

<p>SUBJECT: WATER-INDUCED THERMOTHERAPY AS A TREATMENT FOR BENIGN PROSTATIC HYPERPLASIA</p> <p>POLICY NUMBER: 7.01.57</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 08/15/02 REVISED DATE: 07/17/03, 06/17/04 ARCHIVED DATE: 06/16/05 EDITED DATE: 12/21/06, 12/20/07, 12/18/08, 12/17/09, 06/17/10, 06/16/11, 07/19/12, 07/18/13, 05/22/14 PAGE: 1 OF: 3</p>
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• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.

• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.

• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, water-induced thermotherapy has been medically proven effective and therefore, can be considered **medically appropriate** as a treatment option in the management of symptoms of urinary outflow obstruction secondary to BPH when ALL of the following criteria are met:
 - A. Men over the age of 50 years;
 - B. Prostatic length measures between 2.0 cm and 6.4 cm;
 - C. Clinical diagnosis of symptomatic BPH;
 - D. Failure of medical therapy or intolerance to medical therapy;
 - E. AUA Symptom Score or International Prostate Symptom Score (IPSS) of 11; and
 - F. Peak urinary flow rate less than or equal to 15 ml per second with a voided volume of 125 ml or greater.
- II. Based upon our criteria and assessment of peer-reviewed literature, use of water induced thermotherapy for any other urologic condition (e.g., prostate cancer, prostatitis, pelvic pain syndrome), as yet, has not demonstrated a benefit to patient outcomes and is considered **not medically necessary**.
- III. Relative contraindications to WIT are:
 - A. Confirmed or suspected prostate cancer;
 - B. PSA greater than 10 ng/ml;
 - C. Previous prostate surgery, rectal surgery, radical pelvic surgery or pelvic irradiation;
 - D. Median lobe protruding into bladder;
 - E. Symptomatic urethral strictures, bladder neck contracture or prostatitis;
 - F. Active UTI;
 - G. Immune system deficiency;
 - H. Neurogenic bladder;
 - I. Postvoid residual urine greater than 250 ml on ultrasound;
 - J. Patients with large prostate may not benefit from WIT because of its modest ablative power; and
 - K. Patient interest in future fertility.

POLICY GUIDELINES:

- I. As the WIT procedure does not require general anesthesia and usually requires only topical anesthetic gel, it can be performed in ambulatory surgery, outpatient surgery or a physician's office.
- II. Correct measurement of the prostatic length is essential for selection of the appropriate treatment balloon length. Prostatic length is determined by cystoscopy.
- III. As there is no tissue retrieved for pathological analysis, efforts must be taken pre-operatively to rule-out the presence of prostate cancer.

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DESCRIPTION:

Benign prostatic hyperplasia (BPH) resulting in bladder outlet obstruction is one of the most common afflictions in the aging man. Severe obstructive BPH can lead to urinary retention, infections, hematuria and renal insufficiency. The most common surgical procedure for BPH is transurethral resection of the prostate (TURP). A significant proportion of men will often defer TURP because of the risk of incontinence, impotence, retrograde ejaculation, bleeding, infection, stricture formation and persistence of urinary symptoms.

Water-induced Thermotherapy (WIT) is a minimally invasive treatment alternative to TURP. WIT involves the introduction of heated water (60 degrees C/140 degrees F) into the prostatic urethra by means of a special heat-transmitting balloon catheter. The special catheter design allows for heat to be delivered only to the targeted tissue of the prostatic urethra. The precisely heated water (controlled by a computer console) destroys a predictable amount of tissue by causing coagulative necrosis. Destroyed tissue is either sloughed off or absorbed by the body over time. As conductive heat is delivered (opposed to the radiant heat of Transurethral Microwave Thermotherapy or TUMT), and the catheter shaft is insulated, rectal and urethral temperature monitoring is eliminated. Patients typically require an indwelling catheter for at least one week (or until normal urinary flow is restored) due to post-procedure swelling and sloughing of prostatic tissue.

RATIONALE:

ArgoMed Inc. Thermoflex™ Water-Induced Thermotherapy (WIT) System was approved by the FDA in August 1999. The system is comprised of the prostatic catheter and Thermoflex console. "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 with prostate length between 2.0cm and 6.4 cm who present with symptoms of urinary outflow obstruction secondary to BPH."

The largest clinical trial investigating the efficacy and safety of WIT (125 patients) found WIT to provide significant and sustained improvement in peak flow rates, IPSS and quality of life scores up to 2 years. WIT is well tolerated with minimal discomfort and adverse events were seldom serious or difficult to manage (e.g., protracted hematuria, UTI, urinary retention). Though there are no data directly comparing WIT with either TURP or other minimally invasive therapies (microwave therapy/TUMT, laser prostatectomy), the results of WIT are roughly comparable to those of other minimally invasive therapies. WIT has shown to relieve the symptoms of BPH without the morbidity associated with TURP (e.g., blood loss, general or regional anesthesia, incontinence, impotence).

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: No specific codes

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HCPCS: No specific codes

ICD9:	600.00 Hypertrophy (benign) of prostate without urinary obstruction and other lower urinary tract symptoms (LUTS) 600.01 Hypertrophy (benign) of prostate with urinary obstruction and other lower urinary tract symptoms (LUTS) 600.10 Nodular prostate without urinary obstruction
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- 600.11 Nodular prostate with urinary obstruction
- 600.20 Benign localized hyperplasia of prostate without urinary obstruction and other lower urinary tract symptoms (LUTS)
- 600.21 Benign localized hyperplasia of prostate with urinary obstruction and other lower urinary tract symptoms (LUTS)
- 600.90 Hyperplasia of prostate, unspecified, without urinary obstruction and other lower urinary symptoms (LUTS)
- 600.91 Hyperplasia of prostate, unspecified, with urinary obstruction and other lower urinary symptoms (LUTS)

ICD10:

- N13.8 Other obstructive and reflux uropathy
- N40.0-N40.3 Enlarged prostate (code range)

REFERENCES:

BlueCross BlueShield Association. Water-induced thermotherapy as a treatment of benign prostatic hypertrophy – archived. Medical Policy Reference Manual Medical Policy #2.01.49. 2009 Jul 09.

Blute ML, et al. Minimally invasive therapies for benign prostatic hyperplasia. *Urol* 2001 Dec;58(6 Suppl 1):33-40.

Breda G, et al. Treatment of benign prostatic hyperplasia with water-induced thermotherapy: experience of a single institution. *J Endourol* 2002 Mar;12(2):123-6.

Cioanta I, et al. Water-induced thermotherapy for benign prostatic hyperplasia. *Techniques Urol* 2000 Dec;6(4):294-9.

Corica, AG et al. Fast liquid ablation system for prostatic hyperplasia: a new minimally invasive thermal treatment. *J Urol* 2003 Sep;174(3):874-8.

Corica F, et al. Transurethral hot-water balloon thermoablation for benign prostatic hyperplasia: patient tolerance and pathologic findings. *Urol* 2000;56(1):76-81.

Larson TR. Rationale and assessment of minimally invasive approaches to benign prostatic hyperplasia therapy. *Urol* 2002 Feb;59(2 Suppl 1):12-6.

Muschter R, et al. Transurethral water-induced thermotherapy for the treatment of benign prostatic hyperplasia: a prospective multicenter clinical trial. *J Urol* Nov 2000;164(5):1565-9.

U. S. Food and Drug Administration. Thermoflex™ water-induced thermotherapy system: 510(k) device approval K991847. 1999 [http://www.accessdata.fda.gov/cdrh_docs/pdf/K991847.pdf] accessed 4/2/14.

KEY WORDS:

Hot water balloon therapy, Thermoflex™ water-induced thermotherapy system, Water-induced thermotherapy.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Water-Induced Thermotherapy.