DRAFT Medical Coverage Policy | Laser Interstitial Thermal Therapy for Neurological Conditions

EFFECTIVE DATE: 00|01|2024
POLICY LAST REVIEWED: 07|17|2024

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 and Commercial Products

Laser interstitial thermal therapy (LITT) is considered medically necessary in the treatment of the following conditions:

- refractory epilepsy
- symptomatic, recurrent primary or metastatic malignant brain neoplasms
- symptomatic radiation necrosis in the brain

Medicare Advantage Plans

Laser interstitial thermal therapy (LITT) is not covered for all other indications 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 other indications 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.

Interstitial laser therapy (ILT) is a microinvasive technique that uses image-guided needle probes to deliver laser energy into a tumor to slowly heat and destroy the tumor cells. It has been proposed as a minimally invasive alternative to lumpectomy for fibroadenomas (benign tumors) that are 2 cm or less in size and it is also under investigation for treatment of localized breast cancers. Potential advantages of laser ablation compared to surgical excision include: shorter procedure time, outpatient setting, smaller incision and minimal scarring, less bleeding and tissue damage, lowered risk of infection due to heat sterilization of surrounding tissue and decreased healing time.

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™ MRI-Guided Laser Ablation System (Medtronic; formerly Biotex, Inc.) received initial marketing clearance by the 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.

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 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

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are considered medically necessary when filed with the ICD-10 Diagnosis Codes* listed below:

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

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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)

ICD-10 Diagnosis Codes

C71.0
C71.1
C71.2
C71.3 - C71.9
C79.31
G40.011 -G40.019
G40.111 -G40.119
G40.211 - G40.219
G40.311 - G40.319
G40.A11 - G40.A19
G40.B11 - G40.B19
G40.411 - G40.419
G40.803 - G40.804
40.813 - G40.814
G40.823 - G40.824
G40.911 - G40.919
T66.XXX+

RELATED POLICIES

None

PUBLISHED

Provider Update, March, September, 2024
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Provider Update, March 2022

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