MEDICAL POLICY

SUBJECT: WATER-INDUCED THERMOTHERAPY AS A TREATMENT FOR BENIGN PROSTATIC HYPERPLASIA

POLICY NUMBER: 7.01.57
CATEGORY: Technology Assessment

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, water-induced thermotherapy (WIT) has been medically proven effective and therefore, will be considered medically appropriate as a treatment option in the management of symptoms of urinary outflow obstruction secondary to benign prostatic hyperplasia (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:

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.

<table>
<thead>
<tr>
<th>CPT:</th>
<th>55899</th>
<th>Unlisted procedure, male genital system</th>
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<table>
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<th>HCPCS:</th>
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<tr>
<th>ICD9:</th>
<th>Hypertrophy (benign) of prostate without urinary obstruction and other lower urinary tract symptoms (LUTS)</th>
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<tbody>
<tr>
<td>600.00</td>
<td>Hypertrophy (benign) of prostate with urinary obstruction and other lower urinary tract symptoms (LUTS)</td>
</tr>
<tr>
<td>600.10</td>
<td>Nodular prostate without urinary obstruction</td>
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</tbody>
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ARCHIVED DATE: 06/16/05
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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:


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

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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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

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