Priority Health

MEDICAL POLICY
No. 91640-R1

LASER INTERSTITIAL THERMAL THERAPY (LITT)

Effective Date: March 1, 2025 | **Review Dates: 02/24, 02/25**
Date Of Origin: 02/21/2024 | **Status: Current**

Summary of Changes

- Change: LITT is considered is medically necessary for primary and recurrent brain tumors or relapsed brain metastases when criteria are met.

I. POLICY/CRITERIA

A. Laser interstitial thermal therapy (LITT) also known as Magnetic Resonance-Guided Laser Interstitial Thermal Therapy (e.g., NeuroBlate and Visualase Thermal Therapy System) is medically necessary for refractory epilepsy when all following criteria are met:

1. Documentation of drug resistant or medication-refractory epilepsy
    i. Failure to respond to, or intolerant of, at least 2 antiepileptic drug regimens for disabling and localization-related epilepsy; and
2. Well-defined epileptogenic foci or critical pathways of seizure propagation accessible by (MR-gLITT).
3. Documentation that LITT is the best treatment option as agreed upon by a multidisciplinary team. The multidisciplinary team may include a neurologist, neurosurgeon, neurophysiologist, neuroradiologist and psychiatrist.

B. LITT is considered is medically necessary for primary and recurrent brain tumors or relapsed brain metastases when the following criteria are met:

1. Member is a poor surgical candidate for craniotomy and resection; and
2. Open surgery presents prohibitive surgical risk; or
3. The tumor is located at surgically inaccessible site; and
4. Documentation that LITT has been agreed upon by a multidisciplinary team (e.g. neurosurgery, oncology) after considering all relevant possible treatment approaches.

C. LITT is considered experimental and/or investigational due to insufficient evidence in scientific literature demonstrating its effectiveness on health outcomes for all other conditions, including but not limited to:

1. Radiation necrosis

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a

request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. BACKGROUND

Laser Interstitial Thermal Therapy (LITT), also referred to as Magnetic Resonance-Guided Laser Interstitial Thermal Therapy (MRgLITT), is the selective ablation of a lesion or tissue using heat emitted from a laser device. During a LITT ablation, light energy emitted by the laser is converted into thermal energy by the surrounding tissue when photons emitted by the laser optical fiber are absorbed by tumor cell chromophores. This results in chromophore excitation followed by release of thermal energy. Protein denaturation, cellular necrosis, and tissue coagulation occur when a sufficient temperature is obtained. The intent of LITT is to provide a less invasive nonsurgical technique for patients who would not tolerate a larger surgical

resection, who have difficult-to-access or deep lesions, or who have lesions resistant to alternative therapies (Hayes, 2022).

Refractory epilepsy/Drug resistant epilepsy
American Society for Stereotactic and Functional Neurosurgery published a Position Statement on Laser Interstitial Thermal Therapy for the Treatment of Drug-Resistant Epilepsy (2022) outlining the appropriate criteria/indications for the use of LITT in patients with epilepsy. Indications for the use of MRI-Guided LITT include: 1) Failure to respond to, or intolerance of, at least 2 appropriately chosen medications at appropriate doses for disabling and localization-related epilepsy and 2) well-defined epileptogenic foci or critical pathways of seizure propagation accessible by MRgLITT. (ASSFN, 2022)

Kang and colleagues prospectively tracked seizure outcome in 20 patients at Thomas Jefferson University Hospital with drug-resistant mesial temporal lobe epilepsy (mTLE) who underwent MRI-guided LITT from December 2011 to December 2014. Surgical outcome was assessed at 6 months, 1 year, 2 years, and at the most recent visit. Volume-based analysis of ablated mesial temporal structures was conducted in 17 patients with mesial temporal sclerosis (MTS) and results were compared between the seizure-free and not seizure-free groups. Following LITT, proportions of patients who were free of seizures impairing consciousness (including those with auras only) are as follows: 8 of 15 patients (53%, 95% confidence interval [CI] 30.1-75.2%) after 6 months, 4 of 11 patients (36.4%, 95% CI 14.9-64.8%) after 1 year, 3 of 5 patients (60%, 95% CI 22.9-88.4%) at 2-year follow-up. Median follow-up was 13.4 months after LITT (range 1.3 months to 3.2 years). Seizure outcome after LITT suggests an all or none response. Four patients had anterior temporal lobectomy (ATL) after LITT; three are seizure-free. There were no differences in total ablated volume of the amygdalohippocampus complex or individual volumes of hippocampus, amygdala, entorhinal cortex, parahippocampal gyrus, and fusiform gyrus between seizure-free and non-seizure-free patients. Contextual verbal memory performance was preserved after LITT, although decline in noncontextual memory task scores were noted. The authors concluded that MRI-guided stereotactic LITT is a safe alternative to ATL in patients with medically intractable mTLE, but noted that individualized assessment is warranted to determine whether the reduced odds of seizure freedom are worth the reduction in risk, discomfort, and recovery time. Larger prospective studies are needed to confirm the preliminary findings, and to define optimal ablation volume and ideal structures for ablation (Kang et al., 2016).

A multi-site, single-institution, retrospective study evaluated seizure outcomes and ablation volumes following LITT for medically intractable mesial temporal lobe epilepsy between October 2011 and October 2015. There were 23 patients who underwent mesial temporal LITT within the study period. Fifteen patients (65%) had left-sided procedures. The median follow-up was 34 months (range

12–70 months). The mean ablation volume was 6888 mm3. Median hippocampal ablation was 65%, with a median amygdala ablation of 43%. At last follow-up, 11 (48%) of these patients were seizure free. There was no correlation between ablation volume and seizure freedom ($p = 0.69$). There was also no correlation between percent ablation of the amygdala ($p = 0.28$) or hippocampus ($p = 0.82$) and seizure outcomes. Twelve patients underwent formal testing with computational visual fields. Visual field changes were seen in 67% of patients who underwent testing. Comparing the 5 patients with clinically noticeable visual field deficits to the rest of the cohort showed no significant difference in ablation volume between those patients with visual field deficits and those without ($p = 0.94$). There were 11 patients with follow-up neuropsychological testing. Within this group, verbal learning retention was 76% in the patients with left-sided procedures and 89% in those with right-sided procedures (Grewal et al., 2018).

A prospective cohort study by Donos et al. reported on a series of 43 consecutive laser ablations of the amygdala and hippocampus for the treatment of mesial temporal lobe epilepsy (MTLE) over an interval of 5 years (June 2012 through June 2017) at Memorial Hermann-Texas Medical Center Hospital. All patients underwent unilateral LITT targeting mesial temporal structures. A median of 73.7% of amygdala, 70.9% of hippocampus, and 28.3% of entorhinal cortex was ablated. Engel class I surgical outcome (meaning free of disabling seizures [Wieser et al., 2001]) 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). Furthermore, no significant differences in volumes ablated were found between patients with Engel class IA vs Engel class II-IV outcomes. In patients undergoing LITT in the dominant hemisphere, a decline in verbal and narrative memory, but not in naming function was noted. The significance of these findings are that seizure-free outcomes following LITT may be comparable in carefully selected patients with and without MTS, and these outcomes are comparable with outcomes following microsurgical resection. Failures may result from non-mesial components of the epileptogenic network that are not affected by LITT. Cognitive declines following MTL-LITT are modest, and principally affect memory processes (Donos et al., 2018).

Primary Tumors and Radiation Necrosis

In a prospective, multicenter, open-label study; 42 participants with either metastatic brain lesions (n=20), biopsy-proven radiation necrosis (n=19), or no diagnosis (n=3) and a mean lesion volume of 6.4 cm^3 were treated with LITT. Results showed no significant difference in length of hospital stay between the recurrent tumor and radiation necrosis patients (median 2.3 vs 1.7 days, respectively). Progression-free survival (PFS) and overall survival (OS) rates were 74% (20/27) and 72%, respectively, at 26 weeks. Thirty percent of subjects were able to stop or reduce steroid usage by 12 weeks after surgery. Median

Karnofsky Performance Scale (KPS) score, quality of life, and neurocognitive results did not change significantly for either group over the duration of survival. Adverse events were also similar for the two groups, with no significant difference in the overall event rate. There was a 12-week PFS and OS advantage for the radiation necrosis patients compared with the recurrent tumor or tumor progression patients (Ahluwalia et al., 2019).

Sujijantarat and colleagues compared laser interstitial thermal therapy (LITT) vs. bevacizumab for radiation necrosis in previously irradiated brain metastases. Twenty-five patients underwent LITT and 13 patients were treated with bevacizumab. The LITT cohort had a longer overall survival (median 24.8 vs. 15.2 months for bevacizumab, $p = 0.003$). LITT resulted in an initial increase in lesional volume compared to bevacizumab ($p < 0.001$). However, this trend reversed in the long term follow-up, with LITT resulting in a median volume decrease at 1 year post-treatment of − 64.7% (range − 96.0% to + > 100%), while bevacizumab patients saw a median volume increase of + > 100% (range − 63.0% to + > 100%), $p = 0.010$. The authors note that it remains unclear whether these findings are due only to a difference in efficacy of the treatments or the implications of selection bias (Sujijantarat et al., 2020).

The LAANTERN trial is a multisite, prospective registry which enrolled subjects across 20 centers who had at least 1 brain neoplasm ablated during the index procedure (inclusive of tumor with or without radiation necrosis) with a LITT procedure date on or prior to May 31, 2018 (allowing for approximately 12-mo follow-up). One-year trial results including 223 subjects revealed that of the ablated tumors, 131 were primary and 92 were metastatic. Most patients with primary tumors had high-grade gliomas (80.9%). Patients with metastatic cancer had recurrence (50.6%) or radiation necrosis (40%). The median post procedure hospital stay was 33.4 h (12.7-733.4). The 1-yr estimated survival rate was 73%, and this was not impacted by disease etiology. Patient-reported quality of life as assessed by the Functional Assessment of Cancer Therapy-Brain was stabilized post procedure. Karnofsky Performance Scale (KPS) declined by an average of 5.7 to 10.5 points post procedure; however, 50.5% had stabilized/improved KPS at 6 mo. There were no significant differences in KPS or QoL between patients with metastatic vs primary tumors (Kim et al., 2020)

Cuschieri and colleagues conducted a systematic review attempting to characterize patient demographics and clinical outcomes in patients with biopsy-proven radiation necrosis who underwent treatment with LITT. Eleven studies, all non-randomized cohort studies, were included in this review. Out of all the studies, five of them managed to successfully taper down steroid use post-LITT with some being totally discontinued. Most of the LITT outcomes were measured with Karnofsky Performance Scale (KPS) scores, and only 2 studies showed a moderate improvement in patients post-LITT procedure with others showing no amelioration in KPS. Only 4 of the studies mentioned radiological follow up with

repeat MRIs post-LITT to assess for resolution of surrounding edema and reduction in RN size. Most studies mentioned LITT-related adverse events including edema in the subsequent weeks which slowly resolved over the following months on repeat imaging and clinical examination on follow up. The authors note that a generalization of post-LITT outcomes was difficult to achieve due to several limitations. Immediate post-LITT lesion volumes generally increased compared to baseline; however with time the lesion volumes decreased significantly. Steroid cessation following LITT is a favorable outcome, with the majority of the studies which documented post-LITT steroid status noting a greater proportion of patients being able to stop steroids completely or decrease their respective dose. In addition, literature based on radiological studies suggest almost complete resolution of edema and associated mass effect following LITT. Reported LITT-associated complications were heterogeneous, with the most prevalent being temporary neurological adverse effects. Yet, prolonged adverse effects were noted in 6–32% of patients, warranting further studies on the safety of LITT for radiation necrosis. Such effects included motor or sensory deficit, dysphasia, and seizures (Cuschieri et al., 2023)

National Comprehensive Cancer Network Central Nervous System Cancer Guidelines state that LITT may be considered for patients who are poor surgical candidates (craniotomy or resection). Potential indications include relapsed brain metastases, radiation necrosis, and recurrent glioblastoma (Grade 2B recommendation).

American Association of Neurologic Surgeons/Congress of Neurological Surgeons released a Position Statement on MR-guided Laser Interstitial Thermal Therapy (LITT) for Brain Tumors and Radiation Necrosis in September 2021 stating that with respect to open surgical resection, surgery followed by concurrent chemo/radiation therapy (Stupp protocol) is the typical course of treatment for patients with newly diagnosed high grade gliomas; however there are circumstances when gross total or even subtotal resection via craniotomy is not feasible; including patients with deep seated tumors, tumors adjacent to eloquent structures, or patients who are not candidates for open resection due to other comorbidities. When an open craniotomy resection is not feasible, LITT has been shown to be an effective treatment option in order to achieve maximal cytoreduction of the tumor prior to the administration of chemo and radiation. The use of LITT for ablation of tumors has become a standard alternative to situations where open surgical resection would be considered (ex. gliomas, metastases, radiation necrosis, and even in some circumstances where it is not considered (ex. tumor tissue that is challenging to access). The statement includes recognition of a growing body of peer reviewed published literature which describes LITT being used safely and effectively in patients with primary brain tumors (newly diagnosed and recurrent); brain metastases (recurrent), and for radiation necrosis, utilizing a cytoreductive effect via heat-induced killing that is comparable to

resection when an open excision via craniotomy is not a viable option (AANS/CNS, 2021).

The International Stereotactic Radiosurgery Society (ISRS) gave a weak recommendation, based on low level of supporting evidence, for LITT for patients with symptomatic corticosteroid-refractory RN. The ISRS commented that one advantage of LITT is that it can obtain tissue confirmation during the same procedure. It is important to be mindful that transient worsening of peri-lesional edema may occur post-LITT, due to lack of decompression. LITT is also a resource-intense and invasive procedure that requires specialized equipment and a trained team. Access to LITT in resource-constrained countries limits the utility in RN. Moreover, certain locations – such as those near the dura and cerebral vessels – can be challenging for LITT because of the heat-sink effect. Finally, in patients with a mixture of RN and residual viable disease, additional radiation therapy may be required (Vellayappan, 2024).

In a systematic review and meta-analysis of LITT for recurrent glioblastomas Zhao et al reviewed progression-free survival (PFS) and overall survival (OS) at 6 and 12 months of rGBM patients treated with LITT as the primary therapy. The authors reviewed seven studies involving 120 patients and found the pooled PFS rate at 6 months after LITT was 25% (95% CI 15-37%, $I^2 = 53\%$), and at 12 months, it was 9% (95% CI 4-15%, $I^2 = 24\%$). OS analysis was performed on 54 patients from six studies, with an OS rate of 92% (95% CI 84-100%, $I^2 = 0\%$) at 6 months and 42% (95% CI 13-73%, $I^2 = 67\%$) at 12 months after LITT. LITT demonstrates a favorable safety profile with low complication rates and promising tumor control and overall survival rates in patients with rGBMs. Tumor volume and performance status are important factors that may influence the effectiveness of LITT in selected patients (Zhao et al, 2024).

Khalaffah et al (2024) conducted a retrospective analysis of patients with newly GBM (nGBM) to study safety and efficacy in large-volume, deep-seated, nGBM tumors. A total of 33 patients in the study group (mean ± SD age 65.7 ± 10.2 years, 58% male) with mean tumor volume 36.0 ± 21.6 cm3 were compared to 23 controls (mean age 67.0 ± 12.5 years, 61% male) with mean tumor volume 5.2 ± 2.7 cm3. The authors found no significant differences in hospital length of stay ($p = 0.494$), temporary neurological deficits and edema within 30 days ($p = 0.705$ and $p > 0.999$, respectively), 30-day readmissions ($p = 0.139$), < 30-day complications ($p = 0.918$), complications between 30 days and 3 months ($p = 0.903$), and new motor and speech deficits within 3 months ($p = 0.883$ and $p > 0.999$, respectively) between the study and control groups. Kaplan-Meier analysis did not reveal any statistically significant difference in overall survival (OS) between groups ($p = 0.227$). Multivariate analysis indicated that tumor volume did not significantly affect the hazard ratio for individuals undergoing LITT (HR 1.16, 95% CI 0.83-3.29, $p = 0.150$)

Minimal data on comparative effectiveness with current standard of care is available for review.

V. CODING INFORMATION

CPT/HCPCS Codes:

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)

VI. REFERENCES

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