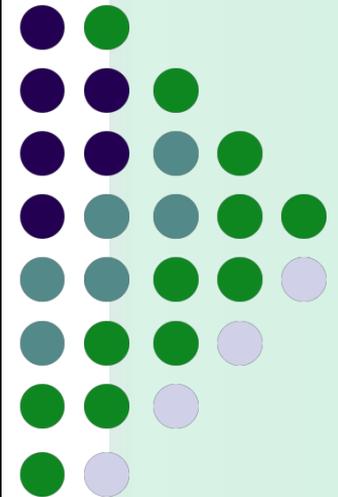


Medifocus, Inc.

OTC: MDFZF TSXV: MFS

www.medifocusinc.com

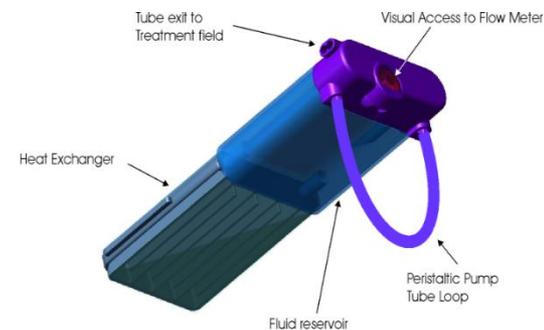
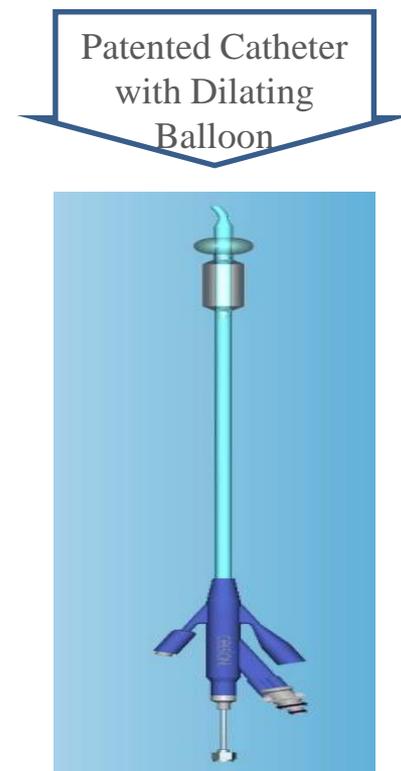
**Public Nomination to Comments to 59452
Federal Register/ Vol. 83, No. 226 as Potentially
Misvalued**



Feb. 2020

Prolieve[®] Transurethral Thermodilatation[™] System

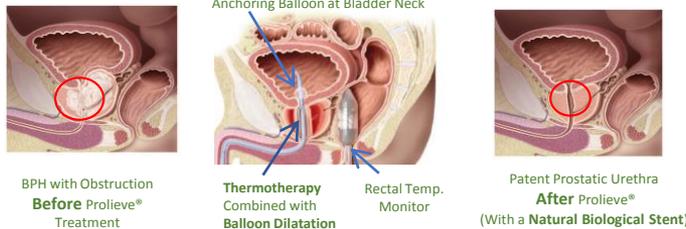
- FDA approved for the treatment of Benign Prostatic Hyperplasia (BPH), a medical term for benign enlargement of prostate
- 50% of men over age 50 and 90% over age 70 will develop symptoms of BPH
- BPH symptoms may include urgency, nocturia, hesitancy, weak stream, dysuria, retention and intermittency
- The quality of life of BPH sufferers is severely compromised
- Most other treatment options are either less effective, or have unacceptable risks of significant side effects.



Prolieve[®] Transurethral Thermodilatation[™] Advantages

The Only TUTD[™]

- The Only TransUrethral ThermoDilatation[™] (TUTD) with a Patented Dilating Balloon
- A 45-minute In-Office Procedure Performed Under Local Anesthesia
- Proven Safety and Efficacy Records - **Over 100,000 Cases Performed in the U.S.**



A Safe & Effective Alternative to BPH Medications & Surgery

- ✓ Minimal/No Sexual Side Effects (E.D. & Retrograde Ejaculation)
- ✓ Proven Long-Term Safety, Efficacy & Durability
- ✓ No Foreign Bodies/Clips/Anchors embedded within the Urinary Tract
- ✓ No Perforation of Prostatic Urethra to minimize Pain & Hemorrhage
- ✓ Improved Patient Comfort & Rare Requirement of Post-Treatment Catheterization

“Prevention of BPH Progression”

12-Year FDA Post Market Study
of Prolieve[®]-Treated Patients with 5-Year Follow-ups
Now Completed and Accepted

- ✓ 85% Post-Treatment Catheter-Free Rate
- ✓ Minimal/No Sexual Side Effects
 - Erectile Dysfunction: 0.3 per 100 person-years
 - Retrograde Ejaculation: 0.3 per 100 person-years
- ✓ Improvement of Mean AUA Symptom Score
 - Baseline = 20.1 vs. Year 5 = 12.8
- ✓ Improvement of Peak Flow Rate (Qmax)
 - Baseline = 8.6 mL/sec vs. Year 5 = 12.8 mL/sec
- ✓ Improvement of Quality of Life (QoL) Score
 - Baseline = 22.0 vs. Year 5 = 16.5
- ✓ Stabilization of BPH Symptoms
 - 83% reported No Progression at Year 5
- ✓ Stabilization of Serum PSA and Prostate Size

FDA's Approval

The RUC committee, in January of 2018, did not have the latest FDA PMS Supplement of Prolieve which was approved on 11/21/18 (*see below*).



November 21, 2018

John Mon
General Manager
Medifocus, Inc.
10240 Old Columbia Road, Suite G
Columbia, MD 21046

Re: P030006/S028
Trade/Device Name: Prolieve Thermodilation System
Product Code: MEQ
Filed: March 30, 2018

Dear John Mon:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) 180-day supplement, which requested approval for a labeling update with the results of the Post-Approval Study (PAS). Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> identifies combination product submissions.

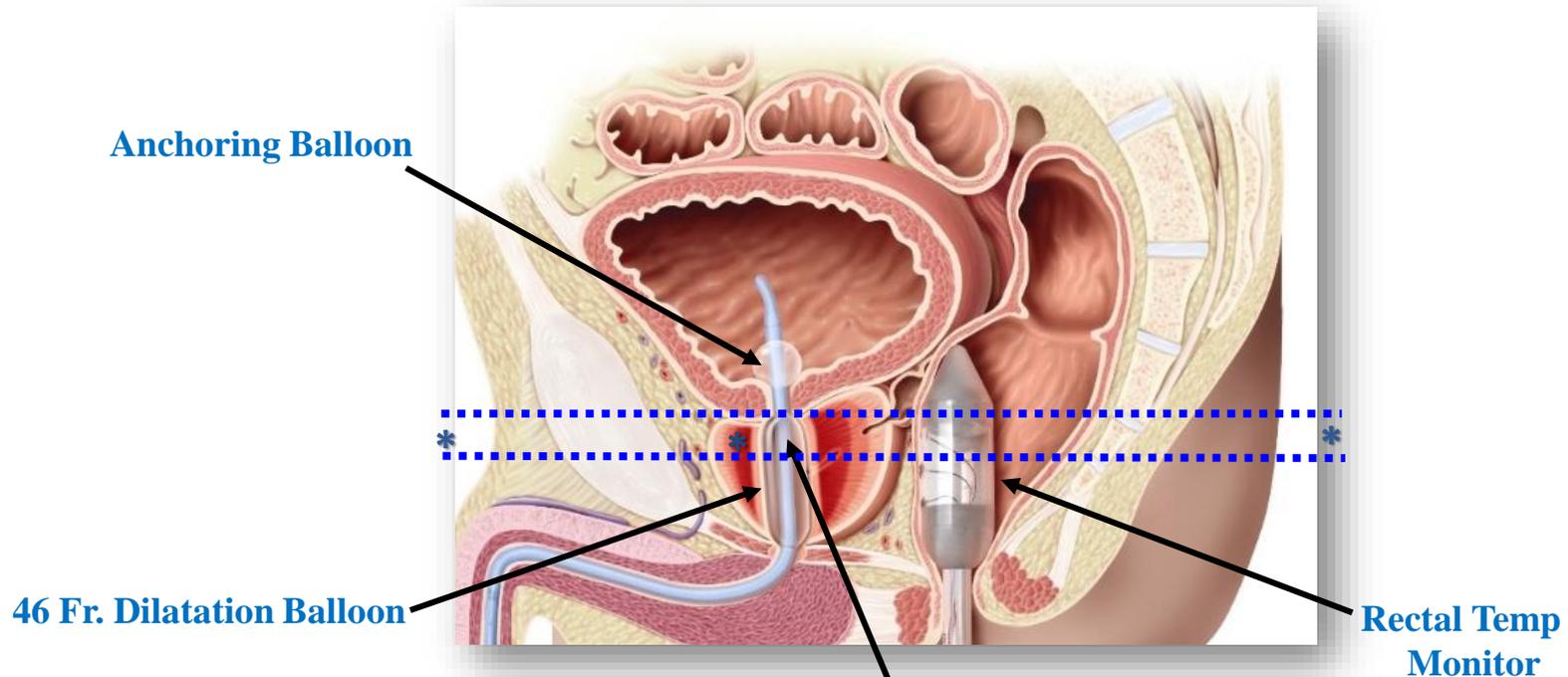
1st & 2nd Generation vs. 3rd Generation

- A. Current CPT Code 53850 is for traditional microwave single modality TUMT.
- B. Prolieve Transurethral Thermodilatation is currently lumped under CPT 53850.
- C. Prolieve is NOT a 1st and 2nd generation TUMT treatment device. We agree with the RUC committee as based upon the 1st and 2nd generation TUMT falling under 53850 as they require less treatment time than the 3rd generation. This justifies the reduction in reimbursement of the CPT code by 24%.
- D. However, that does not take into account Prolieve System also provides the demonstrated clinical benefits of the Prostatic Urethral Dilation Balloon.
- E. The proven immediate and long-term benefits of our office-based treatment, as accepted by the FDA, is attributed to the thermotherapy AND the Prostatic Urethral Dilation Balloon.
- F. The Prolieve TUTD 3rd generation TUMT requires an increase of 50% treatment procedural time over the 1st and 2nd Generation TUMT to provide the added clinical and safety benefits of our TUTD treatment modality.

**Our letter to CMS of 11-11-19 outlines this in detail.*

How is Prolieve[®] Different?

The Only Transurethral ThermoDilatation[™] (TUTD[™])
with a Patented 46 Fr. Dilating Balloon



*A 1.2 cm built-in Microwave Antenna is Positioned At the Base of the Prostate Gland

Prolieve[®] Costs

We believe CPT Code 53850 for Prolieve is misvalued as evidenced by our latest FDA approved 5 year study, which demonstrated durable, lasting results.

Prolieve Time Requirements:

- Additional pre-treatment prep time. This includes a minimum of 15-20 minutes to pressurize the system, pre-heat the heat exchanger, test the rectal temperature monitor and to ensure no leakage of the anchoring and especially the dilatation balloon.
- 10-minutes to administer local intraurethral anesthesia and to assess adequacy of anesthesia.
- 45-minute treatment (as opposed to 1st & 2nd generation of 28.5 minutes); with added complexity required in monitoring of the highly pressurized system and constant assessment of the positioning of the anchoring balloon and rectal temperature probe.
- 5-minute cool-down period to effect a biological stent.
- 15 minutes to de-pressurize the system, fill/irrigate the bladder with saline and removal of the treatment catheter and rectal monitoring probe.
- 20-25 minutes of immediate post-treatment voiding trial with assessment of voiding pattern and of any bleeding/clots, since almost all patients are sent home without an indwelling catheter as opposed to other TUMT or minimally-invasive treatments.

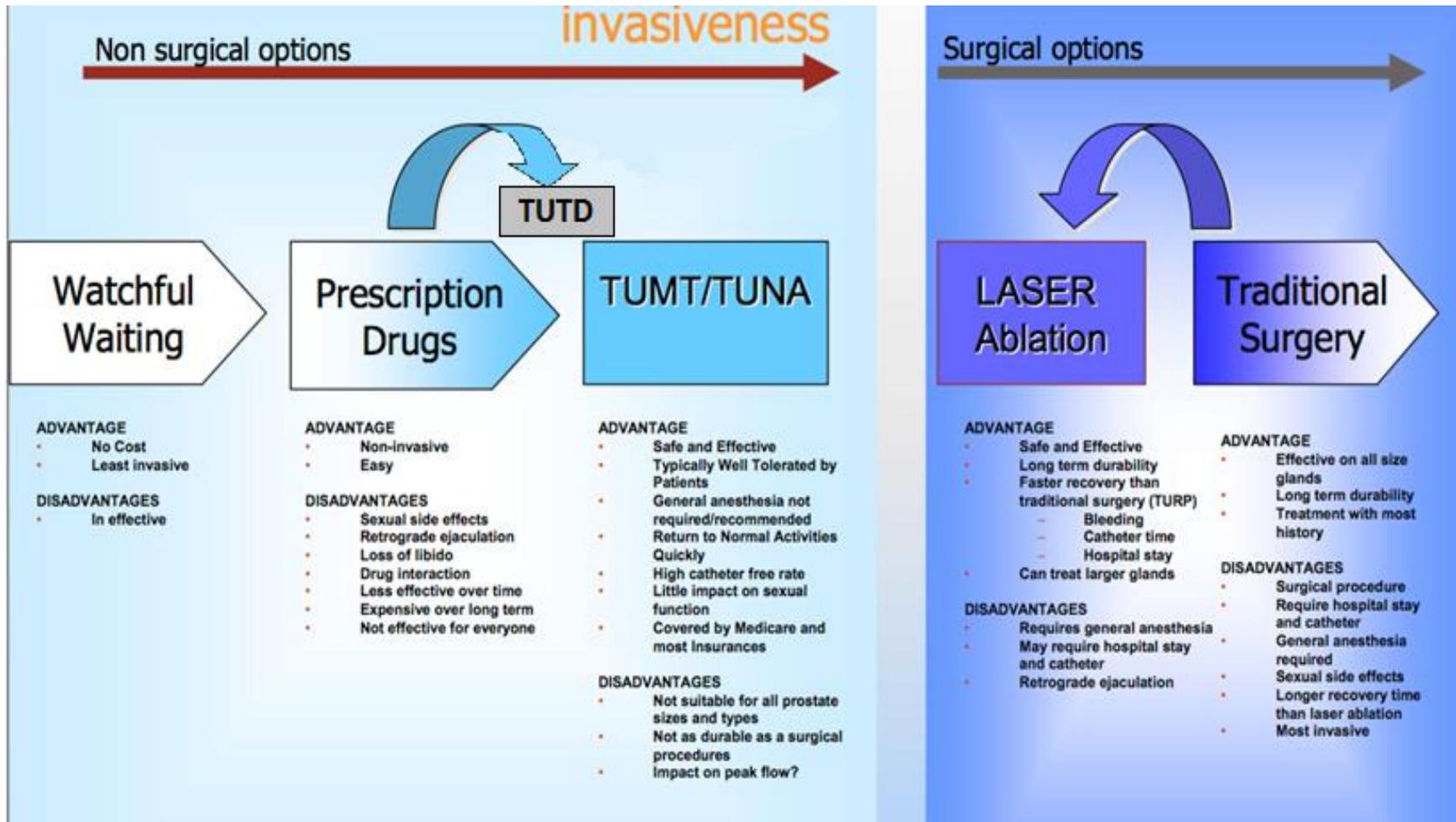
Prolieve Treatment Device/Equipment:

- The sophisticated design of the Prolieve catheter with the embedded microwave antenna and Prostatic Urethral Dilatation Balloon increases the manufacturing costs of Prolieve catheter several times over that of the catheters used in the 1st and 2nd generation TUMT treatment device.
- Cost of treatment console is higher than the 1st & 2nd generation TUMT due to its ability to control/monitor and inflate/pressurize the transurethral prostatic dilatation balloon used in the treatment.
- Increased cost due to pressurized Heat Exchanger to ensure optimum treatment temperature and pressure. This is unique to Prolieve[®] Thermodilatation System.

Healthcare Savings of BPH Management

- Prolieve® is a savings to the overall health care cost for the management of BPH as compared to other treatment modalities such as ie: TURP, Lasers, Urolift and medications.
- We are an office-based treatment so it eliminates the higher costs of hospital or surgery centers.
- It's a safe and effective, patient friendly treatment and **only local anesthesia** is required.
- The majority of patients **do not require** post-treatment catheterization which can be from 1 week to over 1 month with these other treatments.
- It improves the quality of life and does not have side effects like the other treatment options.

BPH Options from least invasive to most invasive



Our Proposed Recommendations

- Increase CPT reimbursement of 53850 to compensate for the significant increase in expertise, equipment cost and time required to perform the Prolieve treatment.
- Allow the bundling of CPT Code 74485 which is for the dilation of ureter(s) or urethra, radiological supervision and interpretation. The dilation feature of Prolieve Transurethral Thermodilatation™ is similar in scope and application to the procedures under CPT Code 74485. Therefore, additional CPT Code 74485 should apply to Prolieve Transurethral Thermodilatation™ procedure.
- New modified CPT code to incorporate the FDA supplemental approval for Prolieve as we are the **only** Thermodilatation treatment platform.

Conclusion

- In conclusion, without consideration for the misvaluation of the Prolieve reimbursement, it is economically not feasible for Medifocus, Inc. to provide our Prolieve treatment to the marketplace.
- The physicians using Prolieve will not be able to provide the Prolieve treatment because they are not fully compensated for the cost of the equipment and their time.
- It will reduce the treatment options of the 3rd generation microwave to the patients who can greatly benefit by its use. To date, Prolieve has already benefited over 100,000 patients.
- Finally, we believe the correction of the misvaluation will fall in line with CMS's agenda in keeping new technologies on the market for the benefit of the patients.