MAC00161-01, Rev G; Sample Letter of Appeal Due to Denial for Medical Necessity

[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 for lack of medical necessity. Prostatic urethral lift (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 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. The PUL procedure was medically necessary for this patient.

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, no instances of new, sustained erectile or ejaculatory 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 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. TURP, laser vaporization or thermal therapy procedures are associated with potentially serious complications such as permanent incontinence, erectile dysfunction, strictures or bladder neck contracture. However, 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.

For medically appropriate patients, like Mr. [insert patient last name], PUL provides unique and necessary benefits that are both rapid acting and durable. PUL was medically necessary for this patient due to his urinary symptoms caused by BPH. [Describe medical necessity, including length of symptoms, size of prostate, previous treatments tried and why they were discontinued, and the results of any other tests or assessments demonstrating medical necessity.] [Describe why UroLift was appropriate for this patient, such as:

* On anticoagulants, therefore more invasive surgeries carry a risk of bleeding
* Need for a less invasive procedure or less anesthesia
* Patient concerned with preserving sexual function
* Fear of risks of permanent side effects such as incontinence, bladder neck contracture, retrograde ejaculation, etc.
* Less chance of post-op catheterization]

Not treating or delaying treatment of BPH can result in eventual deterioration of bladder function, urinary retention, recurring urinary tract infection and deterioration in quality of life.

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.

It is my professional medical opinion that PUL was the best treatment option for this patient not interested in more invasive BPH treatments that include tissue resection or ablation and are commonly associated with increased bleeding, lengthy recovery and sometimes permanent negative collateral side effects.

In summary, the PUL procedure has been well-studied and reported in numerous high quality, peer-reviewed publications. Objective results demonstrate that the PUL procedure offers reliable, repeatable results including rapid relief from symptoms, increased urinary flow, and improvement in quality of life that are durable to at least five years. Based on the abundance of information provided here, it is clear that PUL is broadly accepted as an appropriate treatment option in the urology community, and was medically necessary for this particular patient.

Please reconsider this request for coverage and payment at your earliest convenience or contact me at [phone number] if I can provide additional information.

Sincerely,

[Physician’s name]

Enclosures:

Copy of EOB

Pertinent Medical Records

UroLift bibliography

AUA Guidelines

Supporting letters from the AUA, SMS, and SUFU