**Name of Policy:**
Transurethral Microwave Thermotherapy

**Policy #:** 449  **Latest Review Date:** September 2013  
**Category:** Surgery  **Policy Grade:** B

**Background/Definitions:**
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

**Medical Necessity** means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. 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.
Description of Procedure or Service:
Transurethral microwave thermotherapy (TUMT) has been proposed as an alternative to transurethral resection of the prostate (TURP), or daily medical therapy, for patients who have benign prostatic hyperplasia (BPH). Although TURP has been historically considered definitive treatment, complications from this treatment have encouraged the development of less invasive techniques.

Benign prostatic hyperplasia (BPH) is a condition which 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 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 (TURP) is one of the most commonly performed surgeries and is generally well tolerated, but 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 neurological 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 (TUMT) 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.

Policy:
Effective for dates of service on or after November 3, 2013:
Transurethral microwave thermotherapy for benign prostatic hyperplasia meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients who, based on severity of their BPH symptoms, would be candidates for transurethral resection of the prostate.
Effective for dates of service prior to November 3, 2013:
Transurethral microwave thermotherapy for benign prostatic hyperplasia meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients who, based on severity of their BPH symptoms, would be candidates for transurethral resection of the prostate and who have prostatic lengths of 35–50 mm.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
This policy was originally created in 1996 and was regularly updated with searches of the MEDLINE database through 2002. The policy was on “no further review” status from 2002 until 2010. Literature updates resumed in 2010; the most recent MEDLINE search was performed through June 2013. Following is a summary of the key literature to date:

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 transurethral microwave thermotherapy (TUMT). Specifically, two clinical trials, one randomized and one nonrandomized had compared microwave thermotherapy with transurethral resection of the prostate (TURP). The findings of these trials were supplemented with five 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 benign prostatic hyperplasia (BPH), although TURP was associated with significantly greater improvement after one year of follow-up. Moreover, while symptom relief following TURP appeared to be greater, fewer major complications were seen with TUMT.

In 2012, Hoffman and colleagues published an updated Cochrane Review on transurethral microwave thermotherapy for BPH. The review identified 15 RCTs involving a total of 1,585 patients. No new RCTs were identified since the previous review was published in 2008; the most recent RCT was published in 2002. Six trials were comparisons of microwave thermotherapy with TURP, eight were comparisons with sham thermotherapy, and one was a comparison with alpha blocker therapy. The range of duration of the studies was three to 60 months; the mean age of subjects was 66.8 years. Outcomes were reported in urinary flow rate and International Prostate Symptom Scores (IPSS) or converted to IPSS equivalents. 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 IPSS was -1.00 (95% confidence interval [CI]: -2.03 to -0.03), 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: -5.15, 95% CI: -4.26 to -6.04) on the IPSS and peak urinary flow (WMD: 2.01 mL/s, 95% CI: 0.85 to 3.16).
- 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.

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; six trials compared TUMT to TURP and one 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 six 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 transurethral resection of the prostate (TURP); transurethral microwave thermotherapy (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 transurethral microwave thermotherapy.

**Practice Guidelines and Position Statements**

The American Urological Association (AUA) last updated clinical guidelines for BPH in 2010. The guideline states that, based on a review of the data and consensus of an expert panel, TUMT is a treatment option for BPH. According to the guideline, TUMT is effective in partially relieving lower urinary tract symptoms secondary to BPH and may be considered for men with moderate or severe symptoms.

In 2011, the European Association of Urology (EAU) published guidelines on the treatment of non-neurogenic lower urinary tract symptoms in men. The guidelines included the following statements on TUMT:
“TUMT achieves symptom improvement comparable to TURP, but is associated with decreased morbidity and lower flow improvements” and “Durability is in favor of TURP with lower re-treatment rates compared to TUMT”.

**Key Words:**
Microwave thermotherapy, transurethral, Thermotherapy, transurethral microwave, benign prostatic hyperplasia, transurethral microwave thermotherapy, TUMT, Prolieve® Thermodilation System, Prostalund® CoreTherm™

**Approved by Governing Bodies:**
In December 2002, the Prostalund® CoreTherm™ System (Prostalund Operations AB, Concord, MA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process for use in men with BPH who have 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 earlier safety concerns related to thermal injuries. The treatment is contraindicated in men with a prostate less than 30 grams or a prostate length less than 35 mm.

In February 2004, the Prolieve® Thermodilation System (now owned by Medifocus; Columbia, MD) was approved by the FDA for the treatment of BPH through the PMA process in men with a prostate size of 20 to 80 grams and prostatic urethra length between 1.2 and 5.5 cm, and in whom drug therapy is typically indicated. The treatment is contraindicated in men with prostate sizes less than 20 grams and greater than 80 grams.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member’s benefit plan.
Pre-certification requirements: Not applicable

**Coding:**
CPT Codes:

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<th>Code</th>
<th>Description</th>
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<tr>
<td>53850</td>
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References:

Policy History:
Medical Policy Group, September 2010 (3)
Medical Policy Administration Committee, September 2010
Available for comment September 22-November 5, 2010
Medical Policy Group, September 2011; (3) Updated Key Points and References
Medical Policy Group, October 2012 (3): 2012 Update to Key Points and References
Medical Policy Panel, August 2013
This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.