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 CAP Review:	10/2020
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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.

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 patients with significant comorbidities

As the use of laser interstitial thermal therapy (LITT) for neurological indications evolves, so do the optimal indications and patient selection criteria for use. Impact of the technology on several key outcomes, including survival in the treatment of tumors, is unknown.

Regulatory Status

Visualase ® Thermal Therapy System (Medtronic) received 510K marketing clearance (K071328) from the FDA in 2007 and is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery, in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, for wavelengths 800nm through 1064nm. When therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the Visualase system can process images to determine relative changes in tissue temperature during therapy. The image data may be manipulated and viewed in a number of different ways, and the values of data at certain selected points may be monitored and/or displayed over time. When interpreted by a trained physician, this device provides information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of Visualase analysis.

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. “For example,

MR parameters such as voxel size (measurement of the image resolution or detail) and MR image acquisition time (e.g., up to 8 seconds) may contribute to inaccurate MR thermometry readings and potential errors in the ablation assessment. In addition, MRgLITT devices may not account for the continued thermal spread of energy to the surrounding tissue (as the target ablation area returns to its baseline temperature), which may result in an underestimation of thermal damage."

The NeuroBlate® System (Monteris Medical) received 510K marketing clearance (K162762) from the FDA in 2016 and is "indicated for use to ablate, necrotize, or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers".

******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 patients 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 patient 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.

MRI-guided Laser Interstitial Thermal Therapy for Neurological Indications

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: 64999

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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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)

and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.