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

[Date]

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

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

[Insert Date of Service if available]

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. The American Urological Association (AUA) develops scientifically rigorous, peer-reviewed guidelines in their mission to promote the highest standards of urological clinical care. The 2018 update to their Guidelines on the Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostate Hyperplasia positions the PUL procedure (using the UroLift System) as part of the standard of care alongside TURP, laser, and other established procedures. 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 PUL procedure should no longer be considered experimental or investigational.

The PUL procedure using the UroLift System 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, no new, sustained sexual dysfunction, 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 patients typically return to preoperative activity in under a week and have reduced post-operative catheterization rates compared to alternative interventions, all while avoiding potential 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.

This patient has 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. 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 and is considered a standard of care by the most respected urology specialty society in the U.S. 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

Link to AUA Guidelines: <https://www.auanet.org/guidelines/benign-prostatic-hyperplasia/lower-urinary-tract-symptoms-(2018)>