Aetna considers MRI-guided focal laser ablation (e.g., the Visualase Laser Ablation System) for the treatment (primary or salvage therapy) of prostate cancer experimental and investigational because its effectiveness has not been established.

Aetna considers magnetic resonance imaging-guided transurethral ultrasound ablation for the treatment of prostate cancer experimental and investigational because its effectiveness has not been established.

See also CPB 0766 - High Intensity Focused Ultrasound.

Background

Magnetic Resonance Imaging-Guided Focal Laser Ablation:

Prostate cancer (PCa), accounting for 33% of all male cancers, is the second leading cause of cancer death in men, exceeded only by lung cancer. The disease is histologically evident in as many as 34% of men during their fifth decade of life and in up to 70% of men aged 80 years and older. The American Urological Association (AUA)'s Prostate Cancer Clinical Guideline Update Panel (Thompson et al, 2007) stated that standard options for the management of clinically localized PCa include watchful waiting and active surveillance, interstitial prostate brachytherapy, external beam radiotherapy (EBRT), radical prostatectomy, as well as primary hormonal therapy (including androgen deprivation therapy, e.g., bicalutamide). Other treatment modalities entailed cryotherapy, high-intensity focused ultrasound (HIFU), and combinations of treatments (e.g., EBRT and interstitial prostate bracytherapy). While watchful waiting and active surveillance, radiation therapy, and radical prostatectomy remain the current standard for the treatment of PCa, laser-induced thermal therapy (LITT) has recently been explored as a means of treatment of PCa.

Stafford et al (2010) stated that image-guided ablation of tumors is assuming an increasingly important role in many oncology services as a minimally invasive alternative to conventional surgical interventions for patients who are not good candidates for surgery. Laser-induced thermal therapy is a percutaneous tumor-ablation technique that utilizes high-power lasers placed interstitially in the tumor to deliver therapy. Multiple laser fibers can be placed into the treatment volume and, unlike other interstitial heating techniques, can be fired simultaneously to rapidly treat large volumes of tissue. Modern systems utilize small, compact, high-power laser diode systems with actively cooled applicators to help keep tissue from charring during procedures. Additionally, because this approach
to thermal therapy is easily made magnetic resonance compatible, the incorporation of magnetic resonance imaging (MRI) for treatment planning, targeting, monitoring, and verification has helped to expand the number of applications in which LITT can be applied safely and effectively. These investigators provided an overview of the clinically used technology and algorithms that provide the foundations for current state-of-the-art MR-guided LITT (MRgLITT), including procedures in the bone, brain, liver, and prostate as examples. In addition to advances in imaging and delivery, such as the incorporation of nanotechnology, next-generation MRgLITT systems are anticipated to incorporate an increasing presence of in silico-based modeling of MRgLITT procedures to provide human-assisted computational tools for planning, MR model-assisted temperature monitoring, thermal-dose assessment, and optimal control.

The Visualase Laser Ablation System (Visualase Inc., Houston, TX) is a minimally invasive laser ablation system for the treatment of epilepsy as well as the destruction of tumors (e.g., bone including spinal metastases, brain, kidney, liver and prostate). It consists of a fiber optic laser; its placement is guided by a surgical navigation system, and confirmed by MRI before treatment. It is designed to destroy tumor and limit injury to surrounding structures. For PCa, the Visualase Laser Ablation System is being studied for the treatment of organ-confined disease (Gleason score of 6 or 7 or below).

In a phase I clinical study, Lindner et al (2009) examined the feasibility and safety of image-guided targeted photothermal focal therapy for localized PCa. A total of 12 patients with biopsy proven low-risk PCa underwent interstitial photothermal ablation of the cancer. The area of interest was confirmed and targeted using MRI. Three-dimensional ultrasound was used to guide a laser to the magnetic resonance to ultrasound fused area of interest. Follow-up was performed with a combination of MRI and prostate biopsy. Validated quality-of-life (QOL) questionnaires were used to assess the effect on voiding symptoms and erectile function, and adverse events were recorded. Interstitial photothermal focal therapy was technically feasible to perform. Of the patients studied, 75% were discharged home free from catheter the same day with the remainder discharged home the following day. The treatment created an identifiable hypo-vascular defect that coincided with the targeted prostatic lesion. There were no peri-operative complications and minimal morbidity. All patients who were potent before the procedure maintained potency after the procedure. Continence levels were not compromised. Based on multi-core total prostate biopsy at 6 months, 67% of patients were free of tumor in the targeted area and 50% were free of disease. The authors concluded that image-guided focal photothermal ablation of low-risk and low-volume PCa is feasible. Early clinical, histological and MRI responses suggested that the targeted region can be ablated with minimal adverse effects. It may represent an alternate treatment approach to observation or delayed standard therapy in carefully selected patients. Moreover, they stated that further trials are needed to demonstrate the effectiveness of this treatment concept.

Raz et al (2010) reported the findings of 2 patients with low-risk PCa who were treated with outpatient in-bore MRI-guided focal laser ablation (FLA). The tumor was identified on MRI. A laser fiber was delivered via a catheter inserted through a perineal template and guided to the target with MRI. The tissue temperature was monitored during laser ablation by MRI thermometry. Accumulated thermal damage was calculated in real time. Immediate post-treatment contrast-enhanced MRI confirmed de-vascularization of the target. No adverse events were noted. The authors stated that MRI-guided FLA of low-risk PCa is feasible and may offer a good balance between cancer control and side effects; refinement of this outpatient procedure may result in an inexpensive, minimally invasive alternative to current active therapies. Moreover, they noted that further trials will be necessary to define the safety and oncologic efficacy of this therapy, but these early findings are promising.

Eggener et al (2010) reviewed the rationale, patient selection criteria, diagnostic imaging, biopsy schemes, and treatment modalities available for the focal therapy of localized PCa. A National Center for Biotechnology Information PubMed search was performed from 1995 to 2009 using medical subject headings "focal therapy" or "ablative" and "prostate cancer". Additional articles were extracted based on recommendations from an expert panel of authors. Focal therapy of the prostate in patients with low-risk cancer characteristics is a proposed treatment approach in development that aims to eradicate
all known foci of cancer while minimizing damage to adjacent structures necessary for the preservation of urinary, sexual, and bowel function. Conceptually, focal therapy has the potential to minimize treatment-related toxicity without compromising cancer-specific outcome. Limitations include the inability to stage or grade the cancer(s) accurately, suboptimal imaging capabilities, uncertainty regarding the natural history of untreated cancer foci, challenges with post-treatment monitoring, and the lack of QOL data compared with alternative treatment strategies. Early clinical experiences with modest follow-up evaluating a variety of modalities are encouraging but hampered by study design limitations and small sample sizes. The authors concluded that prostate focal therapy is a promising and emerging treatment strategy for men with a low-risk of cancer progression or metastasis. They stated that evaluation in formal prospective clinical trials is essential before this new strategy is accepted in clinical practice. Adequate trials must include appropriate end points, whether absence of cancer on biopsy or reduction in progression of cancer, along with assessments of safety and longitudinal alterations in QOL.

Nguyen and Jones (2011) evaluated the rationale, effectiveness, and morbidity of various methods of achieving focal prostatic ablation. These investigators performed a literature review of focal therapy in prostate cancer with an emphasis on more established methods (e.g., cryotherapy and HIFU). The authors concluded that focal ablative methods allow targeted destruction of prostatic tissue while limiting the morbidity associated with whole-gland therapy. Local cancer control after focal therapy appears promising but does not approach that of established whole-gland therapies. Until it is feasible to identify patients reliably with truly focal disease and predict their natural history, focal therapy cannot be considered to be the definitive therapy for localized PCa.

Colin et al (2012) noted that current challenges and innovations in PCa management concern the development of focal therapies that allow the treatment of only the cancer areas sparing the rest of the gland to minimize the potential morbidity. Among these techniques, FLA appears as a potential candidate to reach the goal of focusing energy delivery on the identified targets. These investigators performed an up-to-date review of this new therapeutic modality. Relevant literature was identified using Medline database with no language restrictions (entries: focal therapy, laser interstitial thermoderapy, prostate cancer, FLA) and by cross-referencing from previously identified studies. Precision, real-time monitoring, MRI compatibility, and low-cost of integrated system were principal advantages of FLA. Feasibility and safety of this technique have been reported in phase I studies. Focal laser ablation might eventually prove to be a middle ground between active surveillance and radical treatment. The authors concluded that FLA may have found a role in the management of PCa. However, they stated that further trials are needed to demonstrate the oncologic effectiveness in the long-term.

Bozzini et al (2013) reviewed the literature to concentrate on the practical aspects of focal therapy for PCa with the following key words: photodynamic therapy (PDT), high-intensity focused ultrasound, cryotherapy, focal laser ablation, electroporation, radiofrequency, external beam radiation, organ-sparing approach, focal therapy, prostate cancer, and then by cross-referencing from previously identified studies. Prostatic tumor ablation can be achieved with different energies: freezing effect for cryotherapy, thermal effect using focalized ultrasound for HIFU, and using thermal effect of light for FLA and activation of a photo-sensitizer by light for PDT, among others. Radiofrequency and microwave therapy have been tested in this field and demonstrated their usefulness. Electroporation is currently being developed on pre-clinical models. External beam radiation with microboost on neoplastic foci is under evaluation. High-intensity focused ultrasound and cryotherapy require the use of sophisticated and expensive machines and, consequently, the procedure is expensive. Laser techniques seem to be less onerous, with the added advantage of size. The authors concluded that several energy modalities are being developed to achieve the trifecta of continence, potency, and oncologic efficiency. Those techniques come with low-morbidity but clinical experience is limited regarding to oncologic outcome. Comparison of the different focal approaches is complex owing to important heterogeneity of the trials. In the future, it seems likely that each technique will have its own selective indications.
In a review on "Focal therapy in the management of prostate cancer", Nomura and Mimata (2012) noted that a widespread screening with prostate-specific antigen has led increased diagnosis of localized PCa along with a reduction in the proportion of advanced-stage disease at diagnosis. Over the past decade, interest in focal therapy as a less morbid option for the treatment of localized low-risk PCa has recently been renewed due to downward stage migration. Focal therapy stands midway between active surveillance and radical treatments, combining minimal morbidity with cancer control. Several techniques of focal therapy have potential for isolated ablation of a tumor focus with sparing of uninvolved surround tissue demonstrating excellent short-term cancer control and a favorable patient's QOL. However, to date, tissue ablation has mostly used for near-whole prostate gland ablation without taking advantage of accompanying the technological capabilities. The available ablative technologies include cryotherapy, HIFU, and vascular-targeted photodynamic therapy. Despite the interest in focal therapy, this technology has not yet been a well-established procedure nor provided sufficient data, because of the lack of randomized trial comparing the efficacy and morbidity of the standard treatment options. Interestingly, FLA is not mentioned as an emerging approach for the treatment of localized PCa.

An UpToDate review on “Initial approach to low-risk clinically localized prostate cancer” (Klein, 2012) states that “The role of ablation with cryotherapy or HIFU as an alternative to radical prostatectomy or RT [radiation therapy] remains uncertain. Potential advantages in men with localized disease include the ability to destroy cancer cells using a relatively noninvasive procedure. As such, these procedures are associated with minimal blood loss and pain. There is also a more rapid post-treatment convalescence. Whether the long-term outcomes are equivalent to those with definitive surgery or RT is uncertain however. Additional experience and longer follow-up are required to compare the rate of disease control and side effects profiles with other treatment modalities”. This review and another UpToDate review entitled “Cryotherapy and other ablative techniques for the initial treatment of prostate cancer” (Pisters and Spiess, 2012) do not mention the use of FLA.

The National Comprehensive Cancer Network’s clinical practice guideline on "Prostate cancer" (Version 1.2013) does not mention the use of focal laser ablation as a therapeutic option. Furthermore, there is a National Cancer Institute-sponsored phase II clinical trial on “MR Image Guided Therapy in Prostate Cancer” that is ongoing, but not recruiting participants (last verified: July 28, 2017). Its objective is to examine the safety and effectiveness of treating PCa with laser therapy guided by MRI.

Wenger et al (2014) stated that focal laser ablation (FLA) is an emerging treatment paradigm for prostate cancer that aims to successfully eradicate disease while also reducing the risk of side-effects compared with whole-gland therapies. Pre-clinical and phase I clinical trials for low-risk prostate cancer have shown that FLA produces accurate, predictable, and reproducible ablation zones with negligible injury to the surrounding tissues. Because FLA is magnetic resonance compatible, the procedure can be monitored with real-time feedback to optimize targeted treatment of cancerous foci and minimize quality-of-life side-effects. The authors concluded that FLA is a well-tolerated and feasible therapy for low-risk prostate cancer, and the oncologic effectiveness of this treatment modality is currently under investigation in phase II clinical trials at several institutions.

A review by Sankineni et al (2014) summarized the evidence for MRI-guided focused laser ablation for prostate cancer. The article indicated that the feasibility has been demonstrated in a canine model and a cadaveric model (citing Stafford et al, 2010; Woodrum et al, 2010), followed by case reports (citing Raz et al, 2010) and 2 phase I studies, citing a study by Oto et al, 2013 and an abstract by Lindner et al, 2013. The author stated that the most concerning finding of the latter phase I study by Linder et al (2013) was that 26 % of the MRI-guided FLA treated patients showed a positive biopsy at the 4-month follow-up in a site other than the ablated region. Sankineni et al (2014) concluded that “While these results are pointing in the right direction, it is important that larger, long term trials validate these findings”.

There is currently a clinical trial studying laser interstitial thermal therapy (LITT) for the treatment of
PCa. The laser system that will be used is called the Visualase Thermal Therapy System. This system has been used for the treatment of brain, bone (spine), thyroid, and liver cancers. However, this is the first time this system is being studied for use in the treatment of PCa with a trans-rectal approach. This study is currently recruiting participants (last verified September 2016).

Furthermore, there is also a phase II clinical trial to study LITT (using Visualase) in the focal treatment of localized PCa. This study is ongoing, but not recruiting participants (last verified September 2016).

Lepor et al (2015) reported that from April 2013 to July 2014, a total of 25 consecutive men participated in a longitudinal outcomes study following in-bore MRgFLA of PCa. Eligibility criteria were clinical stage T1c and T2a disease; prostate-specific antigen (PSA) less than 10 ng/ml; Gleason score less than 8; and cancer-suspicious regions (CSRs) on multi-parametric MRI harboring PCa. CSRs harboring PCa were ablated using a Visualase cooled laser applicator system. Tissue temperature was monitored throughout the ablation cycle by proton resonance frequency shift magnetic resonance thermometry from phase-sensitive images. There were no significant differences between baseline and 3-month mean American Urological Association Symptom Score or Sexual Health Inventory in Men scores. No man required pads at any time. Overall, the mean reduction in PSA between baseline and 3 months was 2.3 ng/ml (44.2 %). Of 28 sites subjected to target biopsy after FLA, 26 (96 %) showed no evidence of PCa. The authors stated that the findings of this study provided encouraging evidence that excellent early oncologic control of significant PCa can be achieved following FLA, with virtually no complications or adverse impact on quality of life. Moreover, they stated that longer follow-up is needed to show that oncologic control is durable. These researchers stated that early results for focal laser ablation of PCa are very encouraging; however, until long-term oncologic control is confirmed, focal laser ablation must be considered an investigational treatment option.

In a phase I clinical trial, Natarajan and colleagues (2016) examined the safety of trans-rectal MRI-guided (in-bore) FLA in men with intermediate risk PCa. An exploratory end-point is cancer control after 6 months. These researchers studied FLA in 8 men with intermediate risk PCa diagnosed using magnetic resonance-ultrasound fusion. Focal laser ablation was performed by inserting a cylindrically diffusing, water cooled laser fiber into magnetic resonance visible regions of interest, followed by interstitial heating at 10 to 15 W for up to 3 minutes. Secondary safety monitors (thermal probes) were inserted to assess the accuracy of magnetic resonance thermometry. Comprehensive magnetic resonance-ultrasound fusion biopsy was performed after 6 months. Adverse events and health related QOL questionnaires were recorded. Focal laser ablation was successfully performed in all 8 subjects. No grade 3 or greater adverse events occurred and no changes in International Prostate Symptom Score (IPSS) or 5-item version of the International Index of Erectile Function (IIEF-5) were observed. Ablation zones, as measured by post-treatment MRI, had a median volume of 3 cc or 7.7 % of prostate volume; PSA decreased in 7 men (p < 0.01). At follow-up magnetic resonance-ultrasound fusion biopsy cancer was not detected in the ablation zone in 5 men; but was present outside the treatment margin in 6 men. The authors concluded that FLA of the prostate is feasible and safe in men with intermediate risk PCa without serious adverse events or changes in urinary or sexual function at 6 months. They stated that comprehensive biopsy follow-up indicated that larger treatment margins than previously thought necessary may be needed for complete tumor ablation.

In a phase I study, Bomers and associates (2016) correlated treatment effects of MRI-guided FLA in patients with PCa with imaging using prostatectomy as standard of reference. Three weeks before prostatectomy, 5 patients with histopathologically proven, low/intermediate grade PCa underwent trans-rectal MRI-guided FLA. Per patient, only 1 ablation was performed to investigate the effect of ablation on the tissue rather than the effectiveness of ablation. Ablation was continuously monitored with real-time MR temperature mapping, and damage-estimation maps were computed. A post-ablation high-resolution T1-weighted contrast-enhanced sequence was acquired. Ablation volumes were contoured and measured on histopathology specimens (with a shrinkage factor of 1.15), T1-weighted contrast-enhanced images, and damage-estimation maps, and were compared. A significant volume correlation was seen between the ablation zone on T1-weighted contrast-enhanced images and the whole-mount histopathology section (r = 0.94, p = 0.018). The damage-estimation maps and
histopathology specimen showed a correlation of $r = 0.33$ ($p = 0.583$). On histopathology, the homogeneous necrotic area was surrounded by a reactive transition zone (1 to 5 mm) zone, showing neo-vascularization, and an increased mitotic index, indicating increased tumor activity. The authors concluded that the actual ablation zone was better indicated by T1-weighted contrast-enhanced than by damage-estimation maps. Histopathology results highlighted the importance of complete tumor ablation with a safety margin.

Eggener and co-workers (2016) stated that MRI-guided FLA is an investigational strategy for treatment of PCa. These researchers carried out a phase II evaluation of FLA that included men with stage T1c to T2a, PSA less than 15 ng/ml or PSA density less than 0.15 ng/ml3, Gleason less than or equal to 7 in less than or equal to 25 % of biopsies, and MRI with 1 to 2 lesions concordant with biopsy-detected cancer. At 3 months, all had MRI with biopsy of ablation zone(s). At 12 months, all underwent MRI and systematic biopsy. International Prostate Symptom Score (IPSS) and Sexual Health Inventory for Men (SHIM) scores were collected before FLA and at 1, 3 and 12 months. Primary end-point was no cancer on 3-month biopsy of ablation zone; secondary end-points were safety, 12-month biopsy, and urinary/sexual function. Among 27 men, median age was 62 and mean PSA was 4.4 ng/ml. Biopsy Gleason was 6 in 23 (85 %) and Gleason 7 in 4 (15 %); 7 (26 %) had low-volume Gleason 6 outside the intended ablation zone(s). At 3 months, 26 (96 %) had no evidence of cancer on MRI-guided biopsy of the ablation zone. No significant IPSS changes were observed (all $p > 0.05$); SHIM was lower at 1 month ($p = 0.03$), marginally lower at 3 months ($p = 0.05$), and without significant difference at 12 months ($p = 0.38$). At 12-month biopsy, 10 (37 %) had cancer identified, 3 (11 %) within the ablation zone(s) and 8 (30 %) outside the ablation zone(s) (1 had cancer within and outside the ablation zone). The authors concluded that for select men with localized PCa and visible MR lesions, FLA has an acceptable morbidity profile and is associated with encouraging short-term oncologic outcomes. They stated that significantly longer follow-up is mandatory to fully evaluate this novel treatment.

Mathew and Oto (2017) noted that with the advent of focal therapy as a recognized treatment option for men with PCa, there are a host of emerging interventions that take advantage of MRI for image guidance. Focal therapy affords a middle-ground option for patients with low- to intermediate-grade PCa by providing a means of keeping their cancer at bay while avoiding the negative consequences of radical therapies. However, the practice of focal treatment is far from straightforward, with some believing focal treatment errs on the side of over-treatment among patients with low-grade cancer; others worry it is under-treatment in potentially significant multi-focal disease. The authors concluded that further research is needed, both relating to focal therapy in general and to the utility of each MRI-guided focal treatment discussed.

Ouzzane and colleagues (2017) stated that focal therapy may offer a promising therapeutic option in the field of low-to-intermediate risk localized PCa. The aim of this concept is to combine minimal morbidity with cancer control as well as maintain the possibility of re-treatment. Recent advances in MRI and targeted biopsy has improved the diagnostic pathway of PCa and increased the interest in focal therapy. However, before implementation of focal therapy in routine clinical practice, several challenges still needed to be overcome including patient selection, treatment planning, post-therapy monitoring and definition of oncologic outcome surrogates.

Tay and associates (2017) stated that prostate focal therapy offers men the opportunity to achieve oncological control while preserving sexual and urinary function. The prerequisites for successful focal therapy are to accurately identify, localize and completely ablate the clinically significant cancer(s) within the prostate. These investigators evaluated the evidence for current and upcoming technologies that could shape the future of PCa focal therapy in the next 5 years. They summarized current literature on advances in patient selection using imaging, biopsy and biomarkers, ablation techniques and adjuvant treatments for focal therapy. A literature search of major databases was performed using the search terms “focal therapy”, “focal ablation”, “partial ablation”, “targeted ablation”, “image guided therapy” and “prostate cancer”. Advanced radiological tools such as multi-parametric MRI (mpMRI),
multi-parametric US (mpUS), prostate-specific-membrane-antigen positron emission tomography (PSMA-PET) represent a revolution in the ability to understand cancer function and biology. The authors concluded that advances in ablative technologies now provide a menu of modalities that can be rationalized based on lesion location, size and perhaps in the near future, pre-determined resistance to therapy; however, these need to be carefully studied to establish their safety and effectiveness parameters; adjuvant strategies to enhance focal ablation are under development.

In summary, there is currently insufficient evidence to support the use of focal laser ablation for the treatment of prostate cancer. The oncologic efficacy of MRI-guided FLA is currently being evaluated in ongoing phase II clinical trials (Wenger et al, 2014).

**Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation:**

Ghai and associates (2015) reported the 6-month follow-up oncologic and functional data of the initial phase 1 clinical trial of patients treated with focal trans-rectal MRI-guided focused ultrasound. A total of 4 patients with a PSA level of 10 ng/ml or less, tumor classification cT2a or less, and a Gleason score of 6 (3 + 3) were prospectively enrolled in the study and underwent multi-parametric MRI and trans-rectal ultrasound (US)-guided prostate systematic biopsy. Under MRI guidance and real-time monitoring with MR thermography, focused high-frequency US energy was delivered to ablate the target tissue. The incidence and severity of treatment-related adverse events were recorded along with responses to serial QOL questionnaires for 6 months after treatment. Oncologic outcomes were evaluated with multi-parametric MRI and repeat trans-rectal US-guided biopsy 6 months after treatment. Four patients with a total of 6 target lesions were treated and had complications graded Clavien-Dindo I or less; QOL parameters were similar between baseline and 6-months. All 4 patients had normal MRI findings in the treated regions (100 %), biopsy showed that 3 patients (75 %) were clear of disease in the treated regions, representing complete ablation of 5 target lesions (83 %). All patients had at least 1 Gleason 6-positive core outside of the treated zone. The authors concluded that MRI-guided focused US is a feasible method of non-invasively ablating low-risk PCa with low morbidity. They stated that further investigation and follow-up are needed in a larger patient series with appropriate statistical analysis of oncologic and functional outcome measures.

In a prospective, single-arm, phase I clinical trial, Chin and colleagues (2016) determined the clinical safety and feasibility of magnetic resonance imaging-guided transurethral ultrasound ablation (MRI-TULSA) for whole-gland prostate ablation in a primary treatment setting of localized PCa. A total of 30 patients (median age of 69 years; interquartile range [IQR]: 67 to 71 years) with biopsy-proven low-risk (80 %) and intermediate-risk (20 %) PCa were treated and followed for 12 months. Magnetic resonance imaging-TULSA treatment was delivered with the therapeutic intent of conservative whole-gland ablation including 3-mm safety margins and 10 % residual viable prostate expected around the capsule. Primary end-points were safety (adverse events) and feasibility (technical accuracy and precision of conformal thermal ablation). Exploratory outcomes included QOL, PSA, and biopsy at 12 months. Median treatment time was 36 minutes (IQR: 26 to 44) and prostate volume was 44 ml (IQR: 38 to 48). Spatial control of thermal ablation was ±1.3 mm on MRI thermometry. Common Terminology Criteria for Adverse Events included hematuria (43 % grade [G] 1; 6.7 % G2), urinary tract infections (33 % G2), acute urinary retention (10 % G1; 17 % G2), and epididymitis (3.3 % G3). There were no rectal injuries. Median pre-treatment IPSS 8 (IQR: 5 to 13) returned to 6 (IQR: 4 to 10) at 3 months (mean change: -2; 95 % confidence interval [CI]: -4 to 1). Median pre-treatment IIEF 13 (IQR: 6 to 28) recovered to 13 (IQR: 5 to 25) at 12 months (mean change: -1; 95 % CI: -5 to 3). Median PSA decreased 87 % at 1 month and was stable at 0.8 ng/ml (IQR: 0.6 to 1.1) to 12 months. Positive biopsies showed 61 % reduction in total cancer length, clinically significant disease in 9 of 29 patients (31 %; 95 % CI: 15 to 51), and any disease in 16 of 29 patients (55 %; 95 % CI: 36 to 74). The authors concluded that MRI-TULSA was feasible, safe, and technically precise for whole-gland prostate ablation in patients with localized PCa. They stated that these findings from a phase I study are sufficiently compelling to study MRI-TULSA further in a larger prospective trial with reduced safety margins.
In a pilot study, Ramsay and colleagues (2017) evaluated MRI-TULSA as a treatment for MRI-defined focal PCAs using subsequent prostatectomy and histology as the reference standard. A total of 5 men completed this study, which was approved by the institutional review board. Prior to radical prostatectomy focal tumors identified by MRI were treated by coagulating targeted subtotal 3-D volumes of prostate tissue using MRI-TULSA. Treatment was performed with a 3 Tesla clinical MRI unit combined with modified clinical planning software for high intensity focused ultrasound therapy.

After prostatectomy, whole mount histological sections parallel to the MRI treatment planes were used to compare MRI measurements with thermal damage at the cellular level and, thus, evaluating treatment and target accuracy; 3-D target volumes of 4 to 20 cc and with radii up to 35 mm from the urethra were treated successfully. Mean ± SD temperature control accuracy at the target boundary was -1.6 ± 4.8 C and the mean spatial targeting accuracy achieved was -1.5 ± 2.8 mm. Mean treatment accuracy with respect to histology was -0.4 ± 1.7 mm with all index tumors falling inside the histological outer limit of thermal injury. The authors concluded that MRI-TULSA was capable of generating thermal coagulation and tumor destruction in targeted 3-D angular sectors out to the prostate capsule for prostate glands up to 70 cc in volume; US parameters needed to achieve ablation at the prostate capsule were determined, providing a foundation for future studies.

**CPT Codes / HCPCS Codes / ICD-10 Codes**

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

**CPT codes not covered for indications listed in the CPB:**

*There are no specific codes for MRI-guided focal laser ablation of prostate(e.g., the Visualase Laser Ablation System):*

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>C9734</td>
<td>Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance [transurethral]</td>
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**ICD-10 codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C61</td>
<td>Malignant neoplasm of prostate [primary or salvage therapy]</td>
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</tbody>
</table>

**The above policy is based on the following references:**

Magnetic Resonance Imaging-Guided Focal Laser Ablation:


Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation:


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0843 Ablative Procedures for Prostate Cancer

There are no amendments for Medicaid.