Clinical Policy Bulletin: Interstitial Laser Therapy

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Policy

Aetna considers interstitial laser therapy experimental and investigational for the following indications (not an all-inclusive list) because of insufficient evidence of its effectiveness.

- Adrenal metastases
- Brain tumors
- Breast tumors (i.e., benign or malignant)
- Fetal hydrops
- Fetal sacro-coccygeal teratomas
- Liver metastases
- Pancreatic cancer
- Prostate cancer
- Radionecrosis
- Thyroid nodules

See also CPB 0100 - Cryoablation; and CPB 0843 - Focal Laser Ablation for the Treatment of Prostate Cancer.
Background

Minimally invasive therapy has been investigated as a potential means of treating breast tumors with minimal disruption to adjacent soft tissues. The purpose of this approach is to facilitate improved cosmesis and to offer treatment to women who are unfit for surgery (Hall-Craggs and Vaidya, 2002).

Interstitial laser therapy (ILT) is a microinvasive technique that uses image-guided needle probes to deliver laser energy into a tumor to slowly heat and destroy the tumor cells. It has been proposed as a minimally invasive alternative to lumpectomy for fibroadenomas (benign tumors) that are 2 cm or less in size and it is also under investigation for treatment of localized breast cancers. Potential advantages of laser ablation compared to surgical excision include: shorter procedure time, outpatient setting, smaller incision and minimal scarring, less bleeding and tissue damage, lowered risk of infection due to heat sterilization of surrounding tissue and decreased healing time.

The Novilase Interstitial Laser Therapy (Novian Health, Inc., Chicago, IL) system received 510(k) marketing clearance from the U.S. Food and Drug Administration in 2007 for the treatment of breast fibroadenomas that are 2 cm or less in size. It is also used for general surgery procedures (e.g., incision, excision and ablation of soft tissues; coagulative necrosis and interstitial laser coagulation of soft tissue).

In an uncontrolled prospective study, Basu et al (1999) reported the results of the effect of interstitial laser hyperthermia in breast fibroadenomas as an out-patient procedure. Patients younger than 35 years (n = 27) received laser phototherapy of their breast fibroadenomas under real-time ultrasound monitoring. Nd:YAG laser was used in a continuous wave mode to produce interstitial hyperthermia. Follow-ups were done at 2, 4, and 8 weeks. There was a significant decrease in clinical and sonographic sizes (p < 0.001). Follow-up ultrasound showed a progressive change of hyperechoic texture, from a heterogeneous to a nearly homogeneous one. There were minimal scars (2 to 3 mm) and no keloid or abscess formation. The authors concluded that interstitial laser hyperthermia is a safe, precise, and minimally invasive outpatient procedure for in situ destruction of breast fibroadenomas, although it should be noted that excisional biopsy of residual lumps was performed.

In a non-randomized controlled trial, Dowlatshahi et al (2000) reported the results of stereotactically guided laser ablation of mammographically detected breast tumors (n = 36). Patients were treated on a stereotactic table, using a 16- to 18-gauge laser probe, with an optic fiber transmitting a pre-determined amount of laser energy. A multi-sensor thermal probe was inserted into the breast adjacent to the laser probe to monitor treatment. In the last 10 patients, the tumor blood flow was evaluated before and after laser therapy with contrast-enhanced color Doppler ultrasound. One to 8 weeks after laser therapy, the tumors were surgically removed and serially sectioned. Complete necrosis occurred in 66 % of the tumors. Microscopic examination at 1 week showed disintegration of malignant cells, with peripheral acute inflammatory response and at 4 to 8 weeks extensive fibrosis. Contrast-enhanced color Doppler ultrasound revealed loss of tumor circulation after therapy, and positron emission tomography scan correlated well with histologic findings. There were no systemic adverse effects. Two patients sustained 3 x 4-mm skin burns around the laser needle. The authors concluded that a stereotactically guided minimally invasive technique may be effective for the treatment of mammographically detected breast cancer.

Haraldsdóttir et al (2008) reported the results of ILT on invasive breast cancer patients (n = 24). All study patients underwent mammography, ultrasound and core biopsy before treatment. The tumors were classified as invasive ductal carcinoma (n = 15), lobular carcinoma (n = 8) and lobular-ductal cancer (n = 1). Average tumor diameter was 14 mm on ultrasound (range of 5 to 35). Patients were treated in the out-patient clinics under local anesthesia. Probes were placed under ultrasound guidance in 19 patients, and ILT was performed with a diode laser. Standard surgical excision was performed 12 (range of 4 to 23) days after ILT and was preceded by Doppler ultrasound. Treatment-induced necrosis of invasive cancer was 33 % (range 0 to 100) and was complete in 3 patients. At
follow-up before surgery, the extent of laser damage could not be judged with ultrasound, although abolished tumor blood flow was demonstrated after treatment resulting in large necroses. Efficacy of treatment varied negatively with tumor size. The inefficacy of ILT was mainly due to the under-estimation of tumor size by mammography and ultrasound and the shortcomings of these methods to demonstrate tumor borders, tumor irregularity and carcinoma in situ (CIS). Interstitial laser therapy was well tolerated. Five patients had breast tenderness and 3 patients had pain during the first day after treatment. Small skin necroses were observed in 2 patients. The authors concluded that small breast cancers can be treated radically with ILT and that the method may become useful in the treatment of breast cancer but needs further refinement, even for small well-defined breast cancers, if it is going to be employed for radical treatment.

No professional medical society recommends the use of ILT for breast tumors. Excisional biopsy is considered the gold standard for evaluating breast masses and it is both diagnostic and therapeutic. A completely removed mass with good margins of normal tissue may mean that further surgery is not required (Klein, 2005).

Recommendations by the Canadian Association of Radiation Oncologists (1998) on the palpable breast lump stated that whenever reasonable doubt remains as to whether a lump is benign or malignant, a biopsy to remove the entire lump in one piece along with a surrounding cuff of normal tissue for cytological examination should be carried out.

An assessment of ILT for fibroadenomas by the National Institute for Clinical Excellence (NICE, 2005) concluded that "current evidence on the safety and efficacy of interstitial laser therapy for fibroadenomas of the breast does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research." The assessment noted that adverse events include local burns at the needle site and theoretical complications include local infection, and bleeding if the needle strikes a blood vessel. Furthermore, the specialist advisors noted that the lack of material for biopsy means that the benign diagnosis cannot be confirmed.

An assessment of ILT for breast cancer by the National Institute for Clinical Excellence (NICE, 2004) concluded that "Current evidence on the safety and efficacy of interstitial laser therapy for breast cancer does not appear adequate to support the routine use of this procedure. It is suitable for use only within good-quality research studies approved by a research ethics committee and with explicit patient consent." The assessment stated that publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The assessment stated that the evidence of efficacy was limited to three small case series and one case report. The Specialist Advisors to NICE noted that it was still uncertain whether the procedure could achieve thermal ablation of all malignant tissue. They also noted that there were no data comparing outcomes of the procedure with those of wide excision and radiotherapy. A Specialist Advisor stated that the potential adverse effects of the procedure includes necrosis, hemorrhage, and liquefaction caused by overheating of tissue.

Novian Health, Inc. is currently conducting a prospective, observational multi-center study which will evaluate the clinical outcomes of Novilase for benign breast fibroadenomas versus lumpectomy. A trial on the use of Novilase for malignant breast tumors is also being planned by Novian Health, Inc.

At this time, it is not clear who might benefit from ILT for fibroadenomas (e.g., age subgroup, tumor size, etc.) or malignant breast tumors. Benign breast lumps may spontaneously resolve on their own and require no intervention. However, some researchers consider fibroadenomas a long-term risk factor for breast cancer (Dupont, et al, 1994; El-Wakeel and Umpleby, 2003). While a few researchers have reported early results with ILT of breast tumors, no controlled or comparative trials to evaluate ILT versus lumpectomy have been published. Thus, it is not known whether ILT is as effective as lumpectomy for breast tumors.

In a prospective non-randomized study, Wietzke-Braun et al (2004) examined the quality-of-life (QOL) and outcome of ultrasound-guided laser interstitial thermo-therapy (US-LITT) in patients with liver metastases of colorectal cancer. A total of 45 patients with liver metastases of colorectal cancer were
palliatively treated by US-LITT. Patient survival was analyzed by the Kaplan-Meier method and the QOL questionnaire C30 of the European Organization for Research and Treatment of Cancer before, and 1 week, 1 month, and 6 months after initiation of US-LITT. Median survival after initiation of US-LITT was 8.5 +/- 0.7 months with a range of 1.5 to 18 months. Body weight was constant 1 month after US-LITT. In the multi-variate analyses, QOL symptoms and functioning scales did not deteriorate in patients alive at 6 months after initiation of US-LITT. Uni-variate analyses outlined a significant increase of the pain subscale before and at 1 week after US-LITT. The authors concluded that this study first described the QOL in patients with liver metastases of colorectal cancer treated by US-LITT. Potential benefits of the minimal invasive procedure could be prolonged survival time by preserved QOL, but this first impression needs to be verified in a comparative study.

The Swedish Council on Health Technology Assessment's report on LITT for liver metastases (SBU, 2011) states that this method is experimental. It is unclear if LITT extends life in patients with liver metastases; comparative studies are lacking. Studies published to date show that LITT can ablate metastases, and that risks associated with the procedure are minor. However, the beneficial effects of metastases ablation, in terms of symptoms and QOL, has not been demonstrated in the literature. The SBU assessment notes that use of LITT should be limited to controlled trials.

Vogel et al (2007) evaluated the feasibility, safety and effectiveness of CT-guided and MR-thermometry-controlled LITT in adrenal metastases. A total of 9 patients (7 males, 2 females; average age of 65.0 years; range of 58.7 to 75.0 years) with 9 unilateral adrenal metastases (mean diameter 4.3 cm) from primaries comprising colorectal carcinoma (n = 5), renal cell carcinoma (n = 1), esophageal carcinoma (n = 1), carcinoid (n = 1), and hepato-cellular carcinoma (n = 1) underwent CT-guided, MR-thermometry-controlled LITT using a 0.5 T MR unit. Laser interstitial thermo-therapy was performed with an internally irrigated power laser application system with an Nd:YAG laser. A thermo-sensitive, fast low-angle shot 2D sequence was used for real-time monitoring. Follow-up studies were performed at 24 hrs and 3 months and, thereafter, at 6-month intervals (median of 14 months). All patients tolerated the procedure well under local anesthesia. No complications occurred. Average number of laser applicators per tumor: 1.9 (range of 1 to 4); mean applied laser energy 33 kj (range of 15.3 to 94.6 kJ), mean diameter of the laser-induced coagulation necrosis 4.5 cm (range of 2.5 to 7.5 cm). Complete ablation was achieved in 7 lesions, verified by MR imaging; progression was detected in 2 lesions in the follow-up. The authors concluded that these preliminary results suggested that CT-guided, MR-thermometry-controlled LITT is a safe, minimally invasive and promising procedure for treating adrenal metastases.

Schwarzmaier et al (2006) examined the survival after LITT in 16 patients suffering from recurrent glioblastoma multiforme. All patients received standard chemotherapy (temozolomide). The median OS time after the first relapse was 9.4 months, corresponding to a median OS time after laser irradiation of 6.9 months. During the study, however, the median survival after laser coagulation increased to 11.2 months. This survival time is substantially longer than those reported for the natural history (less than 5 months) or after chemotherapy (temozolomide: 5.4 to 7.1 months). These researchers concluded that cytoreduction by laser irradiation might be a promising option for patients suffering from recurrent glioblastoma multiforme. In addition, the data indicate the presence of a substantial learning curve. They stated that future work should optimize the therapeutic regimen and evaluate this treatment approach in controlled clinical trials.

Hawasli et al (2012) described the novel use of AutoLITT System (Monteris Medical, Winnipeg, MB) for focused LITT using intra-operative MRI and stereotactic image guidance for the treatment of metastatic adenocarcinoma to the left insula. The patient is a 61-year old right-handed male with a history of metastatic adenocarcinoma of the colon. He has previously undergone resection of multiple lesions, Gamma Knife and whole brain radiation. Despite treatment to a left insular tumor, serial imaging revealed that the lesion continued to enlarge. Given the refractory nature of this tumor to radiation and
the deep seated location, the patient elected to undergo LITT treatment. The center of the lesion and entry point on the scalp were identified using STEALTH (Medtronic, Memphis, TN) image-guided navigation. The AXiiS Stereotactic Miniframe (Monteris Medical, Winnipeg, MB) for the LITT system was secured onto the skull and a trajectory was defined to achieve access to the centroid of the tumor.

After performing a burr hole, a gadolinium template probe was inserted into the AXiiS base. The trajectory was confirmed via an intra-operative MRI and the LITT probe driver was attached to the base and CO2-cooled, side-firing laser LITT probe. The laser was activated and thermometry images were obtained. Two trajectories, posterior-medial and antero-lateral, produced satisfactory tumor ablation. The authors concluded that LITT using intra-operative MRI and stereotactic image guidance is a newly-available, minimally-invasive, and therapeutically viable technique for the treatment of deep seated brain tumors.

Saccomandi et al (2011) developed and verified a theoretical model to reproduce the thermal response of pancreatic tissue undergoing laser-interstitial thermal therapy (LITT). The model provided the evaluation of: (i) ablated volumes induced by thermal ablation; (ii) tissue response time to irradiation; and (iii) heat extinction time. Theoretical volume values were compared with ex-vivo healthy tissue and in-vivo healthy and neoplastic tissue volume values. The theoretical model takes into account the differences between healthy and neoplastic tissue due to blood perfusion. Mathematical model showed that ablated volume of ex-vivo healthy tissue is greater than in-vivo one after the same treatment. Moreover, ablated neoplastic in-vivo tissue volume is greater than healthy in-vivo one, because of tumor angiogenesis. Ablated volume values were compared with experimental data obtained by laser treatment of 30 ex-vivo porcine pancreases. Experimental ablated volume values show a good agreement with theoretical values, with an estimated increase of 61 % when power increases from 3 W to 6 W, versus 46 % of experimental data, and an estimated increase of 14 % from 6 W to 10 W, versus 21 % of experimental values. LITT could be an alternative or a neo-adjuvant treatment to surgical resection for pancreas cancer removal, and the proposed model could be the basis to supervising the evolution of ablated volumes during tumor treatment.

Dossing and colleagues (2011) evaluated the long-term effectiveness of interstitial laser photocoagulation (ILP) in solitary benign thyroid nodules. A total of 78 euthyroid outpatients (45 participating in randomized trials) with a benign solitary solid and scintigraphically cold thyroid nodule causing local discomfort were assigned to ILP. Interstitial laser photocoagulation (using 1 laser fiber) was performed under continuous ultrasound (US) guidance and with an output power of 1.5 to 3.5â€ŠW. Thyroid nodule volume was assessed by US and thyroid function determined by routine assays, before and during follow-up. Pressure symptoms and cosmetic complaints were evaluated on a visual analog scale (0 to 10â€Šcm). Of the 78 patients, 6 had thyroid surgery 6 months after ILP and 3 were lost to follow-up. The median follow-up for the remaining 69 patients was 67 months (range of 12 to 114). The overall median nodule volume decreased from 8.2â€Šml (range of 2.0 to 25.9) to 4.1â€Šml (range of 0.6 to 33.0; p < 0.001) at the final evaluation, corresponding to a median reduction of 51 % (range of -194 % to 95 %). This correlated with a significant decrease in pressure as well as cosmetic complaints. After 12 to 96 months (median of 38 months) of ILP, 21 patients (29 %) had thyroid surgery because of an unsatisfactory result. All had benign histology. Thyroid function was unaltered throughout and side effects were restricted to mild local pain. The authors concluded that US-guided ILP results in a satisfactory long-term clinical response in the majority of patients with a benign solitary solid cold thyroid nodule. Moreover, they stated that further large-scale studies should aim at optimizing selection criteria for ILP, preferably in randomized studies.

Rahmathulla and colleagues (2012) noted that whole-brain radiotherapy and stereotactic radiosurgery (SRS) play a central role in the treatment of metastatic brain tumors. Radiation necrosis occurs in 5 % of patients and can be very difficult to treat. The available treatment options for radiation necrosis include prolonged high-dose corticosteroids, hyperbaric oxygen, anti-coagulation, bevacizumab, and surgical resection. These investigators presented the first report and results using LITT for medically refractory radionecrosis in a 74-year old diabetic patient who had a history of non-small cell lung cancer with brain metastases and subsequent treatment with SRS, and who presented with a focal
lesion in the left centrum semiovale with progressively worsening edema. Image findings were consistent with radiation necrosis that was refractory despite prolonged, high-dose steroid therapy. His associated co-morbidities obviated alternative interventions and the lesion was not in a location amenable to surgical resection. These investigators used LITT to treat the biopsy-proven radionecrosis. The procedure was well-tolerated and the patient was discharged 48 hours postoperatively. Imaging at 7-week follow-up showed near complete resolution of the edema and associated mass effect. Additionally, the patient was completely weaned off steroids. To the authors’ knowledge, this is the first report using LITT for the treatment of focal radiation necrosis. The authors concluded that LITT may be an effective approach for patients with medically refractory radiation necrosis with lesions not amenable to surgical decompression.

Sloan et al (2013) stated that LITT has been used as an ablative treatment for glioma; however, its development was limited due to technical issues. The NeuroBlate System incorporates several technological advances to overcome these drawbacks. The authors reported a phase I, thermal dose-escalation trial assessing the safety and effectiveness of NeuroBlate in recurrent glioblastoma multiforme (rGBM). Adults with suspected supra-tentorial rGBM of 15- to 40-mm dimension and a Karnofsky Performance Status (KPS) score of greater than or equal to 60 were eligible. After confirmatory biopsy, treatment was delivered using a rigid, gas-cooled, side-firing laser probe. Treatment was monitored using real-time MRI thermometry, and proprietary software providing predictive thermal damage feedback was used by the surgeon, along with control of probe rotation and depth, to tailor tissue coagulation. An external data safety monitoring board determined if toxicity at lower levels justified dose escalation. A total of 10 patients were treated at the Cleveland Clinic and University Hospitals-Case Medical Center. Their average age was 55 years (range of 34 to 69 years) and the median pre-operative KPS score was 80 (range of 70 to 90). The mean tumor volume was 6.8 ± 5 cm³ (range of 2.6 to 19 cm³), the percentage of tumor treated was 78 % ± 12 % (range of 57 % to 90 %), and the conformality index was 1.21 ± 0.33 (range of 1.00 to 2.04). Treatment-related necrosis was evident on MRI studies at 24 and 48 hours. The median survival was 316 days (range of 62 to 767 days); 3 patients improved neurologically, 6 remained stable, and 1 worsened. Steroid-responsive treatment-related edema occurred in all patients but 1; 3 had grade-3 adverse events at the highest dose. The authors concluded that the NeuroBlate represents new technology for delivering LITT, allowing controlled thermal ablation of deep hemispheric rGBM. This was a phase I clinical trial; its findings need to be validated by well-designed studies.

A technology assessment of MRI-guided LITT by the Australian Health Policy Advisory Committee on Technology (Jacobsen, 2013) concluded that “MRT-guided LITT is an emerging therapeutic technique for patients in cases where surgical resection of an intracranial neoplasm is not possible. At present, the effectiveness of MRT-guided LITT is unknown. Consequently, the small body of evidence cannot be used to make an informed decision regarding the use of MRT-guided LITT”.

Torres-Reveron et al (2013) stated that since the inception of radiosurgery, the management of brain metastases has become a common problem for neurosurgeons. Although the use of stereotactic radiosurgery and/or whole brain radiation therapy serves to control the majority of disease burden, patients who survive longer than 6 to 8 months sometimes face the problem of symptomatic radiographically re-growing lesions with few treatment options. These researchers investigated the feasibility of use of MRI-guided stereotactic LITT as a novel treatment option for these lesions. A total of 6 patients who had previously undergone gamma knife stereotactic radiosurgery for brain metastases were included in this study. All patients had an initial favorable response to radiosurgery but subsequently developed re-growth of at least 1 lesion associated with recurrent edema and progressive neurological symptoms requiring ongoing steroids for symptom control. All lesions were evaluated for craniotomy, but were deemed unresectable due to deep location or patient's co-morbidities. Stereotactic biopsies were performed prior to the thermotherapy procedure in all cases. Laser interstitial thermo-therapy was performed using the Visualase system and follow-up MRI imaging was used to determine treatment response. In all 6 patients biopsy results were negative for
tumor and consistent with adverse radiation effects (radiation necrosis). Patients tolerated the procedure well and were discharged from the hospital within 48 hours of the procedure. In 4/6 cases there was durable improvement of neurological symptoms until death. In all cases steroids were weaned off within 2 months. One patient died from systemic causes related to his cancer 1 month after the procedure. One patient had re-growth of the lesion 3 months after the procedure and required re-initiation of steroids and standard craniotomy for surgical resection. There were no complications directly related to LITT. The authors concluded that stereotactic LITT is a feasible alternative for the treatment of symptomatic re-growing metastatic lesions after radiosurgery. The procedure carries minimal morbidity and, in this small series, showed some effectiveness in the symptomatic relief of edema and neurological symptoms paralleled by radiographic lesional control. Moreover, the authors stated that further studies are needed to elucidate the safety of this technology.

Voigt and Torchia (2014) reported on a systematic evidence review of LITT for the treatment of brain neoplasms. These investigators identified a total of 17 studies with 169 patients who received LITT. They found that most of these studies were case-series studies; 1 randomized study of LITT and brachytherapy was identified. These researchers stated that 99 patients were treated for GBM, recurrent malignant gliomas and, rGBM using LITT as a follow-on/salvage therapy. They opined that LITT used as the sole or as adjunctive therapy appeared to prolong survival when compared to historical controls receiving best/palliative care. A total of 24 patients were treated for astrocytomas (WHO I - III) and LITT was used mainly with de-novo lesions in areas of inoperability/eloquence. The authors stated that, in these tumor types, LITT appeared to be well-tolerated and significantly reduced lesion size; 23 patients were treated for metastatic disease. The authors stated that equivocal benefit was found in this small cohort study. The authors concluded that more published studies are needed, most especially in patients with metastatic disease and in less aggressive type cancers based on the small numbers of patients studied in these groups.

Mohammadi and Schroeder (2014) stated that initial results have shown the feasibility of LITT for a variety of brain pathologies; randomized controlled trials (RCTs) are currently planned to continue assessing the effectiveness of LITT for brain neoplasm and long-term follow-up data are awaited.

Fabiano and Alberico (2014) noted that stereotactic radiosurgery is often an effective tool for the treatment of brain metastases. A complication of radio-surgical treatment for brain metastasis can be persistent cerebral edema. Treatments of refractory cerebral edema include observation, corticosteroids, and surgical resection of the edema-inducing mass. Laser-interstitial thermal therapy is a minimally invasive technique for ablating intracranial lesions. It may provide a treatment option for metastases after radiosurgery causing refractory cerebral edema. These investigators reported the case of a 64-year old man with lung adenocarcinoma presenting to the authors’ department with left hemiparesis. Brain MRI showed an 18-mm enhancing lesion in the right external capsule with significant surrounding edema. The lesion was treated by radiosurgery. There was persistent edema after radiosurgery. The patient required continued corticosteroid therapy to maintain his ability to ambulate. He developed refractory hyperglycemia, weight gain, and bilateral proximal muscle weakness secondary to this therapy. Fourteen weeks after radiosurgery, he underwent LITT for lesion ablation. He was weaned off corticosteroids during 2 weeks and maintained his strength during the following month. The authors concluded that LITT may be a treatment option for refractory cerebral edema after stereotactic radiosurgery to a metastasis. This therapy may be of particular use in deep-seated lesions refractory to corticosteroid therapy. Moreover, they stated that long-term outcome data for the treatment of brain metastases with LITT is not yet available; they stated that further study is needed to determine the exact role of LITT in the treatment of patients with brain metastases.

Rao et al (2014) stated that enhancing lesions that progress after stereotactic radiosurgery are often tumor recurrence or radiation necrosis. Magnetic resonance-guided LITT is currently being explored
for minimally invasive treatment of intracranial neoplasms. These researchers reported the largest series to-date of local control with LITT for the treatment of recurrent enhancing lesions after stereotactic radiosurgery for brain metastases. Patients with recurrent metastatic intracranial tumors or radiation necrosis who had previously undergone radiosurgery and had a KPS of greater than 70 were eligible for LITT. A total of 16 patients underwent a total of 17 procedures. The primary end-point was local control using MRI scans at intervals of greater than 4 weeks. Radiographic outcomes were followed-up prospectively until death or local recurrence (defined as greater than 25 % increase in volume compared with the 24-hour post-procedural scan). A total of 15 patients (age of 46 to 82 years) were available for follow-up. Primary tumor histology was non-small-cell lung cancer (n = 12) and adenocarcinoma (n = 3). On average, the lesion size measured 3.66 cm (range of 0.46 to 25.45 cm); there were 3.3 ablations per treatment (range of 2 to 6), with 7.73-cm depth to target (range of 5.5 to 14.1 cm), ablation dose of 9.85 W (range of 8.2 to 12.0 W), and total ablation time of 7.43 minutes (range of 2 to 15 minutes). At a median follow-up of 24 weeks (range of 4 to 84 weeks), local control was 75.8 % (13 of 15 lesions), median progression-free survival was 37 weeks, and overall survival was 57 % (8 of 14 patients). Two patients experience recurrence at 6 and 18 weeks after the procedure. Five patients died of extracranial disease progression; 1 patient died of neurological progression elsewhere in the brain. The authors concluded that MRI-guided LITT is a well-tolerated procedure and may be effective in treating tumor recurrence/radiation necrosis. This was a small, single-arm, non-randomized study. Moreover, the authors stated that "larger studies with longer follow-up that include patient quality of life, decreased steroid dependence and neurological symptoms as end-points are necessary to confirm these findings and better define the appropriate patient for this therapy".

Baud and associates (2013) reported 3 different antenatal therapeutic approaches for fetal lung masses associated with hydrops. Three prospectively followed cases were described, and all 30 previously published minimally invasive cases of fetal therapy for hydropic lung masses were reviewed. Three hydropic fetuses with large intra-thoracic lung masses were presented at 17, 25 and 21 weeks of gestation, respectively. An aortic feeding vessel was identified in each case and thus a broncho-pulmonary sequestration (BPS) was suspected. Under ultrasound guidance, the feeding vessel was successfully occluded with interstitial laser (case 1), radio-frequency ablation (RFA) (case 2) and thrombogenic coil embolization (case 3). Complete (cases 1 and 2) or partial (case 3) resolution of the lung mass and hydrops was observed. A healthy infant was born at term after laser therapy (case 1), and the involved lung lobe was resected on day 2 of postnatal life. In case 2, hydrops resolved completely following RFA, but an iatrogenic congenital diaphragmatic hernia and abdominal wall defect became apparent 4 weeks later. The neonate died from sepsis following spontaneous preterm labor at 33 weeks. In case 3, despite technical success in complete vascular occlusion with coils, a stillbirth ensued 2 days after embolization. The authors concluded that the prognosis of large microcystic or echogenic fetal chest masses associated with hydrops is dismal. This has prompted attempts at treatment by open fetal surgery, with mixed results, high risk of premature labor and consequences for future pregnancies. These researchers had demonstrated the possibility of improved outcome following ultrasound-guided laser ablation of the systemic arterial supply. Moreover, they noted that despite technical success, RFA and coil embolization led to procedure-related complications and need further evaluation.

Miegem et al (2014) stated that large solid sacro-coccygeal teratomas (SCT) can cause high output cardiac failure and fetal or neonatal death. These investigators described the outcomes of minimally invasive antenatal procedures for the treatment of fetal SCT. A total of 5 fetuses with large SCT’s treated antenatally using minimally invasive techniques were included in this analysis; and systematic literature on fetal therapy for solid SCTs was reviewed. Five women were referred between 17.7 to 26.6 weeks gestation for large fetal SCTs with evidence of fetal cardiac failure. Vascular flow to the tumors was interrupted by fetoscopic laser ablation (n = 1), RFA (n = 2) and interstitial laser ablation +/-
vascular coiling (n = 2). There were 2 intra-uterine fetal deaths. The other 3 cases resulted in preterm labor within 10 days of surgery. One neonate died; 2 survived without procedure related complications; but had long-term morbidity related to prematurity. Systematic literature review revealed 15 SCTs treated minimally invasively for (early) hydrops. Including these researchers' subjects, 6 of 20 hydropic fetuses survived after minimally invasive therapy (30%). Survival after RFA or interstitial laser was 45% (n = 5/11). Of 12 fetuses treated for SCT without obvious hydrops, 67% (n = 8/12) survived. Mean gestational age at delivery after minimally invasive therapy was 29.7 ± 4.0 weeks. Survival after open fetal surgery in hydropic fetuses was 55% (n = 6/11) with a mean gestational age at delivery of 29.8 ± 2.9 weeks. The authors concluded that fetal therapy can potentially improve perinatal outcomes for hydropic fetuses with solid SCTs but is often complicated by intra-uterine death and preterm birth.

Furthermore, an UpToDate review on “Nonimmune hydrops fetalis” (Lockwood and Julien, 2014) does not mention the use of interstitial laser therapy as a therapeutic option.

In summary, ILT may be a promising minimally invasive technique for breast tumors and other tumors/malignancies, however, there is insufficient evidence of its clinical effectiveness.

CPT Codes / HCPCS Codes / ICD-9 Codes

There is no specific code for Interstitial Laser Therapy (ILT) for Breast Tumors:

Other CPT codes related to the CPB:

17260 - 17266

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

157.0 - 157.9 Malignant neoplasm of pancreas
174.0 - 174.9 Malignant neoplasm of female breast
175.0 - 175.9 Malignant neoplasm of male breast
185 Malignant neoplasm of prostate
191.0 - 191.9 Malignant neoplasm of brain
197.7 Secondary malignant neoplasm of liver
198.7 Secondary malignant neoplasm of adrenal gland
217 Benign neoplasm of breast
241.0 - 241.9 Nontoxic nodular goiter
990 Effects of radiation, unspecified [Radionecrosis]

The above policy is based on the following references:


http://qawww.aetna.com/cpb/medical/data/700_799/0781_draft.html

11/26/2014


33. Lockwood CJ, Julien S. Nonimmune hydrops fetalis. UpToDate [serial online]. Waltham, MA: UpToDate; reviewed June 2014.