Laser Interstitial Thermal Therapy for Neurological Conditions

Medicare Advantage Medical Policy # MA-220
Original Effective Date: 08/01/2026
Current Effective Date: 08/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider laser interstitial thermal therapy (LITT, also known as magnetic resonance-guided laser interstitial thermal therapy or MRgLITT, i.e., NeuroBlate®‡ System or Visualase™‡ Thermal Therapy System) for treatment of drug-resistant disabling epilepsy to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for laser interstitial thermal therapy (LITT, also known as magnetic resonance-guided laser interstitial thermal therapy or MRgLITT, i.e., NeuroBlate®‡ System or Visualase™‡ Thermal Therapy System) for treatment of drug-resistant disabling epilepsy will be considered when **ALL** of the following criteria are met:

- Evidence of medically refractory and disabling epilepsy with documented failure to respond to at least 2 tolerated antiepileptic drug regimens; **AND**
- Confirmed well-defined 1-2 epileptogenic foci accessible by MRgLITT; **AND**
- Treatment plan to use LITT as the best treatment option for the patient has been agreed upon by a multidisciplinary team of at least 2 specialists, e.g., neurosurgery and neurology.

Note:
Seizures are considered medically refractory when 2 appropriately chosen and used drug schedules (monotherapies or in combination) failed to achieve sustained seizure freedom. Seizures are considered disabling when causing impairment or loss of functional status.

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When 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 Health Plan considers laser interstitial thermal therapy (LITT) for drug-resistant disabling epilepsy when coverage criteria are not met, and for all other neurological indications, including but not limited to patients with primary or metastatic brain tumors and radiation necrosis 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. 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.

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™‡ 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 CO_2.

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.

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).

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 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 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 then 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. 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.

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. 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). 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. 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."

International Stereotactic Radiosurgery Society
In 2024, the International Stereotactic Radiosurgery Society published recommendations for managing radiation necrosis after stereotactic radiosurgery. 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 patients 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 MRgLITT "may be considered for patients who are poor surgical candidates (craniotomy or resection). Potential indications include relapsed brain metastases, radiation necrosis, glioblastoma, and other gliomas." (Category 2B) 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 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. 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			
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)
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.

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Policy History

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05/19/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 05/2027

Coding

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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	All related diagnoses

*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.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide

to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.