BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Laser Interstitial Thermal Therapy (LITT) for Neurological Disorders

Policy #: 728
Latest Review Date: December 2021
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

For dates of service on or after January 1, 2022:

Epilepsy

Blue Advantage will treat **Laser Interstitial Thermal Therapy (LITT)** (e.g., the NeuroBlate and the Visualase Thermal Therapy System) as a **covered benefit** as a treatment of refractory epilepsy when ALL of the following conditions have been met:

- Non-epileptic attacks such as cardiogenic syncope and psychogenic seizures have been ruled out.
- The diagnosis of epilepsy has been documented, and the epileptic seizure type and syndrome has been clearly defined.
- Documented disabling seizures, despite the use of two or more tolerated antiepileptic drug regimens (i.e., medically refractory epilepsy).
- There is a well-defined epileptogenic focus in the temporal lobe or hypothalamus accessible by LITT.

Radiation Necrosis

Blue Advantage will treat **Laser Interstitial Thermal Therapy (LITT)** (e.g., the NeuroBlate and the Visualase Thermal Therapy System) as a **covered benefit** as a treatment for medically refractory radiation necrosis with lesions not amenable to surgical decompression or refractory radiation necrosis despite prolonged, high-dose steroid therapy.

Blue Advantage will treat **Laser Interstitial Thermal Therapy (LITT)** as a **non-covered benefit** and as **investigational** for all other indications.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Laser Interstitial Thermal Therapy (LITT)

Epilepsy

Laser Interstitial Thermal Therapy (LITT) utilizes thermal energy to induce cell death by damaging DNA and triggering protein denaturation. This technique uses heat to target and ablate the region where the seizure begins. This minimally invasive procedure offers alternatives to patients who are not optimal candidates for open resection.

Laser Interstitial Thermal Therapy (LITT) minimizes injury to surrounding brain because it is done through a burr hole. This technology lowers the risk of affecting normal neurological

function, endorses less operative risk, less discomfort, and shorter hospitalizations. Laser Interstitial Thermal Therapy (LITT) is FDA approved for soft tissue ablation and is increasingly utilized to treat epilepsy, especially when seizures arise from deeper structures such as the hippocampus, amygdala, or discrete dysplastic tissue, such as hypothalamic hamartomas. Mesial temporal epilepsy is the most frequently encountered surgically remedial epilepsy suitable for LITT, particularly when there is unilateral hippocampal sclerosis. There is emerging evidence that it can be effective for eliminating seizures in this type of epilepsy, and that it has a lower risk of cognitive deficits than anterior temporal lobectomy.

Radiation Necrosis
Radiation Necrosis, or treatment-induced brain tissue necrosis, is a serious complication that usually develops one to three years after radiation. The dose that causes necrosis may vary by region of the brain. Tissue necrosis is more likely to occur when high doses per fraction are given with concurrent chemotherapy or radio sensitizers. The risk of tissue necrosis after stereotactic radiosurgery (SRS) has been reported to be higher, with a steep dose-response relationship. Tissue necrosis develops at or nearby the original site of the tumor, or the location that received the highest radiation dose. Tissue necrosis can also develop in part of the normal brain parenchyma that was included in the treatment field, such as temporal lobe necrosis that develops in some patients treated for nasopharyngeal cancer or clival chordoma. In this setting, brain tissue necrosis typically presents as new focal neurologic signs, and imaging studies such as computed tomography (CT) or magnetic resonance imaging (MRI) may show an enhancing mass lesion with edema.

The clinical course of brain tissue necrosis is highly variable. Management is primarily symptomatic. The treatment requires a balance between the competing goals of symptom control and avoidance of side effects. In some cases, tissue necrosis is an asymptomatic, self-limited process that can be managed conservatively without intervention. In patients who are symptomatic, initial treatment includes a moderate dose of an oral glucocorticoid, which usually produces prompt symptomatic improvement by reducing cerebral edema. Once symptoms are controlled, glucocorticoids can then be gradually tapered. Follow-up imaging after one to two months is recommended.

For patients who do not achieve symptomatic response to glucocorticoids, or when glucocorticoids cannot be tapered without the reoccurrence of symptoms, surgical resection of the necrotic tissue is sometimes required. Surgery can provide palliative benefit by reducing mass effect and decreasing steroid requirements postoperatively. Minimally invasive laser interstitial thermal therapy (LITT) has been explored as therapeutic intervention in the treatment of radiation necrosis.

KEY POINTS:
Updated searches of the MEDLINE database have been performed, most recently conducted through November 3, 2021.

Summary of Evidence
Laser Interstitial Thermal Therapy (LITT) may be an alternative treatment option for high-risk surgical patients. This minimally invasive approach is considered favorable due to evidence showing fewer complications, reduced length of procedure time, decreased hospitalization time, and a reduction in analgesic requirement when compared to open surgery. The current studies suggest that future research should continue in order to understand the long-term outcomes associated with resection versus laser ablation surgery.

Practice Guidelines and Position Statements
The Congress of Neurological Surgeons
In 2019, the Congress of Neurological Surgeons completed a systematic review and evidence-based guideline on the role of emerging and investigational therapies for the treatment of adults with metastatic brain tumors. Brain metastases associated with systemic cancer remain challenging to treat. Current standard treatment modalities, including surgery and radiation, cannot be applied to all patients and are not uniformly successful when applied. Therefore, novel treatment strategies are necessary.

U.S. Preventive Services Task Force Recommendations

KEY WORDS:
Epilepsy Surgery, Laser Interstitial thermal therapy; LITT; MR-guided stereotactic laser amygdalohippocampotomy; MRgLITT; NeuroBlate; Visualase; thermal therapy; mesial temporal lobe epilepsy; MTLE; focal laser therapy, interstitial laser ablation, interstitial laser coagulation, interstitial laser photocoagulation, laser induced thermal therapy, MRI-guided laser interstitial thermal therapy (MRgLITT) and photothermal therapy.

APPROVED BY GOVERNING BODIES:
The NeuroBlate® System (Monteris Medical, MN) enables MRI-guided neurosurgical ablation, monitoring 3-D and providing real time imaging to support a surgeon's clinical decision matrix. The device was FDA approved on October 26, 2016.

The Visualase® Thermal Therapy System (Medtronic, MN) provides advanced MRI-guided laser ablation technology for thermal ablation markets, including neurosurgery. Delivery of laser energy results in rising temperatures in the target area, destroying the unwanted tissue. The device was FDA approved on September 10, 2008.

On April 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."

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

64999	Unlisted procedure, nervous system

FUTURE CODING:

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 (**Effective 1/1/2022)**
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 (**Effective 1/1/2022**)

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POLICY HISTORY:

Adopted for Blue Advantage, December 2021
Medical Policy Group, December 2021