Date

Medical Director
Address
Contact

RE: Claims Denial

Patient: NAME and POLICY #

Attention: Medical Director

I am writing to appeal (PAYER NAME) denied claim (ADJUDICATION DATE), for my patient (PATIENT NAME) for treatment of benign prostatic hyperplasia (BPH) with Aquablation® therapy, delivered by the PROCEPT BioRobotics' AQUABEAM® Robotic System. The procedure uses a robotically controlled waterjet to remove prostate tissue without the application of heat. The CPT procedure code is 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)*.

Attached to this letter is the original documentation I submitted substantiating medical necessity. I request that you review this information again with attention to the patient's history involving numerous alternative treatments, which have been tried and failed. Despite these treatments, Mr. (PATIENT NAME) had received no relief from his BPH symptoms. Aquablation® therapy was the best treatment for my patient because less invasive alternatives were no longer appropriate. The Aquablation therapy procedure was performed on (DATE) and, on follow up, the patient is (PLACEHOLDER TO EXPAND ON PATIENT RESULTS AND REDUCTION OF SYMPTOMS).

The AQUABEAM Robotic System that delivers Aquablation therapy received *de novo* clearance from the U.S. Food and Drug Administration (FDA) in December 2017. It is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). (see enclosures)

In the randomized, pivotal study against transurethral resection of the prostate (TURP), the WATER study, Aquablation therapy showed the same durable outcomes and low surgical retreatment rate as (TURP) at 2 years for prostate sizes 30-80cc while maintaining a superior ejaculatory profile (Gilling et al., Advances in Therapy 2019-enclosed). The WATER Study enrolled 181 patients, ages 45 to 80 years, with urinary symptoms due to BPH, at 17 sites in the United States, UK, Australia and New Zealand. Randomized to the surgical gold-standard TURP, Aquablation therapy with the AQUABEAM Robotic System met its primary clinical endpoints demonstrating superior primary safety (3 months) and non-inferior primary efficacy (6 months) results.

Of note, three-year outcomes of the WATER study demonstrate Aquablation therapy comparable to TURP in BPH symptom reduction, urinary flow rate improvement, quality of life and retreatment[1]:

- The mean IPSS reduction at 3 years was 14.4 and 13.9 for Aquablation therapy and TURP, respectively
- Aquablation therapy demonstrated statistically superior outcomes in efficacy in subjects with larger prostates (50 – 80 mL) as validated by reduction in symptom scores
- In both groups, maximum 3-year urinary flow rates increased markedly within 1 month after surgery and were maintained at 3 years. Mean 3-year improvements in Qmax were 11.6 and 8.2 for Aquablation therapy and TURP, respectively
- There were no procedure-related adverse event between year 2 and year 3 in either arm
- No subjects required retreatment beyond 20 months post-operatively in either arms with an overall 3-year retreatment rate of 4.3% and 1.5% for Aquablation therapy and TURP, respectively
- Aquablation therapy demonstrated a marked reduction in the risk of postoperative anejaculation

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)[2] 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)[3] Like the NTAP 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.*

Based on the clinical literature, the American Urologic Association (AUA) 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".[4] Effective January 28, 2020, Humana updated its Benign Prostatic Hyperplasia (BPH) Treatments Policy to add Aquablation therapy to their treatment options for BPH when nonsurgical management has failed.[5]

I would welcome an opportunity for a peer-to-peer review that will provide an opportunity for us to fully discuss this patient case and clarify any questions you may have regarding this treatment and my patient's care. Please let me know if we can schedule this. I am happy to provide any additional documentation and medical records for further consideration.

Sincerely,

DOCTOR

CONTACT INFORMATION

Enclosures
CC: PATIENT

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[1] Gilling P, Barber N, Bidair M, et al. Three-Year Outcomes After Aquablation Compared to TURP: results from a blinded randomized trial. *Canadian Journal of Urology* February 2020.

[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

[3] OPPS Final Rule https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-FC.html
[4] https://www.anthem.com/medicalpolicies/policies/mp_pw_a053318.htm

[5] http://apps.humana.com/tad/tad_new/Search.aspx?criteria=0421T&searchtype=freetext&policyType=both.