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Laser Interstitial Thermal Therapy for Neurological Conditions Corporate Medical Policy

File Name: Laser Interstitial Thermal
File Code: 7.01.VT170
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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. Thermal destruction of tissue is achieved via DNA damage, necrosis, protein denaturation, membrane dissolution, vessel sclerosis, and coagulative necrosis. The goal of therapy is selective thermal injury with 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 requires 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. 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. 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.

Coding Information

Click the links below for attachments, coding tables & instructions.
Attachment I

Policy

When a service may be considered medically necessary

Refractory Epilepsy

Laser interstitial thermal therapy (LITT) may be considered **medically necessary** in the treatment of refractory epilepsy when **ALL** of the following criteria are met:

- There is documentation of disabling seizures* despite use of 2 or more antiepileptic drug regimens** (i.e., medication-refractory epilepsy), **AND**
- There are well-defined epileptogenic foci accessible by LITT, **AND**
- A multidisciplinary team of physicians that includes at least 2 specialties (e.g., neurology, neurosurgery), after considering all possible treatments, agrees that LITT is the best treatment option for the patient.

*NOTE: disabling seizures can be defined as seizures that result in impairment or a loss of functional status.

**NOTE: antiepileptic drug regimens are defined as 2 tolerated and appropriately chosen and used antiepileptic drug schedules (as monotherapies or in combination) to achieve sustained seizure freedom.

***NOTE: LITT should be performed by a neurosurgeon who has completed procedure-specific training in the use of a Food and Drug Administration (FDA) approved LITT ablation system and who has been granted hospital privileges to perform brain tumor surgery and LITT ablation procedures.

Relapsed Brain Metastases, Radiation necrosis and Glioblastoma

1. Laser interstitial thermal therapy (LITT) may be considered **medically necessary** for individuals who are poor candidates for craniotomy or resection when the following criteria are met:
    a. Relapsed brain metastases; **OR**
    b. Radiation necrosis; **OR**
    c. Glioblastomas, **AND**

2. The treatment plan to use LITT has been agreed upon by a multidisciplinary team of physicians to include at least 2 specialists (e.g., neurosurgery, oncology) and after considering all relevant possible treatment approaches, is determined to be the best treatment option.

When a service is considered investigational

Laser interstitial thermal therapy for epilepsy radiation necrosis, glioblastomas and relapsed brain metastases that does not meet the above criteria is considered **investigational**.

Laser interstitial thermal therapy is considered **investigational** for all other conditions.

Summary of Evidence

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.

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 OS, disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Overall survival estimates have ranged from 9.0 to 14.4 months in new or recurrent glioblastoma. 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. In a more heterogenous population of patients with primary and metastatic brain tumors who received LITT, 12-month OS rates were slightly lower in patients with brain metastases (56.3%) and high-grade glioma (43.0%) than other analyses. Systematic reviews comparing LITT to open craniotomy with resection or stereotactic radiosurgery (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 well-controlled patient populations are lacking. The evidence is sufficient 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 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 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 well controlled patient populations are lacking. The evidence is sufficient 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. Metaanalyses 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 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 patients with mTLE. 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 LAANTERN registry increased by 72.4%, but this change was not considered statistically significant. For patients with medically-refractory epilepsy and well-defined lesions, studies suggest treatment with LITT may lead to freedom from seizures without the morbidity of temporal lobe resection. Laser interstitial thermal therapy has been considered as a minimally invasive option to surgical resection in patients with foci inaccessible with conventional surgery and in patients with drug resistant epilepsy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Regulatory Status

In August 2007, the Visualase™ MRI-guided Laser Ablation System (Medtronic; formerly Biotex, Inc.) received initial marketing clearance by the U.S. Food and Drug Administration (FDA) through the 510(k) pathway (K071328). 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 patients with medical conditions or implanted medical devices contraindicated for MRI and for patients 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 CO2.

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Related Policies

N/A

Document Precedence

Blue Cross and Blue Shield of Vermont (Blue Cross VT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review

of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, Blue Cross VT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

Blue Cross VT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, Blue Cross VT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval may be required for services outlined in this policy. Benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

04/20/2026	New Policy. Medical necessity criteria established for the use of laser interstitial thermal therapy (LITT) for the treatment of epilepsy, radiation necrosis, glioblastomas and relapsed brain metastases. New coding table added to policy codes 61736 & 61737 require prior approval.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by Blue Cross VT Medical Directors

Tom Weigel, MD, MBA
Vice President and Chief Medical Officer

Attachment I

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
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	Prior Approval Required
CPT®	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)	Prior Approval Required