Healthy Blue

Clinical UM Guideline

Subject:	Minimally Invasive Ablative Procedures for Epilepsy		
Guideline #:	CG-SURG-91	**Publish Date:**	12/16/2020
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Description

This document addresses minimally invasive ablative procedures used in the treatment of medically refractory epilepsy in individuals with symptomatic localized epilepsy. Minimally invasive procedures have been proposed as a means to minimize or eliminate major craniotomy and bone flap incisions, decrease pain and down-time, preserve tissue and decrease neurocognitive adverse effects. These procedures utilize laser, radiofrequency, or cryotherapy techniques, in combination with stereotactic magnetic resonance imaging (MRI) guidance, for targeted ablation of the epileptogenic foci.

Note: Please see the following related documents for other treatments of epilepsy:
- CG-ANC-03 Acupuncture
- CG-MED-05 Ketogenic Diet for Treatment of Intractable Seizures
- MED.00057 MRI Guided High Intensity Focused Ultrasound Ablation for Non-Oncologic Indications
- SURG.00007 Vagus Nerve Stimulation
- SURG.00026 Deep Brain, Cortical, and Cerebellar Stimulation

Clinical Indications

Medically Necessary:

The treatment of medically refractory epilepsy using stereotactic laser techniques (MRI-guided laser interstitial thermal ablation [MRIgLITT]), including stereotactic laser amygdalohippocampotomy (SLAH), is considered **medically necessary** when the following criteria are met:
- Documented disabling seizures despite the use of two or more tolerated antiepileptic drug regimens; **and**
- Documented presence of two or fewer well delineated epileptogenic foci accessible by laser.

The use of stereotactic radiofrequency thermocoagulation (RF-TC) in the treatment of hypothalamic hamartomas is considered **medically necessary.**

Not Medically Necessary:

The treatment of medically refractory epilepsy using stereotactic laser techniques or stereotactic radiofrequency thermocoagulation is considered **not medically necessary** when the criteria above have not been met.

Other minimally invasive procedures to treat medically intractable epilepsy are considered **not medically necessary,** including but not limited to stereotactic radiofrequency amygdalohippocampectomy, sEEG-guided radiofrequency thermocoagulation or stereotactic cryosurgery.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
64999	Unlisted procedure, nervous system [when specified as minimally invasive surgery such as MRI-guided laser interstitial thermal ablation, radiofrequency thermal coagulation]

ICD-10 Diagnosis	
D33.0	Benign neoplasm of brain, supratentorial [specified as hypothalamic hamartoma]
G40.001-G40.919	Epilepsy and recurrent seizures

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met, or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Approximately 1.2-3% of the U.S population, or 3.4 million individuals have active epilepsy (CDC, 2019; Xue, 2018). Active epilepsy is defined as being physician diagnosed and having had one or more seizures in the past year or taking medication to control it, or both (CDC, 2019). Mesial temporal lobe epilepsy is a common type of epilepsy, representing approximately one-quarter of all cases; one-third of these individuals are considered medication refractory (Gross, 2018). Other types of epilepsy have varying degrees of success with pharmacotherapy. The failure of 2 anti-seizure medications is approximately 97% reliable in identifying drug resistance (Kwan, 2010). The International League against Epilepsy defines drug resistant epilepsy as:

> failure of adequate trials of two tolerated and appropriately chosen and used AED schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom (Kwan, 2010).

While pharmacotherapy is the first line of treatment to control seizures, it does not affect complete seizure control in one-third of the individuals (LaRiviere, 2016). For this population, open procedures have been the gold standard in achieving lasting seizure control. These procedures, such as anterior temporal lobectomy (ATL) or selective amygdalohippocampotomy (SAH) involve localizing and excising the epileptogenic zones (Shukla, 2017). These open procedures typically report a 60-80% long-term seizure-free rate with 95% of individuals reporting an improvement (Chang, 2015; Kang, 2016). However, concerns about the invasiveness of the procedure and the effect on neuropsychological function has limited the number of individuals utilizing this option. Approximately 2% of those individuals considered candidates undergo open surgery every year (Kang, 2016). Neuromodulatory device implantation has also been used as a means of seizure frequency reduction and in those who undergo constant stimulation, the success rate is approximately 68-76% (Xue, 2018). Recently, minimally invasive therapies have been explored as alternatives to open surgery. These therapies are proposed to be viable options for those with epileptogenic foci located near deep, eloquently brain structures, multiple comorbidities or those who are poor surgical candidates (Shukla, 2017).

Stereotactic LITT, typically MRI- guided, uses low-voltage laser energy delivered via optical fiber through a burr hole to destroy the targeted tissue while minimizing injury to the surrounding tissue. MRgLITT consists of three elements, stereotactic techniques to exactly position the laser in the therapeutic range, the use of the laser to provide time-dependent thermal tissue ablation and MRI thermography to provide real-time monitoring of temperature and tissue destruction (Dorfer, 2020). Laser energy is converted to thermal energy, which, when applied to tissue leads to coagulative necrosis. Use with MRI guidance allows for monitoring of both the device tip and thermal damage in real time (Gross, 2016; Shukla, 2017). However, LITT is not without drawbacks. Ablative therapies do not allow for tissue to be obtained for pathology, and Kang (2016) noted a technical limitation “The curvature of the hippocampus and the presence of potential heat sinks (i.e., blood and cerebral spinal fluid) may prevent adequate ablation of the epileptogenic network in some individuals.

Laser interstitial therapy

Currently, there are two Food and Drug Administration (FDA) cleared MRgLITT systems, Visualase® thermal therapy (Medtronic, MN) and NeuroBlate® Systems (Monteris Medical, Minneapolis, MN). The Visualase device, approved in 2007, has been used to treat epilepsy since 2012 (Kang, 2016). The NeuroBlate device, approved in 2009, is not commonly used to treat epilepsy, but is typically used to treat brain tumors. The use of NeuroBlate to treat epilepsy is currently undergoing a FDA approved trial.

In 2018, Xue and colleagues conducted a meta-analysis of MRgLITT to assess effectiveness in treatment-resistant epilepsy. In total, 16 studies were identified which included 269 individuals with medication-resistant epilepsy with focal onset of seizures. In the short-term, 61% of the individuals were seizure-free or disabling seizure-free (Engel Class I) following MRgLITT. While approximately 24% of the individuals reported postoperative complications, the authors note that some complications resolve within six months. The authors note that while MRgLITT can achieve good outcomes, there are several factors which affect the effectiveness in the clinical setting. Good clinical outcomes depend upon accurate and precise localization of the epileptogenic zone. Inadequate resection of the epileptogenic focus, wider epileptogenic zones and inadequate training can result in suboptimal results.

Gross and colleagues (2018) evaluated outcomes of 58 individuals with mesial temporal lobe epilepsy (MTLE) with or without mesial temporal sclerosis who had undergone stereotactic laser amygdalohippocampotomy (SLAH). Analysis was limited to those with documented outcomes of 1 year or longer. For those for whom the initial SLAH procedure was ineffective, a repeat SLAH procedure was offered when the postoperative MRI scan showed a remnant region thought to be responsible for the ongoing procedures. Following SLAH, 53.4% (31/58) were considered free from disabling seizures, and 22 of the individuals achieved Engel 1A response at 12 months or longer, including 3 individuals who had undergone a repeat SLAH. An additional 9 individuals achieved Engel 1B-D responses. During the same period 22 individuals underwent open temporal lobe resections, with 50% (11/22) of these individuals considered seizure free at one year. Complications of SLAH include visual field defects in five individuals, with one being persistent and symptomatic. Other complications were transient and treated with resolution of symptoms. The authors reported that 8.2% of the individuals experienced decline in verbal memory, compared to rates of 30 to 60% decline reported for open resection. The authors note:

> Thus, on balance, although SLAH may yield a marginal decrease in the chance of freedom from disabling seizures, and possibly in the rate of being completely seizure-free, as compared to open resection, the cognitive benefits and safety profile of SLAH make it an attractive alternative, especially when considering surgery on the dominant hemisphere.

The outcomes of LITT to treat 43 consecutive individuals with MTLE who underwent unilateral therapy was reported by Donos and associates (2018). In addition to seizure free rates, cognitive function was assessed prior to and following the procedure, although 8 individuals did not return for follow-up testing. At 6 months following their procedure, 79.5% of the individuals had achieved an Engel class I outcome. Additional 5.1% achieved Engel class II and 15.4% were classified as having an Engel III outcome. In later follow-up (mean interval of 20.3 months), 67.4% of the individuals achieved an Engel class I outcome and an additional 16.3% of the individuals each achieved Engel class II and III. There were declines in some aspects of memory following the surgery, but changes observed at the group level were not small and did not reach the level of significance. The authors noted that the follow-up testing was performed at 6 months, and as functional recovery continued, a further improvement in cognitive performance was likely to occur. The results of the study were similar to those of previous studies, the authors reported slightly higher rates of Engel I outcomes.

Kang and associates (2016) described the outcomes of 20 individuals with medically intractable MTLE who underwent MRgLITT between 2011 and 2014. Assessed outcomes included mesial temporal lobe ablated volumes, verbal memory, and surgical outcomes at 6 months, 1 year, 2 years and most recent visit. At 6 months, 8/15 individuals (53%, 95% CI 30.1-75.2%) were free of consciousness impairing seizures. At 1 and 2 years, 4/11 individuals (36.4%, 95% CI 14.9-64.8%) and 3/5 individuals (60%, 95% CI 22.9-88.4%) were free of consciousness impairing seizures respectively. None of the participants reported a statistically reliable decline in logical memory performance. Reported efficacy rates are modestly lower than those reported after anterior temporal lobectomy (ATL). However, verbal learning and memory performance was better preserved in the MRgLITT group compared to the ATL group. In addition, the hospital stay postoperative pain and recovery period was minimal, and individuals were immediately able to return to work. The authors note that this finding might be significant for those with dominant mesial temporal foci, as individuals who undergo ATL in the dominant hemisphere are at higher risk for declines in language function and verbal memory.

In 2015, Waseem and colleagues reported on the outcomes of 7 individuals over the age of 50 who underwent MRgLITT for medically refractory MTLE. The outcomes were compared to 7 individuals who had undergone selective anterior mesial temporal lobe (AMTL) resection. All 7 individuals in the AMTL group were seizure free at 12 months. In the MRgLITT group, 4 individuals were classified as seizure free, 2 individuals reported rare seizures (almost seizure free) and 2 individuals had not reached the 12 month follow-up. Complications at 30 days included one case of aseptic meningitis that resolved with therapy (ATML), 2 cases of postoperative partial visual field deficits (MRgLITT) and 1 case postoperative seizure requiring readmission (MRgLITT). There was no significant differences in neuropsychological outcomes between the two groups. The authors note that MRgLITT might be an acceptable alternative for those individuals who cannot or is not willing to undergo an open surgical intervention.

The current body of evidence is limited to case review and series, and prospective and retrospective studies. While randomized, controlled studies comparing minimally invasive procedures to the gold standard of ATL provides a high level of evidence, this type of study is not feasible for LITT in the current setting. The preponderance of evidence suggests that the efficacy of LITT is comparable to open procedures and has improved safely and tolerance outcomes (Curry, 2012; Drane, 2015; Hawasli, 2013; Lewis, 2015; McCracken, 2016; Patel, 2016; Perry, 2017; Tao, 2018; Tandonb, 2018; Wilfong, 2013; Willie, 2015; Wu, 2019; Youngerman, 2018).

Radiofrequency therapies

Stereoelectroencephalography-guided radiofrequency thermocoagulation (SEEG-guided RF-TC), also called thermo-SEEG, involves the use of implanted SEEG electrodes to both identify the location of seizure-onset zones and to perform multiple stereotactic lesioning of the identified areas. SEEG-guided RF-TC is proposed as alternative in a select population when resective surgery is not feasible, such as when the ictal onset zone size is limited or when the zone is located in a highly functional area (Moles, 2018). Moles (2018) notes the following advantages to SEEG-guided RF-TC:

- (i) there is no additional bleeding risk when compared to a conventional stereotactic procedure as the same electrode is used for both SEEG and RF-TC (all bleedings reported in the literature were related to removal of SEEG electrodes, and these were not those used for RF-TC [9]),
- (ii) it allows a very accurate targeting of the seizure-onset zone, previously delineated by intracranial recordings,
- (iii) multiple lesions can be performed, instead of the single or double lesions usually performed in a conventional stereotactic lesioning procedure, and
- (iv) a functional mapping, through direct electrical stimulation on SEEG electrodes, is done prior to any lesion being made, thus allowing to anticipate the possible adverse effects in detail.

In a retrospective review comparing the outcomes of SEEG-guided RF-TC (n=21) and ATL (n=49) in temporal lobe epilepsy, Moles and associates (2018) reported significantly worse outcomes for the SEEG-guided RF-TC group. At 12 months, none of the SEEG-guided RF-TC group were seizure free while 75.5% of the ATL group were seizure free. Of the 21 individuals in the SEEG-guided RF-TC group, 19 individuals subsequently underwent ATL, 1 individual was waiting to undergo ATL, and the last individual was seizure-free for 2 months before being classified as a responder (at least 50% reduction in seizure frequency).

Bourdillon and associates (2017) evaluated the outcomes 162 individuals who underwent SEEG-guided RF-TC to treat drug-resistant focal epilepsy. The primary outcome was identified as seizure frequency at 2 months and one year following SEEG-guided RF-TC. In addition, the rate of responders, defined as individuals with at least a 50%

decrease in seizure frequency compared the 3 months immediately preceding the procedure, was the secondary outcome. At 2 months, 25% (n=41) of the individuals were seizure free and 67% (n=108) were considered responders. At 12 months, 7% (n=11) of the individuals were seizure free and 48% (n=78) of the individuals were considered responders. A total of 50 individuals underwent a second procedure within the year following the procedure, 2 of those individuals had a second SEEG-guided RF-TC. While the results of this study might suggest that SEEG-guided RF-TC has a favorable risk-benefit ratio compared to conventional surgery and other palliative treatments, the significance of these finding was limited by the prospective nature of the study and the fact this single center study was performed over a 10 year period and included modifications in practice over this time.

Radiofrequency ablation has been studied as a means of eliminating epileptogenic zones without performing a craniotomy. While early results were disappointing, later studies have reported improved outcomes over the earlier data (LaRiviere, 2016). However, these later studies are small, lower quality studies (Guénot, 2004; Guénot, 2011; Krámská, 2017; Malikova, 2014; Wu, 2014). Additional study with long-term follow-up is needed to address question regarding efficacy, safety and durability of outcomes compared to current standard treatments. In a critical review summarizing the literature and personal experiences with SEEG-guided RF-TC, Wu and associates note that in addition to comparing outcomes with standard treatments, more accurate devices are needed, concluding "Technically, developing new devices for RF-TC that provide intraoperative control over lesion temperature and real-time lesion visualization would help produce ablated volumes as expected with better outcomes".

Hypothalamic hamartomas (HH)

HH is a rare congenital ventral hypothalamus malformation which often results in treatment resistant epilepsy (Kerrigan, 2017). The disorder affects an estimated 1 in every 200,000 individuals. HH can present in a number of ways although intractable gelastic seizures are a common symptom (Kemeyama, 2016). In addition to the gelastic seizures, approximately half of the affected individuals also have epileptic encephalopathy, which is exhibited as cognitive impairment and behavioral disorders. Gelastic seizures typically do not respond to pharmacotherapy, treatment options include microscopic surgery, endoscopic disconnection, stereotactic radiofrequency thermocoagulation (SRT), laser interstitial thermal therapy, and Gamma Knife surgery (Tandon, 2018a). The location of HH lesions, near of the midline of the skull base, make the lesions difficult to reach with microsurgical approaches and too invasive to provide total resection (Kameyama, 2016). The success rate of microscopic surgery has been reported as 5-60% with higher rates of morbidity and mortality (Tandon, 2018). In addition to treating gelastic seizures, both laser and radiofrequency procedures have been associated with an improvement in epileptic encephalopathy symptoms (Sonoda, 2017).

Sonoda and associates (2017) evaluated cognitive function outcomes in 88 individuals who underwent SRT as a treatment of drug-resistant gelastic seizures (GS). A total of 87 individuals underwent post-operative follow-up for an average of 3.3 years. At the final hospital visit, 85.2% (75/87) had achieved GS remission. For those individuals in gelastic seizure remission there was a significant post-operative improvement in full-scale intelligence quotient (FSIQ) compared to preoperative scores (preoperative 72.8 ± 25.1 versus postoperative at the last visit: 81.2 ± 26.7; p<0.001; paired t-test)). Individuals who did not achieve GS remission did not achieve a significant improvement in FSIQ scores (preoperative: 68.8 ± 23.3 versus postoperative at the last visit 71.1 ± 24.1: p=0.36; paired t-test).

Kameyama and colleagues (2016) reported on the outcomes of 100 consecutive pediatric (n=70) and adult (n=30) individuals with intractable gelastic seizures who underwent MRI-guided stereotactic radiofrequency thermocoagulation (SRT). In addition to gelastic seizures, 90 of the individuals had other types of seizures including complex partial, secondarily generalized tonic-clonic, tonic, atonic, myoclonic and epileptic. All individuals had SRT as the sole treatment for hypothalamic hamartomas, although 32 individuals underwent multiple (up to 4) SRT procedures for residual disease. Individuals were followed-up between 1 and 17 years. A reported 86% of the individuals achieved freedom from gelastic seizures and 78.9% of the individuals with concurrent non-gelastic seizures also achieved seizure freedom.

Several other studies, including case series, retrospective reviews, reported on the outcomes of either stereotactic laser ablation or stereotactic radiofrequency thermocoagulation used to treat HH lesions have been published. Both laser and SRT trials have reported outcomes superior to microscopic surgery with limited morbidity (Curry, 2018; Kameyama, 2016; Southwell, 2018; Tandon, 2018; Wei, 2018).

Other minimally invasive therapies

To date, there is a paucity of studies regarding other minimally invasive treatments of epilepsy. Chkhenkeli and colleagues (2013) reported on the results of 21 individuals who underwent stereotactic cryosurgery to treat intractable bitemporal epilepsy. However, there have been no additional published regarding the use of cryosurgery for the treatment of epilepsy.

Definitions

Anterior temporal lobectomy (ATL): Surgical resection of the of mesial-basal temporal lobe structures. A limitation of ATL is that access to these structures requires resection of the temporal neocortex which affects cognitive and neuropsychological abilities.

Epilepsy: A disease of the brain when any of the following conditions occur:

- At least two unprovoked (or reflex) seizures occurring > 24 h apart
- One unprovoked, or reflex, seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after two unprovoked seizures, occurring over the next 10 years
- Diagnosis of an epilepsy syndrome

Medically intractable epilepsy: The failure of at least two separate drug regimens to control seizure activity; also known as drug resistant epilepsy.

Selective amygdalohippocampectomy (SAH): Surgical resection of mesial-basal temporal lobe structures which does not involve neocortical resection.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion, References and Websites sections. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Updated Discussion, References and Websites sections.
New	11/08/2018	MPTAC review. Initial document development.