Clinical Policy Title: Laser thermal ablation for epileptic seizures

Clinical Policy Number: 09.03.01

Effective Date: October 1, 2014
Initial Review Date: June 5, 2014
Most Recent Review Date: June 22, 2017
Next Review Date: June 2018

Related policies:

CP# 09.02.01 Vagus nerve stimulation

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of laser thermal ablation for epileptic seizures to be investigational/experimental and, therefore, not medically necessary.

Limitations:

All other uses of laser thermal ablation for epileptic seizures are considered to be investigational/experimental and, therefore, not medically necessary.

Alternative covered services:

Open surgical resection.

Background
A seizure is a temporary disturbance in brain function caused by excessive or abnormal signals in groups of neurons in the brain. Seizures may produce changes in awareness or sensation, involuntary movements, or other changes in behavior. Usually, a seizure lasts from a few seconds to a few minutes. Epilepsy, sometimes referred to as "seizure disorder," is a general term that refers to a tendency to have recurrent seizures (CDC, 2014). The CDC estimates 2.3 million adults and 467,711 children (0–17 years of age) in the United States have epilepsy; nearly 150,000 Americans develop the condition each year. New cases of epilepsy are most common among children and older adults (CDC, 2014).

Causes of epilepsy may be related to hereditary factors, early exposures, and events. In up to two-thirds of epilepsy cases, a specific underlying cause is not identified. Known conditions and events that may lead to epilepsy include (Epilepsy Foundation, 2014):

- Oxygen deprivation (e.g., during childbirth).
- Brain infections (e.g., meningitis, encephalitis, cysticercosis, or brain abscess).
- Traumatic brain injury or head injury.
- Stroke (resulting from a block or rupture of a blood vessel in the brain).
- Other neurologic diseases (e.g., Alzheimer’s disease).
- Brain tumors.
- Certain genetic disorders.

Women with epilepsy can experience difficulties arising from hormonal changes during their reproductive cycle that sometimes affect the tendency to have seizures. Pregnancy brings some special considerations for women with epilepsy, because seizure occurrence and certain drugs taken during this time may sometimes carry a risk of harm to the developing fetus (Epilepsy Foundation, 2014).

Epileptic seizures are categorized broadly as generalized or partial seizures. Primary generalized seizures are seizures that begin with widespread involvement of both sides of the brain, whereas partial seizures begin with involvement of a smaller, localized area of the brain. With some partial seizures, the disturbance can still spread within seconds or minutes to involve widespread areas of the brain — causing a secondary generalized seizure (Epilepsy Foundation, 2014).

**Drug Treatment and drug-resistant epilepsy:**

Antiepileptic drug (AED) therapy is the treatment of choice for persons with epilepsy. For approximately two-thirds of people with a correct diagnosis of epilepsy receiving optimum treatment, AEDs are successful in fully controlling seizures. For the remainder, seizures remain uncontrolled with AEDs. According to the Epilepsy Foundation, while the definition of uncontrolled (also referred to as “refractory,” “medically intractable,” and “pharmacoresistant”) epilepsy varies, there is general agreement the definition should take into account the frequency and severity of seizure activity that is troublesome enough to seriously interfere with quality of life (Epilepsy Foundation, 2014). The International League Against Epilepsy (ILAE) has proposed the following definition of “drug-resistant
epilepsy,” and suggests using this term instead of the term “refractory” epilepsy if both of the following conditions are met (ILAE, 2014):

- Drug-resistant epilepsy occurs when a person has failed to become (and stay) seizure-free with adequate trials of two AEDs.
- These seizure medications must have been chosen appropriately for the person’s seizure type, tolerated by the person, and tried alone or together with other seizure medications.

**Surgical treatment:**

For persons with drug-resistant epilepsy, other treatment options are available for seizure control (Engel, 2014). These include epilepsy surgery, vagus nerve stimulation, and dietary therapies. The goal of surgery is to remove the smallest amount of tissue in order to achieve a seizure-free outcome. Multiple types of surgical interventions are now offered depending on the cause and type of epileptic seizures. Most patients experience a reduction in, or elimination of, disabling seizures and significant improvement in quality of life (CDC, 2014; Engel, 2014).

Surgical therapy is among the most cost-effective treatment options in appropriately chosen patients, in part because pre-surgical evaluation can be performed noninvasively in most cases. Pre-surgical evaluation requires localizing and determining the extent of the epileptogenic region, which is defined as the area of brain necessary and sufficient to generate habitual seizures. A number of different functional and structural tests are used to approximate extent of the epileptic region, including inpatient video- electroencephalogram (EEG) monitoring, neuroimaging, and neuropsychological evaluation (Engel, 2014).

In addition to drug resistance, optimal surgical candidates have partial seizure conditions with a known pathophysiology and progressive features, such as developmental delay in infants and young children, or interictal behavioral disorders, most commonly depression (Engel, 2014). Mesial temporal lobe epilepsy (MTLE) is the most common form of epilepsy in adolescents and adults, the most medically refractory, and the most easily treated surgically (Engel, 2014). In most patients with MTLE, a discrete seizure focus originates within hippocampal sclerosis lesions. Other surgically remediable conditions include focal epilepsies within discrete resectable structural lesions; epilepsies due to diffuse hemispheric disturbances, such as hemimegalencephaly, Rasmussen’s encephalitis, Sturge-Weber syndrome and large porencephalic cysts; and gelastic seizures with hypothalamic hamartomas (Engel, 2014).

**Laser thermal ablation for epilepsy:**

Laser thermal ablation is a minimally invasive, stereotactic surgical technique that combines an image-guided system using magnetic resonance imaging (MRI) with thermal ablation to localize high temperatures generated by the local absorption of laser energy to destroy the desired tissue. Surgeons make a 1-cm incision in the skull through which an intracranial probe is inserted and guided to the target by MRI; thermal ablation can be visualized in real time (Tovar-Spinoza, 2013).
This procedure is also called laser-induced interstitial thermotherapy (LITT), laser interstitial thermal therapy, laser-induced thermotherapy, interstitial laser therapy and laser ablation. As a minimally invasive technique, theoretically critical adjacent tissue can be spared and open resection can be performed in the event ablation is ineffective. Laser thermal ablation may be an alternative to surgical resection for the treatment of focal lesional epilepsy in patients who are considered high-risk surgical candidates.

The U.S. Food and Drug Administration approved the Visualase thermal ablation system in 2010, and the NeuroBlate MRI-guided laser ablation system in 2013. Both assist in identifying the target tissue and hold the patient’s head in place while the laser is situated for precise ablation (MD Edge, 2015).

Searches

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality Guideline Clearinghouse and evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 21, 2017. Search terms were: "magnetic resonance imaging (MeSH),” "epilepsy/surgery (MeSH),” and "laser therapy” (MeSH), and free text terms “laser interstitial thermal therapy,” “laser thermal ablation,” “visualase,” and “epilepsy.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

As of April 2017, there were no professional guidelines that address laser thermal ablation for epileptic seizures. A recent review of 22 articles (n=223) included mostly those having undergone treatment with Visualase® for epilepsy (eight studies). No significant differences were found compared with NeuroBlate therapy for frame, total complications, and length of stay (Lagman, 2017). Another recent review discussed publications of about 200 cases of epilepsy treated with laser thermal ablation; it found
seizure outcome to be slightly worse than respective surgery, and recommended future studies covering patient outcomes and cost-benefit analyses (Hoppe, 2017).

One Hayes report of MRI-guided laser ablation addresses treatment of epilepsy (Hayes, 2017), as does one additional case series (Curry, 2012) that used the Visualase® Thermal Therapy System (Visualase Inc., Houston, TX, now marketed by Medtronic Inc., Minneapolis, MN). The Hayes report included 12 abstracts from the literature, and found a low quality of evidence due to small sample sizes and several reports authored by manufacturers of the product. Despite some promising outcomes, future studies will need to select patients judiciously, and ensure adequate surgeon experience with the new procedure to optimize safety and efficacy (Hayes, 2017).

A group of 38 patients with medically refractory mesial temporal lobe epilepsy were followed from six to 38.5 months. Researchers found lower procedure time, hospitalization time, and analgesic requirement when compared with open surgery, suggesting that this new therapy may lower seizure rates. Longer-term and larger studies are required (Waseem, 2017). The proportion of a group of 20 patients with epilepsy who underwent laser interstitial thermal therapy who had no seizures included:

- 53 percent (eight of 15) after six months
- 36 percent (four of 11) after one year
- 60 percent (three of five) after two years

Another review of 17 pediatric patients with epilepsy (mean age at surgery = 15.3 years) documented an average length of stay after surgery of 1.56 days. Follow-up (mean 16.1 months) showed seven of 17 patients classified as Engel class I (optimal), followed by one, three, and six in classes II, III, and IV (Lewis, 2015).

Other recent reviews conclude that laser interstitial thermal therapy for drug-resistant epilepsy has potential to replace more invasive surgical techniques (Kang, 2017; Wicks, 2017). Pediatric patients with epilepsy may also be candidates for this new therapy (Karsy, 2016; Muh, 2016).

Policy updates:

A total of one guideline/other and eight peer-reviewed references were added to this policy.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hayes (2017)</td>
<td>Key points:</td>
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<tr>
<td>Clinical evidence for Visualase for epilepsy</td>
<td>- Literature search found 12 abstracts of safety and efficacy of Visualase MRI-guided laser ablation therapy for epileptic patients.</td>
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<td></td>
<td>- Overall quality of studies were low due to small samples and several reports with authors who are manufacturers.</td>
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<td>- Some results show promise with this new therapy, but authors cautioned that patients should be selected judiciously, and surgeons need to be experienced.</td>
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</tbody>
</table>
Advantages of Visualase include reduced time of procedure, little/no hair removed, minimal sutures required, shorter stays, less scarring than surgery.

**Key points:**
- Review of 22 articles (n=223) having undergone procedure with Visualase.
- In 8 studies, epilepsy was the indication for Visualase (most common condition).
- Compared to NeuroBlate therapy, Visualase had no significant differences in frame, total complications, and length of stay.

**Key points:**
- 38 patients with MRI-guided laser interstitial thermal therapy, followed six to 38 months.
- Fifty-three percent (18 of 38) had Engel class I outcome.
- Ten patients had repeat procedures, 12 post-procedural complications noted.
- Therapy associated with lower procedure time, hospitalization time, and analgesic requirement, vs. open surgery.

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

There are no NCDs as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

There are no LCDs as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<td>Creation of lesion by stereotactic method, percutaneous, by neurolytic agent (e.g., alcohol, thermal, electrical, radiofrequency); trigeminal medullary tract</td>
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