Sample Letter of Appeal Due to Experimental & Investigational Denial for the UroLift® System Treatment; MAC00115-01 Rev H

[Date]

Re: [Insert Patient Name] [Insert Patient ID #]

[Insert Claim # or Reference #] [Insert Patient DOB]

[Insert Date of Service]

Dear [Name of Medical Director or insurance company]:

I am requesting reconsideration of the above referenced denial of prostatic urethral lift (PUL) using the UroLift® System as experimental and investigational. PUL using the UroLift® System has been cleared for use by the FDA since 2013.

The UroLift ® System is currently indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia, in men 45 years of age or older.

Additionally, the current peer-reviewed, published scientific literature is more than adequate to establish the clinical utility, safety and efficacy of this minimally invasive treatment for BPH. Therefore, the UroLift PUL procedure should no longer be considered experimental or investigational.

The UroLift PUL procedure has been well-studied in high quality trials and is the subject of over 25 peer-reviewed publications, describing two separate RCTs, three meta-analyses, and multiple open label studies. All of the studies show consistent, reliable, and durable improvements in urinary symptoms and quality of life, preservation of sexual function, and reduced recovery time and morbidity compared to alternative treatment options. PUL also does not require an overnight stay, can be conducted under local anesthesia, in many cases can be done in the office, shows return to preoperative activity in under a week, and reduces post-operative catheterization rates compared to alternative interventions, all while avoiding complications associated with other BPH treatments. The transient adverse events associated with PUL, including mild to moderate hematuria, dysuria, micturition urgency, pelvic pain and urge incontinence typically resolve on their own within two to four weeks.

The American Urological Association develops scientifically rigorous, peer-reviewed guidelines. The 2018 update to their Guidelines on the Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostate Hyperplasia positions the Urolift PUL procedure as part of the standard of care alongside TURP, laser, and other established procedures.

The National Institute for Health and Clinical Excellence (NICE) issued an independently reviewed meta-analysis of publications and outcomes in which they conclude that PUL relieves lower urinary tract symptoms while avoiding risks to sexual function in a way that is cost-effective compared to transurethral resection of the prostate (TURP). The European Association of Urology (EAU) has given PUL their highest evidence rating of level 1A. PUL is a widely accepted treatment alternative for BPH and is currently being used in many countries, including over 1500 centers in the USA.

Prior to PUL, this patient suffered from [List all chief complaints: e.g. interrupted sleep due to nocturia, frequency, urgency sometimes with urge incontinence, interrupted flow with frequent need to urinate, etc.] for [duration of condition]. After discussing next steps and alternative treatment options, we chose the PUL procedure because it is associated with significant and rapid symptom improvement, no instances of new, sustained erectile or ejaculatory dysfunction, and can avoid other serious complications associated with TURP, laser or thermal therapy procedures. In fact, the occasional transient adverse effects associated with PUL, including mild to moderate hematuria, dysuria, urinary urgency, pelvic pain, and urge incontinence, usually resolve within two to four weeks. It is my professional medical opinion that minimally invasive, clinically proven PUL was the best treatment option for this patient. Not treating or delaying treatment of this condition can result in eventual deterioration of bladder function, urinary retention, recurring urinary tract infection and deterioration in quality of life.

In summary, the PUL procedure has been well-studied and reported in numerous high quality peer-reviewed publications. Results demonstrate that this BPH procedure offers reliable, repeatable results, including rapid relief from symptoms, increased urinary flow, and improvement in quality of life that are durable through five years. Based on the abundance of information provided here, it is clear PUL is neither experimental nor investigational.

Please reconsider this denial for coverage and payment of the medically necessary, clinically supported and FDA cleared PUL procedure.

If I can provide any additional information, please don’t hesitate to contact me at [phone number].

Sincerely,

[Physician’s name]

Enclosures:

Copy of EOB

Supporting Medical Records

UroLift bibliography

Supporting Letters from the AUA, SMS, and SUFU