BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Alternative Treatments of Benign Prostatic Hypertrophy
Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00126
Original Effective Date: 08/25/2003
Archived Date: 03/20/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the following procedures as treatments for benign prostatic hypertrophy to be **eligible for coverage**:

- Transurethral microwave thermotherapy
- Laser prostatectomy
- Transurethral radiofrequency needle ablation
- Water induced thermotherapy

Patient Selection Criteria
Coverage eligibility will be considered when the following criteria are met:

- **Transurethral Microwave Thermotherapy**
  - Patients who, based on severity of their benign prostatic hypertrophy symptoms, would be candidates for transurethral resection of the prostate; and
  - Prostatic lengths of 35–50 mm; and
  - For technical reasons, transurethral microwave thermotherapy is not suitable for patients who have a large prostate gland (greater than 5 cm in length or larger than 70 g in volume), median lobe enlargement, or bladder neck stenosis.

- **Laser Prostatectomy**
  - Laser prostatectomy, using contact, non-contact or interstitial techniques for patients with benign prostatic hypertrophy who are candidates for transurethral resection of the prostate.

- **Transurethral Radiofrequency Needle Ablation**
  - Transurethral radiofrequency needle ablation for patients with benign prostatic hypertrophy who are candidates for transurethral resection of the prostate.

- **Water-Induced Thermotherapy**
  - Water induced thermotherapy for patients with benign prostatic hypertrophy who are candidates for transurethral resection of the prostate.

Alternative Treatments of Benign Prostatic Hypertrophy

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00126
Original Effective Date: 08/25/2003
Archived Date: 03/20/2013

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on the review of available data, the use of transurethral microwave thermotherapy, laser prostatectomy, transurethral radiofrequency needle ablation and water induced thermotherapy when the patient selection criteria are not met is considered to be **investigational.***

Based on review of available data, the Company considers balloon dilatation of the prostatic urethra to be **investigational.***

Background/Overview

The prostate is a gland located anterior to the rectum, surrounding the urethra and bladder neck in the male anatomy. The gland secretes slightly alkaline fluid that forms a part of the seminal fluid. Benign prostatic hypertrophy (BPH) affects 50% of men older than 50 years and more than 75% of men above the age of 80. Benign prostatic hypertrophy results from the development of multiple non-cancerous nodules within the periurethral region of the prostate gland. Varying degrees of bladder outlet obstruction result from enlargement of the prostate. Incomplete bladder emptying causes stasis and predisposition to infection, inflammation, calculus formation, and when prolonged, to hydronephrosis.

Over the past decade a variety of minimally invasive procedures have been investigated as alternatives to transurethral resection of the prostate (TURP), considered the gold standard treatment of BPH. The These techniques are intended to induce necrosis in prostatic tissue using a variety of energy sources, i.e., various types of laser prostatectomy, transurethral radiofrequency needle ablation (TUNA or RFNA) transurethral microwave thermotherapy (TUMT), water-induced thermotherapy (WIT), and balloon dilitation.

Transurethral Resection of the Prostate (TURP)

This major surgical procedure involves the excision of prostate tissue via a transurethral approach to relieve obstruction.

Transurethral Microwave Thermotherapy (TUMT)

Transurethral microwave thermotherapy has been proposed as an alternative to TURP, or daily medical therapy, for patients who have BPH. Although TURP has been historically considered definitive treatment, complications from this treatment have encouraged the development of less invasive techniques.

Benign prostatic hyperplasia is a condition that may lead to lower urinary tract symptoms, such as urinary frequency, nocturia, urinary hesitancy, and feeling of incomplete voiding. Histologic evidence of BPH is present in approximately 50% of men at age 50 years, and the prevalence increases with advancing age. Glandular overgrowth causes progressive occlusion of the prostatic portion of the urethra in men and will

cause lower urinary tract symptoms to varying degrees. Transurethral resection of the prostate is one of the most commonly performed surgeries and is generally well-tolerated, but it is not without potential complications, such as blood loss (with or without the need for transfusion), retrograde ejaculation, and incontinence. Transurethral resection syndrome is an adverse effect that can occur in up to 2% of cases. The syndrome is caused by absorption of bladder irrigation fluids during the TURP procedure. Depending on the severity, this syndrome can lead to hyponatremia and fluid overload with subsequent neurologic and cardiac complications. Less-invasive techniques have been investigated using various energy sources, such as laser, direct heat, microwave, radiofrequency, and ultrasound. With these techniques, a calculated amount of prostate tissue is destroyed and reabsorbed while leaving the epithelium of the urethral canal relatively intact. This policy addresses the use of microwave energy in the reduction of urethral occlusion and lower urinary tract symptoms.

The goal of microwave thermotherapy is destruction of the prostatic adenoma in the lateral lobes of the prostate to achieve improvement in symptoms and voiding. A transurethral catheter containing a microwave antenna that limits microwave radiation is placed at the prostatic level. Water circulating through the catheter cools the urethra. A Foley-type balloon at the end of the catheter inflates to position the catheter, and fiberoptic sensors are positioned to monitor rectal and urethral temperatures. The correct position of the catheter is verified using transrectal ultrasound of the prostate. The electromagnetic waves emit high-energy photons that interact with molecules in prostatic tissue, producing heat.

Transurethral microwave thermotherapy produces coagulation necrosis of the lateral lobes of the prostate for a distance up to 17 mm from the urethra with the preservation of the urethral surface, distal sphincter, urethral mucosa, bladder neck, and peripheral prostate.

Laser Prostatectomy

Laser prostatectomy, using a variety of lasers, has been investigated as a less invasive alternative to TURP. A variety of lasers have been used in a variety of ways to vaporize or coagulate prostate tissue. For example, Nd: YAG lasers have been used in either a contact or non-contact mode to treat prostatic tissue at its surface. In the contact mode, the Nd:YAG laser directly ablates prostatic tissue, producing an effect similar to a slowly progressive TURP. In the non-contact (side-firing) mode, the laser uses refraction to coagulate tissue and or/vaporize the urethral margin. More recently holmium (Ho): YAG lasers and high power KTP lasers have been investigated. These two non-contact lasers have different absorption properties. The Ho: YAG laser is maximally absorbed at a wavelength of 2000 nm and is selectively absorbed by water. In contrast, the KTP laser (also referred to as a green light laser or photoselective vaporization) is maximally absorbed at a wavelength of 600 nm and is selectively absorbed by oxyhemoglobin. Advocates of the green light laser propose that its absorption by oxyhemoglobin is an advantage since the laser energy is not dissipated in an aqueous environment, and is selectively absorbed by vascular tissue.

Alternative Treatments of Benign Prostatic Hypertrophy

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00126
Original Effective Date: 08/25/2003
Archived Date: 03/20/2013

Interstitial laser prostatectomy using either Nd: YAG or diode lasers has also been investigated as a technique to achieve coagulation necrosis inside the adenoma. In this procedure the laser (either an ND: YAG laser or a diode laser) is inserted into the prostate and activated. After treatment, the coagulated tissue is gradually reabsorbed with subsequent shrinkage of the treated areas. An interstitial laser procedure is similar in concept to transurethral needle ablation, which is also intended to induce interstitial coagulation necrosis, although it uses a different energy source.

Transurethral Radiofrequency Needle Ablation (TUNA or RFNA)

Transurethral radiofrequency needle ablation of the prostate has been proposed as an alternative to TURP for treatment of BPH. Other alternatives include transurethral incision of the prostate, intraurethral stents, balloon dilation, heat therapy (e.g., microwave hyperthermia), high-intensity focused ultrasound (HIFU), roller ball transurethral vaporization of the prostate and laser prostatectomy. The mechanism of TUNA is thermal coagulation necrosis. The TUNA procedure is performed under direct vision. The intraurethral components are contained in a sheath, including two flexible needles that are deployed into the lateral lobes of the prostate adenoma to a depth determined by transrectal ultrasound measurement. Each lobe is treated 2 to 4 times, and the procedure averages 30 minutes in length.

Water-Induced thermotherapy (WIT)

Over the past decade a variety of minimally invasive procedures have been investigated as alternatives to TURP, considered the gold standard treatment of BPH. These techniques are intended to induce necrosis in prostatic tissue using a variety of energy sources, i.e., various types of laser prostatectomy, RFNA and TUMT. Water-induced thermotherapy is a relatively new addition to minimally invasive options. The technique consists of placement of an inflated balloon along the length of the prostate, followed by the circulation of heated water, which circulates through a catheter system. Water-induced thermotherapy is performed in a single, 45-minute outpatient treatment session without anesthesia. Patients typically require catheterization for at least one week due to post-procedure sloughing of prostatic tissue.

Balloon Dilatation

Balloon dilatation of the prostatic urethra, or balloon urethroplasty, is a therapeutic procedure intended to manage symptoms associated with BPH. Under fluoroscopic guidance, a flexible balloon catheter is placed in the urethra at the level of the prostate above the external sphincter. The balloon is then inflated for a short period of time to distend the prostatic urethra. This widening process is intended to relieve obstruction of the urethra caused by the enlarged prostate and alleviate the symptoms of BPH (e.g., urinary retention, urgency, hesitancy, nocturia and dysuria). No surgical specimen is obtained.

Alternative Treatments of Benign Prostatic Hypertrophy

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00126
Original Effective Date: 08/25/2003
Archived Date: 03/20/2013

FDA or Other Governmental Regulatory Approval

TUMT

U.S. Food and Drug Administration (FDA)
In October 2000, the U.S. Food and Drug Administration (FDA) issued an alert regarding 16 unexpected cases of fistula formation or urethral or penile tissue damage following the use of transurethral microwave thermotherapy devices. In this alert, the FDA recommended ensuring the patient meets criteria for eligible prostate size and had not previously received radiation to the area. It further recommended that the physician remain with the patient throughout the procedure to verify placement at all times and to monitor any unusual pain reported. The patient is not to be oversedated.

In December 2002, the "Prostalund®‡ ĩ CoreTherm™‡ ĩ System" (Prostalund Operations AB, Concord, MA) was approved by the FDA through the premarket approval (PMA) process for use in men with a prostate size of 30 to 100 grams and prostatic urethra length of 35 mm or greater. Although similar to previous microwave thermotherapy devices, the company sought PMA due to the addition of temperature feedback features intended to address the safety concerns noted in the 2000 FDA alert described above.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination.

WIT

U.S. Food and Drug Administration (FDA)
In 1999, the Thermoflex™‡ Water-Induced Thermotherapy System received clearance for marketing from the U.S. Food and Drug Administration (FDA) through a 510(k) process for the following labeled indication:

"The Thermoflex system is intended for the treatment of symptoms due to urinary outflow obstruction secondary to BPH. It is indicated for use in men over the age of 50 years with prostate lengths between 2.0 cm and 6.4 cm who present with symptoms of urinary outflow obstruction secondary to BPH."

Balloon Dilitation

U.S. Food and Drug Administration (FDA)
State or federal mandates (i.e., FEP) may dictate that all devices approved by the U.S. FDA may not be considered investigational. Therefore, FDA-approved devices may be assessed on the basis of their medical necessity.

Alternative Treatments of Benign Prostatic Hypertrophy

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00126
Original Effective Date: 08/25/2003
Archived Date: 03/20/2013

Rationale/Source

TUMT

Literature Review

This policy was initially developed following a 1996 TEC Assessment that evaluated transurethral thermotherapy. The Assessment concluded that the results of studies published at the time provided sufficient evidence on the beneficial and harmful outcomes of TUMT. Specifically, 2 clinical trials, one randomized and one nonrandomized, had compared microwave thermotherapy with TURP. The findings of these trials were supplemented with 5 randomized controlled trials (RCTs) comparing TUMT with a sham procedure, as well as a number of published clinical series. Evidence from a randomized trial showed that both TUMT and TURP produce significant relief of the symptoms of BPH, although TURP was associated with significantly greater improvement after 1 year of follow-up. Moreover, while symptom relief following TURP appeared to be greater, fewer major complications were seen with TUMT.

In October 2007, Hoffman and colleagues produced a meta-analysis of 14 RCTs on TUMT for BPH involving a total of 1,493 patients. Six trials were comparisons of microwave thermotherapy with TURP, 7 were comparisons with sham thermotherapy, and 1 was a comparison with alpha blocker therapy. The range of duration of the studies was 3 to 60 months; the mean age of subjects was 66.8 years. Baseline characteristics of urinary flow rate (8.6 mL/sec [range: 7.9 to 10.1]) and symptom scores (19.5 [range 15.7 to 21.3]) were similar. Outcomes were reported in urinary flow rate and International Prostate Symptom Scores (IPSS) or converted to IPSS equivalents. The studies included extended follow-up from studies included in the TEC Assessment, as well as new RCTs initiated after the TEC Assessment. The meta-analysis offered the following observations and conclusions:

- The pooled mean urinary symptom score decreased by 65% with TUMT and 77% with TURP. The weighted mean difference (WMD) for the symptom score was -1.36 (95% confidence interval [CI]: -2.25 to -0.46), favoring TURP. The pooled mean peak urinary flow increased by 70% with TUMT and 119% with TURP. The WMD for peak urinary flow was 5.08 mL/sec (95% CI: 3.88 to 6.28), favoring TURP.
- Compared to TURP, TUMT was associated with a decreased risk of retrograde ejaculation, treatment for strictures, hematuria, blood transfusions and the transurethral resection syndrome. TUMT was associated with an increase in dysuria, urinary retention, and retreatment for BPH symptoms.
- Compared to the sham procedures, microwave thermotherapy also improved symptom scores (WMD: -4.75, 95% CI: -3.89 to -5.60) on the IPSS and peak urinary flow (WMD: 1.67 mL/s, 95% CI: 0.99 to 2.34).
- In the single study comparing TUMT to alpha blockade, TUMT led to greater improvement in symptom scores (WMD: -4.20, 95% CI: -3.15 to -5.25) and peak urinary flow (WMD: 2.30 mL/s, 95% CI: 1.47 to 3.13) than in the group receiving alpha blockers.

Since 2008, no new randomized controlled trials on microwave thermotherapy for BPH have been published, and no ongoing randomized trials were identified in the online clinicaltrials.gov database.

In 2012, Biester and colleagues published a systematic review of studies comparing standard surgical treatment to minimally invasive procedures in the treatment of BPH. Seven RCTs with a total of 675 patients were identified that evaluated TUMT; 6 trials compared TUMT to TURP and 1 trial compared it to transurethral incision of the prostate. In the studies, the mean prostatic size ranged from 34 to 72 mL, and patients were followed for a mean of 6 to 60 months. The systematic review aimed to determine whether the minimally invasive treatments were non-inferior to surgery. The authors noted that none of the trials investigated non-inferiority, and they therefore based their threshold, 0.25 standard deviations (SD), for non-inferiority on the published literature. In a meta-analysis of study findings, the authors found that TUMT did not meet their threshold to be considered non-inferior to standard procedures. The pooled SD at 18-24 months was 0.46 (i.e., greater than 0.25) and the 95% CI was 0.15 to 0.77. The authors concluded that there is a lack of high-quality RCTs and RCTs that are designed to investigate non-inferiority.

Summary
Although not clearly superior to standard surgical therapy with TURP, TUMT is an effective therapeutic option and has fewer adverse effects. There is sufficient evidence for patient and providers considering a surgical intervention to make an informed choice between resection of the prostate and TUMT. Therefore, TUMT may be considered eligible for coverage in men who meet the conditions in the coverage statement.

Laser Prostatectomy
This policy is based on a 1996 TEC Assessment, which was updated in 2005 with further information on different types of lasers used for laser prostatectomy, specifically the diode laser used for interstitial laser coagulation necrosis and the KTP laser. However, the policy statement regarding laser prostatectomy, which does not distinguish among the various lasers that may be used, is unchanged. A literature search did not identify any clinical trials that directly compared the outcomes using different lasers; therefore, there are inadequate data to determine the equivalence or superiority of different approaches. A recent review suggests that Ho:YAG lasers and high-power KTP lasers (i.e., green light lasers) are most commonly used, while there is declining enthusiasm for interstitial or contact laser coagulation.

TUNA or RFNA
The 1998 TEC Assessment offered the following conclusions:

- Clinical series including a total of 910 patients consistently report decreases in symptoms and demonstrate improvement in urodynamic measures such as peak maximal flow and post-voiding residual 3 to 6 months after RFNA.
- A randomized clinical trial has also been published, comparing RFNA with TURP. The results from the clinical trial report significant symptomatic and urodynamic improvement with both treatments showing improvement. Although TURP produced greater improvement in symptoms

and urologic functions, the average American Urological Association symptoms score for patients who underwent RFNA improved from severe to the moderate range of BPH symptoms severity. Adverse events associated with RFNA were transient and significantly less than for TURP. In addition, RFNA did not produce the harmful outcomes related to blood transfusion and post-TURP syndrome.

WIT

Evaluation of minimally invasive treatments of BPH have typically included trials comparing treatment results with both placebo and TURP. Outcomes are typically assessed in terms of urodynamics and patient subjective improvement, as assessed by the American Urologic Association Symptom Index. Regarding WIT, the largest study was published by Muschter and colleagues. This prospective multicenter clinical trial enrolled 125 patients with BPH who underwent WIT. Urodynamic measures and symptom scores were measured at 3, 6 and 12 months after treatment. At 12 months, the symptom scores had improved by a median of 12.5 points compared to baseline (a change of 9 points is considered a marked improvement), and 78% of patients reported moderate or greater symptomatic improvement, peak urinary flow rate by a mean 6.4 ml per second. No adverse impact of WIT on sexual function was noted. The treatment was well tolerated; duration of catheterization was 1 week in 45% of patients, 2 weeks in 30%, and 3 to 5 weeks in 24% of patients. There are no data directly comparing WIT either to placebo, TURP or other minimally invasive therapies. However, the results noted for WIT are roughly comparable to those achieved with other minimally invasive techniques.

Two year outcomes of 98 of the original 125 patients have been presented in abstract form. A total of seven patients required retreatment with TURP. No cases of impotence, retrograde ejaculation or permanent incontinence were reported. The mean improvements in both symptom scores and urodynamics were still apparent at 24 months.

Balloon Dilatation

A review of the peer-reviewed literature found no controlled clinical trials on balloon dilatation of the prostate. Based on the paucity of published literature it appears that balloon dilatation of the prostate has declined in popularity, in part due to the advent of other minimally invasive treatments of BPH.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Transurethral Microwave Thermotherapy”, 7.01.52, 8:2012.
2. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Laser Prostatectomy” - Archived, 7.01.49, 2:2005.
3. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Transurethral Radiofrequency Needle Ablation of the Prostate” - Archived, 7.01.59, 2:2003.
4. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Water-Induced Thermotherapy as a Treatment of Benign Prostatic Hypertrophy” - Archived, 2.01.49, 1:2003.

5. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Balloon Dilatation of Prostate" - Archived, 7.01.04, 3:2003.
6. Petrovich Z, Ameye F, Baert L et al. New trends in the treatment of benign prostatic hyperplasia and carcinoma of the prostate. Am J Clin Oncol 1993; 16(3):187-200.
7. Mebust WK, Holtgrewe HL, Cockett AT et al. Transurethral prostatectomy: immediate and postoperative complications. Cooperative study of 13 participating institutions evaluating 3,885 patients. J Urol, 141: 243-247, 1989. J Urol 2002; 167(1):5-9.
8. FDA Public Health Notification 2000 Archived document. FDA Public Health Notification: Serious Injuries from Microwave Thermotherapy for Benign Prostatic Hyperplasia. Available online at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/UCM062277.
9. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transurethral microwave thermotherapy for benign prostatic hyperplasia. TEC Assessments 1996; Volume 11, Tab 19.
10. Hoffman RM, Monga M, Elliot SP et al. Microwave thermotherapy for benign prostatic hyperplasia. Cochrane Database Syst Rev 2007; (4):CD004135.
11. Biester K, Skipka G, Jahn R et al. Systematic review of surgical treatments for benign prostatic hyperplasia and presentation of an approach to investigate therapeutic equivalence (non-inferiority). BJU Int 2012; 109(5):722-30.
12. 1996 TEC Assessment
13. Martenson AC, de la Rosette JJ. Interstitial laser coagulation in the treatment of benign prostatic hyperplasia using a diode laser system: results of an evolving technology. Prostate Cancer Prostatic Dis 1999; 2(3):148-54.
14. Floratos DL, Sonke GS, Francisca EA et al. Long-term follow-up of laser treatment of lower urinary tract symptoms suggestive of bladder outlet obstruction. Urology 2000; 56(4):604-9.
15. Virdi JS, Chandrasekar P, Kapasi F. Interstitial laser ablation (Indigo) of the prostate – a randomised prospective study, three-year follow-up (abstract). J Urol 2001; 165(suppl):368.
16. Te AE, Malloy TR, Stein BS et al. Photoselective vaporization of the prostate for the treatment of benign prostatic hyperplasia: 12 month results from the first United States multicenter prospective trial. J Urol 2004; 172(4 pt 1):1404-8.
17. Sandhu JS, Ng C, Vanderbrink BA et al. High-power potassium-titanyl-phosphate photoselective laser vaporization of prostate for treatment of benign prostatic hyperplasia in men with large prostates. Urology 2004; 64(6):1155-9.
18. Tan AH, Gilling PJ. Lasers in the treatment of benign prostatic hyperplasia: an update. Curr Opin Urol 2005; 15(1):55-8.
19. 1998 TEC Assessment, Tab 25
20. Muschter R, Schorsch I, Danielli L et al. Transurethral water-induced thermotherapy for the treatment of benign prostatic hyperplasia: a prospective multicenter clinical trial. J Urol 2000;164(5):1565-9.
21. Schorsch I, Muschter R, Danielli L et al. Two year follow up of a multi-center clinical study using water-induced thermotherapy for BPH. Presented at American Urological Annual Meeting, Atlanta, Georgia, May 2, 2000.
22. Larson TR. Rationale and assessment of minimally invasive approaches to benign prostatic hyperplasia therapy. Urology 2002; 59(2 suppl 1):12-6.
23. Breda G, Isgro A. Treatment of benign prostatic hyperplasia with water-induced thermotherapy; experience of a single institution. J Endourol 2002; 16(2):123-6.

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines (BCBSLAMPCG) are obtained from Current Procedural Terminology (CPT®) ‡, copyright 2012 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules,

Alternative Treatments of Benign Prostatic Hypertrophy

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00126
Original Effective Date: 08/25/2003
Archived Date: 03/20/2013

relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	52647, 52648, 53850, 53852
HCPCS	No code
ICD-9 Diagnosis	600.00 thru 600.21
ICD-9 Procedure	60.21, 60.29, 60.95, 60.96, 60.97, 60.99

Policy History

Original Effective Date: 08/25/2003

07/15/2003	Medical Policy Committee review
08/25/2003	Managed Care Advisory Council approval
11/02/2004	Medical Director review
11/16/2004	Medical Policy Committee review. Format revision. No substance change to policy.
11/29/2004	Managed Care Advisory Council approval
10/05/2005	Medical Director review
10/18/2005	Medical Policy Committee review. Format revision. FDA approval information added. Eligibility coverage unchanged.
10/27/2005	Quality Care Advisory Council approval
11/01/2006	Medical Director review
11/15/2006	Medical Policy Committee approval. Coverage eligibility unchanged. TURP was removed from this policy. Title was changed to Alternative Treatments of Benign Prostatic Hypertrophy.
12/12/2007	Medical Director review
12/19/2007	Medical Policy Committee approval
12/03/2008	Medical Director review
12/17/2008	Medical Policy Committee approval. No change to coverage.
12/04/2009	Medical Policy Committee approval
12/16/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2010	Medical Policy Committee review
12/15/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/08/2011	Medical Policy Committee review
12/21/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2012	Medical Policy Committee review

Alternative Treatments of Benign Prostatic Hypertrophy

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00126
Original Effective Date: 08/25/2003
Archived Date: 03/20/2013

12/19/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2013 Medical Policy Committee review. Recommend archiving policy.
03/20/2013 Medical Policy Implementation Committee approval. Archived.
Next Scheduled Review Date: Archived medical policy

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.