7.01.170	Laser Interstitial Thermal Therapy for Neurological Conditions		
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Section:	7.0 Surgery	**Page:**	Page 1 of 20

Policy Statement

Laser interstitial thermal therapy (LITT) is considered **investigational** for **all** neurological indications, including but not limited to patients with the following conditions:

I. Drug-resistant epilepsy
II. Primary or metastatic brain tumors
III. Radiation necrosis

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

The following CPT codes may be used for laser interstitial thermal therapy (LITT):

- **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)

Description

Laser interstitial thermal therapy (LITT) involves the introduction of a laser fiber probe to deliver thermal energy for the targeted ablation of diseased tissue. The goal of therapy is selective thermal injury through the maintenance of a sharp thermal border, as monitored via the parallel use of real-time magnetic resonance (MR) thermography and controlled with the use of actively cooled applicators. In neurological applications, LITT involves the creation of a transcranial burr hole for the placement of the laser probe at the target brain tissue. Probe position, ablation time, and intensity are controlled under MRI guidance. LITT has been proposed as a less invasive treatment option for patients with neurological conditions compared to surgery. Two LITT systems, Visualase and NeuroBlate, have received marketing clearance from the FDA.

Related Policies

- Intensity-Modulated Radiotherapy: Central Nervous System Tumors
- Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In August 2007, the Visualase™ Thermal Therapy System (Medtronic; formerly Biotex, Inc.) received initial marketing clearance by the FDA through the 510(k) pathway (K071328). As of March 2019, the system is indicated for use "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 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 800 nm through 1064 nm" (K181859). Data from compatible MRI sequences can be processed via proton resonance-frequency shift analysis and image subtraction to relate imaging changes to relative changes in tissue temperature during therapy. The Visualase™ cooling applicator utilizes saline.

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

On April 25, 2018, the FDA issued a safety alert on MR-guided LITT (MRgLITT) devices with a letter to healthcare providers stating that the FDA is currently evaluating data suggesting that potentially inaccurate MR thermometry information can be displayed during treatment, which may contribute to a risk of tissue overheating and potentially associated adverse events, including neurological deficits, increased intracerebral edema or pressure, intracranial bleeding, and/or visual changes.[4] Several risk mitigation strategies were recommended. In an updated letter released on November 8, 2018, risk mitigation recommendations specific to the Visualase™ and NeuroBlate® systems were issued.[5]

Rationale

Background

Laser Interstitial Thermal Therapy

Laser interstitial thermal therapy (LITT) involves the introduction of a laser fiber probe to deliver thermal energy for the targeted ablation of diseased tissue. Thermal destruction of tissue is mediated via DNA damage, necrosis, protein denaturation, membrane dissolution, vessel sclerosis, and coagulative necrosis.[1] The goal of therapy is selective thermal injury through the maintenance of a sharp thermal border, as monitored via the parallel use of real-time magnetic resonance (MR) thermography and controlled with the use of actively cooled applicators.[2] In neurological applications, LITT involves the creation of a transcranial burr hole for the placement of the laser probe at the target brain tissue. Probe position, ablation time, and intensity are controlled under MRI guidance.

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

are temporary and typically resolve after corticosteroid therapy. Contraindications to MRI are also applicable to the administration of LITT.

Literature Review
Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Primary or Metastatic Brain Tumors
Clinical Context and Therapy Purpose
The purpose of magnetic resonance (MR)-guided laser interstitial thermal therapy (LITT) is to use a focused thermal therapy technique to ablate primary or metastatic brain tumors and to avoid potential complications associated with alternative surgical interventions.

The following PICO was used to select literature to inform this review.

Populations
The population of interest is patients with primary or metastatic brain tumors that are inaccessible surgically or located in proximity to eloquent or radiosensitive areas. LITT is typically used when surgery is contraindicated due to a high risk of procedural morbidity and/or presence of comorbidities that preclude candidacy for open surgery. LITT may be preferred by patients desiring a less invasive surgical alternative and its use has been explored in first-line, adjunct, and salvage settings.

Primary intracranial malignant tumors include gliomas, astrocytomas, malignant meningiomas, and primitive neuroectodermal tumors (i.e., medulloblastoma, pineoblastoma). Treatment of primary brain tumors such as gliomas is more challenging, due to their generally larger size and infiltrative borders.

Intracranial metastases tend to have a smaller spherical size and noninfiltrative borders. Brain metastases occur frequently, seen in 25 to 30% of all patients with cancer, particularly in those with cancer of the lung, breast, colon, kidney, and melanoma.

Interventions
The therapy being considered is LITT as an alternative to open craniotomy with resection or stereotactic radiosurgery (SRS). LITT is performed under real-time magnetic resonance imaging (MRI) guidance.

Comparators
The following therapies are currently being used to treat primary and metastatic brain tumors: surgical resection, SRS, radiotherapy, and systemic therapies (e.g., chemotherapy).

Outcomes
Primary outcomes of interest are overall survival (OS) and progression-free survival (PFS). Additional outcomes include local disease control, symptom improvement, functional outcomes, change in disease status, quality of life, and treatment-related morbidity. Follow-up duration of at least 2 to 3 years is of interest for survival outcomes. For patients with tumors associated with a poor prognosis (e.g., recurrent glioblastoma), shorter follow-up durations may be appropriate.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with the 'best available evidence approach', within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Systematic Reviews
Systematic review characteristics and survival outcomes are summarized in Table 1.

Chen et al (2021) published a systematic review and meta-analysis of retrospective studies and case series investigating the efficacy of LITT for brain metastases with in-field recurrence or radiation necrosis following treatment with SRS.[6] A meta-analysis of 14 studies (470 patients with 542 lesions) was performed. The overall 12-month local control rate ranged between 56.0% and 84.7% with a pooled rate of 69.0% (95% CI, 60.0% to 76.7%; I^2 = 50.584%; p=.048) and pooled OS of 17.15 months (95% CI, 13.27 to 24.8). Among 153 recurrent brain metastastic lesions across 5 studies, the 12-month local control rate was 59.9% (95% CI, 47.9% to 70.9%). Among 75 radiation necrosis lesions across 4 studies, the 12-month local control rate was 76.3% (95% CI, 65.0% to 84.8%). Thus, LITT provided more favorable local control efficacy in patients with radiation necrosis compared to those with brain metastasis recurrence. No significant difference in median OS at 1 year was determined between the radiation necrosis and brain metastasis groups (66.5% vs. 66.8%; p=.978). Survival outcomes were not stratified by pathology and safety outcomes were not reported. Compared to previously reported estimates for surgical resection with a local control rate ranging from 62% to 93% and a median OS of 8.7 months, the authors concluded that LITT demonstrates comparable local control but a more satisfactory survival benefit. The analysis is limited by study heterogeneity, small sample sizes, and the lack of a standardized definition for local disease control.

de Franca et al (2020) published a systematic review and meta-analysis of LITT as a therapy for brain tumors compared to SRS based on 25 studies.[7] Patient populations included patients with brain metastasis and recurrent glioblastoma multiforme (rGBM). A significant improvement in median OS was observed in patients treated with LITT compared to SRS among patients with brain metastasis (12.8 vs. 9.8 mo; p<.02) and was associated with a 15% reduction in risk of adverse events overall. The authors concluded that "there is no evidence that LITT can be used as a treatment of choice when compared to SRS," but use of LITT may have a role in lowering the risk of adverse events. The analysis was limited by inclusion of heterogeneous populations, the small number of patients treated with LITT (n=39), and a lack of reporting on prior treatments.

In particular, patients treated with SRS varied in their degree of radiosensitivity and prior radiation exposure, which may have influenced the higher rate of adverse events observed in this group.

Barnett et al (2016) conducted a systematic review and meta-analysis comparing LITT (8 studies; 77 patients) to open craniotomy (12 studies; 1036 patients) for the treatment of high-grade gliomas in or near areas of eloquence, with a focus on adverse events.[8] Proportions of major complications occurred in 5.7% (95% CI: 1.8 to 11.6) and 13.8% (95% CI: 10.3 to 17.9) of patients treated via LITT and craniotomy, respectively. Studies were rated at high risk of bias due to lack of randomization and blinding. The analysis was also limited by heterogeneous patient populations (e.g., age, Karnofsky score, recurrent vs. primary disease) and lack of reporting on health outcomes.

Table 1. Systematic Review & Meta-Analysis Characteristics and Results

Study	Dates	Studies	Participants	N (Range)	Design	Duration	Survival Outcomes
Chen et al (2021)[6]	2011-2020	14	Patients treated with LITT for brain metastases with in-field recurrence or radiation necrosis following treatment with SRS • Median age, 59.6 y (range, 23 to 90) • Male, 34.5% • Median KPS, 85 (range, 50 to 100) • Median pre-operative lesion volume, 4.6 cm^3 (range, 0.2 to 38.9) • Radiation necrosis, 168/470 (35.7%)	470 (7 to 92)	Phase I-II nonrandomized; Prospective registry; Retrospective case-control; Retrospective case series	At least 6 to 12 mo	OS at 6 mo: 76.0% (95% CI, 71.4% to 80.0%; I^2=43.81%; p=.059) OS at 12 mo: 63.4% (95% CI, 52.9% to 72.7%; I^2=68.2%; p=.001)
de Franca et al (2020)[7]	2007-2017	25	Patients with brain metastasis or recurrent glioblastoma multiforme treated with LITT or SRS • Mean age, 55.8 to 59.4 • Median Karnofsky score, 70 to 87.5	BM: 12 (LITT); 1555 (SRS) rGBM: 27 (LITT); 232 (SRS)	Randomized controlled study (SRS); Prospective cohort studies; Retrospective studies	NR	Median OS: LITT: • BM: 12.8 mo (range, 9.3 to 16.3) • rGBM: 10.5 (NA)[1] SRS: • BM: 9.8 mo (range, 8.3 to 9.9)

Study	Dates	Studies	Participants	N (Range)	Design	Duration	Survival Outcomes
			• Mean tumor volume, 6.8 to 20.1 cm^3				• rGBM: 10.5 mo (range, 9.9 to 11.4)
Barnett et al (2016)[8]	1992-2014	20	Patients with recurrent or primary high-grade gliomas (WHO grade III or IV) in or near areas of eloquence treated with LITT or craniotomy, respectively • Mean age, 54.3 vs. 45.6 (p<.00001) • Male, 64.2% vs. 58.8% (p=.37) • Karnofsky score, 73.4 vs. 78.4 (p=.0006) • Recurrent glioma, 68% vs. 22% (p<.00001)	LITT: 67 Craniotomy: 522	Prospective cohort studies; Retrospective studies	NR	NR

BM: brain metastasis; CI: confidence interval; KPS: Karnofsky Performance Status; LITT: laser interstitial thermal therapy; M-A: meta-analysis; NR: not reported; OS: overall survival; rGBM: recurrent glioblastoma multiforme; SR: systematic review; SRS: stereotactic radiosurgery; WHO: World Health Organization.
[1] Only 1 study result reported.

Comparative Observational Studies

Mohammadi et al (2019) conducted a multicenter retrospective review of survival outcomes in patients with deep seated newly diagnosed glioblastoma treated with upfront MR-guided LITT prior to chemo/radiotherapy (n=24; median age, 54 y; 50% male; 71% <70 yr) compared to a matched cohort of biopsy-only patients (n=24; median age, 64 yr; 58% male; 75% <70 yr).[9] Patients were matched based on age, gender, tumor location (deep vs. lobar), and tumor volume. Median follow-up was 9.3 mo (range, 2 to 43 mo) and 14.7 mo (range, 2 to 41 mo) in LITT and biopsy-only cohorts, respectively. Overall median estimates of OS and progression-free survival in the LITT cohort was 14.4 and 4.3 mo compared to 15.8 and 5.9 mo for the biopsy-only cohort. Age <70 y and tumor volume <11 cm^3 were identified as favorable prognostic factors for OS. The study was limited by its retrospective design, lack of randomization, small sample size, and short follow-up durations. Additionally, concurrent chemotherapy and radiotherapy regimens were not specified.

Single-Arm Studies

The Laser Ablation of Abnormal Neurological Tissue Using Robotic NeuroBlate System (LAANTERN) registry is an ongoing industry-sponsored, multicenter, multinational prospective registry of the NeuroBlate device enrolling patients with primary and metastatic brain tumors, epileptic foci, and movement disorders (NCT02392078). Rennert et al (2019) reported procedural safety outcomes for the first 100 patients enrolled in the LAANTERN registry (42% male, 86% white), including 48 and 34 patients with primary or metastatic intracranial tumors, respectively.[10] The

majority of patients (81.2%) had undergone prior surgical or radiation treatment and received LITT for a single lesion (79%). The average length of intensive care and overall hospital stays were 38.1 and 61.1 hours, respectively. A total of 11 adverse events among 9 patients were observed. Five adverse events were attributed to energy deposition from laser ablation, including neurological deficits (n=2), postoperative seizures (n=2), and delayed intraparenchymal hemorrhage (n=1). One mortality occurring within 30 days of laser ablation was reported and was not attributed to LITT.

Kim et al (2020) reported 12-month survival and quality of life outcomes among 223 patients enrolled in the LAANTERN registry with primary (n=131) or metastatic (n=92) brain tumors who received treatment with the NeuroBlate device.[11.] The majority of patents with primary tumors had high-grade glioma (n=90) and patients with metastatic disease had recurrent tumors (n=43) or radionecrosis (n=34). The 1-yr estimated OS rate was 73% (95% CI, 65.3% to 79.2%), which was not found to be significantly different between primary or metastatic tumors (74.6% vs. 70.7%, respectively). Quality of life assessments with the Functional Assessment of Cancer Therapy - Brain (FACT-Br) questionnaire did not meet the criteria for a clinically meaningful change (>10%) and EQ-5D questionnaires indicated an overall decline of 0.1 points from baseline.
Ahluwalia et al (2018) reported results from the multicenter, prospective Laser Ablation After Stereotactic Radiosurgery (LAASR) study, which assessed the efficacy and safety of LITT as salvage treatment in patients with radiographic progression after SRS for brain metastasis.[12.] Forty-two patients were enrolled, including 20 patients with recurrent brain tumors, 19 patients with biopsy-proven radiation necrosis, and 3 patients with no diagnosis. Progression-free survival rates for patients with recurrent tumors was 54% at 12 weeks and 62% at 26 weeks. Corresponding OS rates were 71% at 12 weeks and 64.5% at 26 weeks. Of 4 tumor lesions that received total ablation, 3/4 achieved a complete response, compared to 0/8 that received subtotal ablation. Patient Karnofsky performance, quality of life, and neurocognitive scores did not change significantly over the duration of survival. Overall, 35/42 (83%) patients developed adverse events, including 5 cases of immediate LITT-related neurological complications and 14 surgery-related adverse events.

Patel et al (2016) conducted a retrospective analysis of patients who underwent MR-guided LITT with the Visualase system at a single center in the United States between 2010 and 2014.[13.] The majority of patients (87/102) were treated for intracranial tumors. Fourteen (13.7%) developed new neurological deficits following treatment, of which 9 achieved complete resolution within 1 month, 1 achieved partial resolution within 1 month, 2 had no resolution at most recent follow-up, and 2 died without resolution of symptoms. The authors concluded that LITT, albeit minimally invasive, must be used with caution as unintended thermal damage to critical and eloquent structures may occur despite MRI guidance.

Section Summary: Primary or Metastatic Brain Tumors
Evidence for the use of LITT in primary or metastatic brain tumors includes systematic reviews and meta-analyses, 1 retrospective matched-cohort study, and several single-arm studies. Overall survival estimates ranged from 12.8 to 14.8 months. Among patients with metastatic tumors receiving LITT following prior SRS, OS rates have ranged between 72 to 76% at 6 months and 63 to 65% at 12 months. Systematic reviews comparing LITT to open craniotomy with resection or SRS suggest a reduced incidence of adverse events with LITT; however, neurological deficits attributable to LITT-induced thermal damage have been observed despite concurrent MRI guidance. Studies are limited by predominantly retrospective designs, small sample sizes, and population heterogeneity, with study subjects varying by performance status, lesion volume and location, extent of prior therapies, and extent of ablation. Prospective comparative studies in well-defined and -controlled patient populations are required to assess net health outcomes.

Radiation Necrosis
Clinical Context and Therapy Purpose
The purpose of LITT is to use a focused thermal therapy technique to ablate regions of cerebral radiation necrosis in symptomatic patients with an insufficient or intolerable response to

medications, and to potentially avoid complications associated with alternative surgical interventions.

The following PICO was used to select literature to inform this review.

Populations
The population of interest is patients with symptomatic cranial radiation necrosis with insufficient response or intolerance to medication management. LITT is typically used when open surgery is contraindicated due to high risk of procedural morbidity and/or presence of comorbidities that precludes candidacy for open surgery.

Treatment-induced brain tissue necrosis (also referred to as cranial radiation necrosis or radionecrosis) is a serious delayed complication of cranial irradiation that typically develops after 1 to 3 years. Radiation necrosis is more likely to occur with high-dose fractionation and potentially with concurrent chemotherapy or use of radiosensitizers. The risk of radiation necrosis following SRS has been reported to be higher, with a steep dose-response relationship. Differentiating radiation necrosis from recurrent brain tumors via imaging can be difficult, as conventional structural MRI may reveal features that overlap with the typical radiographic appearance of high-grade primary or metastatic brain tumors. Biopsy may be required for a definitive diagnosis of radiation necrosis, particularly among patients who are symptomatic or with worsening radiographic findings over time.

Symptoms of radiation necrosis are dependent on the location of the lesion and may include focal neurologic deficits or more generalized signs and symptoms of increased intracranial pressure. Seizures are observed in approximately 20% of patients.

Interventions
The therapy being considered is LITT as an alternative to open craniotomy with resection or medication management. LITT is performed under real-time MRI guidance.

Comparators
The following therapies are currently being used to treat primary and metastatic brain tumors: surgical resection and medication management. Medications used in the management of radiation necrosis include corticosteroids and bevacizumab, a vascular endothelial growth factor (VEGF) inhibitor.

Outcomes
Outcomes of interest are symptom improvement, medication use, quality of life, treatment-related morbidity, OS, and progression-free survival. Follow-up duration of at least 2 to 3 years is of interest for survival outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Systematic Reviews
The meta-analysis published by Chen and coworkers (2021), described previously in Table 1, included 168 (35.7%) patients with radiation necrosis who received LITT following prior treatment with SRS.[6.] The local control rate for patients with radiation necrosis at 6 and 12 months was 83.1%

(95% CI, 68.4% to 91.8%) and 66.8% (95% CI, 49.1% to 80.8%), respectively, and was more satisfactory compared to patients with recurrent brain metastasis. Overall survival was 83.1% versus 69.2% at 6 months and 66.8% versus 66.5% at 12 months for radiation necrosis and recurrent brain metastasis groups, respectively. Pre-ablation biopsy, which can accurately diagnose radiation necrosis, was not routinely performed in all analyzed studies, highlighting a major limitation of this meta-analysis given that it can be quite challenging to accurately distinguish radiation necrosis from brain metastases based on radiograhic evidence alone.

Comparative Observational Studies
Sujijantarat et al (2020) conducted a retrospective chart review comparing outcomes for patients with biopsy-confirmed radiation necrosis treated with LITT (n=25) or bevacizumab (n=13) at a single center between 2011 and 2018.[14] The LITT group had a significantly longer OS compared to bevacizumab (median 24.8 vs. 15.2 months; p=.003). Time to local recurrence was not statistically significant between groups (p=.091), but trended longer in the LITT cohort. Among 13 patients with pre-treatment symptoms in the LITT group, 9 (69%) achieved symptom relief. Among 11 patients with pre-treatment symptoms in the bevacizumab group, 4 (36%) achieved symptom relief. No significant difference was noted between groups for the ability to wean off concurrent steroids. Given that only 50% of lesions treated with LITT were symptomatic compared to 80% of lesions treated with bevacizumab, the authors suggest that LITT treatment may be more successful before radiation necrosis lesions become symptomatic. The study is limited by its retrospective design, small samples size, and population heterogeneity.

Hong et al (2019) conducted a single-center retrospective chart review of patients treated with LITT or craniotomy for previously irradiated brain metastasis, including 42 patients with recurrent brain tumors and 33 patients with radiation necrosis.[15] Among the 33 radiation necrosis patients, 15 received craniotomy and 18 received LITT, of which 20% and 38.9% received adjuvant post-operative bevacizumab, respectively. No significant differences for mean length of hospital stay, symptom improvement, ability to wean off steroids, or rate of perioperative complications were observed between LITT and craniotomy groups. Overall progression-free survival for patients with radiation necrosis was 73.2% and 86.7% at 24 months for patients treated with LITT and craniotomy, respectively. Overall survival for patients with radiation necrosis at 24 months was 64.6% for those receiving craniotomy and 63.2% for those receiving LITT. Study interpretation is limited by its retrospective nature and heterogeneity of prior and adjuvant treatments.

Single-Arm Studies
The LAASR study, described previously [Ahluwalia et al (2018)],[12] included 19 patients with biopsy-confirmed radiation necrosis who received LITT following prior treatment with SRS for brain tumors. Progression-free survival and OS were 100% and 91%, respectively, at 12 weeks, and 100% and 82.1%, respectively, at 26 weeks. Progression-free survival was significantly higher at 12 weeks for patients with radiation necrosis compared to patients with recurrent tumors (p=.016) but was not significantly different at 12 weeks (p=.166). Similar trends were seen for OS in patients with radiation necrosis at 12 weeks (p=.02) and 26 weeks (p=.09). Thirty percent of subjects were able to stop or reduce steroid usage by 12 weeks after surgery. For patients with radiation necrosis, regardless of whether a lesion was totally or subtotally ablated, LITT resulted in close to 100% lesion control and >80% survival at 6 months. No significant differences in Karnofsky performance status, quality of life, or neurocognitive scores were detected between subgroups.

Section Summary: Radiation Necrosis
Evidence on the use of LITT in patients with radiation necrosis includes 1 meta-analysis, 2 nonrandomized comparative studies, and 1 single-arm study. Studies have reported improved local control and survival outcomes in patients with radiation necrosis compared to those with brain metastases. One study comparing LITT to bevacizumab suggested that LITT treatment may be more successful among patients before radiation necrosis lesions become symptomatic. One study comparing LITT to craniotomy did not report significant survival differences between groups. Studies are limited by retrospective designs, small sample sizes, population heterogeneity, and unclear relevance, as symptomatic status was not consistently reported.

Prospective comparative studies in well-defined and -controlled patient populations are required to assess a net health outcome.

Drug-Resistant Epilepsy
Clinical Context and Therapy Purpose
The purpose of LITT is to use a focused thermal therapy technique to ablate epileptogenic foci when seizures have become drug-resistant or medication-related adverse events are intolerable, and to potentially avoid complications associated with alternative surgical interventions.

The following PICO was used to select literature to inform this review.

Populations
The population of interest is patients with drug-resistant or medication-intolerant epilepsy, defined as failure to achieve sustained seizure freedom despite adequate trials of 2 or more appropriately chosen and tolerated antiseizure medications, as specified by the International League Against Epilepsy (ILAE) Commission on Therapeutic Strategies consensus definition for drug resistant epilepsy.[16,]

Epilepsy is diagnosed when an individual has unprovoked seizures. Primary seizure disorders include multiple subtypes that are recognizable by the degree and type of impairment of consciousness and motor capacity. Seizure disorders may be secondary to brain tumors or other space-occupying intracranial lesions such as congenital malformations, stroke, genetic syndromes, brain trauma, and cerebral infections. Mesial temporal lobe epilepsy, also known as complex partial seizures, is a focal epilepsy syndrome. The epileptogenic foci may present in the hippocampus, amygdala, or parahippocampal gyrus. The most common non-traumatic or non-infectious etiology of mesial temporal lobe epilepsy is hippocampal sclerosis. The associated neuronal loss is a partial explanation for the difficulties in achieving satisfactory seizure control with antiepileptic medication. Approximately one-third of patients with epilepsy do not achieve adequate seizure control with antiepileptic drugs.

Patients with an identifiable seizure focus that can be targeted to achieve seizure freedom are primary candidates for epilepsy surgery, but patients with multifocal or generalized epilepsy may also be considered.

Interventions
The therapy being considered is LITT as an alternative to open craniotomy with resection, SRS, or neurostimulation. LITT is performed under real-time MRI guidance.

Comparators
The following therapies are currently being used to treat medication-refractory epilepsy: open craniotomy with resection, SRS, vagus nerve stimulation, and responsive cortical neurostimulation. Surgical treatment may be considered in instances where seizures have proven refractory to medical management and when the frequency and severity of the seizures significantly diminish quality of life.

Outcomes
Outcomes of interest are symptom improvement, change in disease status, quality of life, hospitalizations, medication use, treatment-related morbidity, and disease-specific survival. Key outcome measures are summarized in Table 2.

Table 2. Epilepsy Outcome Measures

Outcome Domain	Outcome Measures
Symptom Improvement	Change in seizure frequency (>50% reduction considered clinically meaningful)
Change in Disease Status	Time to cessation of seizures; Postoperative outcome status, as measured by the Engel classification:[17,]

Outcome Domain	Outcome Measures
	• Class I: Free of disabling seizures • Class IA: Completely seizure free since surgery • Class II: Rare disabling seizures • Class III: Worthwhile improvement • Class IV: No worthwhile improvement
Quality of Life	QOLIE-89 or QOLIE-31 multi-scale questionnaires (higher scores indicate improved health outcomes); eligibility to drive
Treatment-related Morbidity	Neuropsychological and neurocognitive testing
Disease-specific Survival	Incidence of SUDEP

QOLIE: Quality of Life in Epilepsy questionnaire; SUDEP: sudden unexpected death in epilepsy.

Follow-up duration of at least 2 years is of interest to evaluate the effect of the procedure when compared to resection or neurostimulation. Follow-up durations of 2 to 3 years are appropriate when compared to SRS, due its known latency for seizure reduction or remission. Rarely, a transient increase in seizure frequency and severity may be observed following surgical interventions. Therefore, time to cessation of seizures and proportion of patients with increased seizure frequency represent additional outcomes of interest.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Kohlhase et al (2021) performed a systematic review and meta-analysis to compare outcomes and complications from MR-guided LITT, radiofrequency ablation (RFA), and conventional open surgery (i.e., anterior temporal lobe resection [ATL] or selective amygdalohippocampectomy [sAHE]) in patients with drug-refractory mesial temporal lobe epilepsy (mTLE).[18] Forty-three studies were identified (13 LITT; 6 RFA; 24 conventional surgery) between 1995 and 2018. Meta-analytic estimates for the proportion of patients achieving Engel I outcomes were 34% (95% CI, 15% to 61%), 57% (95% CI, 53% to 61%), 65% (95% CI, 58% to 72%) and 69% (95% CI, 62% to 75%) for RFA, LITT, sAHE, and ATL, respectively. No significant difference in outcome was noted between LITT and RFA (p=.098), whereas significantly better outcomes were observed following conventional surgery with both sAHE (p=.0247) and ATL (p=.0113) compared to LITT. In a subgroup analysis of patients with follow-up duration ≥60 months, both ATL (p=.009) and sAHE (p=.043) resulted in significantly higher rates of Engel I outcomes compared to LITT. Among patients treated with LITT, significantly better outcomes were observed in patients with mTLE and hippocampal sclerosis (p=.0035). Overall complication rates were 14.1%, 17.5%, 31.3%, and 18.2% for LITT, RFA, ATL, and sAHE, respectively, with corresponding major complication rates of 3.8%, 3.7%, 10.9%, and 7.4%. However, meta-analysis revealed no significant differences concerning overall and major complication rates between procedures. The authors concluded that overall, patients treated with MR-guided LITT had a lower chance of achieving an Engel I outcome compared to those who received conventional surgery and that the presence of mesial hippocampal sclerosis might be a prognostic factor for a more favorable outcome with LITT.

Brotis et al (2021) conducted a meta-analysis to estimate the efficacy of LITT for mTLE.[19] Sixteen retrospective case series published between 2012 and 2019 representing 575 patients (range, 1 to 231) were identified. Overall, seizure freedom was achieved in 54.7% (95% CI, 50.6% to 58.8%; I^2=18.7%) of patients undergoing LITT with a median follow-up duration of 18 months

(interquartile range [IQR], 12 to 26 months). Sensitivity analyses yielded similar results. Four studies representing 150 patients indicated that the prevalence of Engel Class IA outcomes decreased with time, estimated at 64.2%, 46.9%, and 42.4% at 12-, 24-, and 36-month follow-up, respectively. The overall quality of evidence was regarded as 'very low' according to GRADE recommendations, with only 4 studies including more than 20 patients. The authors concluded that while mTLE resective surgeries are invasive and irreversible, they offer better seizure control rates, with previously reported seizure-free rates ranging from ranging from 60% to 90% for mTLE.

Grewal et al (2019) published a systematic review and meta-analysis comparing MR-guided LITT versus SRS for medically intractable temporal lobe epilepsy (TLE).[20] A total of 19 studies published between 2008 and 2018 representing 404 patients (range, 5 to 58) were identified, including 9 retrospective studies on LITT (n=239). The overall seizure freedom rate was not found to be significantly different between LITT (50%; 95% CI, 44% to 56%) and SRS (42%; 95% CI, 27% to 59%; p=.39), nor was it significantly different for patients with lesional conditions (62% [95% CI, 48% to 74%] vs. 50% [95% CI, 37% to 64%]; p=.23). While LITT was associated with a significantly lower procedural complication rate (20% vs. 26%; p=.06), reoperation rates were not significantly different (15% vs. 27%; p=.31). The authors noted that the quality of evidence was low and that large-scale studies directly comparing LITT and SRS are required to validate findings.

Xue et al (2018) reported postoperative outcomes for MR-guided LITT in the treatment of drug-resistant epilepsy.[21] Sixteen nonrandomized studies published between 2014 and 2018 representing 269 patients (range, 5 to 30) were included in the meta-analysis. The prevalence of Engel Class I, II, III, and IV outcomes was 61%, 12%, 16%, and 15%, respectively. The prevalence of postoperative complications was 24% (95% CI, 16% to 32%). Interpretation of outcomes is limited by small study size and short follow-up durations (range, 7 days to 51 months).

Hoppe and Helmstaedter (2018) reported postoperative outcomes for pediatric patients <18 years treated with LITT for drug-resistant epilepsy.[22] Twenty-five case series representing 179 patients were included in the review, with the majority of cases attributed to hypothalamic hamartomas (64.2%). Among published cases, the overall complication rate was 23.5% with a 3.4% rate of severe complications. Engel I seizure-free outcomes were achieved by 57.5% of patients across studies, including individuals with short follow-up (e.g., 1 month) and repeat treatments. No studies reported on cognitive outcomes on the basis of standardized psychometric measures. Overall, the authors concluded that the published evidence does not yet allow a scientific or clinical judgement on the utility of LITT for pediatric epilepsy surgery.

Comparative Observational Studies

Hale et al (2019) reported postsurgical outcomes in 26 pediatric patients with insular epilepsy treated with LITT (n=14) or open resection (n=12).[23] Mean follow-up was 2.43 years. Engel Class I outcomes were achieved in 43% of patients treated with LITT compared to 50% who underwent open insular resection at 1 year post-surgery. Postoperative complications occurred in 6 patients treated with LITT and 7 patients treated with resection, all of which resolved within 3 to 4 months. The authors concluded that further studies are needed to determine the noninferiority of LITT with respect to resection in terms of complication rates and seizure freedom, especially in cases of cortical dysplasia that may involve extensive regions of the brain.

Petito et al (2018) published a retrospective, single center analysis of 100 consecutive neuro-surgeries performed between 2013 and 2015 in patients with drug-resistant epilepsy, representing 33 LITT procedures and 21 open resections with mean follow-up durations of 21.7 and 21.3 months, respectively.[24] A discrete lesion was radiographically identified in 85% of patients treated with LITT and 65% of patients treated with resection. The mean post-operative hospital length of stay was significantly shorter for LITT compared to resection (1.18 vs. 3.43 days; p=.0002). Patients treated with resection were significantly younger, with a mean age of 35.4 years (p=.001). At 12 months, seizure freedom was achieved in 56.3% (95% CI, 39.3% to 71.8%) and 60% (95% CI, 38.7% to 78.12%) of patients treated with LITT and resection, respectively (p=0.79). Among patients with focal lesions, the seizure freedom outcomes were not significantly

different between groups (p=.21). For nonlesional patients, LITT treatment trended towards a better outcome, but did not achieve statistical significance (p=.05). Study interpretation is limited by the small sample size, retrospective analysis, and population heterogeneity.

Single-Arm Studies

Landazuri et al (2020) reported 1-year outcomes following LITT of epileptogenic foci with the NeuroBlate system in patients with drug resistant epilepsy enrolled in the previously described LAANTERN registry (see Rennert et al [2019]).[25,10,] Engel Class I outcomes were achieved in 27/42 (64.3%; 95% CI, 48.0% to 78.5%) patients at 1 year. No significant difference was observed in patients with mesial TLE (70.8%) versus other etiologies. Five adverse events were reported, with 1 categorized as serious. Median baseline QOLIE-31 was 51.7 (range, 8.7 to 77.3). Median scores increased by 14.1 points reflecting a 72.4% improvement (95% CI, 52.8% to 87.3%) in quality of life measures. However, the total score change was not statistically significant (p=.2173). Seizure worry and social functioning sub-scores were considered statistically significant (p=.0219 and p=.0175, respectively). The authors noted that the primary success of LITT remains in well localized lesions/localizations, such as those seen in mesial TLE/mesial temporal sclerosis (MTS), cortical dysplasia, and hypothalamic hamartoma.

Wu et al (2019) published the results of a multicenter, retrospective cohort study of 234 patients with drug-resistant mTLE who underwent LITT between 2011 and 2017.[26,] At both 1 and 2 years after LITT, 58% of patients achieved Engel I outcomes. Engel I outcomes were associated with ablations involving more anterior, medial, and inferior temporal lobe structures, which tended to involve greater amygdalar volume. Presence or absence of hippocampal sclerosis did not have a significant effect on seizure outcomes. Overall, Engel I or II outcomes were achieved by 76.9% of patients at the time of last follow-up. A total of 42 complications were observed in 35 patients, of which 34 persisted at last follow-up.

Section Summary: Drug-Resistant Epilepsy

The evidence for the use of LITT in drug-resistant epilepsy includes systematic reviews and meta-analyses, 2 nonrandomized comparative studies, and 2 single-arm studies. Meta-analyses have reported seizure freedom rates ranging from 50 to 61% but are limited by heterogeneous study populations and follow-up durations. Studies comparing LITT to open resection have reported comparable outcomes in patients with pediatric insular epilepsy and adult TLE. In one meta-analysis comparing LITT to RFA and conventional surgery, superior outcomes were noted with conventional surgery among patients with mesial TLE. Total quality of life scores reported in the ongoing LAANTERN registry increased by 72.4%, but this change was not considered statistically significant (p=.2173). Prospective comparative studies in well-defined and -controlled patient populations are required to assess a net health outcome and to identify patients most likely to benefit from LITT.

Summary of Evidence

For individuals who have primary or metastatic brain tumors who receive MR-guided LITT, the evidence includes systematic reviews and meta-analyses, 1 retrospective matched-cohort study, and several single-arm studies. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Overall survival estimates ranged from 12.8 to 14.8 months. Among patients with metastatic tumors receiving LITT following prior SRS, OS rates have ranged between 72 to 76% at 6 months and 63 to 65% at 12 months. Systematic reviews comparing LITT to open craniotomy with resection or SRS suggest a reduced incidence of adverse events with LITT; however, neurological deficits attributable to LITT-induced thermal damage have been observed despite concurrent MRI guidance. Studies are limited by predominantly retrospective designs, small sample sizes, and population heterogeneity, with study subjects varying by performance status, lesion volume and location, extent of prior therapies, and extent of ablation. Prospective comparative studies in well-defined and -controlled patient populations are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic cranial radiation necrosis who receive MR-guided LITT, the evidence includes 1 meta-analysis, 2 nonrandomized comparative studies, and 1 single-arm study. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Studies have reported improved local control and survival outcomes in patients with radiation necrosis compared to those with brain metastases. One study comparing LITT to bevacizumab suggested that LITT treatment may be more successful among patients before radiation necrosis lesions become symptomatic. One study comparing LITT to craniotomy did not report significant survival differences between groups. Studies are limited by retrospective designs, small sample sizes, population heterogeneity, and unclear relevance, as symptomatic status was not consistently reported. Prospective comparative studies in well-defined and -controlled patient populations are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have drug-resistant epilepsy who receive MR-guided LITT, the evidence includes systematic reviews and meta-analyses, 2 nonrandomized comparative studies, and 2 single-arm studies. Relevant outcomes are disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Meta-analyses have reported seizure freedom rates ranging from 50 to 61% but are limited by heterogeneous study populations and follow-up durations. Studies comparing LITT to open resection have reported comparable outcomes in patients with pediatric insular epilepsy and adult TLE. In one meta-analysis comparing LITT to RFA and conventional surgery, superior outcomes were noted with conventional surgery among patients with mesial TLE. Total quality of life scores reported in the ongoing LAANTERN registry increased by 72.4%, but this change was not considered statistically significant. Prospective comparative studies in well-defined and -controlled patient populations are required to assess a net health outcome and to identify patients most likely to benefit from LITT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Neurological Surgeons et al
In September 2021, the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) Joint Section on Tumors issued a position statement regarding the use of LITT for brain tumors and radiation necrosis.[27.] The statement concludes that "LITT is an appealing option because it offers a method of minimally invasive, targeted thermal ablation of a lesion with minimal damage to healthy tissue. There is a growing body of evidence to demonstrate that LITT is an effective and well tolerated cytoreductive option for treatment of [newly diagnosed gliobastoma multiforme (GBM), recurrent GBM, and primary or recurrent brain metastases.] Intracranial LITT is also an effective option for addressing radiation necrosis with an overall reduction in steroid dependence for these patients. Especially in instances where the therapeutic window is narrowed such that craniotomy is not a viable option, LITT can play an important role in treatment for glioma or metastatic brain cancer."

American Society for Radiation Oncology

The American Society for Radiation Oncology (ASTRO) clinical practice guideline on radiotherapeutic and surgical management for newly diagnosed brain metastases (2012) does not address the use of LITT.[28]

American Society for Stereotactic and Functional Neurosurgery

In September 2021, the American Society for Stereotactic and Functional Neurosurgery (ASSFN) issued a position statement on the use of LITT in drug-resistant epilepsy.[29] The statement recommends consideration of MR-guided LITT (MRgLITT) as a treatment option when all of the following criteria are met:

- "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."

Congress of Neurological Surgeons

The Congress of Neurological Surgeons (CNS) guidelines for the treatment of adults with metastatic brain tumors (2019) state that "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."[30]

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for central nervous system cancers (v.2.2021) states that MRI-guided laser interstitial thermal therapy "may be considered for patients who are not surgical candidates (craniotomy or resection). Potential indications include relapsed brain metastases and radiation necrosis." (Category 2B)[31]

National Institute for Health and Care Excellence

In 2020, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on the use of MRI-guided LITT for drug-resistant epilepsy.[32] The NICE recommends that LITT should only be used with special arrangements, given serious but well-recognized safety concerns and low quality evidence for efficacy.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In 1997, the Centers for Medicare and Medicaid Services (CMS) issued a national coverage determination on the use of laser procedures, stating that "in the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, Medicare Administrative Contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary, and, therefore, covered."[33]

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04596930	MR-guided LITT Therapy in Patients With Primary Irresectable Glioblastoma: a Randomized Pilot Study (EMITT)	15	Dec 2021 (recruiting)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02970448	Expedited Laser Interstitial Thermal Therapy and Chemoradiation for Patients With Newly Diagnosed High Grade Gliomas	45	Dec 2021 (recruiting)
NCT02844465[a]	Stereotactic Laser Ablation for Temporal Lobe Epilepsy (SLATE)	150	May 2022 (recruiting)
NCT04181684	Pilot Study of Laser Interstitial Thermal Therapy Followed By Hypofractionated Radiation Therapy for Treatment of Recurrent Gliomas (GCCC 19140)	32	Feb 2023 (recruiting)
NCT05075850[a]	Patient Neuropsychological Outcomes After Laser Ablation (PENSAR)	250	Jun 2023 (recruiting)
NCT04187872[a]	Recurrent Brain Metastasis Immune Effects and Response to Laser Interstitial Thermotherapy (LITT) and Pembrolizumab in Combination (TORCH)	16	October 2023 (recruiting)
NCT04699773	Laser Interstitial Thermal Therapy Followed By Hypofractionated Radiation Therapy For Treatment Of Newly Diagnosed High-Grade Gliomas (GCC 20138)	32	Dec 2025 (recruiting)
NCT02392078[a]	Laser Ablation of Abnormal Neurological Tissue Using Robotic NeuroBlate System (LAANTERN) Prospective Registry	1000	Dec 2028 (recruiting)
Unpublished			
NCT02389855[a]	Laser Ablation in Stereotactic Neurosurgery (LAISE): NeuroBlate® Retrospective Registry	144	Aug 2016 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	61736	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion

Type	Code	Description
	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)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
02/01/2022	New policy.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
(New Policy) **Policy Statement:** N/A	**Laser Interstitial Thermal Therapy for Neurological Conditions 7.01.170** **Policy Statement:** Laser interstitial thermal therapy (LITT) is considered **investigational** for **all** neurological indications, including but not limited to patients with the following conditions: I. Drug-resistant epilepsy II. Primary or metastatic brain tumors III. Radiation necrosis