SAMPLE APPEAL

Date
Medical Director
Insurance Company
RE: Claims / Preauthorization Denial
Patient's Name/Policy number
Subscriber Name/Group Name

Dear Dr. *[Insert name of Medical Director]*

I am writing to appeal [*insert name of insurance company*]'s recent denial of benefits for my patient [*insert patient name*] for treatment of [*eg. Benign prostatic hyperplasia (BPH), insert other diagnoses*] using the Aquablation robotic transurethral waterjet ablation procedure. The denial states the procedure is investigational [***note, this will be the most common reason for denial. If there is a different reason for denial, modify this letter accordingly.***] I dispute the conclusion that the Aquablation procedure is experimental/investigational and I am appealing this decision. The Aquablation procedure using the AQUABEAM® System was cleared under a *de novo* request in December 2017. The AQUABEAM System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms due to benign prostatic hyperplasia.

[*Insert patient name*] has been thoroughly evaluated and has been diagnosed with [*insert patient's diagnosis[es]].* Attached to this letter is the original documentation I submitted substantiating medical necessity. I request that you review this information again with particular attention to the patient's history of [*insert patient specific history and treatments*]. Numerous conservative attempts at treatment have been tried and failed such as [*insert previous treatments*.]

Despite these treatment attempts, [*insert patient name*] has received no relief from symptoms *[or has worsening symptoms]* and is currently *[insert detailed patient history with description of patient's current condition including diagnosis, length of time problem has existed, current/ongoing complaints, and level of impairment evidenced by diagnostic tests, prostate volume, etc. Describe functional impairments, and how the patient's condition has impacted his activities of daily life.].*

I have reviewed the clinical literature, including a double-blinded, multicenter prospective randomized controlled trial, 181 patients with moderate-to severe lower urinary tract symptoms related to BPH underwent transurethral resection of the prostate using either standard electrocautery [TURP] or robotic waterjet [Aquablation therapy]. The primary efficacy endpoint was reduction in International Prostate Symptom Score [IPSS] at 6 months. The primary safety endpoint was the occurrence of Clavien-Dindo persistent grade 1 or Grade 2 or higher operative complications at 3 months.

In patients with moderate-to-severe LUTS due to BPH, surgical prostate resection using a robotically guided waterjet showed non-inferior symptom relief compared to TURP. Avoiding thermal energy induces an earlier benefit with storage symptoms. The combination of robotics and image guidance significantly reduces tissue resection time regardless of prostate size. In addition, the trial documented a lower risk of sexual dysfunction. Other points to note:

- Aquablation therapy met both primary safety and efficacy endpoints compared to TURP
- Aquablation therapy and TURP had similar reductions in PSA at 6 mo
- Aquablation therapy provided TURP-like results despite newness of procedure
- Aquablation therapy produced superior safety and efficacy results in larger glands
- Aquablation therapy preserves ejaculatory function and continence to a greater degree than TURP

[IF PATIENT HAS A PROSTATE > 50g, ADD]
Men with prostate size >50 g [prespecified analysis] had statistically superior improvements in IPSS after Aquablation therapy compared to TURP [p<0.02]. With larger prostates comes increased variability for TURP, which allow the robotics to demonstrate superior efficacy against TURP. There is no contraindication for Aquablation therapy in prostates > 80g.

I believe Aquablation therapy is the best treatment for *[insert patient name]* because less invasive alternatives are no longer appropriate and [*insert rationale, eg. efficacy in line with TURP with fewer adverse events such as sexual side effects due to more precise tissue targeting, heat free option, and if relevant, patient prostate size.*

I would welcome an opportunity for a peer-to-peer review that will provide an opportunity for us to fully discuss this patient case. Please let me know if we can schedule this. I am happy to provide any additional documentation and medical records for further consideration.

Sincerely,

[Name and credentials of treating surgeon]

Enclosures
(Bibliography with summary and links)

CC: Patient