=0.00) was most likely related to the sizes of the ablated lesions. ✓ MRgLiTT in both the hypothalamic hamartoma group (99 %) and the temporal lobe epilepsy group (59 %) achieved efficacy and low heterogeneity; patients with temporal lobe epilepsy and mesial temporal sclerosis (MTS) did not achieve better seizure control than non-MTS patients did (p=0.142).

Brain Neoplasms and Radiation Necrosis Literature

Diagnosis	Number of patients	Type of laser	Author / year	Key Points
brain metastases with in-field recurrence following SRS	470 14 studies	Not stated	Chen 2021	✓ Meta-analysis ✓ The 6-month (LC-6) and 12-month (LC-12) local control rates were 78.5% and 69.0%, separately. ✓ Pooled median OS was 17.15 months (13.27-24.8). The overall OS-6 and OS-12 rates were 76.0% (71.4-80.0%) and 63.4% (52.9-72.7%), separately. ✓ LITT provided more favorable local control efficacy in RN than BM recurrence (LC-6: 87.4% vs. 67.9%, p = 0.009; LC-12: 76.3% vs. 59.9%, p = 0.041).
Mixed Epilepsy and brain mass	223	NeuroBlate and Visualase	Lagman 2017	✓ Quantitative analysis of case reports and case series ✓ Head-to-head comparison of these systems was difficult given the variance in indications (and therefore patient population) and disparate literature ✓ LITT procedures have demonstrated effectiveness in the treatment of a variety of epilepsy etiologies and tumor pathologies but long-term outcomes have yet to be fully elucidated.
Brain tumor Gliomas (70.2%), radiation necrosis (21.0%), and metastasis (8.8%)	207	NeuroBlate	Shao 2020	✓ Retrospective case series ✓ Median follow-up was 8.4 months, and 52% had progression during follow-up. ✓ Temporary complications occurred in 30.2% of patients, and permanent deficits occurred in 10.8% of patients. ✓ There was a significant decrease in permanent motor deficits over time (15.5 vs. 4.4%; p=0.005) ✓ 30-day mortality (4.1% vs. 1.5%) decreased (not statistically significant) in the recent cohort. ✓ Poor preoperative Karnofsky Performance Status (≤70) were significantly correlated with increased permanent deficits (p=0.001) and decreased overall survival (p < 0.001 for all time points).
recurrent glioblastoma (rGBM	134 (11 studies)	mixed	Munoz-Casabella 2021	✓ Literature review ✓ 5 studies used NeuroBlate; 3 studies used the Visualase; 2 studies used neodymium-yttrium aluminum garnet laser (Nd:YAG laser); and 1 study used both the NeuroBlate and Visualase

Diagnosis	Number of patients	Type of laser	Author / year	Key Points
				✓ A total of 8 studies with 107 patients had available data for overall median survival. The pooled overall survival was found to be 18.6 months (16.2- 21.1). ✓ A total of 6 studies with 93 patients had available data for post-LITT survival. The pooled post-LITT survival was found to be 10.1 months (8.8-11.6). ✓ A total of 8 studies with 119 patients had available data for progression-free survival. Pooled progression free survival was found to be 6 months (5.3-6.7).
Mixed	120	NeuroBlate	Kamath 2017	✓ Retrospective evaluation ✓ Glioblastomas, metastases, WHO grade III gliomas, WHO grade II gliomas, epilepsy foci, WHO grade I gliomas, radiation necrosis, teratoma and encephalocele ✓ Median follow-up was 9.5 months, with 18 patients lost to follow-up. ✓ The rate of complications/unexpected readmission was 6.0%, and the mortality rate was 2.2%. ✓ Progression-free survival reported by tumor grade ✓ There were 8 perioperative complications (6.0%) and 8 unplanned readmissions (6.0%). Of these, there were 3 perioperative mortalities (2.2%).
newly diagnosed glioblastoma (nGBM)	111 11 studies	NeuroBlate	Viozzi 2021	✓ Systematic review ✓ All included studies were conducted in the US, with a great majority using the Neuroblate–Monteris system (81%). ✓ All papers suffered from serious or critical risk of bias, and the quality of evidence was graded as very low according to the GRADE criteria. None of the studies was randomized and reporting of confounders and other parameters was poor. ✓ Median overall survival (OS) ranged from 4.1 to 32 months and progression free survival (PFS) from 2 to 31 months. ✓ The mean complication rate was 33.7%. ✓ The low quality of evidence shows the need for a well-designed prospective multicenter randomized controlled trial.
Mixed	102	Visualase	Patel 2016	✓ Retrospective analysis ✓ intracranial tumors (n=87), chronic pain syndrome (cingulotomy, five patients), or epilepsy (ten patients). ✓ 27 cases of morbidity, including new-onset neurological deficits, and two perioperative deaths. ✓ Fourteen patients (13.7%) developed new deficits after the MRgLITT procedure, and of those 14 patients, 64.3% (n = 9) had complete resolution of deficits within 1 month. ✓ Authors warn thermal damage to critical and eloquent structures can occur despite MRI guidance. Once the learning curve is overcome, the overall procedural complication rate is low.
metastatic recurrence			Hong 2020;	✓ Review article and retrospective study

Diagnosis	Number of patients	Type of laser	Author / year	Key Points
and RN			Hong 2019	✓ MRgLITT compares favorably to standard of care craniotomy for the treatment of recurrent brain metastases after prior SRS for lesions <3 cm. ✓ Craniotomy was shown to be more effective for providing relief of preoperative neurological symptoms but a larger number of the craniotomy patients with symptoms had lesions >3 cm diameter. ✓ Subset analysis of patient with tumors <3 cm in diameter eliminated the symptom relief advantage of craniotomy and further exhibited equivalent 12-month PFS rates (72.2% for LITT vs. 61.1% for craniotomy) and 12-month OS rates (69.0% vs. 69.3%).

UpToDate
An UpToDate posting on delayed complications of cranial irradiation (Dietrich et al. 2021) notes under Brain tissue necrosis that in patients who do not achieve symptomatic response to glucocorticoids, or when glucocorticoids cannot be tapered without return of symptoms, a variety of other treatment options have been explored, including bevacizumab and laser interstitial thermal therapy (LITT). Under Summary, Dietrich et al. notes that surgical resection of the necrotic tissue is sometimes required, particularly in cases in which there is diagnostic uncertainty as to whether the radiographic changes are indicative of tumor progression or tissue necrosis, or in patients with severe necrosis who have contraindications to bevacizumab. Laser interstitial thermal therapy (LITT) is an option in this context but is less preferred in patients with preoperative neurologic deficits.

An UpToDate posting on the treatment of brain metastases (Loeffler et al. 2021) notes under 'Recurrent disease' section that local techniques, such as laser interstitial thermal therapy, are under investigation for recurrent brain metastases as well as radiation necrosis.

Professional Societies/Organizations
A review of National Comprehensive Cancer Network® (NCCN) Clinical Guidelines in Oncology™ Central Nervous System (CNS) cancers includes a 2B recommendation that addresses MRI-guided laser interstitial thermal therapy (LITT), noting that it may be considered for patients who are not surgical candidates (craniotomy or resection). Potential indications include relapsed brain metastases and radiation necrosis (NCCN CNS Version 2.2021 — Sept 8, 2021).

The Congress of Neurological Surgeons/American Association of Neurological Surgeons (CNS/AANS): A Position Statement on MR-guided Laser Interstitial Thermal Therapy (LITT) for Brain Tumors and Radiation Necrosis (September 2021) states the following indications for use:

> "LITT is a neurosurgical tool FDA indicated for use to ablate, necrotize, or coagulate intracranial soft tissue, including brain structures (e.g., brain tumor, radiation necrosis and epileptogenic foci as identified by non-invasive and invasive neurodiagnostic testing, including imaging), through interstitial irradiation or thermal therapy in the discipline of neurosurgery with laser technology."
>
> The CNS/AANS notes "there is consensus that intracranial LITT should be considered as a potential option for patients with recurrent or progressive malignant tumor (primary or metastatic), lesion(s) inaccessible to surgical resection, or when the patient is unable to tolerate surgical resection due to medical comorbidities" (Barnett, et al., 2021).

The American Society for Stereotactic and Functional Neurosurgery (ASSFN) Position Statement on Laser Interstitial Thermal Therapy for the Treatment of Drug-Resistant Epilepsy (DRE) (September 2021) lists the following indications for the use of MRgLITT as a treatment option for patients with DRE:

1. Failure to respond to, or intolerance of, at least 2 appropriately chosen medications at appropriate doses for disabling, localization-related epilepsy AND

2. Well-defined epileptogenic foci or critical pathways of seizure propagation accessible by MRgLITT (Wu, et al., 2021)

The Guideline on the Role of Emerging and Investigational Therapies for the Treatment of Adults With Metastatic Brain Tumors (Chapter 9; Elder, et al., 2019) states "There is insufficient evidence to make a recommendation regarding the routine use of laser interstitial thermal therapy (LITT), aside from use as part of approved clinical trials.

The CNS/AANS Guidelines on the Management of Patients with Vestibular Schwannoma (Chapter 9; Van Gompel, et al., 2018) does not address LITT. The AANS/CNS Joint Guidelines Committee document 'The role of cytoreductive surgery in the management of progressive glioblastoma: a systematic review and evidence-based clinical practice guideline' (Ryken, et al. 2014) does not address LITT. The AANS/CNS Joint Guidelines Committee document 'The role of targeted therapies in the management of progressive glioblastoma: a systematic review and evidence-based clinical practice guideline' (Olson, et al., 2014) does not address LITT. The CNS/AANS guidelines do not address epilepsy.

The American Academy of Neurology (AAN) has several guidelines addressing epilepsy, none of which address LITT. The American Epilepsy Society lists several Evidence-based Guidelines and Practice Parameters; none address laser interstitial thermal therapy.

The American Academy of Neurology, in Association with the American Epilepsy Society and the American Association of Neurological Surgeons Practice Parameter 'Temporal lobe and localized neocortical resections for epilepsy' (Engel, et al., 2003) does not address LITT. (Guideline being updated)

The Epilepsy Foundation of America website includes information on 'LITT (Thermal Ablation)'. It states, "When seizures persist despite adequate trials of two or more seizure medicines, the next step is to see if surgery is possible. In some people, seizures are caused by a single focus. For some of these people, epilepsy can be cured with surgery by removing the focus. A surgical evaluation tries to find the seizure focus and see if it can be safely removed. Mesial temporal lobe epilepsy (MTLE) is the most common type of focal epilepsy and can be treated surgically. It accounts for 17% to 31% of all epilepsy surgeries. The LITT procedure has become a good option for people with MTLE when seizure medicines don't work. The LITT procedure can also help people who have seizures from lesions, such as a small brain malformation, a blood vessel malformation or hypothalamic hamartoma. Children with similar types of lesions have also been helped with the the LITT procedure."

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative
No relevant information.

Use Outside of the US
National Institute for Health and Care Excellence (NICE): NICE published Interventional Procedures Guidance on MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy (March 4, 2020), noting the following: Evidence on the safety of MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy shows there are serious but well-recognised safety concerns. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
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)

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2. American Academy of Neurology. Policy and Guidelines. Accessed August 2021. Available at URL address: https://www.aan.com/policy-and-guidelines/guidelines/ https://www.aan.com/Guidelines/Home/ByTopic?topicId=23

3. American Association of Neurological Surgeons (See Congress of Neurological Surgeons.)

4. American Association of Neurological Surgeons. Position Statements. Accessed August 2021. Available at URL address: https://www.aans.org/en/About-Us/Position-Statements

5. American Epilepsy Society. Guidelines. Accessed August 2021. Available at URL address: https://www.aesnet.org/clinical-care/clinical-guidance (In development: AES/AAN/CNS Epilepsy Surgery Systematic Review and Guideline)

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