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Subject: Interstitial Laser Therapy

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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DESCRIPTION:

Interstitial laser therapy (ILT)/laser interstitial thermal therapy (LITT) is a thermoablative procedure that uses a laser to produce a precise and minimally invasive heat injury to target tissue. This technology has been proposed as a minimally invasive means of treating medically refractive epilepsy, brain tumors that are difficult to access or as an alternative to open craniotomy, and radiation necrosis. The procedure involves placement of a laser probe using either frameless or frame-based stereotactic techniques. 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 U.S. Food and Drug Administration (FDA) have cleared through the 510(k) process several devices (e.g., Novilase® Laser Therapy System, Monteris Medical NeuroBlate™ System, Visualase® Thermal Therapy System) for interstitial irradiation or thermal therapy.

Summary and Analysis of Evidence: There is published medical evidence in the peer-reviewed literature regarding the safety and efficacy of interstitial laser therapy for intracranial (brain) tumors, brain metastases (metastatic brain tumors), glioblastoma, radiation necrosis, epilepsy (drug resistant, refractory, temporal lobe).

Laser interstitial thermal therapy (LITT) is a minimally invasive treatment option for brain tumors including glioblastoma, other primary central nervous system (CNS) neoplasms, metastases, and radiation necrosis. LITT employs a fiber optic coupled laser delivery probe stabilized via stereotaxis to deliver thermal energy that induces coagulative necrosis in tumors to achieve effective cytoreduction. LITT complements surgical resection, radiation treatment, tumor treating fields, and systemic therapy, especially in patients who are high risk for surgical resection due to tumor location in eloquent regions or poor functional status. These factors must be balanced with the increased rate of cerebral edema

post LITT compared to surgical resection. LITT has also been shown to induce transient disruption of the blood-brain barrier (BBB), especially in the peritumoral region, which allows for enhanced CNS delivery of anti-neoplastic agents, thus greatly expanding the armamentarium against brain tumors to include highly effective anti-neoplastic agents that have poor BBB penetration. In addition, hyperthermia-induced immunogenic cell death is another secondary side effect of LITT that opens up immunotherapy as an attractive adjuvant treatment for brain tumors. Numerous large studies have demonstrated the safety and efficacy of LITT against various CNS tumors and as the literature continues to grow on this novel technique so will its indications (Melnick et al 2021).

Radiation necrosis is a well described complication after radiosurgical treatment of intracranial pathologies - best recognized after the treatment of patients with arteriovenous malformations and brain metastases but possibly also affecting patients treated with radiosurgery for meningioma. The pathophysiology of radiation necrosis is still not well understood but is most likely a secondary local tissue inflammatory response to brain tissue injured by radiation. Radiation necrosis in brain metastases patients may present radiographically and behave clinically like recurrent tumor. Differentiation between radiation necrosis and recurrent tumor has been difficult based on radiographic changes alone. Biopsy or craniotomy therefore remains the gold standard method of diagnosis. For symptomatic patients, corticosteroids are first-line therapy, but patients may fail medical management due to intolerance of chronic steroids or persistence of symptoms. In these cases, open surgical resection has been shown to be successful in management of surgically amenable lesions but may be suboptimal in patients with deep-seated lesions or extensive prior cranial surgical history, both carrying high risk for peri-operative morbidity. Laser interstitial thermal therapy has emerged as a viable, alternative surgical option. In addition to allowing access to tissue for diagnosis, thermal treatment of the lesion can also be delivered precisely and accurately under real-time imaging guidance (Hong et al 2020).

POSITION STATEMENT:

Laser interstitial thermal therapy (LITT) with an FDA approved device **meets the definition of medical necessity** for the following:

Laser interstitial thermal therapy (LITT) **meets the definition of medical necessity** in the treatment of epilepsy when the following criteria are met:

- There is documentation of disabling seizures despite use of two or more antiepileptic drug regimens (e.g., medically refractory epilepsy); **AND**
- There are well-defined epileptogenic foci accessible by LITT.

Laser interstitial thermal therapy (LITT) **meets the definition of medical necessity** in the treatment of brain tumors or radiation necrosis of the brain when the following criteria are met:

- Recurrent or progressive malignant tumor (primary or metastatic); **OR**
- Lesion(s) inaccessible to surgical resection; **OR**
- The member is unable to tolerate surgical resection due to medical comorbidities; **AND**
- The treatment plan for LITT has been agreed upon by a multidisciplinary team of physicians and, after considering all relevant possible treatment approaches, is determined to be the best treatment option; **AND**

- The LITT is being performed by a neurosurgeon who has completed procedure specific training in the use of an FDA approved LITT ablation system.

Laser interstitial thermal therapy (LITT) is considered **experimental or investigational** for all other indications. There is insufficient evidence to support conclusions regarding the effect of laser interstitial thermal therapy (LITT) on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

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)

REIMBURSEMENT INFORMATION:

Refer to [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

[Cryosurgical Ablation of Solid Tumors Other Than Liver or Prostate Tumors, 02-99221-12](#)

[Radiofrequency Ablation of Solid Tumors Other Than Liver Tumors, 02-99221-13](#)

OTHER:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Interstitial laser ablation

Interstitial laser coagulation (ILC)

Interstitial laser therapy (ILT)

Interstitial laser thermotherapy

Kelsey Interstitial Laser Therapy System

Laser interstitial thermal therapy (LITT)

Magnetic Resonance Image-Guided Thermal Therapy System

Magnetic Resonance-Guided Laser Induced Thermal Therapy (MRgLITT)

MRI guided laser interstitial thermal therapy (LITT)

Monteris Medical NeuroBlate™ System

Novilase™ Interstitial Laser Therapy System

Stereotactic laser ablation (SLA)

Visualase® Thermal Therapy System

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 02/27/25.

GUIDELINE UPDATE INFORMATION:

04/15/10	New Medical Coverage Guideline.
04/15/11	Scheduled review; position statement unchanged; references updated.
04/15/12	Scheduled review with literature search; position statement unchanged.
04/15/13	Scheduled review with literature search; position statement unchanged; references updated; Program Exceptions section updated.
04/15/14	Scheduled annual review with literature search; position statement unchanged; references updated.
11/01/15	Revision: ICD-9 Codes deleted.
07/15/18	Review; revised position statement. Updated description and references. Changed guideline name to "Interstitial Laser Therapy".
06/15/19	Review; no change in position statement. Updated references.
10/15/21	Review; no change in position statement. Updated references.
01/01/22	Annual CPT/HCPCS coding update. Added 61736 and 61737.
10/15/22	Review; added medically necessity position statement. Updated references.
08/21/23	Update to Program Exceptions section.
03/15/24	Review; no change in position statement. Updated references.
03/15/25	Review; no change in position statement. Updated references.