



**Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2010**

1. Technology Name: [Auto Laser Interstitial Thermal Therapy \(AutoLITT™\) System](#)
2. Manufacturer Name: [Monteris Medical](#)
3. Trade Brand of Technology: [AutoLITT System](#)

4. Brief Description of Service or Device:

[The AutoLITT™ System is a minimally-invasive, MRI-guided, MRI-thermometry method for delivering focused laser-induced interstitial thermal therapy \(f-LITT\). The technology enables a physician to selectively and precisely heat brain tumors to cause coagulative tissue death throughout the tumor. The procedure involves inserting a thin \(3mm\) side-firing laser probe through a small burr hole in the skull into a tumor, then firing the laser to heat the tumor from the inside out to the tumor boundary. Conducted with the patient in a standard MRI, the neurosurgeon visualizes and controls thermal energy deposition and resultant tumor cell death in real-time using the Company's proprietary thermal imaging software and treatment mechanisms.](#)

**Newness Criterion**

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

[December 2008](#)

6. Was the product available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation for any delay (i.e. manufacturing issues, shelf life concerns or other reasons).

[N/A, product not yet approved. However, upon FDA approval, active marketing and selling of the AutoLITT system will commence in the US.](#)

7. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

- a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

[Yes, an application is pending. A presentation for new procedure codes for the AutoLITT system was recently made at the September 24-25<sup>th</sup>, 2008 ICD-9-CM Coordination and Maintenance Committee Meeting. CMS's recommendation at this meeting was to create a new category of](#)

“MRI-guided LITT of lesion or tissue of brain and other sites”, with the potential for implementation in October 2009. Please note that the application submitted requested an expedited implementation date of April 2009. These new codes included the following:

New category 17.6 MRI-guided laser interstitial thermal therapy (LITT)  
Focused Laser Interstitial Thermal Therapy LITT (f-LITT)  
under MRI guidance

New code 17.61 MRI-guided laser interstitial thermal therapy (LITT) of  
lesion or tissue of brain

New code 17.62 MRI-guided laser interstitial thermal therapy (LITT) of  
lesion or tissue of head and neck

New code 17.63 MRI-guided laser interstitial thermal therapy (LITT) of  
lesion or tissue of lung

New code 17.64 MRI-guided laser interstitial thermal therapy (LITT) of  
lesion or tissue of breast

New code 17.65 MRI-guided laser interstitial thermal therapy (LITT) of  
lesion or tissue of liver

New code 17.66 MRI-guided laser interstitial thermal therapy (LITT) of  
lesion or tissue of prostate

New code 17.69 MRI-guided laser interstitial thermal therapy (LITT) of  
lesion or tissue of other and unspecified site

- b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to [http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01\\_overview.asp#TopOfPage](http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp#TopOfPage) for more information.) We note that, if the product were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-9-CM code(s) in the MedPAR claims data in order to receive add-on payment. N/A

8. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to [http://www.cms.hhs.gov/HospitalOutpatientPPS/04\\_passthrough\\_payment.asp#TopOfPage](http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage) for more information.)

As of yet, no application has been submitted. However, as the AutoLITT technology develops, the intention is to initiate trials evaluating the potential for outpatient procedures. When this occurs, the intention would be to submit for a transitional pass through payment code.

## **Cost Criterion**

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by DRG. The most recent version of Table 10 can be downloaded at: [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage).

Provide the following information to demonstrate the technology or service meets the criterion.

8. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form. [The anticipated average standardized charge per case involving the AutoLITT technology is: \*\*\\$79,777.\*\*](#)
9. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)? What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs-** Average dosage or number of units per patient (ml/kg/hr); **Devices-** breakdown of the cost of all components used in the new technology, clearly showing which components are the “new” ones).

[The cost of the technology to the hospital will be \\$6,300 per patient for all AutoLITT products required for the procedure.](#)

[Additionally the hospital will use miscellaneous single-use items common to any minimally-invasive surgical procedure, such as drapes, staples, anesthesia catheter lines, anesthesia ventilation disposables, contrast agent, etc.](#)

10. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.

[Based on initial discussions with CMS back on October 2007, we believe that existing MS-DRGs 25-27 would be affected by the AutoLITT.](#)

DRG	Description
25	Craniotomy & endovascular intracranial procedures with MCC
26	Craniotomy & endovascular intracranial procedures with CC
27	Craniotomy & endovascular intracranial procedures without CC

11. What is the anticipated volume of Medicare cases involving of this technology in FY 2010 (by DRG)?

[It is estimated that 150 units in total will be sold in the US during FY 2010. Of these units, approximately 45% of them will be used on patients  \$\geq 65\$  years of age<sup>1</sup>. Further it is anticipated that the usage of these units by DRG \(25-27\) would be expected to be uniform. Therefore it is expected that approximately 65-70 Monteris AutoLITT units would be used by for patients  \$\geq 65\$  yrs of age under DRGs 25-27](#)

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<sup>1</sup> Incidence of Glioblastoma Multiforme in  $\geq 65$  year age group. Central Brain Tumor Registry of the US. 2007-2008 statistical report

### Calculation:

150 units X 45% = 68 units used in ≥65 year age group.

Usage by DRG 25-27 is split equally amongst them = 33.3%

Therefore, 68 units (for age ≥65 year age group) X 33.3% = 22-23 units per each DRG

## **Clinical Improvement Criterion**

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services.

12. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.
  - a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

LITT (and more recently, the use of LITT plus MRI) has been used clinically for treating brain tumors for a number of years. In a number of these patients, LITT was the treatment of last resort, due to either the unresponsiveness or inability of these therapies (chemotherapy, immunotherapy, whole-brain radiation therapy and radiosurgery)<sup>2,3</sup> to treat the brain tumor (due to tumor location, type, size, etc.). Further, the use of LITT improved the clinical outcomes for this patient population as compared to currently available treatments. Examples of these outcomes as outlined above in #4, are: reduced recovery time<sup>4,5,6,7,8</sup>, and a reduced rate of complications (i.e. infection, brain edema) compared to existing treatments (i.e. surgery)<sup>9,10,11</sup>. These criteria as described in the Federal Register<sup>12</sup> (i.e. treatment option for disease refractory to other treatments, clinical outcomes) meet the new technology requirement of substantial clinical improvement. We therefore believe the Monteris AutoLITT represents a substantial clinical improvement over existing services or technologies.

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<sup>2</sup> Von Templehoff, W et al. (2002). LITT (Laser Induced Interstitial ThermoTherapy) of Benign and Malignant Gliomas in the OPEN MR (0.5 Tesla, GE Signa SP). *Med Laser Appl.*;17:170-178.

<sup>3</sup> Carpentier, A. et al (2008). Real-Time Magnetic Resonance-Guided Laser Thermal Therapy for Focal Metastatic Brain Tumors. *Neurosurgery*;63:ONS21-ONS29.

<sup>4</sup> Reimer, P et al. (1998). MR-monitored LITT as a palliative concept in patients with high grade gliomas: preliminary clinical experience. *Jrl. Mag Reson Imaging*;8:240-244.

<sup>5</sup> Kowalik, K et al. (2000). Initial assessment of costs and benefits of MRI-guided brain tumor resection. *Eur. Radiol*;10:S366-367 [Suppl. 3]

<sup>6</sup> Hall, WA et al. (2002). Costs and Benefits of Intraoperative MR-Guided Brain Tumor Resection. *Acta Neurochir*;85:137-142. [Suppl]

<sup>7</sup> Schwarzmeier, HJ et al. (2006). MR-guided laser-induced interstitial thermoTherapy of recurrent glioblastoma multiforme: Preliminary results in 16 patients. *Eur Jrl. Radiology*;59:208-215.

<sup>8</sup> Carpentier, A. et al. (2008). Real-Time Magnetic Resonance Guided Laser Thermal Therapy for Focal Metastatic Brain Tumors. *Neurosurgery*;63:ONS21-ONS29 [ONS Suppl 1]

<sup>9</sup> Reimer, P et al. (1998). MR-monitored LITT as a palliative concept in patients with high grade gliomas: preliminary clinical experience. *Jrl. Mag Reson Imaging*;8:240-244.

<sup>10</sup> Paleologos, TS et al. (2000). Clinical Utility and Cost-Effectiveness of Interactive Image Guided Craniotomy: Clinical Comparison between Conventional and Image Guided Meningioma Surgery. *Neurosurgery*;47:40-48

<sup>11</sup> Mehrkens, J. et al. (2005). Interstitial Photodynamic Therapy of Recurrent Malignant Gliomas Using 5-Aminolevulinic Acid (5-ALA). *Neuro-Oncology*;Abstract #110; Abstracts from the World Federation of Neuro-Oncology Second Quadrennial Meeting and the Sixth Meeting of the European Association for Neuro-Oncology. May 5-8, 2005

<sup>12</sup> Federal Register, 66 CFR 46914-15, September 7, 2001

- b. List all published peer-review articles relevant to the new service or technology.

**Table 1: Probe directed thermal therapy for treating brain tumors:** This section provides the clinical support for use of thermal therapy in the brain

<b>Study</b>
<b>Roux, FX et al. (1992).</b> Laser Interstitial Thermotherapy in Stereotactical Neurosurgery. <i>Lasers in Medical Science</i> ,7:121-126.
<b>Sakai, T. et al (1992).</b> Interstitial laserthermia in neurosurgery. <i>J. Clin. Laser Med Surg</i> ;10:37-40.
<b>Kahn, T et al, (1994).</b> MRI-guided laser-induced interstitial thermotherapy of cerebral neoplasms. <i>Jrl. Computer Assisted Tomography</i> ,18:519-532
<b>Anzai, Y et al. (1995).</b> Preliminary experience with MR-guided thermal ablation of brain tumors. <i>AJNR</i> ,16:39-48
<b>Kahn, T et al (1996).</b> Mapping of the cortical motor hand area with functional MR Imaging and MR Imaging-guided Laser-induced interstitial thermotherapy of brain tumors. <i>Radiology</i> ,200:149-157
<b>Schwabe, B. et al. (1997).</b> Laser-Induced Thermal Lesions in the Human Brain: Short and Long-Term Appearance on MRI. <i>Jrl. Computer Assisted Tomography</i> ,21:818-825.
<b>Kahn, T. et al. (1997).</b> Preliminary Experience with the Application of Gadolinium
<b>Reimer, P et al. (1998).</b> MR-monitored LITT as a palliative concept in patients with high grade gliomas: preliminary clinical experience. <i>Jrl. Mag Reson Imaging</i> ,8:240-244.
<b>Sneed, PK et al. (1998).</b> Survival benefit of hyperthermia in a prospective randomized trial of brachtherapy boost ± hyperthermia for glioblastoma multiforme. <i>Int. J. Radiation Oncology Biol. Phys.</i> ;1998:287-295
<b>Leonardi, MA et al. (2001).</b> Sterotactic Guided Laser-Induced Interstitial Thermotherapy (SLITT) in Gliomas with Intraoperative Morphologic Monitoring in an Open MR-Unit. <i>Minim Invas Neuosurg</i> ,44:37-42.
<b>Leonardi, MA et al. (2002).</b> Sterotactic Guided Laser-Induced Interstitial Thermotherapy (SLITT) in Gliomas with Intraoperative Morphologic Monitoring in an Open MR-Unit: Clinical Experience. <i>Minim Invas Neurosurg</i> ,45:201-207.
<b>Von Templehoff, W et al. (2002).</b> LITT (Laser Induced Interstitial Thermotherapy) of Benign and Malignant Gliomas in the OPEN MR (0.5 Tesla, GE Signa SP). <i>Med Laser Appl.</i> ;17:170-178.
<b>Kato, A. et al. (2004).</b> Volumetric thermal devascularization of large meningiomas. <i>Journal Neurosurgery</i> ,2004:779-786.
<b>Mehrkens, J. et al. (2005).</b> Interstitial Photodynamic Therapy of Recurrent Malignant Gliomas Using 5-Aminolevulinic Acid (5-ALA). <i>Neuro-Oncology</i> ;Abstract #110; Abstracts from the World Federation of Neuro-Oncology Second Quadrennial Meeting and the Sixth Meeting of the European Association for Neuro-Oncology. May 5-8, 2005
<b>Schwarzmaier, HJ et al. (2005).</b> MR-Guided Laser Irradiation of Recurrent Glioblastomas. <i>Jrl. Magnetic Resonance Imaging</i> ,22:799-803.
<b>Schwarzmeier, HJ et al. (2006).</b> MR-guided laser-induced interstitial thermotherapy of recurrent glioblastoma multiforme: Preliminary results in 16 patients. <i>Eur Jrl. Radiology</i> ,59:208-215.
<b>Carpentier, A. et al. (2008).</b> Real-Time Magnetic Resonance Guided Laser Thermal Therapy for Focal Metastatic Brain Tumors. <i>Neurosurgery</i> ;63:ONS21-ONS29 [ONS Suppl 1]

**Table 2: Probe directed thermal therapy for treating head and neck tumors:** This section provides the clinical support for use of thermal therapy in other parts of the anatomy

<b>Study</b>
<b>Vogl, TJ, et al. (1995).</b> Recurrent Nasopharyngeal Tumors: Preliminary Clinical Results with Interventional MR Imaging-controlled Laser-induced Thermotherapy. <i>Radiology</i> ;196:725-733.
<b>Paiva, MB et al. (2001).</b> Palliative Laser Induced Thermal-Therapy for Recurrent Head and Neck Cancer: a Phase II Clinical Study. <i>Proc Am Soc Clin Oncol</i> ;20:abstract # 938
<b>Jäger, H. et al. (2005).</b> MR Imaging – Guided Interstitial Photodynamic Laser Therapy for Advanced Head and Neck Tumors. <i>AJNR</i> , 26:1193-1200.
<b>Paiva, MB et al. (2006).</b> Minimally invasive laser-induced thermal therapy (LITT) for head and neck cancer: A comprehensive review. <i>Jrl. Clinical Oncology</i> ,24:No 18S, abstract # 5572
<b>Bublik, M. et al. (2007).</b> Predictor Factors For Patients with Recurrent Head and Neck Cancer Treated By Laser Thermal Therapy. <i>Oral Abstract Presented at the 2007 Annual Meeting of the American Head &amp; Neck Society</i> ; Abstract #5, page 42.
<b>Goor, KM et al. (2007).</b> Corpectomy by CO <sub>2</sub> Laser or Radiotherapy for Small T1a Glottic Carcinomas: Costs, Local Control, Survival, Quality of Life, and Voice Quality. <i>Head &amp; Neck</i> ;29:128-136.
<b>Dey, P. et al. (2007).</b> Radiotherapy versus open surgery versus endolaryngeal surgery (with or without laser) for early laryngeal squamous cell cancer (Review). <i>The Cochrane Collaboration</i> ;Issue 4.

**Table 3: Probe directed thermal therapy for treating liver tumors:** This section provides the clinical support for use of thermal therapy in other parts of the anatomy

<b>Study</b>
<b>Nolsøe, CP, et al. (1993).</b> Interstitial Hyperthermia of Colorectal Liver Metastases with a US-guided Nd-YAG Laser with a Diffuser Tip: A Pilot Clinical Study. <i>Radiology</i> ;187:333-337.
<b>Vogl, TJ, et al. (1998).</b> Internally Cooled Power Laser for MRI guided Interstitial Laser-induced Thermotherapy of Liver Lesions: Initial Results. <i>Radiology</i> ,209:381-385
<b>Wacker, FK et al. (2001).</b> Laser induced Thermotherapy of Hepatic Metastases: Effect of Blood Flow Reduction on Lesion Diameter. <i>Proc. Intl. Soc. Mag, Reson. Med</i> ,9:319
<b>Pacella, CM et al. (2001).</b> Laser Thermal Ablation in the Treatment of Small Hepatocellular Carcinoma: Results in 74 Patients. <i>Radiology</i> ,221:712-720.
<b>Vogl, TJ et al. (2002).</b> Malignant Liver Tumors Treated with MR Imaging-guided Laser-induced Thermotherapy: Experience with Complications in 899 Patients (2,520 lesions). <i>Radiology</i> ,225:367-377.
<b>Vogl, TJ, et al. (2003).</b> Liver Metastases: Neoadjuvant Downsizing with Transarterial Chemoembolization before Laser-Induced Thermotherapy. <i>Radiology</i> ;229:457-464.
<b>Nikfarjam, M. et al. (2003).</b> Interstitial laser thermotherapy for liver tumours. <i>Brit. Jrl. Surgery</i> ,90:1033-1047
<b>Vogl, TJ et al. (2004).</b> Colorectal Carcinoma Metastases in Liver: Laser-induced Interstitial Thermotherapy-Local Tumor Control Rate and Survival Data. <i>Radiology</i> ,230:450-458.
<b>Sala, M. et al. (2004).</b> Initial Response to Percutaneous Ablation Predicts Survival in Patients with Hepatocellular Carcinoma (HCC). <i>Hepatology</i> ,40:1352-1360.
<b>Mack, MG, et al (2004).</b> Breast Cancer Metastases in Liver: Laser-induced Interstitial Thermotherapy-Local Tumor Control Rate and Survival Data. <i>Radiology</i> ;233:400-409



<b>Study</b>
<b>Christophi, C et al. (2004).</b> Long-term survival of patients with unresectable colorectal liver metastases treated by percutaneous interstitial laser thermotherapy. <i>World Journal Surgery</i> ;28:987-994.
<b>Vogl, TJ et al. (2005).</b> Interstitial laser therapy of liver tumors. <i>Medical Laser Applications</i> , 20:115-118; available online at: <a href="http://www.klinik.uni-frankfurt.de/zrad/Diagnostik/pub/article-interstitial-laser-therapy1.pdf">http://www.klinik.uni-frankfurt.de/zrad/Diagnostik/pub/article-interstitial-laser-therapy1.pdf</a>
<b>Mack, MG, et al. (2005).</b> Long-term results of MR-guided laser induced thermotherapy (LITT) of colorectal carcinoma metastases in the liver. <i>Jrl. Clinical Oncol.</i> ,23:abstract # 3610, No 16S (June 1 Supplement)
<b>Walser, EM. (2005).</b> Percutaneous Laser Ablation in the Treatment of Hepatocellular Carcinoma with a Tumor Size of 4 cm or Smaller: Analysis of Factors Affecting the Achievement of Tumor Necrosis. <i>JVIR</i> ;16:1427-1429.
<b>Pacella, CM et al. (2005).</b> Percutaneous Laser Ablation in the Treatment of Hepatocellular Carcinoma with Small Tumors: Analysis of Factors Affecting the Achievement of Tumor Necrosis. <i>JVIR</i> ,16:1447-1457.
<b>Arienti, V. et al. (2006).</b> Complications of percutaneous laser ablation for hepatocellular carcinoma (HCC): a multicentric study in 520 patients. <i>Giornale Italiano di Ecografia</i> ;9:30; abstract accepted as oral communication
<b>Aprile, G. et al. (2006).</b> Impact of size of the metastases on the outcome of patients with non-resectable colorectal liver metastases treated with percutaneous laser-induced thermoablation (pLIT). <i>Jr. Clinical Oncol.</i> ;24: abstract # 13556
<b>Eickmeyer, F. et al. (2006).</b> Survival of Patients with Unresectable Colorectal Liver Metastases after MR-Guided Laser-Induced Interstitial Thermotherapy in an Open 0.5 Tesla MRI Scanner. <i>Oral Abstract presented at the World Conference on Interventional Oncology 2006</i> ; accessed at: <a href="http://www.wcio2008.com/2006/Abstracts.cgi">http://www.wcio2008.com/2006/Abstracts.cgi</a>
<b>Mack MG, et al. (2007).</b> Long-term Experience after Laser Ablation of 2800 Colorectal Carcinoma Metastases in the Liver in 950 Patients. <i>Presentation at the 2007 RSNA</i> , Abstract #V121-10.
<b>Vogl, T., et al. (2008).</b> Volumetric Evaluation of Liver Metastases after Thermal Ablation: Long-Term Results Following MR-guided Laser-Induced Thermotherapy. <i>Radiology</i> ;published online before print September 23, 2008

**Table 4: Probe directed thermal therapy for treating lung tumors:** This section provides the clinical support for use of thermal therapy in other parts of the anatomy

<b>Study</b>
<b>Kato, H. et al. (1996).</b> Photodynamic therapy for early stage bronchogenic carcinoma. <i>Journal of Clin Laser Medicine &amp; Surgery</i> ;14:235-238
<b>Diaz-Jiménez, JP et al. (1999).</b> Efficacy and safety of photodynamic therapy versus Nd-YAG laser resection of NSCLC with airway obstruction. <i>Eur Respir.</i> ;14:800-805.
<b>Maziak, DE, et al. (2004).</b> Cancer Care Ontario Practice Guidelines Initiative Linger Cancer Disease Site Group. Photodynamic therapy in nonsmall cell lung cancer: a systematic review. <i>Annals Thoracic Surgery</i> ;77:1484-1491.
<b>National Institute for Health and Clinical Excellence (NICE).</b> Photodynamic therapy for localized inoperable endobronchial cancer; published: November 2005; accessed at: <a href="http://www.nice.nhs.uk/nicemedia/pdf/ip/IPG137guidance.pdf">http://www.nice.nhs.uk/nicemedia/pdf/ip/IPG137guidance.pdf</a>
<b>Weigel, C et al. (2006).</b> Laser ablation of lung metastases: results according to diameter and location. <i>Eur. Radiol.</i> 16:1769-1778.

(For the complete application requirements, please see the instructions at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage)--.

**Note:** The information provided on this tracking form will be made publicly available.

<b>Study</b>
<b>Sponza, M et al. (2006).</b> Percutaneous laser-induced thermoablation (LIT) of non-resectable lung metastases and primary lung tumors. A preliminary evaluation of technical aspects and local efficiency. <i>Jrl. Clinical Oncol</i> ;24:abstract #17106

**Table 5: Probe directed thermal therapy for treating thyroid tumors:** This section provides the clinical support for use of thermal therapy in other parts of the anatomy

<b>Study</b>
<b>Spiezia, S. et al. (2003).</b> Ultrasound-Guided Laser Thermal Ablation in the Treatment of Autonomous Hyperfunctioning Thyroid Nodules and Compressive Nontoxic Nodular Goiter. <i>Thyroid</i> ,13:941-947
<b>Pacella, C, et al. (2004).</b> Thyroid Tissue: US-guided Percutaneous Laser Thermal Ablation. <i>Radiology</i> ,232:272-280

**Table 6: Probe directed thermal therapy for treating oral & esophageal tumors:** This section provides the clinical support for use of thermal therapy in other parts of the anatomy

<b>Study</b>
<b>Dallal, HJ et al. (2001).</b> A randomized trial of thermal ablative therapy versus expandable metal stents in the palliative treatment of patients with esophageal carcinoma. <i>Gastrointestinal endoscopy</i> ;54:549-557.
<b>Paiva, MB et al. (2004).</b> Survival and Quality of Life after Palliative Laser Thermal Therapy for Recurrent Oral Squamous Cell Carcinoma. <i>Abstract presented at the 2004 Frontiers in Cancer Prevention Research</i> ; Abstract #B83, page 131

**Table 7: Probe directed thermal therapy for treating breast tumors:** This section provides the clinical support for use of thermal therapy in other parts of the anatomy

<b>Study</b>
<b>Mumtaz, H. et al. (1996).</b> Laser Therapy for Breast Cancer: MR Imaging and Histopathologic Correlation. <i>Radiology</i> ,200:651-658.
<b>Harms, S. (1998).</b> Magnetic Resonance Guided Interstitial Laser Photocoagulation for the Treatment of Breast Cancer. <i>University of Arkansas, prepared for the US Army Medical Research and Materiel Command, Grant # DAMD17-97-1-7087</i>
<b>Harms, S. et al (1999).</b> MRI Directed Interstitial Ablation of Breast Fibroadenomas, <i>Abstract presented at the 1999 International Society For Magnetic Resonance in Medicine (ISMRM)</i> ; abstract # 362; Accessed at: <a href="http://cds.ismrm.org/ismrm-1999/PDF2/362.pdf">http://cds.ismrm.org/ismrm-1999/PDF2/362.pdf</a>
<b>Ismail, MS, et al. (1999).</b> Laser Induced Thermoablation (LITT) for Retreatment of Locally Advanced Recurrences of Breast Cancer, <i>Lasers in Medical Science</i> ,14:136-142
<b>Dowlatshahi, K. et al. (2000).</b> Stereotactically Guided Laser Therapy of Occult Breast Tumors. <i>Archives Surgery</i> ,135:1345-1352.

**Table 8: Probe directed thermal therapy for treating renal tumors:** This section provides the clinical support for use of thermal therapy in other parts of the anatomy

<b>Study</b>
<b>de Jode, M. et al. (1999).</b> MR-Guided Laser Thermoablation of Inoperable Renal Tumors in an Open-Configuration Interventional MR Scanner: Preliminary Clinical Experience in Three Cases. <i>J.</i>

(For the complete application requirements, please see the instructions at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage)--.

**Note:** The information provided on this tracking form will be made publicly available.



<b>Study</b>
<i>Mag. Res. Imaging</i> ;10:545-549.
<b>Dick, EA, et al. (2002).</b> Magnetic Resonance imaging-guided laser thermal ablation of renal tumors. <i>BJU International</i> ;90:814-822.
<b>Lewin, JS, et al. (2004).</b> Phase II Clinical Trial of Interactive MR Imaging-guided Interstitial Radiofrequency Thermal Ablation of Primary Kidney Tumors: Initial Experience. <i>Radiology</i> ;232:835-845.

**Table 9: Probe directed thermal therapy for treating prostate tumors:** This section provides the clinical support for use of thermal therapy in other parts of the anatomy

<b>Study</b>
<b>Böni, R. et al. (1997).</b> Laser Ablation-induced Changes in the Prostate: Findings at Endorectal MR Imaging with Histological Correlation. <i>Radiology</i> ;202:232-236.

**Table 10: Probe directed thermal therapy for treating benign tumors:** This section provides the clinical support for use of thermal therapy in other parts of the anatomy

<b>Study</b>
<b>Gangi, A. et al. (1997).</b> Interstitial Laser Photocoagulation of Osteoid Osteomas with Use of CT Guidance. <i>Radiology</i> ;203:843-848.
<b>Gangi, A. et al. (1998).</b> Percutaneous Laser Photocoagulation of Spinal Osteoid Osteomas under CT Guidance. <i>Am. J. Neuroradiol.</i> ;19:1955-1958.
<b>Clymer, MA et al. (1998).</b> Interstitial Nd:YAG Photocoagulation for Vascular Malformations and Hemangiomas in Childhood. <i>Arch Otolaryngol Head Neck Surg.</i> ;124:431-436.
<b>Mueller-Lisse, UG, et al. (1999).</b> Coagulative Interstitial Laser-induced Thermotherapy of Benign Prostatic Hyperplasia: Online Imaging with a T2-weighted Fast Spin-Echo MR Sequence – Experience in Six Patients. <i>Radiology</i> ;210:373-379.
<b>Muschter, R. et al. (1999).</b> Interstitial Laser Therapy of Benign Prostatic Hyperplasia. <i>European Urology</i> ;35:147-154.
<b>Law, P et al. (1999).</b> Magnetic-resonance-guided percutaneous laser ablation of uterine fibroids. <i>Lancet</i> ;354:2049-2050.
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<b>Algermissen, B et al. (2001).</b> Interstitial Thermotherapy (ITT) Using Nd:YAG Laser as a New Option for the Treatment of Neuroma. <i>Med. Laser Appl.</i> ;16:129-134
<b>Døssing H. et al. (2002).</b> Benign Solitary Solid Cold Thyroid Nodules: US guided Interstitial Laser Photocoagulation – Initial Experience. <i>Radiology</i> ;225:53-57.
<b>Gangi, A. et al. (2007).</b> Osteoid Osteoma: Percutaneous Laser Ablation and Follow-Up in 114 patients. <i>Radiology</i> ;242:293-301.

**Table 11: Outcomes from other (non-LITT with guidance) diagnostic and therapeutic procedures for treating brain tumors:**

<b>Study</b>
<b>Sawaya, R. et al. (1998).</b> Neurosurgical Outcomes in a Modern Series of 400 Craniotomies for Treatment of Parenchymal Tumors. <i>Neurosurgery</i> ;42:1044-1055
<b>Hall, WA. (1998).</b> The safety and efficacy of stereotactic biopsy for intracranial lesions. <i>Cancer</i> ;82:1749-55.
<b>Jackson, RJ et al. (2001).</b> Limitations of stereotactic biopsy in the initial management of gliomas.

(For the complete application requirements, please see the instructions at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage)--.

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<b>Study</b>
<i>Neuro-Oncology</i> ,3:193-200.
<b>Paleologos, TS, et al. (2001).</b> Clinical Validation of True Frameless Stereotactic Biopsy: Analysis of the First 125 Consecutive Cases. <i>Neurosurgery</i> ,49:830-837.
<b>Chang, SM et al. (2003).</b> Perioperative complications and neurological outcomes of first and second craniotomies among patients enrolled in the Glioma Outcome Project. <i>Journal Neurosurgery</i> ,98:1175-1181.
<b>Laws, ER, et al. (2003).</b> Survival following surgery and prognostic factors for recently diagnosed malignant glioma: data from the Glioma Outcomes Project. <i>Journal Neurosurgery</i> ,99:467-473.
<b>Nimsky, C. et al. (2004).</b> Intraoperative High-Field-Strength MR Imaging: Implementation and Experience in 200 Patients. <i>Radiology</i> ,233:67-78.
<b>McGirt, MJ, et al. (2005).</b> Independent predictors of morbidity after image-guided stereotactic brain biopsy: a risk assessment of 270 cases. <i>Journal Neurosurgery</i> ,102:897-901.
<b>Murphy, M et al. (2005).</b> Maximal resection of low-grade intrinsic brain tumors using “awake” craniotomy and multiple marginal smear biopsies: operative complication rates and 10-year survival data. <i>Neurosurgery</i> ;57:409, Abstract #841
<b>Oppido, P. et al. (2006).</b> Italian Study on Neuroendoscopic biopsies: A retrospective survey. <i>Neuro-Oncology; Abstracts from the 7<sup>th</sup> Congress of the European Association for Neuro-Oncology (EANO)</i> ,Abstract #O70:314

**Table 12: Costs and cost effectiveness analyses of diagnosing & treating brain tumors; cost effectiveness of LITT & MRI vs. other treatment modalities.**

<b>Study</b>
<b>Kucharczyk, W. et al. (1997).</b> Do the Benefits of Image Guidance in Neurosurgery Justify the Costs? From Stereotaxy to Intraoperative MR. <i>AJNR</i> ;18:1855-1859
<b>Mehta, M. et al. (1997).</b> A Cost-Effectiveness and Cost-Utility Analysis of Radiosurgery vs. Resection for Single-Brain Metastases. <i>Int. J. Radiation Oncology Bio. Phys.</i> ;39:445-454
<b>Kowalik, K. et al. (2000).</b> Initial assessment of costs and benefits of MRI-guided brain tumor resection. <i>Eur. Radiol.</i> ;10:S366-367 (Suppl. 3)
<b>Paleologos, TS, et al. (2000).</b> Clinical Utility and Cost-Effectiveness of Interactive Image Guided Craniotomy: Clinical Comparison between Conventional and Image Guided Meningioma Surgery. <i>Neurosurgery</i> ,47:40-48.
<b>Kaakaji, W. et al. (2001).</b> Clinical and economic consequences of early discharge of patients following supratentorial stereotactic brain biopsy. <i>Jour. Neurosurgery</i> ,94:892-898.
<b>Hall, WA, et al. (2002).</b> Costs and Benefits of Intraoperative MR-Guided Brain Tumor Resection. <i>Acta Neurochir.</i> ;85:137-142 [suppl]
<b>Ronkainen, J. et al. (2006).</b> Cost comparison of low-field (0.23 T) MRI-guided laser ablation and surgery in the treatment of osteoid osteoma. <i>Eur. Radiol.</i> ,16:2858-2865.
<b>Kane, AD et al. (2006).</b> Image-Guided Cranial Surgery: Expensive Toy or Cost-Effective Tool? <i>Neuro-Oncology; Abstracts from the 7<sup>th</sup> Congress of the European Association for Neuro-Oncology (EANO)</i> ,Abstract #P216:366

(For the complete application requirements, please see the instructions at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage)--).

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