Cigna Medical Coverage Policy

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Coverage Policy

Cigna does not cover the following treatments for benign prostatic hypertrophy (BPH) because each is considered experimental, investigational or unproven (this list may not be all-inclusive):

- absolute ethanol injection
- cryosurgical ablation
- high-intensity focused ultrasound (HIFU)
- histotripsy
- interstitial laser coagulation (ILC)
- plasma kinetic vaporization (e.g., PlasmaKinetic™ Tissue Management System)
- prostate artery embolization
- prostatic urethral lift
- transrectal thermal therapy
- transurethral balloon dilation of the prostatic urethra
- transurethral ultrasound-guided laser incision of the prostate (TULIP)
- water-induced thermotherapy (WIT)

General Background

Benign prostatic hypertrophy/hyperplasia (BPH), also known as hyperplasia, is a common non-malignant condition in men that can result in bothersome lower urinary tract symptoms (Hoffman, 2009). The most frequent indications for surgical management are moderate-to-severe irritative voiding symptoms that are refractory to medical management, such as urgency to urinate, frequent urination, weak stream and straining,
refractory urinary obstruction or retention, renal insufficiency, hydronephrosis, and recurrent gross hematuria. Other symptoms may include recurrent or persistent urinary tract infections, urosepsis, large bladder diverticula, and bladder stones.

**Treatment Options**
Proposed treatment options for an individual with bothersome moderate to severe symptoms of BPH include watchful waiting, medications, phytherapeutic agents and other dietary supplements, minimally invasive therapies, and surgery. Transurethral resection of the prostate (TURP) is considered the gold standard for surgical treatment of BPH.

**Phytotherapy**

**Food and Drug Administration (FDA)**
Several devices have received FDA approval for the treatment of BPH, including the following:

- The AquaTherm device, formerly known as the Thermoflex™ Water-Induced Thermotherapy System (ACMI, Southborough, MA, previously Argomed, Inc., Cary, NC) is a catheter-based thermal therapy device for the treatment of symptoms due to urinary outflow obstruction secondary to BPH. FDA 510(k) class II approval was received in 1999.
- The Indigo OPTIMA Laser System (Ethicon Endo-Surgery, Inc., Cincinnati, OH) was noted by the FDA (December, 2001) to be substantially equivalent to the Indigo LaserOptic Treatment System which received FDA clearance in December, 1997. It is intended to be used in the non-contact mode to photoagulate, vaporize/ablate soft tissue (muscle, connective tissue, organ) and for cutting, incision, excision, and for coagulation in the contact mode for open/closed surgical procedures. The Diffuser Tip Fiberoptic is intended for the treatment of BPH.
- In July 2003, the PlasmaKinetic Superpulse System (Gyrus, Maple Grove, MN) received 510K premarket notification that the device is substantially equivalent to predicate devices and is safe and effective in its intended use. It is intended for use for ablation, removal, resection and coagulation of soft tissue and where associated hemostasis is required. Predicate devices are the PlasmaKinetic Generator, the PlasmaKinetic Endourology Generator, and the Endourology Axiopolar Resectoscope Electrode.
- In September 2013, the FDA granted a de novo classification clearance for the NeoTract® UroLift System (NeoTract, Inc., Pleasanton, CA); the system was classified as an implantable transprostatic tissue retractor system. The de novo process provides a route to market for medical devices that FDA considers to be low to moderate risk but receive class III classification because FDA has found them to be "not substantially equivalent" to any previous device that is already legally marketed (ECRI, 2014). According to the FDA summary document, the UroLift system "is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to [BPH] in men age 50 and above." In December 2013, FDA granted 510(k) clearance for a modified version of the NeoTract UroLift System, with the prior version serving as the predicate device.

**Surgical and Minimally Invasive Therapies**
A number of surgical and minimally invasive therapies are considered safe and effective for the treatment of BPH based on evidence in the published peer-reviewed scientific literature; others are considered standard of care based on published guidelines of professional societies/organizations. These therapies are as follows:

<table>
<thead>
<tr>
<th>TREATMENT</th>
<th>CPT® CODE</th>
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<tbody>
<tr>
<td>Contact laser ablation of the prostate (CLAP)</td>
<td>52648</td>
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<tr>
<td>Holmium laser ablation, enucleation, resection (HoLAP, HoLEP, HoLRP)</td>
<td>52649</td>
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<tr>
<td>Laser vaporization and laser ablation/coagulation</td>
<td>52647, 52648</td>
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<tr>
<td>Open/laparoscopic prostatectomy</td>
<td>55801, 55821, 55831</td>
</tr>
<tr>
<td>Photoselective vaporization of the prostate (PVP)</td>
<td>52648</td>
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</tbody>
</table>
Stents (e.g., UroLume® endourethral prosthesis) 53855
Transurethral resection of the prostate (TURP) 52601, 52630
Transurethral needle ablation (TUNA), also known as radiofrequency needle ablation (RFNA) 53852
Transurethral electrovaporization (TUVP, TVP, TUEP), also known as transurethral vapor resection of the prostate (TUVRP) 52648
Transurethral microwave thermotherapy (TUMT) 53850
Transurethral incision of the prostate (TUIP) 54520

Additional Therapies
There is insufficient evidence in the published peer-reviewed scientific literature to demonstrate safety and effectiveness of the following therapies:

**Absolute Ethanol Injection:** Injecting absolute ethanol into the prostate is a technique used to cause coagulation necrosis (chemoablation), which destroys the tissue (American Urological Association [AUA], 2010). Published guidelines from the European Association of Urology (2013), Canadian Urological Association (2010) and the National Institute for Clinical Excellence (NICE) (United Kingdom) (NICE, 2010) do not recommend absolute ethanol injection for the treatment of BPH.

**Literature Review**
Randomized controlled trials data are lacking regarding the safety and effectiveness of absolute ethanol injection compared to standard therapy for the treatment of BPH. Two small prospective nonrandomized studies without comparators totaling 71 patients demonstrated improvements in International Prostate Symptom Score (IPSS), quality of life scores, and significant differences in peak flow volumes and post void residual after therapy (Sakr, 2009; Magno, 2008).

**Cryosurgical Ablation:** There are scarce data in the published peer-reviewed scientific literature to support the safety and effectiveness of cryosurgical ablation for the treatment of BPH. At this time the role of this therapy has not yet been established.

**High-Intensity Focused Ultrasound (HIFU):** High-intensity focused ultrasound (HIFU) is a procedure which uses a small probe to produce bursts of ultrasound that creates coagulation necrosis in a specific area of tissue. Frequencies range from 4–10 MHz, although 4 MHz is most frequently used. HIFU devices use imaging ultrasound for treatment planning and monitoring, and they deliver targeted high-intensity ultrasound that rapidly elevates the temperature in a precise focal zone. The increased tissue temperature is designed to kill excess prostate tissue (in the case of BPH). The same probe can be used for imaging, which allows both diagnostic and therapeutic testing at the same time.

There are scarce data in the published peer-reviewed scientific literature regarding the safety and effectiveness of HIFU for the treatment of BPH. Further, published guidelines of the Canadian Urological Association (2010), The National Institute for Clinical Excellence (NICE) (United Kingdom) (NICE, 2010), and the Ontario Ministry of Health and Long-Term Care, medical Advisory Secretariat (2006) do not recommend HIFU as an appropriate treatment for benign prostatic hypertrophy (BPH). At this time the role of high-intensity focused ultrasound for the treatment of BPH has not been established.

**Histotripsy:** Histotripsy is an experimental extracorporeal ultrasound technology that has been proposed to treat BPH. Histotripsy is a form of focused ultrasound therapy that utilizes cavitational mechanisms to produce tissue necrosis in prostatic tissue. There are scarce data in the published peer-reviewed scientific literature to support the safety and effectiveness of histotripsy for the treatment of BPH. At this time the role of this therapy has not yet been established (Lusuardi, et al., 2013; Hempel, et al., 2011).

**Interstitial Laser Coagulation (ILC):** ILC of the prostate by the transurethral route has been attempted using several laser and delivery devices. In the United States, a diode-laser device, the Indigo 830e (Ethicon Endo-Surgery, Cincinnati, OH) has been evaluated. The laser enters the prostate and the tissue is coagulated. Intraprostatic lesions reabsorb and the tissue atrophies. Consequently, some volume reduction occurs (AUA, 2010).
Literature Review
Indigo 830e has been studied in the United States; however, its role in treating lower urinary tract symptoms has yet to be defined. The lack of randomized controlled studies comparing ILC to other approaches has resulted in no consensus on the ILC technique.

Ng et al. (2005) conducted a study to evaluate the impact of improvements in surgical techniques and patient selection of overall outcomes of ILC of the prostate. Over a four-year period, 66 patients underwent interstitial coagulation (ILC) using the Indigo 830e. They were stratified into two groups: group one consisted of those treated during the first two years (n=47) and those treated during the latest two years (n=19) were labeled as group two. At 12 months, maximum flow rates improved by 47% in group one and 85% in group two. Subjective measures were significantly improved from baseline in both groups but did not differ between groups. The incidence of adverse events was similar in the two groups. In a prospective study of 49 men with symptomatic benign prostatic hypertrophy (BPH) who underwent ILC, Daehlin et al. (2007) reported a decrease in International Prostate Symptom Scores (IPSS), and an increase in peak urinary flow; however, twenty-two patients (50%) required retreatment.

At present there is insufficient evidence in the published peer-reviewed scientific literature to support the effectiveness of interstitial laser coagulation (ILC); its role in the treatment of benign prostatic hyperplasia/hypertrophy (BPH) has not yet been established.

Plasma Kinetic Vaporization using the PlasmaKinetic™ Tissue Management System: The PlasmaKinetic™ Tissue Management System (Gyrus ACMI, Southborough, MA) uses plasma energy to vaporize tissue with minimal thermal spread and enhanced hemostasis.

Literature Review
There are scarce data in the published, peer-reviewed scientific literature regarding the safety or effectiveness of this therapy and its role in the treatment of BPH has not yet been established.

Prostate Artery Embolization: Prostate artery embolization for BPH has been proposed to reduce the blood supply of the prostate gland, causing some of it to undergo necrosis with subsequent shrinkage.

Literature Review
There are scarce data in the published, peer-reviewed scientific literature regarding the safety and effectiveness of prostate artery embolization compared to standard therapy for the treatment of BPH (Gao, et al., 2014; Pisco, et al., 2013).

In a prospective randomized study (n=114), Gao et al., (2014) compared prostatic arterial embolization (PAE) (n=57) and transurethral resection of the prostate (TURP) (n=57) in the care of patients with benign prostatic hyperplasia (BPH). The groups were compared regarding relevant adverse events and complications. Functional results including improvement of International Prostate Symptom Score (IPSS), quality of life (QOL), peak urinary flow, postvoiding residual urine volume, prostate-specific antigen (PSA) level, and prostate volume were assessed at 1-, 3-, 6-, 12-, and 24-month follow up. Overall technical success rates for TURP and PAE were 100% and 94.7%, respectively; the clinical failure rates were 3.9% and 9.4%, respectively. The six functional results showed improvements after TURP and PAE at all follow-up time points when compared with preoperative values (p=0.001).The TURP group showed greater degrees of improvement in the IPSS, QOL, peak urinary flow, and postvoiding residual urine volume at 1 and 3 months, as well as greater reductions in the PSA level and prostate volume at all follow-up time points, when compared with the PAE group (p<0.05). The PAE group showed more overall adverse events and complications (p=0.029), mostly related to acute urinary retention (25.9%), postembolization syndrome (11.1%), and treatment failures (5.3% technical; 9.4% clinical). The authors reported that “the advantages of the PAE procedure must be weighed against the potential for technical and clinical failures in a minority of patients.”

The National Institute for Clinical Excellence (NICE, 2013) does not recommend prostate artery embolization an appropriate treatment for BPH.
Prostatic Urethral Lift (PUL): It has been proposed that PUL using the UroLift ™ (NeoTract Inc., Pleasanton, CA) implant holds the prostate lateral lobes apart improving the voiding channel and lower urinary tract symptoms (LUTS). The procedure is performed outpatient under local anesthesia (Barkin, et al., 2012).

Literature Review
Evidence in the published, peer-reviewed scientific literature consists of one randomized controlled sham trial (Roehrborn, et al., 2013) and smaller prospective, retrospective and case series studies. The evidence suggests that PUL using the UroLift System relieves symptoms in men age 50 years or older who have urinary outflow obstruction secondary to BPH however there is a lack of large randomized studies with long-term outcomes data comparing PUL with other established BPH treatments including TURP (Shore, et al., 2014; Cantwell, et al., 2014; McVary, et al., 2013; McNicholas, et al., 2013; Chin, et al., 2012; Woo, et al., 2011,2012).

Transrectal Thermal Therapies:
There are scarce data in the published peer-reviewed scientific evidence to determine the safety and efficacy of thermal therapy via the rectum as a treatment option for BPH. At this time the role of this therapy has not yet been established.

Transurethral Balloon Dilation of the Prostatic Urethra: Transurethral balloon dilation of the prostatic urethra, also known as endoscopic balloon dilation of the prostatic urethra, involves the insertion of a balloon catheter through the urethra into the prostatic urethra where it is inflated to stretch the urethra where it has been narrowed by the prostate.

Literature Review
There are scarce data regarding the safety and effectiveness of this therapy for the treatment of BPH and its role has not yet been established.

Transurethral Ultrasound Guided Laser Incision of the Prostate (TULIP): TULIP is a procedure that is similar to transurethral incision of the prostate except that cuts are made with a laser. Laser energy is delivered under ultrasound guidance, producing necrosis. TULIP is a difficult procedure with a very high incidence of incontinence, a delayed onset of improvement, and no ability to obtain tissue for histological examination. TULIP is rarely used by urologists because it has been surpassed by instruments that are easier to use (Fitzpatrick, 2011).

Literature Review
There are scarce data in the published, peer-reviewed scientific literature regarding the effectiveness of TULIP and the role of this therapy in the treatment of BPH has not yet been established.

Water-Induced Thermotherapy (WIT): WIT is a minimally-invasive therapy that uses hot water circulating through a urethral balloon catheter to deliver heat energy to prostate tissue and thereby shrink the prostate and treat symptoms of BPH. It is generally considered only for patients who cannot undergo TURP or who require less invasive treatments (ECRI, 2012), however the long-term safety and effectiveness of this treatment in this or other proposed subsets of individuals has not been proven.

Literature Review
There are scarce data in randomized controlled clinical trials or comparative studies regarding outcomes of WIT as a treatment for BPH. Minardi et al. (2004) reported that WIT resulted in a reduction of prostatic volume of 5.2% compared with a decrease of 48.4% when transurethral resection of the prostate (TURP) was performed. The urine flow rate increased more after TURP (75.3%) than after WIT (16.7%). Residual prostate volume decreased more after TURP (89.8%) than after WIT (25.2%), an increase of maximum flow rate of 16.7% and a decrease of residual volume of 25.2%. The relief of bladder outlet obstruction was indicated by the decrease of detrusor pressure at maximum flow rate in comparison to baseline values; decreases of 27.5% were noted for WIT compared with decreases of 48% for transurethral resection of the prostate (TURP). Additionally, published guidelines from the Canadian Urological Association (2010), and the National Institute for Clinical Excellence (UK, 2010) do not recommend WIT as an appropriate option for the treatment of BPH.

At this time there is insufficient evidence in the peer-reviewed scientific evidence to determine the safety and effectiveness of WIT for the treatment of BPH. Additionally, there is insufficient direct comparison of WIT to
other treatment options for BPH; optimal protocols have not been established and long-term information regarding duration of treatment effect or adverse effects is lacking.

Professional Societies/Organizations
American Urological Association (AUA): The 2003 Guidelines on Management of Benign Prostatic Hyperplasia note that transurethral heat-based therapies, interstitial laser coagulation, water-induced thermal therapy, and the PlasmaKinetic™ Tissue Management System are emerging therapies. The Guideline also notes that “It is not inappropriate for these options to be offered to the patient, but the uncertainty of outcomes compared to the recommended treatment options should be discussed with the patient.” High-intensity focused ultrasound and absolute ethanol injection are investigational at this time and should not be offered outside the framework of clinical trials.” However, the updated Guideline, Benign Prostatic Hyperplasia (2010) does not discuss these therapies. The minimally invasive therapies that are mentioned include transurethral needle ablation and transurethral microwave thermotherapy. There has been no update to this guideline since 2010.

European Urology Association (EUA): The 2013 EAU Guideline on the Treatment and Follow-up of Non-Neurogenic Male Lower Urinary Tract Symptoms Including Benign Prostatic Obstruction note that intraprostatic ethanol injection is an emerging operation. The guideline also notes that “Ethanol injections are considered a minimally invasive treatment option for patients with moderate-to-severe lower urinary tract symptoms secondary to benign prostatic obstruction. However, the mechanism of action, patient selection, and application of ethanol (number of injection sites and injection volume) have not been well investigated, severe adverse events occurred in some patients, and long-term results are sparse” (Oelke, et al., 2013).

National Institute for Clinical Excellence ([NICE] United Kingdom: In 2014, NICE published an Interventional Procedure Guidance Guideline for Insertion of Prostatic Urethral Lift Implants to Treat Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia which includes the following recommendations:

- “Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- During the consent process clinicians should, in particular, advise patients about the range of possible treatment options and the possible need for further procedures if symptoms recur.
- The procedure should only be carried out by clinicians with specific training in the insertion of prostatic urethral lift implants.
- NICE encourages further research and publication of results from consecutive case series of patients having this procedure. Details of patient selection should be clearly documented. Reported outcomes should include the effects of the procedure on symptoms and quality of life, the duration of benefits, and the need for further procedures. All complications should be reported. NICE may review this procedure in the light of longer-term outcomes.”

The clinical evidence to support the recommendations is based on 391 patients from one randomized controlled sham trial n=206 (Roehrborn, et al., 2013) and three case series n=19-102 (McNicholas, et al., 2013; Chin, et al., 2012; Woo, et al., 2011).

In 2013 NICE published an Interventional Procedure Guidance Guideline for Prostate Artery Embolisation for Benign Prostate Hyperplasia which includes the following:

- “Current evidence on the safety and efficacy of prostate artery embolisation for benign prostatic hyperplasia is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.
- Prostate artery embolisation for benign prostatic hyperplasia should only be undertaken following consideration of the patients by a multidisciplinary team that includes a urologist and an interventional radiologist.
Further research in the form of randomised trials or cohort studies (for example, using an appropriate register) should clearly document patient selection criteria and all complications, specifically including disturbance of sexual function. Efficacy outcomes should include measures of urinary function, symptoms and quality of life. Information about longer-term outcomes, including the need for further treatment, would be valuable.

In 2010, NICE published a Guideline for “The Management of Lower Urinary Tract Symptoms in Men” which includes the following:

- “For men with voiding symptoms, offer surgery only if voiding symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are not appropriate.
- If offering surgery for managing voiding LUTS presumed secondary to BPH, do not offer minimally invasive treatments (including transurethral needle ablation [TUNA], transurethral microwave thermotherapy [TUMT], high-intensity focused ultrasound [HIFU], transurethral ethanol ablation of the prostate [TEAP] and laser coagulation) as an alternative to TURP, TUVP or HoLEP.
- Do not offer homeopathy, phytotherapy or acupuncture for treating LUTS in men.”

Canadian Urological Association ([CUA], 2009, updated 2010): Updated Guidelines note the following evolving minimally invasive surgical therapies are not recommended as standard options at this time: absolute ethanol injection, high intensity focused ultrasound, water induced thermotherapy.

Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat ([MAS], 2006): MAS published a technology assessment “Energy Delivery Systems for Treatment of Benign Prostatic Hyperplasia” that notes “The application of HIFU has not been demonstrated in any randomized controlled trials.”

Summary
A number of surgical and minimally-invasive therapies are appropriate for the treatment of benign prostatic hypertrphy/hyperplasia (BPH). Transurethral resection of the prostate (TURP) remains the benchmark therapy for the treatment of BPH. Data in the published, peer-reviewed literature demonstrate improved outcomes, and support the safety and effectiveness of selected alternatives to TURP: contact laser ablation of the prostate, Holmium laser ablation, enucleation, and resection, laser prostatectomy, open and laparoscopic prostatectomy, photoselective vaporization of the prostate, stents, transurethral needle ablation, also known as radiofrequency needle ablation, transurethral microwave thermotherapy, transurethral electrovaporization, and transurethral incision of the prostate.

For other therapies, there is insufficient evidence in the published peer-reviewed scientific literature to support safety and effectiveness for the treatment of BPH. There are limited data to demonstrate improved health outcomes for individuals with BPH treated with the following therapies:

- absolute ethanol injection
- cryosurgical ablation
- high-intensity focused ultrasound (HIFU)
- histotripsy
- interstitial laser coagulation (ILC)
- plasma kinetic vaporization (e.g., PlasmaKinetic™ Tissue Management System)
- prostate artery embolization
- prostatic urethral lift
- transrectal thermal therapy
- transurethral balloon dilation of the prostatic urethra
- transurethral ultrasound-guided laser incision of the prostate (TULIP)
- water-induced thermotherapy (WIT)

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
   2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible
Experimental/Investigational/Unproven/Not Covered when used to report any procedure listed in this policy for the treatment of benign prostatic hypertrophy (BPH):

<table>
<thead>
<tr>
<th>CPT* Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>37204</td>
<td>Transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck (Code deleted 12/31/2013)</td>
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<tr>
<td>37242</td>
<td>Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)</td>
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<td>52647</td>
<td>Laser coagulation of prostate including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration, and/or dilation, and internal urethrotomy are included if performed)</td>
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<tr>
<td>52648</td>
<td>Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)</td>
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<tr>
<td>52649</td>
<td>Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)</td>
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<td>53899</td>
<td>Unlisted procedure, urinary system</td>
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<td>55873</td>
<td>Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)</td>
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<td>55899</td>
<td>Unlisted procedure, male genital system</td>
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<td>76999</td>
<td>Unlisted ultrasound procedure (eg, diagnostic, interventional)</td>
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<th>Description</th>
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<td>C9734</td>
<td>Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance</td>
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<td>C9739</td>
<td>Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants</td>
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<tr>
<td>C9740</td>
<td>Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants</td>
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<tr>
<td>L8699</td>
<td>Prosthetic implant, not otherwise specified</td>
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References


