MEDICAL POLICY DETAILS

<table>
<thead>
<tr>
<th>Medical Policy Title</th>
<th>TRANSURETHRAL MICROWAVE THERMOTHERAPY</th>
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<tr>
<td>Policy Number</td>
<td>7.01.28</td>
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<tr>
<td>Category</td>
<td>Technology Assessment</td>
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<tr>
<td>Effective Date</td>
<td>09/16/99</td>
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| Product Disclaimer   | • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.  
                        • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.  
                        • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. |

POLICY STATEMENT

I. Based upon our criteria and assessment of peer-reviewed literature, transurethral microwave thermotherapy (TUMT) for benign prostatic hyperplasia (BPH) has been medically proven to be effective and, therefore, is considered medically appropriate as a treatment option for patients who would be candidates for transurethral resection, based on the severity of their BPH symptoms, when BOTH of the following criteria have been met:
   A. prostatic length of 30-55 mm (the prostate size should meet the labeled indications of the specific device used for TUMT); and
   B. the patient must have failed medical therapy prior to proceeding with TUMT.

II. Based upon our criteria and assessment of peer-reviewed literature, transurethral microwave thermotherapy has not demonstrated a benefit to patient outcomes and is, therefore, considered not medically necessary for the treatment of other prostatic conditions (e.g., prostate cancer, chronic prostatitis).

III. Contraindications:
   A. Patients who have large prostate glands (greater than 5.5 cm in length or greater than 70 g in volume), medium lobe enlargement or bladder neck stenosis;
   B. Patients with metallic implants (e.g., artificial joints, pacemaker);
   C. Patients with bladder or prostate carcinoma;
   D. Patients with a history of previous prostate surgery or pelvic radiation therapy;
   E. Penile implants;
   F. Neurologic disorders that may influence bladder function;
   G. Neurogenic bladder;
   H. Diabetic neuropathy; or
   I. Urethral stricture.

DESCRIPTION

Benign prostatic hyperplasia (BPH) resulting in bladder outlet obstruction is one of the most common afflictions in the aging man. Transurethral microwave thermotherapy (TUMT) is an alternative to transurethral resection of the prostate (TURP) for patients with BPH. Microwave thermotherapy is the use of controlled heat at high temperatures to safely destroy excess prostate tissue. This minimally invasive procedure can be performed safely in an outpatient setting (ambulatory surgery setting or physician’s office) with the use of local anesthesia such as lidocaine gel and without the use of general or spinal anesthesia. Microwave thermotherapy effectively destroys excess prostate tissue and relieves the
pressure it places on the urethra, thus alleviating the symptoms and difficulties with urination. Some patients may need to use a catheter for a short time due to swelling of prostate tissue following treatment.

The FDA has approved several microwave thermotherapy devices for the treatment of BPH; including but not necessarily limited to the following devices: Prostatron (Edap Technomed, Inc), Prostalund® CoreTherm™ (ProstaLund Operations AB), Prolieve® Thermodilation System (Medifocus), Targis™ (Urologix Inc), Urowave System (Dornier Medical Systems), and TherMatrix® (TherMatrix Inc). The FDA recommends that prostate size should meet the label indications of the specific device used for transurethral microwave therapy.

RATIONALE

Evidence from clinical trials demonstrates that TUMT provides relief of lower urinary symptoms comparable to TURP without the need for inpatient hospitalization or general/spinal anesthesia. TUMT also provides significantly greater improvement of lower urinary tract symptoms when compared to medication therapy. TUMT produces fewer major harmful complications (bleeding, impotence, incontinence, TUR syndrome) than TURP. Symptom relief and voiding improvement have proven to be durable up to 3-4 years after TUMT.

Safety and efficacy of this technology for other prostatic conditions (e.g., prostatic carcinoma) have not been established in clinical trials.

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.

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REFERENCES


*Key Article

**KEY WORDS**

TUMT

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for transurethral microwave thermotherapy (TUMT).