

# Sample Letter of Medical Necessity – Prior Authorization

*The following letter should be attached to all written prior authorization requests for treatment using The Spanner.*

[Date]

[Health Plan Name]  
[Street Address]  
[City, State Zip]

RE: [Patient's Name/Policy Number]

To Whom It May Concern:

I am writing to request prior authorization for treatment of [insert patient diagnosis] using The Spanner™ Prostatic Stent on behalf of my patient [patient's name]. [Note whether this patient has undergone previous treatments and how long the patient has had symptoms.] In order to prevent [\_\_\_\_\_], I recommend that he be treated with The Spanner. I strongly believe that this patient's condition and medical history makes him a viable candidate to receive this treatment. This procedure is medically necessary and warrants coverage in this case.

The Spanner received FDA clearance on December 14, 2006. It is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-catheterization. The Spanner is the first approved prostatic stent indicated for *temporary* use and offers the benefit of voluntary urination. It is only the second prostatic stent ever approved by the FDA, its predecessor being the Urolume®, a permanent stent.

The Spanner is a steel wire reinforced silicone stent. The Surveyor is first used to measure the length of the urethra from the bladder neck to the distal side of the sphincter. Insertion is accomplished with the stent mounted on an Introducer that is passed into the bladder. The distal balloon is then inflated using sterile water and the Introducer withdrawn until the balloon abuts the bladder neck. The stent is the only component which remains in situ. The stent lies between the bladder neck and external sphincter; a suture crosses the external sphincter which allows the patient to remain continent and void actively. The retrieval tether is trimmed such that the distal end is just inside the meatus or it may be left extending beyond the meatus.

The Spanner randomized controlled trial evaluated the safety, efficacy and patient tolerance of The Spanner in men during their post- microwave thermotherapy (TUMT) healing period. The outcomes of 100 men in the Spanner group were compared to those of 86 men in the Standard of Care control group.

Spanner men had significantly greater improvements in BPH symptoms as measured by the International Prostate Symptom Score (p=0.019), and in the uroflowmetry parameters such as peak flow rate (p<0.05) and post void residual (p =0.001) compared to the control group. As assessed just prior to removal, patient satisfaction with the stent exceeded 86%. Also, 85% of subjects indicated that they would recommend Spanner use to a friend.

Eighty-two percent of the Spanner patients reported “no” or “mild” discomfort during insertion. During removal 82% of subjects reported “no” or “mild” discomfort.

Cystoscopic assessment of the two groups was comparable suggesting that the urethra and bladder were in similar condition post-TUMT regardless of the presence of the Spanner. Finally there was no statistical difference between the Spanner and the Standard of Care control group for the rates of adverse events requiring treatment.

The Spanner insertion procedure is most appropriately billed with CPT code 0084T (*Insertion of a temporary prostatic urethral stent*). In the Medicare system, the primary patient population for The Spanner, the Category III codes are considered to be status C. Status C codes can be covered by the carrier if the service is deemed medically appropriate. An independent survey was conducted by Relative Value Studies, Inc. and an interim value for code 0084T was established. The values are published in two separate products; *Relative Values for Physicians*, published by Ingenix and Relative Value Studies, Inc. *The Complete RBRVS*, published by Relative Value Studies, Inc. In order to provide guidance for reimbursement relative to other services in both the public and private sectors, *The Complete RBRVS* has published a value of 21.98\*. This is a global value which encompasses both the insertion of the stent as well as the practice expense and malpractice values for this procedure.

*\* this value does not include the 2007 budget neutrality adjustment*

Since the Centers for Medicare and Medicaid Services (CMS) do not assign relative values for Category III CPT codes, I would like to inform you that I am submitting a charge of [SXXX], which represents the device cost, time, skill, and medical decision making necessary to perform this procedure.

I request confirmation that this treatment is a covered benefit based on medical necessity, and that associated professional fees for this device and treatment will be covered. The Spanner insertion procedure for [patient name] is scheduled for [date].

If you require additional information, please contact me at [insert telephone number].

Sincerely,

(Physician Name)  
(Provider number)  
(Street Address)  
(City, State Zip)