SAMPLE PRIOR AUTHORIZATION LETTER
Date
Payer
Re: *[Insert patient name and subscriber number]*

Dear Medical Director:

Please consider this request for preauthorization of benefits to treat my patient, *[insert patient name]*, who suffers from benign prostatic hyperplasia [BPH]. It is my clinical judgment that *[insert patient name]* is an ideal candidate for transurethral waterjet ablation.

I am seeking preauthorization for my patient.

Patient History

A problem-focused history and exam was performed. The findings of these test results support my request for treatment.

- *[Insert patient name]* presented to me with complaints of *[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.]*
- Previous treatments efforts include: *[indicate pharmaceutical therapy, procedures, and/or therapies attempted - include outcome of each treatment].* Despite these treatments and therapies, *[insert patient name] remains symptomatic from BPH [insert specific symptoms here]*.

Proposed Treatment and Clinical Evidence

Aquablation therapy, delivered by PROCEPT BioRobotics' AQUABEAM® Robotic System, uses a robotically controlled waterjet to remove prostate tissue without the application of heat. The AQUABEAM Robotic System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms due to benign prostatic hyperplasia. The AQUABEAM Robotic System was cleared under a *de novo* request in December 2017.

The double blind, prospective, multicenter randomized WATER Study compared Aquablation therapy to TURP in 181 male patients, age 45 to 80 years with urinary symptoms due to BPH. 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. Clavien-Dindo is a rating system for postoperative complications (Gilling et al., Journal of Urology, 2018).

Mean total operative time was similar between Aquablation therapy and TURP [33 vs. 36 minutes, p=.2752] but resection time was lower in Aquablation therapy [4 vs. 27 minutes, p<.0001 At month 6, both groups had large IPSS improvements; the difference in IPSS change

[Aquablation therapy – TURP] was 1.8 points larger [95% CI-0.4 – 4.0] after Aquablation therapy compared to TURP, meeting the study's non-inferiority hypothesis.

Both groups had large and similar improvements in urinary flow rates and post-void residual volumes. The 3-month primary safety endpoint rate was lower in Aquablation therapy (26%) compared to TURP (42%), meeting the study's primary non-inferiority safety hypothesis and subsequently demonstrating superiority.

Amongst sexually active subjects, the rate of retrograde ejaculation was lower in patients treated with Aquablation therapy [10% vs. 36%, p<0.001]. The study met its primary endpoints, indicating that surgeons were able to deliver high-quality TURP-like outcomes using Aquablation therapy.

Data Summary:

Endpoints	Aquablation therapy vs. TURP
Primary Safety (Rate at 3M)	Superior
Primary Efficacy (Reduction in BPH Symptoms)	Similar
Reduction in BPH Symptoms: Large prostates (≥50 mL)	Superior
Uroflow – Max urinary flow rate	Similar
Anejaculation events	Superior
Change in MSHD-EjD	Superior
Change in erectile Function	Similar
Incontinence Severity	Similar

The two-year results from the WATER Study were recently published. At two-years, the improvements in symptom scores were maintained in both arms as well as the improvements in maximum urinary flow rates. Both arms demonstrated very low surgical retreatment rates. The Aquablation therapy group maintained its significant advantage maintaining a superior ejaculatory profile (Gilling et al., Advances in Therapy 2019 - enclosed).

Please see clinical articles and bibliography.

[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.

In the WATER II Study Aquablation therapy showed similar hospital length of stay and outcomes at 1 year for prostate sizes of 80-150cc as observed in prostates 30-80cc. (Bhojani et al., UROLOGY 2019-enclosed) The large prostates of this size range are typically treated with an in-patient open simple prostatectomy rather than TURP. Aquablation therapy provides a minimally invasive option to an open surgical procedure. The WATER II Study enrolled 101 male patients, ages 45 to 80 years, with urinary symptoms due to BPH, at 16 sites in the United States and Canada. Aquablation therapy with the AQUABEAM Robotic System met its primary clinical endpoints for

both safety (3 months) and efficacy (3 months) results compared to the pre-defined measures. The data demonstrated that use of Aquablation therapy in men with large prostates (80 to 150 mL) resulted in a significant improvement in both symptom scores and urinary flow rates.

Based on both the WATER and WATER II studies, the Centers for Medicare and Medicaid Services (CMS) found Aquablation therapy to represent a "substantial clinical improvement" to both TURP and simple prostatectomy in the FY 2019 Inpatient Prospective Payment System (IPPS) ruling (CMS-1694-F) granting Aquablation a New Technology Add-On Payment (NTAP):

- *Results of the WATER study are statistically significant and superior to TURP in safety as evidenced by a lower proportion of persistent CD Grade 1 adverse events.*
- *Patients enrolled in the WATER study with prostate sizes > 50 mL and treated with Aquablation therapy had superior IPSS improvement [compared to] TURP.*
- *Results from the WATER II study for patients with large prostate volumes demonstrate better outcomes of the AquaBeam System over the standard-of-care, the open prostatectomy.*

On November 1, 2019, CMS granted approval for a Transitional Pass-Through (TPT) payment for Aquablation Therapy as part of the 2020 Outpatient Prospective Payment System (OPPS) ruling (CMS-1717-FC)[1]. Like the NTAP[2] designation, CMS determined Aquablation represents a "substantial clinical improvement" to current surgical techniques for BPH, stating "In conclusion, after review of the additional data and literature, we agree that the AquaBeam® System provides a substantial clinical improvement." Specifically, CMS noted the following in the final rule:

- *CMS concluded that the WATER study findings were statistically significant and showed Aquablation superior to TURP in safety, as well as that patients in the WATER study with prostates larger than 50 mL in volume treated with Aquablation had superior improvement in quantifiable symptom outcomes.*
- *The additional scientific data provided demonstrated Aquablation therapy's superiority to other techniques, specifically reducing operative time and complications in general, especially for larger prostates.*
- *The results of the WATER clinical study were statistically significant and show Aquablation therapy was superior to TURP in safety as evidenced by a lower proportion of persistent adverse events (incontinence, ejaculatory dysfunction and erectile dysfunction) at three months.*
- *Additionally, results from the WATER II clinical study for patients with large prostates demonstrated better outcomes from Aquablation therapy over open prostatectomy, regarding shorter operative time, shorter length of stay, and decreased rates of severe hemorrhage and transfusions. The minimally invasive nature of Aquablation therapy offers men with large prostates (>80mL) an outpatient option.*

[1] OPPS Final Rule https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC.html

[2] IPPS Final Rule https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Regulations.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending

Based on the clinical literature, the American Urologic Association (AUA) recently included Aquablation therapy in its 2019 Practice Guidelines for the "Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia".

In addition, effective December 18, 2019, Anthem Blue Cross Blue Shield updated its medical policy, *#SURG 00028 Surgical and Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH)* to include Waterjet tissue ablation, also known as Aquablation® Therapy, among the procedures that "are considered medically necessary as an alternative to open prostatectomy or transurethral resection of the prostate for the treatment of benign prostatic hyperplasia".[3]

I believe Aquablation therapy is the best treatment for *[insert patient name]* because less invasive alternatives are no longer appropriate and [*insert rationale, e.g. 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.]*

Coding and Charges

The code to report the procedure is:

- CPT code 0421T Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
- [Add additional codes as applicable]

My charge is $ [fill in your charge] based on the comparative procedure work to *[insert procedure name/CPT code, for example, laser vaporization of the prostate (52648) or TURP (52601)]*

This procedure will be performed on [*indicate anticipated date]* at *[indicate site of service and name of facility where the procedure will be performed].* Please confirm if there are any restrictions on performing this procedure in this setting.

Feel free to contact me if you would like additional information about the treatment or patient case. My contact information is

[Physician contact].

Sincerely,

[Name and credentials of treating surgeon]

Enclosures
(Bibliography with summary and links)

[3] https://www.anthem.com/medicalpolicies/policies/mp_pw_a053318.htm