

## Corporate Medical Policy

### MRI-guided Laser-induced Thermoablation for Neurological Indications

<b>File Name:</b>	Mri-guided_laser-induced_thermoablation_for_neurological_indications
<b>Origination:</b>	2/2017
<b>Last CAP Review:</b>	10/2018
<b>Next CAP Review:</b>	10/2019
<b>Last Review:</b>	10/2018

#### Description of Procedure or Service

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Magnetic resonance imaging (MRI)-guided laser ablation technology has been proposed as a means of treating high-grade glioblastomas, medically refractory epilepsy, and brain tumors that are difficult to access. Laser energy is delivered to the target area using a laser applicator. As light is delivered through the laser applicator, temperatures in the target area begin to rise, destroying the unwanted tissue.

Proposed advantages of MRI-guided laser ablation technology include:

- Most procedures are completed in less time when compared to open procedures
- Most patients have little or no hair removed
- Minimal sutures required
- Shorter stay when compared to open procedures
- Reduced scarring compared to open procedures

#### Regulatory Status

Visualase® Thermal Therapy System 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 a 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."

# MRI-guided Laser-induced Thermotherapy for Neurological Indications

**\*\*\*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

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**MRI-guided Laser-induced Thermotherapy for Neurological Indications is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.**

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

## Benefits Application

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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-induced Thermotherapy for Neurological Indications is covered

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Not applicable.

## When MRI-guided Laser-induced Thermotherapy for Neurological Indications is not covered

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MRI-guided Laser-induced Thermotherapy for Neurological Indications is considered investigational for all applications.

## Policy Guidelines

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

There has been interest in the use of minimally invasive surgery such as magnetic resonance-guided laser induced thermal therapy (MRgLITT) in the surgical management of a number of clinical conditions, including intra-cranial tumors and epilepsy. Surgical debulking, by both operational resection and by LITT, does not yet provide a significant solution to mortality in glioblastoma multiforme. Systematic evidence reviews of LITT for the treatment of intracranial neoplasms from 2014 concluded that large multi-center prospective trials are needed to establish its effectiveness. Preliminary findings suggest that MRgLITT has the potential to improve the effectiveness and reduce the morbidity associated with the surgical management of lesional, drug-resistant epilepsy in certain patients (depending on type of epilepsy, kind of lesion that is the source of the epilepsy, and other factors related to the particular laser treatment used). However, multi-center, prospective studies are needed to delineate optimal candidates for MRgLITT, and larger cohorts are needed to define outcome and complication rates. Long-term outcomes from laser ablation therapy are not known, and further studies are ongoing to track long-term outcomes.

## Billing/Coding/Physician Documentation Information

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# MRI-guided Laser-induced Thermotherapy for Neurological Indications

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](http://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

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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](http://www.accessdata.fda.gov/cdrh_docs/pdf7/k071328.pdf). Accessed January 31, 2017.

Carpentier A. et.al. Laser thermal therapy: realtime MRI-guided and computer-controlled procedures for metastatic brain tumors. *Lasers Surg Med*. December 2011; 43(10): 94350.

American College of Radiology/American Society of Neuroradiology. (2014). ACR/ASNR practice parameter for the performance of non-breast magnetic resonance imaging (MRI) guided procedures. Retrieved January 31, 2017 from [www.acr.org](http://www.acr.org).

Lewis, E. C., Weil, A. G., Duchowny, M., Bhatia, S., Ragheb, J., & Miller, I. (2015). MR-guided laser interstitial thermal therapy for pediatric drug-resistant lesional epilepsy. *Epilepsia*, 56 (10), 1590-1598. Retrieved January 31, 2017 from <http://onlinelibrary.wiley.com/doi/10.1111/epi.13106/abstract>

Medvid, R., Ruiz, A., Komotar, R. J., Jagid, J. R., Ivan, M. E., Quencer, R. M., et al. (June 2015). Current applications of MRI-guided laser interstitial thermal therapy in the treatment of brain neoplasms and epilepsy: a radiologic and neurosurgical overview. *American Journal of Neuroradiology*. Retrieved January 31, 2017 from <http://www.ajnr.org/content/36/11/1998.full.pdf+html>

Mohammadi, A. M., Hawasli, A. H., Schroeder, J. L., Laxton, A. W., Elson, P., et al. (2014). The role of laser interstitial thermal therapy in enhancing progression-free survival of difficult-to-access high-grade gliomas: a multicenter study. *Cancer Medicine*, 3 (4), 971-979. Retrieved January 31, 2017 from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4303165/pdf/cam40003-0971.pdf>

Sloan, A. E., Ahluwalia, M. S., Valerio-Pascua, J., Manjila, S., Torchia, M. G., Jones, S. E., et al. (2013). Results of the NeuroBlate System first-in-humans Phase I clinical trial for recurrent glioblastoma: clinical article. *Journal of Neurosurgery*, 118 (6), 1202-1219. Retrieved January 31, 2017 from <http://thejns.org/doi/pdf/10.3171/2013.1.JNS1291>

Sun, X. R., Patel, N. V., & Danish, S. F. (2015). Tissue ablation dynamics during magnetic resonance-guided, laser-induced thermal therapy. *Neurosurgery*, 77 (1), 51-58. Retrieved January 31, 2017 from [https://www.researchgate.net/profile/Xiaonan\\_Sun/publication/276439554\\_Tissue\\_Ablation\\_Dynamics\\_During\\_Magnetic\\_Resonance-Guided\\_Laser-Induced\\_Thermal\\_Therapy/links/55f3436008ae6a34f6605d15.pdf](https://www.researchgate.net/profile/Xiaonan_Sun/publication/276439554_Tissue_Ablation_Dynamics_During_Magnetic_Resonance-Guided_Laser-Induced_Thermal_Therapy/links/55f3436008ae6a34f6605d15.pdf)

Voigt JD, Torchia M. Laser interstitial thermal therapy with and without MRI guidance for treatment of brain neoplasms – A systematic review of the literature. *Photon Lasers Med*. 2014;3(2):77-93.

# MRI-guided Laser-induced Thermo-therapy for Neurological Indications

Gomez FM, Patel PA, Stuart S, Roebuck DJ. Systematic review of ablation techniques for the treatment of malignant or aggressive benign lesions in children. *Pediatr Radiol*. 2014;44(10):1281-1289.

Karsy M, Guan J, Ducis K, Bollo RJ. Emerging surgical therapies in the treatment of pediatric epilepsy. *Transl Pediatr*. 2016;5(2):67-78. Retrieved February 1, 2017 from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855197/pdf/tp-05-02-067.pdf>

Willie JT, Laxpati N, Drane D, et al. Real-Time Magnetic Resonance-Guided Stereotactic Laser Amygdalohippocampotomy for Mesial Temporal Lobe Epilepsy. *Neurosurgery*. 2014 June; 74(6):569-585. Retrieved February 1, 2017 from [http://neurosurgery.washington.edu/attachments/Willie\\_NSg\\_2014.pdf](http://neurosurgery.washington.edu/attachments/Willie_NSg_2014.pdf).

Kang JY, Wu C, Tracy J, et al. Laser interstitial thermal therapy for medically intractable mesial temporal lobe epilepsy. *Epilepsia*. 2016;57(2):325-334. Retrieved February 1, 2017 from [file:///C:/Users/u748997/Downloads/Kang\\_et\\_al-2016-Epilepsia.pdf](file:///C:/Users/u748997/Downloads/Kang_et_al-2016-Epilepsia.pdf).

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Epilepsy Foundation of America. Information For Professionals. Diagnosis & Treatment. Magnetic Resonance-Guided Laser Interstitial Thermal Therapy (MR-g LITT). Accessed September 2018. Available at: <https://www.epilepsy.com/learn/professionals/diagnosis-treatment/magnetic-resonance-guided-laser-interstitial-thermal-therapy>

U.S. Food and Drug Administration. Safety Alerts for Human Medical Products. Magnetic Resonance-guided 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>

Specialty Matched Consultant Advisory Panel 10/2018

## Policy Implementation/Update Information

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- 4/28/17 New policy developed. MRI-guided Laser-induced Thermo-therapy 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)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.