Laser Interstitial Thermal Therapy

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Coverage Policy
Laser Interstitial Thermal Therapy (LITT) is considered experimental, investigational or unproven for all indications.

Overview
This Coverage Policy (CP) addresses 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.

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.

Benefits and Risks
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.

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, and anesthesia-related risks 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 lever/technology learning curve. 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

Brain – Literature Review
The use of MR-guided LITT for treatment of benign and malignant brain tumors, intractable epilepsy, and radiation necrosis is evolving. The majority of studies are small, retrospective case series. A review of the current peer-reviewed literature reveals three areas of concern: 1) safety/adverse events, especially during technology learning curves 2) optimal patient populations are still being defined and 3) lack of long-term comparative prospective studies. The majority of studies reported in the literature are small retrospective case series and include patients who have failed other non-surgical and/or surgical treatment options or are not candidates for open surgery. Long-term comparative trials are needed to validate the safety and efficacy of LITT and to define optimal patient selection.

Health Technology Assessments
A Hayes Health Technology Assessment on Laser Interstitial Thermal Therapy (LITT) for Treatment of Glioblastoma in Adults (September 20, 2019) noted the inability to draw a conclusion regarding the benefits and potential associated risks of LITT for the treatment of GBM, citing a very low-quality body of evidence.

A Hayes Health Technology Assessment on Laser Interstitial Thermal Therapy (LITT) for Refractory Temporal Lobe Epilepsy (February 19, 2020) explained that available low-quality evidence is insufficient to draw conclusions regarding the benefits and potential associated risks of LITT for treatment of drug refractory MTLE.

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.

Trials currently recruiting
Two clinical trials are currently recruiting:

- ClinicalTrials.gov Identifier: NCT02844465
  Title: Stereotactic Laser Ablation for Temporal Lobe Epilepsy (SLATE) trial
  Status: Recruiting
  Principal Investigator: Michael Sperling MD
  Prospective, multicenter, single-arm study (Visualase) of patients with intractable mesial temporal lobe epilepsy (MTLE).
• ClinicalTrials.gov Identifier: NCT02392078
Title: Laser Ablation of Abnormal Neurological Tissue Using Robotic NeuroBlate System (LAANTERN) trial
Status: Recruiting
Principal Investigator: Eric Leuthardt MD
Prospective multicenter registry (NeuroBlate) of patients with intracranial lesions such as low and high-grade gliomas, brain metastases, radiation necrosis, and seizure foci

Initial publications from the LAANTERN trial:
• Rennert et al. (2018): First 100 patients undergoing Stereotactic Laser Ablation (SLA) for primary intracranial tumors (48%), brain metastases (34%), epilepsy (16%), and other/not reported (2%).
• Rennert et al. (2020): Prospective procedural safety and hospitalization data from the first 100 treated patients (81.2% had undergone prior surgical or radiation treatment). There were 5 adverse events (AEs) attributable to SLA (5/100; 5%). After the procedure, 84.8% of patients were discharged home. There was 1 mortality within 30 d of the procedure (1/100; 1%), which was not attributable to SLA.
• Landazuri et al. (2020): drug resistant epilepsy, 42 patients with one year follow up. Engel I outcome was achieved in 64.3 % at one year follow up.
• Kim et al. (2020): 223 brain tumor patients with median length of follow-up 223 days. Primary brain tumor (131; 58.7%) or metastatic brain tumor (92; 41.3%). The 1-yr estimated survival rate was 73%, and this was not impacted by disease etiology. There was no significant difference observed between patients with metastatic or primary tumors in overall survival (p = .32)

Meta-analysis

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| temporal lobe epilepsy     | 551                | Not specified | Kerezoudis 2020 | ✅ **Meta-analysis**
|                            |                    |               |               | The mean follow-up ranged from 6 to 42.9 months.                            |
|                            |                    |               |               | 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). |
|                            |                    |               |               | Seizure freedom rate for patients with MTS was 66% and was also not found to be significantly associated with total ablation volume (p=0.15). |
|                            |                    |               |               | Overall complication rate was 17%. The permanent complication rate was 5%, the temporary complication rate was 10%. |
| drug-resistant epilepsies (DRE) | 414                | Not specified | Wang 2020     | ✅ **Meta-analysis**
|                            |                    |               |               | 16 studies with MRgLITT (414 patients)                                      |
|                            |                    |               |               | 10 studies with stereoelectroencephalography-guided radiofrequency thermocooagulation (SEEG-RFTC) (390 patients) |
|                            |                    |               |               | Follow-up minimum 6 months                                                  |
|                            |                    |               |               | Overall complication rate across all samples in the two approaches (5%).     |
|                            |                    |               |               | In this analysis, authors included those who received repeated ablations and became seizure free into the seizure-free group. |
|                            |                    |               |               | 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. |
| treatment resistant epilepsy | 269                | Only Visualase mentioned | Xue 2018       | ✅ **Meta-analysis**
<p>|                            |                    |               |               | The 16 studies include postoperative follow-up of between 7 days to 51 months. |
|                            |                    |               |               | The prevalence of Engel Class I (free from disabling seizures) after ablation were reported in 12 studies that included a total of 189 individuals. |</p>
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| medically intractable temporal lobe epilepsy | 250 | Not stated | Grewal 2019 | ✓ The pooled prevalence of patients who achieved postoperative freedom from epileptic seizures was 61%.  
✓ Seven studies reported postoperative complications, with a total of 26 complications in 101 patients. The pooled prevalence was 24%.  
✓ Meta-analysis  
✓ 19 studies (total of 415 patients with medically intractable temporal lobe epilepsy). Of those studies, 9 were on LITT, with a total of 250 patients (60%), and 10 were on SRS, with a total of 165 patients (40%)  
✓ minimum of 12-month follow-up for inclusion in analysis  
✓ Overall seizure freedom rate was comparable between the 2 procedures (LITT 50% vs. SRS 42%, p=0.39)  
✓ Compared with SRS, LITT was associated with lower complication rates (LITT 20% vs. SRS 32%, p= 0.06)  
✓ Similar reoperation rates (15% vs. 27%, p=0.31) |
| mixed | 79 | NeuroBlate and Visualase | Barnett 2016 | ✓ Meta-analysis  
✓ high-grade primary or recurrent brain tumors (WHO grade III or IV) in or near areas of eloquence and/or of a deep-seated nature (e.g. brain stem)  
✓ Compared 79 LITT patients with craniotomy patients (n = 1,036) from other studies  
✓ Major complications of 5.7% and 13.8% for MRgLITT and craniotomy, respectively. (p value not provided)  
✓ extent of ablation (EOA)/ extent of resection (EOR) of 85.4 ± 10.6% with brain LITT versus 77.0 ± 40% with craniotomy (mean difference: 8%; p = 0.01) |
| brain metastasis and recurrent glioblastoma (rGBM) | 39 | NeuroBlate and Visualase | de Franca 2020 | ✓ Meta-analysis  
✓ 4 studies included totaling 39 LITT patients (12 with brain metastasis and 27 with recurrent glioblastoma [rGBM])  
✓ LITT for BM patients presented a higher median overall survival (MOS) when compared to SRS (12.8 vs. 9.8 months). However, only one LITT study demonstrated MOS evaluation, which weakens the comparison among treatments.  
✓ In rGBM patients, MOS analysis was also deficient by its absence in 66% of studies, demonstrating the need for additional clinical research and data collection consistency. |

Other Publications

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| mesial temporal lobe epilepsy (mTLE) | 234 | Not stated | Wu 2019 | ✓ Retrospective cohort from 11 centers in the USA  
✓ At both 1 and 2 years after LITT, 58.0% achieved Engel I outcomes.  
✓ A history of bilateral tonic-clonic seizures decreased chances of Engel I outcome.  
✓ Ablations posterior to the lateral mesencephalic sulcus yields diminishing returns and has been associated with increased complications.  
✓ Further work is needed to elucidate the nuances of ablation location and its impact on seizure and nonseizure outcomes |
| mixed (epilepsy and brain mass) | 223 | NeuroBlate and Visualase | Lagman 2017 | ✓ Quantitative analysis of case reports and case series USA  
✓ Head-to-head comparison of these systems was difficult given the variance in indications (and therefore patient population) and disparate literature |
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| brain tumor Gligomas (70.2%), radiation necrosis (21.0%), and metastasis (8.8%) | 207 | NeuroBlate | Shao 2020 | ✓ 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.  
✓ Retrospective case series USA  
✓ 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.  
✓ 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). |
| mixed | 120 | NeuroBlate | Kamath 2017 | ✓ Retrospective analysis USA  
✓ 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 15 patients lost to follow-up.  
✓ The rate of complications/unexpected readmission was 6.0%  
✓ There were 8 perioperative complications (6.0%) and 8 unplanned readmissions (6.0%). Of these, there were 3 perioperative mortalities (2.2%). |
| mixed | 102 | Visualase | Patel 2016 | ✓ Retrospective analysis USA  
✓ Mixed 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 state 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. |
| dural-based lesions | 91 | Visualase | Shah 2020 | ✓ Retrospective chart review USA  
✓ meningiomas (4%), intracranial metastases (45%), newly diagnosed glioblastoma (nGBM) (11%), recurrent glioblastoma (rGBM) (14%), and RN (20%). The remaining 6 LITT procedures were classified as “other”.  
✓ Median 7.2 months follow-up  
✓ 61% remain alive with 72% local control  
✓ Median time to recurrence (TTR) and OS were 31.9 and 16.9 mo, respectively  
✓ Complication rate was 4%. |
| pediatric brain tumors | 86 | unknown | Arocho-Quinones 2020 (Abstract only) | ✓ Retrospective data review, multicenter USA  
✓ 76 low-grade (I or II) and 10 high-grade (III or IV) tumors  
✓ The mean follow-up time was 24 months  
✓ At the last follow-up, the volume of SLA-treated tumors had decreased in 80.6% of patients with follow-up data.  
✓ A total of 29 acute complications in 23 patients were reported and included malpositioned catheters (n = 3), intracranial hemorrhages (n = 2), transient neurological deficits (n = 11), permanent neurological deficits (n = 5), symptomatic perilesional edema (n = 2), hydrocephalus (n = 4), and death (n = 2).  
✓ On long-term follow-up, 3 patients were reported to have worsened neuropsychological test results. |
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<tr>
<td>tumor with proximity to critical structures</td>
<td>80</td>
<td>NeuroBlate system</td>
<td>Sharma 2016</td>
<td>✓ <em>Retrospective case series</em> USA&lt;br&gt;High-grade glioma (n = 46) was the most common indication&lt;br&gt;Median follow-up time was 7.0 months&lt;br&gt;Postoperative motor deficits (partial or complete) were seen in 14 patients (11 with permanent and 3 with temporary PMDs).</td>
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<td>gelastic epilepsy related to hypothalamic hamartomas</td>
<td>71</td>
<td>Visualase (one case with NeuroBlate)</td>
<td>Curry 2018</td>
<td>✓ <em>Retrospective chart review</em> USA&lt;br&gt;25%, had failed other surgical or radiosurgical interventions prior to this trial&lt;br&gt;93% of the patients were free of their gelastic seizures at one year, and 78% of the patients with less than a year of follow-up are free of gelastic seizures.&lt;br&gt;21 had secondary seizures that were lessened by ablation and controlled with medicines.&lt;br&gt;14 patients, 20%, required two ablations, and 2 patients required three ablations.</td>
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<td>brain metastasis</td>
<td>70</td>
<td>Visualase</td>
<td>Kaye 2020</td>
<td>✓ <em>Retrospective case series</em> USA&lt;br&gt;in-field recurrence (IFR) after SRS&lt;br&gt;Median follow-up 12 months among all patients.&lt;br&gt;Median follow-up 24.6 months among survivors.&lt;br&gt;Three patients had new permanent neurological deficits after LITT, yielding a major complication rate of 4.3%.&lt;br&gt;The 24-month cumulative incidence of neurologic and non-neurologic death was 35.1% and 38.6%, respectively.&lt;br&gt;Etiologies of neurologic death included local recurrence (n = 7), recovery failure (n = 7), distant progression (n = 5), and other (n = 1).</td>
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<td>metastatic brain tumors</td>
<td>61</td>
<td>Visualase</td>
<td>Bastos 2020</td>
<td>✓ <em>Retrospective case series</em> USA&lt;br&gt;82 lesions (5 newly diagnosed, 46 recurrence, and 31 radiation necrosis&lt;br&gt;Freedom from local recurrence at 6 mo was 69.6%, 59.4% at 12, and 54.7% at 18 and 24 mo.&lt;br&gt;Complication rate was 26.2%</td>
</tr>
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<td>mesial temporal lobe epilepsy (MTLE)</td>
<td>59</td>
<td>Visualase</td>
<td>Hernandez 2019</td>
<td>✓ <em>Retrospective analysis</em> of prospectively-collected data USA&lt;br&gt;progressive enhancing inflammatory reaction (PEIR) that represents either tumor recurrence or radiation necrosis, or a combination of both&lt;br&gt;Median follow-up of 44.6 weeks&lt;br&gt;Local control rate was 83.1%&lt;br&gt;Most patients were weaned off steroids post-LITT.</td>
</tr>
<tr>
<td>hypothalamic hamartoma in pediatric patients with gelastic seizures</td>
<td>58</td>
<td>Visualase</td>
<td>Gadgil 2020</td>
<td>✓ <em>Retrospective records review</em> USA&lt;br&gt;A total of 47 patients (81.0%) were completely free of gelastic seizures at last follow-up. An additional 5 patients (8.6%) had &gt;90% reduction in frequency of gelastic seizures.&lt;br&gt;A total of 6 patients (10.3%) had continued gelastic seizures, though with worthwhile improvement in seizure burden compared to preoperative baseline.</td>
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| intracranial tumors in Geriatric patients                                 | 55                 | Visualase     | Ginalis 2020  | ✓ **Retrospective geriatric cohort (≥ 65 years of age)** USA  
✓ 30 day follow-up  
✓ The majority of lesions (40 (62.5%)) treated were recurrent brain metastases or radiation necrosis.  
✓ Nine patients (14.1% of cases) were found to have acute neurological complications following LITT, with nearly all patients showing complete or partial recovery at follow-up.  
✓ The authors grouped patients into two distinct age cohorts: 65–74 years (group 1) and 75 years or older (group 2).  
✓ The 30-day postoperative mortality rate was 1.6% (1 case).  
✓ The complication and 30-day postoperative mortality rates were not significantly different between the two age groups. |
| glioblastoma (GBM)                                                       | 54                 | NeuroBlate    | Kamath 2019 (Hawasli 2013, Kamath 2017) | ✓ **Retrospective records review** USA  
✓ 58 LITT treatments, 41 were recurrent tumors while 17 were frontline treatments  
✓ Median overall survival after LITT for the total cohort was 11.5 mo, and median progression free survival 6.6 mo. |
| posterior fossa neoplasms                                                | 48                 | Visualase     | Ashraf 2020 (Abstract only) | ✓ **Retrospective records review, multicenter** USA  
✓ There were a total of 15 primary tumors and 45 secondary tumors (44 cases of infield recurrence and one untreated metastatic tumor).  
✓ Median follow-up was 9.5 months  
✓ LITT resulted in an overall local control rate of 84.0% (42/50). Stratifying patients by tumor location revealed a local control rate of 50.0% (2/4) for brainstem tumors and 87.0% (40/46) for cerebellar locations (p = 0.115).  
✓ There was a total of 14 complications in this study (24.1%), consisting of two procedural complications and new neurological deficits in 12 patients. |
| epilepsy, CNS tumors, and radiation necrosis                             | 46                 | Visualase     | Pruitt 2017   | ✓ **Retrospective case series** USA  
✓ Follow-up period not stated  
✓ Some form of adverse event occurred in 11 (22.4%) of 49 procedures. These included 4 catheter malpositions, 3 intracranial hemorrhages, 3 cases of neurological deficit related to thermal injury, and 1 technical malfunction resulting in an aborted procedure. Of these, direct thermal injury was the only cause of prolonged neurological morbidity and occurred in 3 of 49 procedures. |
| mesial temporal lobe epilepsy                                             | 43                 | Visualase     | Donos 2018    | ✓ **Retrospective case series** USA  
✓ Engel class I surgical outcome was obtained in 79.5% and 67.4% of the 43 patients at 6 and 20.3 months of follow-up, respectively.  
✓ No significant differences in surgical outcomes were found across patient subgroups (hemispheric dominance hippocampal sclerosis, or need for intracranial evaluation). |
| brain metastases                                                         | 42                 | NeuroBlate    | Ahluwalia 2018 NCT01651 078 | ✓ **Multicenter Prospective Phase II study** USA  
✓ patients with evidence of radiographic lesion growth following prior treatment with SRS  
✓ 27 patients (64%) completed the 12-week follow-up, and 16 patients (38%) completed the full 26-week follow-up  
✓ Progression-free survival and OS rates were 74% (20/27) and 72%, respectively, at 26 weeks. |
| extratemporal lobe epilepsy (ETLE)                                       | 35                 | Visualase     | Gupta 2020    | ✓ **Retrospective case series** USA  
✓ Mean follow-up was 27.3 months  
✓ Of 32 patients with >12 months of follow-up, 17 (53%) achieved good outcomes (Engel class I + II) of whom 14 (44%) were Engel class I. |
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<tr>
<td>difficult-to-access high-grade glioma</td>
<td>34</td>
<td>NeuroBlate</td>
<td>Mohammad i 2014</td>
<td>• Major adverse events included one patient with a brain abscess that required stereotactic drainage and one patient with persistent hypothalamic obesity. Three deaths—two seizure-associated and one suicide—were unrelated to surgical procedures.</td>
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<tr>
<td>42 had recurrent tumor (56% and 33 (44%) had radiation necrosis (RN) (75 total, 34 underwent LITT)</td>
<td>34</td>
<td>NeuroBlate</td>
<td>Hong 2019</td>
<td>• Retrospective records review • Of patients with tumor, 26 underwent craniotomy and 16 LITT. For radiation necrosis (RN), 15 had craniotomy and 18 LITT • No significant difference between LITT and craniotomy in ability to taper off steroids or neurological outcomes. • 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.</td>
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**Brain – UpToDate**

An UpToDate posting on delayed complications of cranial irradiation (Dietrich et al. 2020) 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. 2020) 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.

**Brain – Professional Societies/Organizations**


The Congress of Neurological Surgeons/American Association of Neurological Surgeons (CNS/AANS): 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 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.”

Breast – Literature Review
Percutaneous treatments have been developed to reduce morbidity and improve esthetic results. Few studies have been published evaluating LITT of targeted nodules in malignant and benign breast disease. Most studies do not utilize the NeuroBlate or Visualase system. In a 2017 review, Fleming et al. suggests tumors larger than two cm do not appear to be good candidates for laser therapy, nor do those with an extensive in situ component. Although lasers can be placed under ultrasound or stereotactic guidance, the treatment zone is not well visualized, and MRI may be more useful in this regard. Conventional imaging techniques to explore breasts are x-ray and ultrasound (US). Kerbage et al. (2017) notes “LITT is a minimally invasive technique that is under development for the in situ destruction of solid-organ tumors”. “Our review and the heterogeneous results of the different studies suggest that several issues must be addressed before this technique can be used in clinical practice.” Kerbage et al. (2017) goes on to state that “current research in breast cancer ablative therapy is focused on thermotherapies (LITT, radiofrequency ablation, microwave irradiation, HIFU, cryoablation)”. Hayes, Inc. Evidence Analysis Research Brief on Laser Interstitial Thermotherapy for Treatment of Breast Cancer (Mar 22, 2018; ARCHIVED Apr 22, 2019) stated the published evidence was insufficient to assess the safety and/or impact on health outcomes or patient management of laser interstitial thermotherapy (LITT) for treatment of breast cancer.

Breast – Professional Societies/Organizations
The American Society of Breast Surgeons (ASBS) Consensus Guideline on the Use of Transcutaneous and Percutaneous Methods for the Treatment of Benign and Malignant Tumors of the Breast notes ‘At this time, there are no FDA approved percutaneous or transcutaneous ablative treatments for breast cancer. At the present time, cryoablation is approved for treatment of soft tissue malignancies. However, there is emerging data from clinical trials utilizing percutaneous ablative therapies for patients with early stage breast cancer without surgical excision. Techniques being evaluated include ablation by focused ultrasound, laser, cryotherapy, microwave, and radiofrequency’ (ASBS, 2018).

**Osteoid Osteoma – Literature Review**

Hayes, Inc. Evidence Analysis Research Brief on Laser Interstitial Thermotherapy for Treatment of Osteoid Osteoma (Mar 28, 2018; ARCHIVED Apr 28, 2019) stated there is sufficient published evidence to evaluate this technology. The study abstracts present conflicting findings regarding laser interstitial thermotherapy (LITT) for the treatment of osteoid osteoma.

Tsoumakidou et al. (2016) used a diode laser with combined CT and fluoroscopic guidance in 57 spinal osteoid osteoma patients. OO was in the vertebral body for 18 of 57 patients, the neural arch for 21 of 57 patients, and the articular process for 18 of 57 patients. Primary clinical success at one month was 98.2%. Total recurrence rate was 5.3%. No major complications were noted.

Roqueplan et al (2010) reported using computed tomography (CT)-guided interstitial laser ablation (ILA) in 100 patients with osteoid osteoma. Results were retrospectively compared with 26 patients treated with percutaneous trephine resection (PR). The median follow-up for CT-guided ILA treated patients was 47 months. The clinical success rate was 96% at six-month and 94% at 24-month follow-up, with 4% (4/100) transient complications (one common fibular nerve contusion, one hematoma, one infection and one tendinitis). Four ILA procedures were repeated, one because of initial failure and three because of recurrence (at 6.5, 15 and 32 months). Two were successful and two failed again. In the group treated by PR, the clinical success rate was 96% at six-month and 95% at 24-month follow-up, with 12% (3/26) transient complications (one meralgia, two skin burns).

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

**Osteoid Osteoma – Professional Societies/Organizations**

The National Comprehensive Cancer Network® (NCCN®) national guidance that is published for the treatment of bone cancer (1.2021 – November 20, 2020) does not address laser interstitial thermal therapy.

American Academy of Orthopaedic Surgeons Clinical Practice Guidelines do not address osteoid osteoma. Their 'OrthoInfo' Diseases and Conditions webpage on Osteoid Osteoma mentions Curettage and Radiofrequency ablation under Surgical Treatment.

**Spine – Literature Review**

de Almeida Bastos et al. (2020) published a retrospective comparison including 80 patients with metastatic thoracic epidural spinal cord compression (ESCC) scores of 1c or higher. A total of 40 patients underwent spinal laser interstitial thermotherapy (SLITT) using Visualase versus 40 underwent open surgical decompression. There was no significant difference in demographics or clinical characteristics between the cohorts. The median follow-up time was 13 months. PFS and OS were similar between groups (p = 0.510 and p = 0.868, respectively). The SLITT cohort had a smaller postoperative decrease in the extent of ESCC but a lower estimated blood loss (117 vs 1331 ml, p < 0.001), shorter LOS (3.4 vs 9 days, p < 0.001), lower overall complication rate (5% vs 35%, p= 0.003), fewer days until radiotherapy or SSRS (7.8 vs 35.9, p < 0.001), and systemic treatment (24.7 vs 59 days, p = 0.015). The authors concluded that that SLITT plus SSRS is not inferior to open decompression surgery plus SSRS in regard to local control, with a lower rate of complications and faster resumption of oncological treatment. A prospective randomized controlled study is needed to compare SLITT with open decompressive surgery for ESCC.

Tatsui et al. (2016) retrospectively reported on 19 patients who underwent spinal laser interstitial thermotherapy (SLITT) using Visualase, followed by stereotactic radiosurgery. The patients had spinal metastasis due to radio-resistant tumors, without motor deficits. All patients had epidural tumors compressing the spinal cord or cauda equina. Seven patients had an ESCC grade 1c; 8 patients had ESCC grade 2; and 4 patients had ESCC grade 3. Median follow-up was 28 weeks. We observed a mean reduction of 22.0% in the median thickness of the epidural tumor at 2 months post-SLITT. Follow-up MR imaging after 2 months revealed significant
decompression of the neural component in 16 patients. However, 3 patients showed progression at follow-up, 1 was treated with surgical decompression and stabilization and 2 were treated with repeated SLITT.

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

**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

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<tr>
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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 Experimental/Investigational/Unproven:**

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<th>CPT®* Codes</th>
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<td>Unlisted procedure, endocrine system</td>
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<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
</tbody>
</table>


### References

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


103. Williams D, Loshak H. Laser Interstitial Thermal Therapy for Epilepsy and/or Brain Tumours: A Review of Clinical Effectiveness and Cost-Effectiveness [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2019 Jun. CADTH Rapid Response Reports.


107. Youngerman BE, Oh JY, Anbarasan D, Billakota S, Casadei CH, Columbia Comprehensive Epilepsy Center Co-Authors, et al. Laser ablation is effective for temporal lobe epilepsy with and without mesial
temporal sclerosis if hippocampal seizure onsets are localized by stereoelectroencephalography. 