

**EFFECTIVE DATE:** 05 | 01 | 2022

**POLICY LAST UPDATED:** 01 | 19 | 2022

## OVERVIEW

Laser interstitial thermal therapy (LITT) involves the introduction of a laser fiber probe to deliver thermal energy for the targeted ablation of diseased tissue. 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. 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. 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 FDA.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

### Medicare Advantage Plans

Laser interstitial thermal therapy (LITT) is not covered for all neurological indications, including but not limited to patients with primary or metastatic brain tumors, radiation necrosis, and drug-resistant epilepsy, as the evidence is insufficient to determine the effects of the technology on health outcomes.

### Commercial Products

Laser interstitial thermal therapy (LITT) is not medically necessary for all neurological indications, including but not limited to patients with primary or metastatic brain tumors, radiation necrosis, and drug-resistant epilepsy, as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

## BACKGROUND

### Laser Interstitial Thermal Therapy

Laser interstitial thermal therapy (LITT) 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. 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. 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 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. 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. 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™ Thermal Therapy System (Medtronic; formerly Biotex, Inc.) received initial marketing clearance by the FDA through the 510(k) pathway (K071328). As of March 2019, the system 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 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 800 nm through 1064 nm” (K181859). Data from compatible MRI sequences can be processed via proton resonance-frequency shift analysis and image subtraction 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 CO<sub>2</sub>.

On April 25, 2018, the FDA issued a safety alert on MR-guided LITT (MRgLITT) devices with a letter to healthcare providers stating that the FDA is currently evaluating data suggesting 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.

### CODING

**The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:**

- 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 (New code effective 01/01/2022)
- 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) (New code effective 01/01/2022)

### RELATED POLICIES

None

### PUBLISHED

Provider Update, March 2022

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