Medical Coverage Policy | Laser Interstitial Thermal Therapy for Neurological Conditions

EFFECTIVE DATE: 05|01|2022
POLICY LAST REVIEWED: 01|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

Laser interstitial thermal therapy (LITT) is not covered for all neurological indications, including but not limited to individuals 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 individuals 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.

For individuals who have primary or metastatic brain tumors who receive magnetic resonance (MR)-guided laser interstitial thermal therapy (LITT), the evidence includes systematic reviews and meta-analyses and several nonrandomized comparative and single-arm studies. Relevant outcomes are overall survival (OS),disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Overall survival estimates have ranged from 9.0 to 14.4 months in new or recurrent glioblastoma. Among patients with metastatic tumors receiving LITT following prior stereotactic radiosurgery (SRS), OS rates have ranged between 72% to 76% at 6 months and 63% to 65% at 12 months. In a more heterogenous population of patients with primary and metastatic brain tumors who received LITT, 12-month OS rates were slightly lower in patients with brain metastases (56.3%) and high-grade glioma(43.0%) than other analyses. Systematic reviews comparing LITT to open craniotomy with resection or SRS suggest a reduced incidence of adverse events with LITT; however, neurological deficits attributable to LITT-induced thermal damage have been observed despite concurrent magnetic resonance imaging (MRI)guidance. Studies are limited by predominantly retrospective designs, small sample sizes, and population heterogeneity, with study subjects varying by performance status, lesion volume and location, extent of prior therapies, and extent of ablation. Prospective comparative studies in well-defined and -controlled patient populations are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic cranial radiation necrosis who receive MR-guided LITT, the evidence includes meta-analyses, nonrandomized comparative studies, and a single-arm study. Relevant outcomes are OS, disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Studies have reported improved local control and survival outcomes in patients with radiation necrosis compared to those with brain metastases. One study comparing LITT to bevacizumab suggested that LITT treatment may be more successful among patients before radiation necrosis lesions become symptomatic. One study comparing LITT to craniotomy and one study comparing LITT to medical management did not report significant survival differences between groups. Studies are limited by retrospective designs, small sample sizes, population heterogeneity, and unclear relevance, as symptomatic status and steroid-related morbidity were not consistently reported. Prospective comparative studies in well-defined and -controlled patient populations are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have drug-resistant epilepsy who receive MR-guided LITT, the evidence includes systematic reviews and meta-analyses, nonrandomized comparative studies, and single-arm studies. Relevant outcomes are disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Meta-analyses have reported seizure freedom rates ranging from 50% to 61% but are limited by heterogeneous study populations and follow-up durations. Studies comparing LITT to open resection have reported comparable outcomes in patients with pediatric insular epilepsy and adult temporal lobe epilepsy (TLE). In one meta-analysis comparing LITT to radiofrequency ablation (RFA) and conventional surgery, superior outcomes were noted with conventional surgery among patients with TLE. A subsequent meta-analysis concluded that while there is no evidence to suggest that LITT is less effective then open surgical resection in the short term, long-term data are lacking. Total quality of life scores reported in the ongoing LAANTERN registry increased by 72.4%, but this change was not considered statistically significant. Prospective comparative studies in well-defined and -controlled patient populations are required to assess a net health outcome and to identify patients most likely to benefit from LITT. The evidence is insufficient to determine that thetechnology results in an improvement in the net health outcome.

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 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

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)

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, March 2024
Provider Update, March 2023
Provider Update, March 2022

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