Laser Interstitial Thermal Therapy for Neurological Conditions

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy is addressed separately in medical policy 00045.

Note: Vagus Nerve Stimulation is addressed separately in medical policy 00134.

Note: Responsive Neurostimulation for the Treatment of Refractory Partial Epilepsy is addressed separately in medical policy 00674.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers laser interstitial thermal therapy (LITT) for all neurological indications, including but not limited to patients with primary or metastatic brain tumors, radiation necrosis, and drug-resistant epilepsy to be **investigational.***

Background/Overview

Laser Interstitial Thermal Therapy

Laser interstitial thermal therapy (LITT) involves the introduction of a laser fiber probe to deliver thermal energy for the targeted ablation of diseased tissue. Thermal destruction of tissue is mediated via DNA damage, necrosis, protein denaturation, membrane dissolution, vessel sclerosis, and coagulative necrosis. 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.[1] 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. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In August 2007, the Visualase™‡ Thermal Therapy System (Medtronic; formerly Biotex, Inc.) received initial marketing clearance by the FDA through the 510(k) pathway (K071328). As of March 2019, the system is indicated for use "to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, for wavelengths 800 nm through 1064 nm" (K181859). Data from compatible MRI sequences can be processed via proton resonance-frequency shift analysis and image subtraction to relate imaging changes to relative changes in tissue temperature during therapy. The Visualase™‡ cooling applicator utilizes saline.

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

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

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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

Summary of Evidence

For individuals who have primary or metastatic brain tumors who receive MR-guided LITT, the evidence includes systematic reviews and meta-analyses, 1 retrospective matched-cohort study, and several single-arm studies. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Overall survival estimates ranged from 12.8 to 14.8 months. Among patients with metastatic tumors receiving LITT following prior SRS, OS rates have ranged between 72 to 76% at 6 months and 63

to 65% at 12 months. Systematic reviews comparing LITT to open craniotomy with resection or SRS suggest a reduced incidence of adverse events with LITT; however, neurological deficits attributable to LITT-induced thermal damage have been observed despite concurrent MRI guidance. Studies are limited by predominantly retrospective designs, small sample sizes, and population heterogeneity, with study subjects varying by performance status, lesion volume and location, extent of prior therapies, and extent of ablation. Prospective comparative studies in well-defined and -controlled patient populations are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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

health outcome and to identify patients most likely to benefit from LITT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

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

American Association of Neurological Surgeons et al

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

American Society for Radiation Oncology

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

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. 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."

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

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

U.S. Preventive Services Task Force Recommendations
Not applicable.

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

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			
NCT04596930	MR-guided LITT Therapy in Patients With Primary Irresectable Glioblastoma: a Randomized Pilot Study (EMITT)	15	Dec 2021 (recruiting)
NCT02970448	Expedited Laser Interstitial Thermal Therapy and Chemoradiation for Patients With Newly Diagnosed High Grade Gliomas	45	Dec 2021 (recruiting)
NCT02844465[a]	Stereotactic Laser Ablation for Temporal Lobe Epilepsy (SLATE)	150	May 2022 (recruiting)
NCT04181684	Pilot Study of Laser Interstitial Thermal Therapy Followed By Hypofractionated Radiation Therapy for Treatment of Recurrent Gliomas (GCCC 19140)	32	Feb 2023 (recruiting)
NCT05075850[a]	Patient Neuropsychological Outcomes After Laser Ablation (PENSAR)	250	Jun 2023 (recruiting)
NCT04187872[a]	Recurrent Brain Metastasis Immune Effects and Response to Laser Interstitial Thermotherapy (LITT) and Pembrolizumab in Combination (TORCH)	16	October 2023 (recruiting)
NCT04699773	Laser Interstitial Thermal Therapy Followed By Hypofractionated Radiation Therapy For	32	Dec 2025 (recruiting)

	Treatment Of Newly Diagnosed High-Grade Gliomas (GCC 20138)		
NCT02392078[a]	Laser Ablation of Abnormal Neurological Tissue Using Robotic NeuroBlate System (LAANTERN) Prospective Registry	1000	Dec 2028 (recruiting)
Unpublished			
NCT02389855[a]	Laser Ablation in Stereotactic Neurosurgery (LAISE): NeuroBlate®‡ Retrospective Registry	144	Aug 2016 (completed)

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

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	61736, 61737
HCPCS	No codes
ICD-10 Diagnosis	C71.0-C71.9, C79.31, C79.32

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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