



FEP Medical Policy Manual

FEP 7.01.170 Laser Interstitial Thermal Therapy for Neurological Conditions

Annual Effective Policy Date: April 1, 2024

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Related Policies:

6.01.10 - Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

8.01.59 - Intensity-Modulated Radiotherapy: Central Nervous System Tumors

Laser Interstitial Thermal Therapy for Neurological Conditions

Description

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 patients with neurological conditions compared to surgery. Two LITT systems, Visualase and NeuroBlate, have received marketing clearance from the U.S. Food and Drug Administration (FDA).

OBJECTIVE

The objective of this evidence review is to determine whether the use of MR-guided laser interstitial thermal therapy (LITT) improves the net health outcomes in individuals with neurological conditions.

POLICY STATEMENT

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.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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). 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 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 (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 CO₂.

RATIONALE

Summary of Evidence

For individuals who have primary or metastatic brain tumors who receive magnetic resonance (MR)-guided laser interstitial thermal therapy (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 have ranged from 9.0 to 14.4 months in new or recurrent glioblastoma. Among patients 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 heterogeneous 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 SRS suggest a reduced incidence of adverse events with LITT; however, neurological deficits attributable to LITT-induced thermal damage have been observed despite concurrent magnetic resonance imaging (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 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 -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 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 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 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 laser interstitial thermal therapy (LITT) for brain tumors and radiation necrosis.³⁴ 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 glioblastoma 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).³⁵ 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.³⁶ 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."³⁷

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for central nervous system cancers (v.1.2023) states that MRgLITT "may be considered for patients who are poor surgical candidates (craniotomy or resection). Potential indications include relapsed brain metastases, radiation necrosis, and recurrent glioblastoma." (Category 2B)³⁸.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 RT [radiation therapy] for primary brain tumor or metastatic disease. Consultation with adept neurosurgeons trained in LITT should be done when the procedure is considered."

National Institute for Health and Care Excellence

In 2020, NICE published an interventional procedures guidance on the use of MR-guided LITT for drug-resistant epilepsy.³⁹ 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."⁴⁰

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2022	New policy	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.
March 2023	Replace policy	Policy updated with literature review through November 14, 2022. Minor editorial refinements to policy statement; intent unchanged.
March 2024	Replace policy	Policy updated with literature review through October 24, 2023; references added. Policy statements unchanged.

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