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Laser Interstitial Tumor Therapy (LITT)

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None

Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Treatment of epilepsy using magnetic resonance image (MRI)-guided laser interstitial tumor therapy (LITT) **may be considered medically necessary** when the following criteria are met:

1. There is documentation of disabling seizures despite use of 2 or more antiepileptic drug regimens (i.e., medically refractory epilepsy), **AND**
2. There are well-defined epileptogenic foci accessible by LITT.

Treatment of brain tumors or radiation necrosis of the brain using MRI-guided laser interstitial tumor therapy **may be considered medically necessary** when the following criteria are met:

1. LITT is being used to treat:
 - a. Recurrent or progressive malignant tumor (primary or metastatic), or
 - b. Lesion(s) inaccessible to surgical resection, or
 - c. The individual is unable to tolerate surgical resection due to medical comorbidities,**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.

NOTE 1: 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.

Laser interstitial tumor therapy is **considered experimental, investigational and/or unproven** when the criteria above are not met or for all other indications, including:

- Adrenal metastases;
- Breast tumors (benign or malignant);
- Liver metastases;
- Lung cancer and lung metastasis;
- Osteoid osteomas;
- Pancreatic cancer;
- Prostate cancer;
- Spinal metastasis;
- Thyroid nodules.

Policy Guidelines

- As of 1/1/2022, the appropriate CPT code(s) to report magnetic resonance imaging (MRI)-guided laser interstitial tumor therapy (LITT), intracranial of single and/or multiple or complex lesion(s) include 61736 and 61737. All other uses for LITT are typically billed as an unlisted code.
- Transperineal/transrectal focal laser ablation of the prostate with magnetic resonance fused images or other enhanced ultrasound imaging is billed under 0655T.

Description

Laser Interstitial Thermal Therapy

Laser interstitial tumor therapy (LITT) also known as laser-induced thermal therapy/thermotherapy, interstitial laser therapy (ILT), interstitial laser photocoagulation/coagulation, magnetic resonance imaging (MRI)-guided LITT (e.g., Neuroblate, Visualase) and stereotactic laser ablation (SLA), 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. (1) 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. (2) 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).

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. (2) 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. (3) 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.

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. FDA product codes: GEX, ONO. (4, 5)

In April 2013, the NeuroBlate® System (Monteris Medical) received initial clearance for marketing by the FDA through the 510(k) pathway (K120561). Currently, the system is indicated for use "to ablate, necrotize, or coagulate intracranial soft tissue, including brain structures (e.g., brain tumor, radiation necrosis, and epileptogenic 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 in individuals 2 years of age and older. (K240877). 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. FDA product codes: GEX, ONO. (6, 7)

In April 2018, the FDA issued an FDA alert specific to magnetic resonance (MR)-Guided LITT which included a letter to providers stating that the FDA is evaluating data which suggests 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. (8, 9)

Laser interstitial tumor therapy typically utilizes MRI guidance. Applications of LITT currently evolving and include, but are not limited to, cancer, epilepsy, osteoid osteoma, radiation necrosis and tumors using MRI guidance and/or ultrasound guidance. (10)

Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging is currently an active area of research and uses the same principles as LITT. The Echolaser X4 system (Elasta, Calenzano, Italy), marketed as the EchoLaser SoracteLite™ received 510k clearance from the FDA in 2018. FDA product code: GEX. (11)

Refer to <<https://accessdata.fda.gov>> for current U.S. FDA approved devices with their specific indication for use and for any potential risk mitigation strategies.

Rationale

This policy is based on relevant professional society guidelines.

Professional Guidelines and Position Statements

Epilepsy

Epilepsy Foundation of America

The Epilepsy Foundation of America website includes information for professionals which addresses MRI-guided laser interstitial tumor therapy (LITT). The foundation supports the use of LITT in individuals with mesial temporal lobe epilepsy (mTLE) who have persistent seizures despite adequate trials of 2 or more seizure medicines. They also state that the LITT procedure can also benefit people who have seizures from lesions, such as a small brain malformation, a blood vessel malformation, or hypothalamic hamartoma. (12, 13)

Individuals most appropriate for this type of surgery include:

- Individuals who have a clearly defined area of brain where seizures begin, and
- Individuals who would benefit from a less invasive approach to epilepsy surgery.

National Institute for Health and Clinical Excellence (NICE)

The 2025 NICE guidelines (14) state that drug resistant epilepsy is when seizures persist, and seizure freedom is very unlikely to be attained with further manipulation of antiseizure medication. Defined by the International League Against Epilepsy as 'failure of adequate trials of 2 tolerated and appropriately chosen and used antiseizure medication schedules (whether as monotherapy or in combination) to achieve sustained seizure freedom'.

American Society for Stereotactic and Functional Neurosurgery

The 2022 American Society for Stereotactic and Functional Neurosurgery (ASSFN) Position Statement include the following indications for the use of MRI-guided LITT as a treatment option for patients with Drug-Resistant Epilepsy (DRE) (15):

- 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 MRg-LITT.

The ASSFN recommendations are based on:

- Safety and efficacy demonstrated in multiple peer reviewed large case series demonstrating the safety and efficacy of MRI-guided LITT in reducing seizure frequency in patients with drug resistant epilepsy (DRE) that is nearly comparable to data obtained from cases series of open surgical procedures.
- Published literature demonstrates that MRI-guided LITT is a less invasive option for many types of focal DRE that involves a shorter hospital stay and less surgical and neurologic morbidity as compared to open surgical resection for such common epilepsy etiologies as mesial temporal epilepsy, hypothalamic hamartomas, and focal cortical dysplasia/periventricular nodular heterotopia.
- Some published studies indicate that MRI-guided LITT may better preserve cognitive functions as compared to open epilepsy surgery.
- When offered a choice between open surgery and MRI-guided LITT, patients increasingly prefer LITT to open surgery and many will otherwise refuse surgical treatment at all. Moreover, MRI-guided LITT has also become the first choice procedure of many epilepsy teams for treatment of many focal epilepsies and has essentially completely supplanted open surgery for epilepsy due to hypothalamic hamartomas. These trends make it unlikely that any randomized trials between MRI-guided LITT and open surgery will be performed

Brain Tumors/Radiation Necrosis

National Comprehensive Cancer Network (NCCN)

The 2025 NCCN guidelines for central nervous system (CNS) cancer (16) includes a 2B recommendation that addresses MRI-guided LITT as a treatment option for individuals who are poor surgical candidates (craniotomy or resection). Potential indications include relapsed brain metastases, radiation necrosis, glioblastomas, and other gliomas. The involvement of an interdisciplinary team, including neurosurgeons, radiation oncologists, medical oncologists and neuroradiologists is a key factor in appropriate management in individuals with CNS cancers. For any type of malignant brain tumor, NCCN strongly recommends a brain tumor board multidisciplinary review of each individual case once pathology is available.

NCCN also states LITT can be considered on a case-by-case bases for treatment of radiation necrosis in individuals with a history of radiation therapy for primary brain tumor or metastatic

disease. Consult with neurosurgeons trained in LITT should be performed when this procedure is being considered. (2A recommendation)

American Society of Clinical Oncology (ASCO) and the NICE

In 2021, the 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). (17) 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 Association of Neurological Surgeons

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. (18) 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."

Thyroid Cancer

American Thyroid Association

The 2015 American Thyroid Association Guidelines on Medullary Thyroid Carcinoma (19) states surgical resection should be considered in patients with large solitary lung metastases. Radiofrequency ablation should be considered when the metastases are peripheral and small. Systemic therapy should be considered in patients with multiple metastases that are progressively increasing in size. (Grade C Recommendation)

Liver Cancer (Including Metastasis)

National Comprehensive Cancer Network (NCCN)

Most liver metastases originate within the colon or rectum therefore, the NCCN Clinical Practice Guideline (CPG) for colon and rectal cancer were examined. (20, 21) Guidance offers resection as the standard approach for local treatment of resectable metastatic disease. Ablative therapy, alone or in conjunction with resection, is discussed for metastatic disease when all measurable disease can be treated. NCCN does not specifically address MRI-guided LITT as an ablation technique for colon or rectal cancer.

Lung Cancer and Lung Metastasis

National Comprehensive Cancer Network (NCCN)

The NCCN guideline for non-small cell lung cancer (22) recommends thermal ablation (radiofrequency ablation, microwave ablation, cryoablation) techniques in select individuals, but does not specifically include MRI-guided LITT among the list of thermal techniques.

The NCCN guideline for small cell lung cancer (23) does not specifically include MRI-guided LITT as a treatment option for small cell lung tumors.

Prostate Cancer/Transperineal Focal Laser Ablation (TPLA)

NCCN acknowledges that multiple focal laser ablative therapies are actively being investigated for individuals with localized and recurrent prostate cancer although they do not specifically mention LITT. (24) NCCN includes the following guidance for focal therapies:

- For local prostate cancer, focal therapy is an experimental and emerging technology for the initial treatment of localized prostate cancer as it lacks randomized controlled trials with long term follow-up showing superiority or noninferiority to current recommended management strategies therefore is not a standard treatment.
- For individuals with newly diagnosed or previously treated prostate cancer:
 - Active surveillance is preferred for low-risk prostate cancer and focal therapies are discouraged in this population
 - Ablative focal therapy should be discouraged in individuals with high or very high risk, regional or metastatic prostate cancer outside of a clinical trial
 - There is insufficient comparative effectiveness evidence for focal therapy to be recommended for individuals with intermittent risk prostate cancer, and there is uncertainty about the long term efficacy and toxicity of these treatments. Therefore, should only be used in the context of a clinical trial.

Other Cancers

National Comprehensive Cancer Network (NCCN) Guidelines

NCCN guidelines focus on established evidence-based treatments that have robust evidence of efficacy and long-term safety. The lack of inclusion in the primary guidelines suggests that LITT does not meet the necessary criteria for standard of care due to insufficient clinical evidence. The NCCN Guidelines do not include MRI-guided LITT as a recommended treatment modality in the guidelines that address the following cancer types:

- Adrenal metastasis (25)
- Breast cancer (26)
- Osteoid osteomas (27)
- Pancreatic cancer (28)
- Spinal cancer (16)
- Thyroid cancer (29).

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	19499, 20999, 27599, 32999, 47399, 48999, 53899, 55899, 60699, 61736, 61737, 64999, 0655T
HCP Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. Removed spinal cord compression and tremor disorders from existing experimental, investigation and or unproven statement. No change in intent. Added references 13, 17, 18, 25; others updated/some removed.
10/15/2024	Document updated with literature review. No change in coverage. Added references 1-3, 5, 7, 9, 58, 71, 78-80; others updated, some removed.
05/01/2023	Reviewed. No changes.
12/15/2022	Document updated with literature review. The following changes were made in Coverage: 1) Added lung metastasis, spinal instability and tremor disorders to the existing “including but not limited to” experimental, investigational and/or unproven statement. 2) Removed “MRI-guided” from the existing experimental, investigational and/or unproven statement. 3)

	Title changed from "Magnetic Resonance Image Guided Laser Interstitial Tumor Therapy (LITT)" 4) Added references 3, 5, 19, 40, 41, 44, 69, 78, 82-85; others updated.
09/15/2021	Reviewed. No changes.
01/01/2021	Document updated with literature review. The following change was made to Coverage: Added conditionally medically necessary coverage for epilepsy, brain tumors, and radiation necrosis of the brain. Expanded experimental, investigational and/or unproven statement to include lung cancer and osteoid osteomas; Added references 5, 10-20, 22, 33-35, 37, 38, 40, 50, 55, 61, 65, 71-74, 79; some removed/updated. Title changed from Laser Interstitial Tumor Therapy (LITT/ILT) and Laser Ablation.
12/15/2019	Document updated with literature review. Added "epilepsy" to the current experimental, investigational and/or unproven coverage statement. Added references 11, 12, 14, 20, 25-43, 48, 51-58, and 66. Some references removed. Title changed from Laser Induced Interstitial Tumor Therapy (LITT/ILT) and Laser Ablation of Tumors.
12/18/2018	Document updated with literature review. Added "spinal compression" to the current experimental, investigational and/or unproven coverage statement. Added references 5, 10, 11, 13, 15-17, 21, 25-28, 35, 37, 39, 40. Some references removed.
11/01/2017	Reviewed. No changes.
01/01/2017	Document updated with literature review. Added spinal metastasis as an example under the experimental, investigational and/or unproven coverage statement.
07/15/2015	Reviewed. No changes.
07/01/2014	New Medical Document. Laser Interstitial Tumor Therapy (LITT/ILT) and Interstitial Laser Ablation (ILA) of Tumors are considered experimental, investigational and/or unproven: for any indication, including but not limited to: Adrenal metastases; brain tumors; breast tumors (benign or malignant); liver metastases; pancreatic cancer; prostate cancer; radionecrosis; thyroid nodules.