



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Benign Prostatic Hypertrophy (BPH) Treatments**

**Effective Date ..... 9/15/2009**  
**Next Review Date..... 9/15/2010**  
**Coverage Policy Number ..... 0159**

## Table of Contents

Coverage Policy .....	1
General Background .....	2
Coding/Billing Information .....	9
References .....	10
Policy History .....	14

## Hyperlink to Related Coverage Policies

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

## Coverage Policy

**CIGNA covers ANY of the following procedures:**

- open/laparoscopic prostatectomy
- transurethral resection of the prostate (TURP)
- transurethral radiofrequency needle ablation (TUNA), also known as radiofrequency needle ablation (RFNA)
- transurethral microwave thermotherapy (TUMT)
- laser prostatectomy (e.g., laser vaporization, laser ablation/coagulation, Holmium laser, photoselective vaporization of the prostate)
- transurethral electrovaporization (TUVP, TVP, TUEVP), also known as transurethral vapor resection of the prostate (TUVRP)
- transurethral incision of the prostate (TUIP)
- stents (e.g., UroLume® endourethral prosthesis)

**as medically necessary for the treatment of benign prostatic hypertrophy (BPH) that following evaluation appears to be causing ANY of these conditions:**

- irritative voiding symptoms refractory to medical management
- refractory urinary obstruction or retention
- renal insufficiency

- hydronephrosis
- recurrent gross hematuria
- recurrent or persistent urinary tract infections
- urosepsis
- large bladder diverticula
- bladder stones

**CIGNA does not cover the following treatments for BPH because they are considered experimental, investigational or unproven (this list may not be all-inclusive);**

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

## General Background

Benign prostatic hypertrophy (BPH), also known as hyperplasia, is a common condition in older men that can result in bothersome lower urinary tract symptoms (Hoffman, 2009). The most frequent indications for surgical management are irritative voiding symptoms refractory to medical management, and may also include renal insufficiency, hydronephrosis, recurrent or persistent urinary tract infections, urosepsis, large bladder diverticula, and bladder stones.

### Treatment Options

Treatment options for patients with bothersome moderate to severe symptoms of BPH include medications, phytotherapeutic agents and other dietary supplements, minimally invasive therapies, and surgery. According to the AUA (2006) phytotherapeutic agents are investigational at this time and should not be offered outside the framework of clinical trials.

### Surgical and Minimally-Invasive Surgical Treatments

**Open and Laparoscopic Prostatectomy:** Open prostatectomy is the surgical removal of the inner portion of the prostate generally by suprapubic or retropubic approach. The prostate may also be removed by laparoscopy. This procedure is typically performed on patients with prostate volumes greater than 80 to 100 mL and usually performed under general or spinal anesthesia.

**Transurethral Resection of the Prostate (TURP):** Transurethral resection of the prostate is considered the gold standard to which other surgeries for BPH are compared; however, the number of patients undergoing TURP has decreased annually as the treatment of BPH shifts toward medical and minimally invasive therapies (Sakr, 2008). This procedure is performed under general or regional anesthesia and usually takes less than 90 minutes. The surgeon inserts a resectoscope into the urethra and uses an electric loop to remove the obstructing tissue and to seal blood vessels.

Multiple meta-analyses, randomized controlled trials (RCTs), and nonrandomized case studies have evaluated the use of TURP compared with other technologies for the treatment of BPH in > 8000 participants). Comparators included transurethral needle ablation (TUNA), transurethral microwave thermotherapy (TUMT), transurethral incision of the prostate (TUIP), laser coagulation, holmium laser enucleation, laser vaporization, transurethral vaporessection, bipolar transurethral resection, and bipolar transurethral vaporization. Data regarding complication rates reflect lower occurrence of blood transfusions, stricture, and urinary incontinence with the use of TUNA, TUMT, and laser coagulation compared with TURP. Improved outcomes were noted for peak urine flow and urinary retention, and the number of urinary tract infections was lower with TURP compared with TUNA, TUMT, and laser coagulation. Regarding comparison of TURP and TUIP there was no evidence that

the two interventions were different in terms of symptomatic outcome, urinary retention, urinary tract infection, strictures, or incontinence. Hospital stay is generally one day shorter for the newer technologies; blood transfusion rates were higher for transurethral resection. It was not possible to reliably identify if any of the newer procedures are more effective than transurethral resection of the prostate (TURP). Outcomes for a comparison of transurethral microwave thermotherapy (TUMT) and sham were also reported in 11 studies with 1209 participants. The data suggested that TUMT both reduces symptoms and increases peak urine flow rate at three months after the procedure. Reoperation rates for TUMT were lower than for sham, while patients who underwent TUMT had a higher risk of developing urinary retention (Lourenco, 2008a) (Lourenco, 2008a, Lourenco, 2008b, Minardi, 2004).

**Transurethral Needle Ablation (TUNA):** TUNA, also known as radiofrequency needle ablation (RFNA), is a procedure in which low-level radiofrequency (RF) energy is delivered through needles to a localized area of the prostate, increasing the temperature, and inducing necrosis of prostatic tissue. Patient selection criteria for TUNA are similar to those for TURP but also include patients not considered suitable candidates for surgery.

TUNA<sup>®</sup> system (Medtronic, Inc., Minneapolis, MN) and The TUNA Office System, an updated version of the original system received 510(k) approval from the U.S. Food and Drug Administration (FDA) as a Class II device in February 2001.

Several meta-analyses and randomized controlled trials (RCTs) assessing the use of TUNA have demonstrated the safety and clinical effectiveness of this device for the treatment of benign prostatic hypertrophy (BPH) (Boursa, 2006; Boyle, 2004; Hill, 2004). TUNA improves symptoms with respect to baseline, although improvement does not reach the same level as with transurethral resection of the prostate (TURP). The incidence of retrograde ejaculation, postoperative erectile dysfunction, incontinence and stricture formation was greater in TURP than in TUNA. The study found significantly fewer adverse events for TUNA than for TURP. Data suggest that TUNA therapy may be an option for men who do not wish to undergo long-term medical therapy, are poor candidates for surgery, or are concerned about the side effects of TURP.

In October 2003, The National Institute for Clinical Excellence (NICE) issued guidance on the use of TUNA for the treatment of benign prostatic obstruction (BPO). According to the NICE guidance, the literature demonstrated that TUNA was a safe procedure with fewer postoperative complications (e.g., bleeding) than TURP and was efficacious in the short term. The guidance noted that the current evidence was adequate to support the use of TUNA in the treatment of benign prostatic obstruction.

**Transurethral Microwave Thermotherapy (TUMT):** Microwave energy (heat) is applied to the enlarged prostatic tissue, causing reduction of the enlarged tissue with simultaneous protective cooling of adjacent urethral tissue. TUMT can be performed as an outpatient procedure, and has fewer, as well as less severe, side effects than TURP (Hoffman, 2009).

A variety of TUMT systems have been developed, including low-energy systems, which achieve intraprostatic temperatures of < 50–60 °C, and high-energy systems, which achieve intraprostatic temperatures of 70–75 °C. Because unexpected procedure-related injuries have been associated with the use of TUMT devices, the FDA has recommended safety considerations including careful patient selection, following labeling instructions, physician supervision, and avoiding over-sedation.

The FDA premarket-approved TUMT class II systems include the Prostatron<sup>®</sup> microwave thermotherapy system (Urologix, Inc., Minneapolis, MN) (FDA, 1996), including several versions of the ProstateSoft 2.0 (software), the Urologix Targis<sup>™</sup> (T3) System (Urologix, Minneapolis, MN) (FDA, 1998), the CoreTherm<sup>®</sup> (Gyrus ACMI, Southborough, MA), and the TherMatrx<sup>®</sup> device (American Medical Systems, Minnetonka, MN).

Microwave thermotherapy is a relatively safe and effective treatment option for BPH. The data suggest that TUMT can provide symptom reduction in some patients with BPH. It also appears that greater improvement in voiding function may be achieved with high- versus low-energy therapy. Compared with TURP, TUMT is associated with decreased risks for retrograde ejaculation, treatment for strictures, hematuria, blood transfusions, and transurethral resection syndrome, but increased risks for dysuria, urinary retention, and retreatment for BPH symptoms. TUMT improves symptom scores and peak urinary flow compared with sham procedures. Data suggest that microwave thermotherapy, which delivers microwave energy to produce

coagulation necrosis in prostatic tissue, is a safe, effective treatment for benign prostatic hypertrophy (BPH) (Hoffman, 2009; Trock, 2004; Erichsen, 2003).

**Laser Prostatectomy (LAP):** Laser prostatectomy for BPH is a minimally-invasive therapy that uses laser-generated heat to vaporize or coagulate prostate tissue. It has been shown to be an effective treatment option for patients with BPH who have clinically documented obstructive and voiding symptoms and no clinical signs of prostate cancer. The evidence suggests that laser prostatectomy (e.g., noncontact laser ablation, contact laser vaporization, hybrid LAP, HoLEP, HoLRP) can provide significant improvement in urodynamic obstruction, BPH symptom scores, voiding function, urinary retention, quality of life, and sexual function, compared with pretreatment levels. Compared with transurethral resection of the prostate (TURP), laser prostatectomy techniques have slightly lower rates of efficacy and are associated with somewhat higher re-operation rates, but they carry a lower risk of certain complications, such as bleeding.

The different types of lasers used to perform laser prostatectomy include the neodymium: yttrium aluminum garnet (Nd:YAG), potassium-titanyl-phosphate (KTP), holmium (Ho:YAG), and the new high-powered lasers 80-W KTP and holmium laser enucleation (HoLEP). In addition, different laser techniques can be used to remove the obstructing tissue, such as:

- laser ablation/coagulation of the prostate (e.g., Nd:YAG laser, KTP/Nd:YAG laser)—a laser light focused on the enlarged prostatic tissue, coming in no direct contact with the prostate, causes thermal injury or coagulation.
- laser vaporization of the prostate (e.g., Nd:YAG laser)—the tip of the laser device is placed in direct contact with the prostate vaporizing the target tissue.
- hybrid laser ablation of the prostate (e.g., KTP/Nd:YAG laser) involves both ablation/coagulation and vaporization.
- photoselective vaporization of the prostate (e.g., high-powered 60–80-W KTP laser)—involves both ablation/coagulation and vaporization.
- Holmium laser (e.g., Ho:YAG/Nd:YAG [HoLRP], HoLEP)—a laser specifically designed to be used as a scalpel which, when used in a near-contact sweeping motion, resects the prostate gland in a manner similar to TURP.

Several laser systems, including holmium laser technologies, have been granted approval by the FDA as class II devices (510k approval) for use in laser prostatectomy for ablation, enucleation, and resection of the prostate.

Kuntz et al. (2008) reported on the five year follow-up results of a randomized trial comparing holmium laser enucleation of the prostate (HoLEP) (n=60) with open prostatectomy (OP) (n=60) in men with prostates greater than 100g in weight. Assessments included maximum flow (Qmax), post void residual (PVR), and the American Urological Association Symptom Score (AUA-SS). Mean AUA-SS and Qmax were equivalent both groups. The post void residual (PVR) volume was increased in the HoLEP cohort compared with the OP group (p=0.25). Reoperative rates were 5% in the HoLEP group and 6.7% in the OP group (p=1.0). None of the patients had recurrence of benign prostatic hypertrophy (BPH). The data suggest that after five years the improvements obtained and the reoperation rates were equivalent.

Outcomes of photoselective vaporization of the prostate (PVP) were compared with those of transurethral resection of the prostate (TURP) for the treatment of BPH in > 1800 subjects in several systematic reviews and recent prospective, non-randomized clinical trials (Horasanli, 2008; Ruszat, 2008; Tugcu, 2008; Hoffman, 2004). Mean age, mean baseline symptom score, and mean baseline peak urinary flow did not differ by treatment group. Improvements for mean urinary symptoms and mean peak urinary flow were greater for TURP compared with lasers. Overall, laser subjects were less likely to receive transfusions or develop strictures and their hospitalizations were shorter. Noncontact laser subjects were more likely to have dysuria, urinary tract infection, and retention. Re-operation occurred more often following laser procedures. Data were insufficient to compare laser techniques with other minimally invasive procedures. The International Prostate Symptom Score (IPSS) and post void residuals (PVR) were similar in the Ruszat and Tugcu studies, although significant differences in IPSS, Qmax, and PVR values in favor of TURP were observed within the follow-up period in the study by Horasanli. Outcomes demonstrate that laser techniques are a useful alternative to transurethral resection of the prostate (TURP) for treating benign prostatic hypertrophy (BPH). Small sample sizes and differences in study

design limit any definitive conclusions regarding the preferred type of laser technique. The major advantage of PVP are the shorter catheterization times and shorter hospital stay.

The relative safety and efficacy of HoLEP has been assessed in multiple randomized controlled trials (RCTs), and case studies involving >800 patients with benign prostatic hypertrophy (BPH) (Ahyai, 2007; Wilson, 2006; Elzayat, 2005, Tooher, 2004). Advantages with HoLEP included shorter catheterization times, shorter hospital stays, more prostate tissue retrieved, lack of transurethral resection (TUR) syndrome, shorter convalescent time, increased PVR, and improvement in symptom scores. Complications include need for blood transfusions in some patients, irritative symptoms, and transient stress incontinence. Limitations also included longer operation time. At 24 months, there were no significant differences between the two groups with respect to symptom scores, quality of life scores or maximum flow (Q<sub>max</sub>) values. In these studies, results for HoLEP were as durable as transurethral resection of the prostate (TURP), demonstrated less perioperative morbidity, and produced superior urodynamic outcomes when treating prostates over 40g. The data suggests that HoLEP and TURP compare favorably in the long-term with equally low complication rates.

The National Institute for Clinical Excellence (NICE) published guidance in November 2003 on the holmium laser prostatectomy that stated the current evidence on the safety and efficacy of holmium laser prostatectomy appeared adequate to support its use. According to the NICE guidance, the literature demonstrated that holmium laser prostatectomy was at least as effective as TURP in improving bladder neck obstruction, symptom scores and quality of life and that there was no significant difference in safety between holmium laser prostatectomy and TURP. In May 2005, NICE also issued guidance on KTP laser vaporization of the prostate for the treatment of BPH. NICE determined that “the current evidence on the safety and short term efficacy of KTP laser vaporization of the prostate for benign prostatic obstruction appears adequate to support the use of this procedure.”

**Transurethral Electrovaporization:** Transurethral electrovaporization (TUVP, TVP, TUEVP), also known as transurethral vapor resection of the prostate (TUVRP), is a procedure that combines the concepts of vaporization and desiccation, which is the drawing out of water from tissue. TUVP steams tissue away using high heat, and dries out the tissue using lower heat (Fitzpatrick, 2007).

Although long-term data are needed, published peer-reviewed data suggests that the efficacy of transurethral electrovaporization appears similar to that of TURP, with advantages to the use of TUVP including earlier catheter removal and less bleeding-related complications. Short-term improvements equivalent to those of TURP were seen in symptom scores, quality of life indices, urinary flow rate, impotence and retrograde ejaculation. Statistically significant differences favored transurethral electrovaporization over TURP for operative time, catheterization time, hospital length of stay, transfusion requirement, the incidence of clot retention and alterations of serum sodium levels. The rates of postoperative irritative voiding symptoms, dysuria and urinary retention appear to be higher than TURP along with the need for unplanned secondary catheterization. Each technique, however, provided distinct advantages over the other in terms of secondary outcomes (Fowler, 2005; Nuhoglu, 2005; Poulakis, 2004).

The National Institute for Clinical Excellence (NICE) guidance regarding the safety and efficacy of TUVP as a minimally invasive treatment option to the standard surgical treatment of benign prostatic obstruction (BPO) was published in October 2003. According to the guidance, the literature demonstrates that TUVP is a well-established treatment that is as efficacious as TURP in the short term with similar complications rates. The NICE guidance concluded that the current evidence is adequate to support the use of TUVP in the treatment of BPO (NICE, 2003).

**Stents:** Prostatic stents, which may be temporary or permanent, are placed into the prostatic urethra and expanded to relieve the obstruction from surrounding prostatic tissue. Due to the complications associated with these stents, including stent migration, encrustation, urinary tract infection and chronic pain, these stents are more frequently recommended for use in patients with urinary retention who are at poor surgical risk and not candidates for other types of interventions (American Urological Association [AUA], 2006). Newer stents are being viewed as possible methods of overcoming the temporary retention that can occur as a complication of laser therapy or high-energy transurethral microwave therapy (Fitzpatrick, 2007).

FDA approval of these types of stents comes with many contraindications, warnings and precautions. Examples of prostatic stents currently approved by the FDA include UroLume<sup>®</sup> endourethral prosthesis (American Medical Systems, Inc., Minnetonka, MN) (FDA, 1997), and the Spanner<sup>™</sup> Temporary Prostatic Stent (AbbeyMoor Medical, Inc., Parkers Prairie, MN) (FDA, 2006).

Although prostatic stents are associated with significant complications, data suggest they may be an effective alternative to permanent indwelling catheterization in patients that are poor surgical risks. Several prospective trials have demonstrated improved International Prostate Symptom Score (IPSS) scores, peak flow rates, and quality of life scores compared to baseline with the use of the UroLume stent in >1000 men with moderate/severe lower urinary tract symptoms (Armitage, 2007; Masood, 2004; Oesterling, 1994). Symptoms scores and peak flow rate improved over time. Complications included urinary tract infections, epididymo-orchitis, perineal pain and irritative symptoms. The most common reason of stent failure was migration or misplacement of the stent. These studies are limited by small sample size and lack of comparison to standard treatment.

Corica et al. (2004) evaluated the effectiveness of the Spanner stent when used to relieve prostatic urethral obstruction in 30 patients. The mean overall maximum flow rate (Q<sub>max</sub>) at baseline and after insertion were 8.2 and 11.6mLs, respectively, representing a 48% improvement (p< 0.001). The change in mean overall voided volume was not significant. There was a 64% decrease (p=0.004) in the post void residual (PVR). The data suggest that use of the Spanner temporary stent may improve the voiding function and quality of life of patients diagnosed with prostatic urethral obstruction.

**Transurethral Incision of the Prostate (TUIP):** TUIP is used to treat a prostate that is not greatly enlarged. The surgeon makes one or more cuts in the bladder neck where the urethra joins the bladder, extending to the prostate. This procedure reduces the urethral resistance and makes urination easier. The advantages of TUIP are that it is quick, technically easier, and associated with less morbidity and a decrease in retrograde ejaculation compared with TURP (0%–37% versus 50%–95%, respectively) (Fitzpatrick, 2007). TUIP may provide relief with a lower incidence of retrograde ejaculation than transurethral resection of the prostate (TURP); however, its long-term benefits and risks compared to those of TURP have not been established.

Several meta-analyses, and randomized controlled trials (RCTs) have compared the outcomes of TUIP with those of TURP in >800 men with prostate volumes ≤ 30 grams (Tkocz, 2001; Yang, 2001; Riehmman, 1995). The advantages of TUIP over TURP included lower incidence of complications, fewer blood transfusions, decreased risk of retrograde ejaculation, shorter operative times, and hospital stays. In the study by Tkocz, significant improvements were noted in both groups for daytime and nocturnal voiding frequencies, maximal flow rates, and passive urethral resistance were noted at a follow-up of 24 months. In the study by Riehmman, there were no statistically significant differences between the TUIP and TURP cohorts for symptom scores, subjective assessment of surgical outcome, and mean voided volumes. Postoperative irritative and obstructive scores decreased significantly at follow-up for both groups. TURP demonstrated a statistically significant improvement for maximal flow rate over TUIP. Based on the information reviewed, data suggest that TUIP may be as effective as transurethral resection of the prostate within the first 12 months in patients with smaller prostates; however, data on the comparison of long-term effectiveness was lacking, and no patient selection criteria regarding prostate size had been determined.

According to the American Urological Association (AUA), there is sufficient evidence in the peer-reviewed scientific literature to support the use of TUIP for the treatment of BPH in smaller prostates (i.e. 30 grams of resected weight or less) (2006).

**Transurethral Ultrasound Guided Laser Incision of the Prostate (TULIP):** TULIP is a procedure that is similar to transurethral incision of the prostate (TURP) 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, 2007).

There is scarce data in the published, peer-reviewed scientific literature regarding the use of TULIP. At this time the role of this therapy for the treatment of BPH has not been established.

**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 fiber enters the prostate and the tissue is coagulated. Intraprostatic lesions reabsorb and the tissue atrophies. Consequently, some volume reduction occurs (AUA, 2006).

Ng et al. (2005) conducted a study to evaluate the impact of improvements in surgical techniques and patient selection of overall outcomes of interstitial laser coagulation (ILC) of the prostate. Over a four-year period, 66 patients underwent ILC using the Indigo 830e. Patients were seen at 3, 6, and 12 months postoperatively. They were stratified into two groups; group 1 consisted of those treated during the first two years (n=47) and those treated during the latest two years (n=19) were group 2. At 12 months, maximum flow rates improved by 47% in group 1 and 85% in group 2. 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. Indigo 830e has been widely studied in the United States; however, its role in treating lower urinary tract symptoms has yet to be defined. The lack of studies comparing ILC to other approaches has resulted in no consensus on the ILC technique.

According to the AUA (2006), ILC is considered an emerging therapy and additional data are needed before ILC can be considered a recommended treatment option. At present, there is insufficient evidence in the published, peer-reviewed literature to support the use of ILC in the treatment of benign prostatic hypertrophy (BPH).

**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. The long-term safety and efficacy of this treatment are not known. The Thermoflex™ System (Argomed, Inc., Cary, NC) was 510(k) is an FDA class II approved device (1999).

There is 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 water induced thermotherapy (WIT) resulted in a reduction of prostatic volume of 5.2%, 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 to decreases of 48% for transurethral resection of the prostate (TURP).

The American Urological Association (AUA) guideline on the management of benign prostatic hyperplasia (2006) does not recommend WIT as a treatment option for BPH stating it is an emerging therapy and additional data are needed.

At this time there is insufficient evidence in the peer-reviewed scientific evidence to determine the safety and efficacy of WIT for the treatment of BPH. 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 any adverse effects is lacking.

#### **Additional Therapies**

**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. According to the AUA, this system may potentially eliminate the possibility of hyponatremia and TURP syndrome; however, the AUA determined that additional data are required before the PlasmaKinetic™ Tissue Management System can be considered as a recommended treatment option (AUA, 2006). There is scarce data in the published, peer-reviewed scientific literature and at this time the role of this therapy for the treatment of BPH has not been established.

**High-Intensity Focused Ultrasound (HIFU) and Absolute Ethanol Injection:** 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. The same probe can be used for imaging, which allows both diagnostic and therapeutic testing at the same time. Injecting absolute ethanol into the prostate is a technique used to cause coagulation necrosis (chemo-ablation), which destroys the tissue (AUA, 2006).

According to the American Urological Association (AUA), “high-intensity focused ultrasound and absolute ethanol injection are investigational at this time and should not be offered outside the framework of clinical trials” (AUA, 2006).

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).

There is scarce data in the published peer-reviewed scientific literature regarding the use of these therapies for the treatment of benign prostatic hypertrophy (BPH). At this time the role of this therapy for the treatment of BPH has not 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 (AUA, 2006). According to the AUA (2006), balloon dilation has not been adequately studied and therefore is not a recommended treatment option for patients with symptoms of BPH.

**Transrectal Thermal Therapies:** There is 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 been established.

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

### **Professional Societies/Organizations**

Guidelines from the American Urological Association (AUA, 2006) support the use of transurethral resection of the prostate (TURP), which is noted to be the benchmark for the treatment of benign prostatic hypertrophy (BPH). The Guidelines also support the use of minimally invasive therapies including transurethral microwave thermotherapy (TUMT), transurethral needle ablation (TUNA), and the UroLume stent (i.e., for patients at poor surgical risk). Surgical therapies include TURP, transurethral electrovaporization, transurethral incision of the prostate, transurethral holmium laser resection/enucleation, transurethral laser vaporization, transurethral laser coagulation (e.g., visual laser ablation), and open prostatectomy. Therapies such as injection of absolute ethanol into the prostate, high intensity focused ultrasound, and certain other transurethral heat-based therapies (i.e., interstitial laser coagulation, water-induced thermotherapy), and the Plasma Kinetic™ Tissue Management System are listed as emerging therapies.

The European Association of Urology ([EAU], 2006) published Guidelines on Benign Prostatic Hyperplasia which note that the mode of action of phytotherapeutic agents is unknown, and biological effects are unclear although a few randomized clinical trials show encouraging results. The most frequent indication for surgical management is bothersome lower urinary tract symptoms refractory to medical management. According to the EAU, strong indications for surgery include refractory or recurrent urinary retention, recurrent hematuria refractory to medical treatment with 5-alpha reductase inhibitors, renal insufficiency, bladder stones and increased post-void residual volume. The Guidelines also note that surgical prostatectomy (e.g., open, TURP, TUIP, TUVF) results in significant subjective and objective improvements superior to medical or minimally invasive treatment. All four surgical procedures have been evaluated in randomized controlled trials. TUIP is the surgical therapy of choice for men with prostates < 30 mL and no middle lobes.

### **Summary**

Transurethral resection of the prostate (TURP) remains the benchmark therapy for the treatment of benign prostatic hypertrophy (BPH). There is sufficient evidence in the published, peer-reviewed literature to support selected alternatives to TURP in carefully selected subsets of individuals. Although prostatic stents are associated with significant complications, they may be an effective alternative to permanent indwelling catheterization in patients at poor surgical risk.

There is insufficient evidence in the published peer-reviewed scientific literature to support the use of absolute ethanol injection; transurethral/endoscopic balloon dilation of the prostate; high-intensity focused ultrasound (HIFU); PlasmaKinetic™ Tissue Management System; transurethral, ultrasound-guided laser incision of the prostate (TULIP); transrectal thermal therapy, cryosurgical ablation, and water-induced thermotherapy (WIT) for the treatment of BPH.

## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
52282	Cytourethroscopy, with insertion of urethral stent
52450	Transurethral incision of prostate
52601	Transurethral electroresection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)
52647	Laser coagulation of prostate including control of postoperative bleeding, complete (vasectomy, urethral calibration and or dilation, meatotomy, cystourethroscopy, and internal urethrotomy are included if performed).
52648	Laser vaporization including control of postoperative bleeding, complete (vasectomy, urethral calibration and or dilation, meatotomy, cystourethroscopy, internal urethrotomy and transurethral resection of prostate are included if performed).
52649	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)
53850	Transurethral destruction of prostate tissue; microwave thermotherapy
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy
55801	Prostatectomy, perineal, subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy)
55821	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); suprapubic, subtotal, one or two stages
55831	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); retropubic, subtotal

<b>HCPCS</b> <b>Codes</b>	<b>Description</b>
0084T	Insertion of a temporary prostatic urethral stent

<b>ICD-9-CM</b> <b>Diagnosis</b> <b>Codes</b>	<b>Description</b>
600.00	Hypertrophy (benign) of prostate without urinary obstruction
600.01	Hypertrophy (benign) of prostate with urinary obstruction
	Multiple/varied

**Experimental/Investigational/Unproven/Not Covered:**

CPT* Codes	Description
53853	Transurethral destruction of prostate tissue by water induced thermotherapy
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)
55899†	Unlisted procedure, urinary system

†**Note: Experimental, Investigational/Unproven/Not Covered when used to report water induced thermotherapy or any other procedure listed as Experimental/Investigational/Unproven/Not Covered in this policy.**

ICD-9-CM Diagnosis Codes	Description
	All codes

\*Current Procedural Terminology (CPT®) © 2008 American Medical Association: Chicago, IL.

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	9/15/2007	0159	Benign Prostatic Hypertrophy (BPH) Treatments
Great-West Healthcare	11/20/2006	04.252.02	Benign Prostatic Hyperplasia (BPH), Coverage Guidelines
	11/20/2006	04.256.02	BPH, Balloon Dilatation
	11/20/2006	04.253.02	BPH, Laser Prostatectomy
	11/20/2006	04.255.02	BPH, Transurethral Microwave Thermotherapy (TUMT)
	11/20/2006	04.254.02	BPH, Transurethral Needle Ablation (TUNA)
	11/20/2006	04.257.02	BPH, Water-Induced Thermotherapy (WIT)

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.