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MEDICAL POLICY – 7.01.170

Laser Interstitial Thermal Therapy for Neurological Conditions

BCBSA Ref. Policy:	7.01.170
Effective Date:	Mar. 1, 2025
Last Revised:	Feb. 10, 2025
Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.143	Responsive Neurostimulation for the Treatment of Refractory Partial Epilepsy
7.01.593	Vagus Nerve Stimulation

Select a hyperlink below to be directed to that section.

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Laser interstitial thermal therapy (LITT) is a type of minimally invasive surgery that can be used for medical conditions that affect the brain. These may include cancerous and non-cancerous brain tumors, loss of brain tissue due to radiation treatment, and epilepsy that does not respond to drug therapy. LITT uses real-time magnetic imaging (MRI) to guide the location and length of the surgery. A small hole is drilled through the skull, and a laser probe is inserted. The probe uses heat to destroy the targeted tissue. The goal of this treatment is to remove only the damaged brain tissue. The use of laser interstitial thermal therapy to treat all neurological conditions is unproven (investigational). More studies are needed to see if this procedure improves health outcomes.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Therapy	Investigational
Laser interstitial thermal therapy (LITT)	**Laser interstitial thermal therapy (LITT) is considered investigational for all neurological indications, including but not limited to individuals with primary or metastatic brain tumors, radiation necrosis, and drug-resistant epilepsy.**

Coding

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
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)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

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 magnetic resonance imaging (MRI) guidance. LITT has been proposed as a less invasive treatment option for individuals with neurological conditions compared to surgery. Two LITT systems, Visualase and NeuroBlate, have received marketing clearance from the US Food and Drug Administration (FDA).

Background

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 individuals 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.

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 and several nonrandomized comparative and single-arm studies. Relevant outcomes are overall survival (OS), disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and

treatment-related morbidity. Overall survival estimates ranged from 9.0 to 14.4 months in new or recurrent glioblastoma. Among individuals with metastatic tumors receiving LITT following prior stereotactic radiosurgery (SRS), OS rates have ranged between 72% to 76% at 6 months and 63% to 65% at 12 months. In a more heterogenous population of patients with primary and metastatic brain tumors who received LITT, 12-month OS rates were slightly lower in individuals with brain metastases (56.3%) and high-grade glioma (43.0%) than other analyses. 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 meta-analyses, nonrandomized comparative studies, and a 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 individuals with radiation necrosis compared to those with brain metastases. One study comparing LITT to bevacizumab suggested that LITT treatment may be more successful among individuals before radiation necrosis lesions become symptomatic. One study comparing LITT to craniotomy and one study comparing LITT to medical management 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 and steroid related morbidity were 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, nonrandomized comparative studies, and 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 individuals with pediatric insular epilepsy and adult temporal lobe epilepsy (TLE). In one meta-analysis comparing LITT to radiofrequency ablation (RFA) and conventional surgery, superior outcomes were noted with conventional surgery among

individuals with TLE . A subsequent meta-analysis concluded that while there is no evidence to suggest that LITT is less effective than open surgical resection in the short term, long-term data are lacking. Total quality of life scores reported in the ongoing Laser Ablation of Abnormal Neurological Tissue Using Robotic NeuroBlate System (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 individuals most likely to benefit from LITT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1.**

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06161610	Randomized Clinical Trial of Efficiency and Safety of Recurrent High Grade Glioma Treated by Laser Interstitial Thermal Therapy (REGALITT)	135	Sept 2027 (recruiting)
NCT06428045	Synergistic Treatment With Antiretrovirals and Laser Interstitial Thermal thErapy (STARLITE) for Unresectable High-Grade Gliomas: A Phase 1 Study	24	May 2029 (not yet recruiting)
NCT06341075	Real-World Study of Magnetic Resonance-guided Laser Interstitial Thermal Therapy for Patients With Drug-resistant Epilepsy	150	Mar 2026 (enrolling by invitation)
NCT02970448	Expedited Laser Interstitial Thermal Therapy and Chemoradiation for Patients With Newly Diagnosed High Grade Gliomas	45	Jan 2025 (recruiting)
NCT04181684	Pilot Study of Laser Interstitial Thermal Therapy Followed By Hypofractionated Radiation Therapy for Treatment of Recurrent Gliomas (GCCC 19140)	32	Dec 2026 (recruiting)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04699773	Laser Interstitial Thermal Therapy Followed By Hypofractionated Radiation Therapy For Treatment Of Newly Diagnosed High-Grade Gliomas (GCC 20138)	32	Dec 2027 (recruiting)
NCT05124912[a]	REMASTer: REcurrent Brain Metastases After SRS Trial	261	Oct 2028 (recruiting)
Unpublished			
NCT05075850[a]	Patient Neuropsychological Outcomes After Laser Ablation (PENSAR)	87	Sept 2023
NCT02844465[a]	Stereotactic Laser Ablation for Temporal Lobe Epilepsy (SLATE)	114 (actual)	Dec 2023

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

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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.[40] 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 of Clinical Oncology et al

In 2021, the American Society of Clinical Oncology (ASCO) issued a joint evidence-based guideline on the treatment of brain metastases with the Society for Neuro-Oncology (SNO) and the American Society for Radiation Oncology (ASTRO).[41] The guideline stated that "no recommendation can be made for or against laser interstitial thermal therapy (Type: informal consensus; Evidence quality: low; Strength of recommendation: none)."

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.[42] 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."[43]

International Stereotactic Radiosurgery Society

In 2024, the International Stereotactic Radiosurgery Society published recommendations for managing radiation necrosis after stereotactic radiosurgery.[17] Patients with corticosteroid-refractory symptoms can be considered for LITT based on low quality evidence (weak recommendation). The suggested management flowchart includes LITT as a treatment option for patients with refractory symptoms after noninvasive therapy such as bevacizumab or hyperbaric oxygen therapy, and as first-line or second-line therapy for individuals with more severe symptoms who require invasive treatment.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for central nervous system cancers (v.3.2024) states that MRI-guided LIIT "may be considered for patients who are poor surgical candidates (craniotomy or resection). Potential indications include relapsed brain metastases, radiation necrosis, and glioblastoma, and other gliomas." (Category 2B)[44] The guidelines additionally state that LITT "can be considered on a case-by-case basis for treatment of radiation necrosis in patients with a history of radiation therapy (RT) for primary brain tumor or metastatic disease. Consultation with neurosurgeons trained in LITT should be done when the procedure is considered."

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 MR-guided LITT for drug-resistant epilepsy.[45] 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.

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."[46]

Regulatory Status

In August 2007, the Visualase MRI-Guided Laser Ablation System (Medtronic; formerly Biotex, Inc.) received initial marketing clearance by the FDA through the 510(k) pathway (K071328). In January 2022 (K211269), the system (software version 3.4) was classified as a neurosurgical tool with narrowed indications for use, including "to ablate, necrotize or coagulate intracranial soft tissue including brain structures (for example, brain tumor, radiation necrosis 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 800 nm through 1064 nm lasers." The device is contraindicated for individuals with medical conditions or implanted medical devices contraindicated for MRI and for individuals whose physician determines that LITT or invasive surgical procedures in the brain are not acceptable. Data from compatible MRI sequences can be processed 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.

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History

Date	Comments
03/01/22	New policy, approved February 8, 2022. Policy created with literature review through November 3, 2021. Laser interstitial thermal therapy is considered investigational for all neurological indications, including but not limited to primary and metastatic brain tumors, radiation necrosis, and drug-resistant epilepsy.
02/01/23	Annual Review, approved January 23, 2023. Policy updated with literature review through November 14, 2022. Minor editorial refinements to policy statement; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. Removed effective date from CPT codes 61736 & 61737.
03/01/24	Annual Review, approved February 12, 2024. Policy updated with literature review through October 24, 2023; references added. Policy statements unchanged.
09/11/24	Minor update to related policies. 7.01.20 was replaced with 7.01.593 Vagus Nerve Stimulation.

Date	Comments
03/01/25	Annual Review, approved February 10, 2025. Policy updated with literature review through October 14, 2024; references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.