CIGNA MEDICAL COVERAGE POLICY

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

Effective Date 9/15/2010
Next Review Date……..9/15/2011
Coverage Policy Number 0159

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Hyperlink to Related Coverage Policies

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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 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 the 80 to 100 mL and usually performed under general or spinal anesthesia. Prostatectomy is an accepted treatment option for selected individuals with BPH.

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 involves endoscopic resection of the obstructive component of the prostate. TURP is highly effective, improving symptoms in up to 95% of patients (Badlani, 2009).

Literature Review

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 include transurethral needle ablation (TUNA), transurethral microwave thermotherapy (TUMT), transurethral incision of the prostate (TUIP), laser coagulation, holmium laser enucleation, laser vaporization, transurethral vaporesection, 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 transurethral resection of the prostate (TURP) compared with transurethral needle ablation (TUNA), transurethral microwave therapy (TUMT), and laser coagulation. Regarding comparison of transurethral resection of the prostate (TURP) and transurethral incision of the prostate (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 (Lourenco, 2008a, Lourenco, 2008b, Minardi, 2004).

Transurethral Needle Ablation (TUNA)/Radiofrequency Needle Ablation (RFNA): 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® 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.

Literature Review
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 less with TUNA than with TURP. 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): In this procedure, 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® microwave thermotherapy system (Urologix, Inc., Minneapolis, MN) (FDA, 1996), including several versions of the Prostasoft 2.0 (software), the Urologix Targis™ (T3) System (Urologix, Minneapolis, MN) (FDA, 1998), the CoreTherm® (Gyrus ACMI, Southborough, MA), and the TherMatrx® device (American Medical Systems, Minnetonka, MN).

Literature Review
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; Mattiasson, 2007; 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 benign prostatic hypertrophy (BPH) who have clinically documented obstructive and voiding symptoms and no clinical signs of prostate cancer. The evidence suggests that laser prostatectomy 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 high-powered lasers 80-W KTP and holmium laser. 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 enucleation and laser resection (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.

Literature Review:
Holmium Laser Enucleation of the Prostate (HoLEP): 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) (Burke, 2010; Kuntz, 2008; Ahyai, 2007; Wilson, 2006; Elzayat, 2005, Tooher, 2004). Compared with TURP, 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. 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.

Photoselective Vaporization of the Prostate (PVP): 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 (Burke, 2010;

Horasanli, 2008; Ruszat, 2008; Tugcu, 2008; Hoffman, 2004). 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 IPPS, 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 photoselective vaporization of the prostate (PVP) are the shorter catheterization times and shorter hospital stay.

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).

Literature Review
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® endourethral prosthesis (American Medical Systems, Inc., Minnetonka, MN) (FDA, 1997), and the Spanner™ Temporary Prostatic Stent (AbbeyMoor Medical, Inc., Parkers Prairie, MN) (FDA, 2006).

Literature Review
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; Corica, 2004; Masood, 2004). 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.

Transurethral Incision of the Prostate (TUIP): TUIP is highly effective on prostate glands less than 30 grams and is the treatment of choice for small gland BPH in men concerned with fertility and ejaculation (Badlani, 2009). The surgeon makes one or more cuts in the bladder neck where the urethra joins the bladder, extending to the prostate, which 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) (Badlani, 2009; Fitzpatrick, 2007). TUIP may provide relief with a lower incidence of retrograde ejaculation than transurethral resection of the prostate (TURP).

Literature Review
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; Riehmann, 1995). 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.

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 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.

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, 2006).

Literature Review
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 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 interstitial laser coagulation (ILC) of the prostate. Over a four-year period, 66 patients underwent ILC using the Indigo 830e. 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. In a prospective study of 49 men with symptomatic BPH who underwent ILC, Daehlin et al. (2007) reported a decrease in International Prostate Symptom Scores, and an increase in peak urinary flow; however, twenty-two patients (50%) required retreatment.

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 effectiveness of interstitial laser coagulation (ILC); its role in the treatment of benign prostatic hypertrophy (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. 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 are scarce data in randomized controlled clinical trials or comparative studies regarding outcomes of WIT as a treatment for BPH and data on durability are lacking. Minardi et al. (2004) reported that 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 effectiveness 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 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.

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).

Literature Review

Randomized controlled trials comparing HIFU to standard therapy have not been published. 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).

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).

There are scarce data in the published peer-reviewed scientific literature regarding the safety and effectiveness of these therapies for the treatment of benign prostatic hypertrophy (BPH). At this time their roles in the treatment of BPH have 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 (American Urological Association [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 benign prostatectomy (BPH).

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.

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.

Professional Societies/Organizations
American Urological Association (AUA): Guidelines from the AUA (2006) support the use of transurethral resection of the prostate (TURP), which is noted to be the benchmark for the treatment of 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 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.

European Association of Urology (EAU): The EAU published Guidelines on Benign Prostatic Hyperplasia (2006) 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. The Guidelines also note that surgical prostatectomy (i.e., open prostatectomy, TURP, TUIP, TUVP) results in significant subjective and objective improvements superior to medical therapy or minimally invasive treatment. The Guidelines note that TUIP is the surgical therapy of choice for men with prostates < 30 mL and no middle lobes.

Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat (MAS): The MAS published a technology assessment “Energy Delivery Systems for Treatment of Benign Prostatic Hyperplasia” that notes “Based on effectiveness, economic analysis and complication rates it is appropriate to offer TURP, HoLEP, bipolar, or monopolar electrovaporization to patients for the treatment of BPH.” The MAS also notes that the application of HIFU has not been demonstrated in any RCTs.

Summary
Transurethral resection of the prostate (TURP) remains the benchmark therapy for the treatment of benign prostatic hypertrophy (BPH). Data in the published, peer-reviewed literature supports the safety and effectiveness of selected alternatives to TURP in individuals with BPH. Prostatic stents 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 effectiveness 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). The role of these therapies for the treatment of BPH has not yet been established.

Coding/Billing Information

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

Covered when medically necessary:

CPT®* Codes	Description
52282	Cytourethroscopy, with insertion of urethral stent
52450	Transurethral incision of prostate
52601	Transurethral electrosurgical resection 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
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement
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

HCPCS Codes	Description
0084T	Insertion of a temporary prostatic urethral stent (Code deleted 1/1/10, replaced by code 53855)

ICD-9-CM Diagnosis Codes	Description
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 (Code deleted 1/1/2009, replaced by code 55899)
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®) ©2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
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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