Corporate Medical Policy

MRI-guided Laser Interstitial Thermal Therapy for Neurological Indications

File Name: mri-guided_laser_interstitial_thermal_therapy_for_neurological_indications
Origination: 2/2017
Last Review: 10/2023

Description of Procedure or Service

Magnetic resonance imaging (MRI)-guided laser ablation 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 stereotactic insertion of a fiberoptic laser probe into the target area followed by laser activation. As light is delivered through the laser applicator, temperatures in the target area begin to rise, destroying the intended targeted tissue. When performed under MRI monitoring, the heat generation can be contoured to minimize injury to the surrounding normal tissue. In neurological applications, laser interstitial thermal therapy (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 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.

Proposed advantages of MRI-guided laser ablation technology over craniotomy for resection include:

- Decreased morbidity with a minimally invasive procedure
- Faster recovery time
- Shorter hospital and intensive care stay
- Ability to access lesions not amenable to surgery
- An alternative to surgery in individuals with significant comorbidities

As the use of LITT for neurological indications evolves, so do the optimal indications and patient selection criteria for use. Contraindications to MRI are also applicable to the administration of LITT. Impact of the technology on several key outcomes, including survival in the treatment of tumors, is unknown.

Regulatory Status

Visualase™ MRI-Guided Laser Ablation (Medtronic; formerly Biotex, Inc.) received 510K marketing clearance (K071328) from the FDA in 2007. 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.

On 04/25/2018, the FDA issued an FDA Alert on MR-Guided Laser Interstitial Thermal Therapy Devices with a letter to providers stating the FDA is currently 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.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for MRI-guided Laser Interstitial Thermal Therapy for Neurological Indications when it is determined the medical criteria and guidelines below are met.

Some individuals may be eligible for coverage under Clinical Trials. Refer to the policy on Clinical Trial Services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When MRI-guided Laser Interstitial Thermal Therapy for Neurological Indications is covered

Treatment of epilepsy using laser interstitial thermal therapy (LITT) may be considered **medically necessary** when the following criteria are met:

1. There is documentation of disabling seizures despite use of two 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 LITT 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 two specialists (eg neurosurgery, oncology) and, after considering all relevant possible treatment approaches, is determined to be the best treatment option, AND

3. The LITT is being performed by a neurosurgeon who has completed procedure-specific training in the use of an FDA-approved LITT ablation system and who has been granted hospital privileges to perform brain tumor surgery and LITT ablation procedures.

When MRI-guided Laser Interstitial Thermal Therapy for Neurological Indications is not covered

MRI-guided laser interstitial thermal therapy (LITT) when the criteria above are not met is considered **investigational**.

Policy Guidelines

This procedure is also referred to as laser-induced interstitial thermotherapy (LITT), laser-induced thermotherapy, interstitial laser therapy and stereotactic laser ablation.

The evidence for use of LITT for neurological indications consists mainly of retrospective case series with systematic reviews of these low-quality studies. Prospective studies do not include comparative evidence. Published studies include heterogeneous patient populations and outcomes reported, limiting conclusions that can be drawn about the effectiveness of LITT. For epilepsy, case series suggest that for patients with medically-refractory epilepsy and well-defined lesions, treatment with LITT may lead to freedom from seizures without the morbidity of temporal lobe resection. For use of LITT for brain tumors, questions remain as to the optimal patient population, tumor type and treatment setting (primary vs recurrent). Ongoing, prospective registry data is being collected to track long-term outcomes and complication rates.

Cost analyses support LITT as a cost-effective alternative relative to open surgery.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 61736, 61737

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA). Visualase ® Thermal Therapy System (k071328). Biotex, Inc., Houston, Texas. Available at http://www.accessdata.fda.gov/cdrh_docs/pdf7/k071328.pdf . Accessed January 31, 2017.

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U.S. Food and Drug Administration. Safety Alerts for Human Medical Products. Magnetic Resonanceguided Laser Interstitial Thermal Therapy (MRgLITT) Devices: Letter to Health Care Providers - Risk of Tissue Overheating Due to Inaccurate Magnetic Resonance Thermometry. Posted 4/25/18. Accessed September 2018 at: https://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm605609.htm

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Medical Director review 10/2023

Policy Implementation/Update Information

4/28/17	New policy developed. MRI-guided Laser-induced Thermotherapy for Neurological Indications is considered investigational. Policy noticed 4/28/2017 for effective date 6/30/2017. (sk)
11/10/17	Specialty Matched Consultant Advisory Panel review 10/25/2017. (sk)
11/9/18	References added. Specialty Matched Consultant Advisory Panel review 10/24/2018. (sk)
2/25/20	Policy titled changed from MRI-Guided Laser-induced Thermotherapy for Neurological Indications to MRI-Guided Laser Interstitial Thermal Therapy for Neurological Indications.

	Medically necessary criteria added for refractory epilepsy. References added. Specialty Matched Consultant Advisory Panel review 10/16/2019. (sk)
7/21/20	Medically necessary criteria added for brain tumors and radiation necrosis. (hb)
11/10/20	Specialty Matched Consultant Advisory Panel review 10/21/2020. (sk)
12/30/21	Specialty Matched Consultant Advisory Panel review 10/20/2021. Added codes 61736 and 61737 to Billing/Coding section. (sk)
5/2/23	Policy update. Specialty Matched Consultant Advisory Panel review 10/19/2022. (sk)
11/7/23	Updated Description, Regulatory Status and references. Removed CPT code 64999. Specialty Matched Consultant Advisory Panel review 10/2023. Medical Director review 10/2023. (ldh)