January 21, 2025

Michael Hopkins, M.D.
Senior Medical Director
Chief Medical Officer
Palmetto GBA
17 Technology Circle
Columbia, SC 29203

RE: Request to Retire or Reconsider LCD L38549 - Transurethral Waterjet Ablation of the Prostate

Dear Dr. Hopkins:

We are writing to request that the Palmetto GBA retire LCD L38549 for Transurethral Waterjet Ablation of the Prostate (Aquablation). We wish to thank you for reaching out via email and offering to consider our broader set of points for reconsideration of L38549 without delaying the process underway from our reconsideration request originally submitted to Palmetto GBA on October 4, 2023. We wish to withdraw our original reconsideration request and substitute this updated request for Palmetto GBA to either retire L38549 or revise the LCD with respect to the four clinical issues discussed below.

For your convenience, we wish to confirm that these four points are the same points that we raised when we met with you and your peer MAC CMDs in September 2024 and that we addressed in writing to the MACs at that time. In addition, we wish to thank you and your colleagues for participating in an informal meeting on September 17, 2024 with representatives from the MACs, PROCEPT BioRobotics, and two expert urologists.

PROCEPT BioRobotics is a U.S.-based medical device company that manufacturers the AQUABEAM® and HYDROS™ Systems, which are transurethral waterjet ablation systems for treating individuals with symptomatic benign prostatic hyperplasia (BPH).

We request that Palmetto GBA retire the LCD listed above based on the following considerations:

- Palmetto GBA should retire the water jet ablation LCD because water jet ablation is now an established part of the standard of care for treating symptomatic benign prostatic hypertrophy.

- Palmetto GBA should retire the water jet ablation LCD because the clinical evidence now supports removal of the key limitations in coverage established under the original LCD, rendering the LCD unnecessary.

These points are discussed in greater detail below.

Palmetto GBA Should Retire the Water Jet Ablation LCDs because Water Jet Ablation is Now an Established Part of the Standard of Care for Treating Symptomatic Benign Prostatic Hypertrophy

The Aquablation procedure has been widely accepted as an important part of the standard of care for the treatment of lower urinary tract symptoms (LUTS) due to BPH based on the clinical literature and its history of safety and effectiveness. All the MACs have covered the Aquablation procedure since 2020. The five major U.S. commercial insurers - Anthem, Aetna, Cigna, Humana, and United - have also extended coverage to the procedure over that time frame. There are over 400 robotic systems deployed around the country, and from January 1, 2021 through September 24, 2024, almost 47,000 Aquablation procedures were performed in the U.S.

Based on these volumes, wide acceptance within the medical community, and compelling clinical literature, a Category I CPT code was awarded to the procedure at the May 2024 CPT panel meeting. The new CPT code is scheduled to become effective on January 1, 2026.

The cornerstone of data supporting Aquablation is two, prospective, FDA trials with 5-year data; WATER[1] and WATER II[2]. The WATER study (the U.S. pivotal trial for FDA approval) randomized Aquablation therapy against TURP, which has been the standard of care for resection of prostates smaller than 80ml, in a double-blinded study. The trial demonstrated superior safety and comparable efficacy to TURP in prostates 30ml to 80ml in size and superior safety and efficacy in prostates 50ml to 80ml in size. The WATER II study included men with a prostate size greater than 80ml undergoing Aquablation. The study met its pre-specified performance goal for safety and efficacy. The two, FDA trials with 5-year follow-up have demonstrated consistent results across various prostate anatomy. We understand that many of the inclusion and exclusion criteria in the LCDs were drawn from these studies.

In the United Kingdom, the National Institute for Health and Care Excellence (NICE) uses the term “Standard Arrangements” which is their most positive level of recommendation. When a procedure earns this designation from NICE through its rigorous process, it means that there is enough evidence for doctors to consider this procedure as an option.

Aquablation received this designation[3] from NICE in 2023. NICE recognized Aquablation as effective as TURP for the removal of prostate tissue for men with BPH. NICE published MedTech Innovation Briefing[4] (MIB) from a panel of clinical experts saying the technology is innovative compared to the standard of care and offers additional benefits, such as increased ability to preserve sexual function. The consensus from MIB was that the technology has the potential to replace transurethral resection of the prostate and will challenge holmium laser enucleation of the prostate for larger prostates. NICE’s policy covering Aquablation does not provide any specific indications or limitations, rather it leaves the determination in the hands of the surgeon.

---

[1] Gilling PJ, et al. Five-year outcomes for Aquablation therapy compared to TURP: results from a double-blind, randomized trial in men with LUTS due to BPH. Can J Urol. 2022;29(1):10960-10968.
[2] Bhojani N, et al. Aquablation Therapy in Large Prostates (80-150 mL) for Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia: Final WATER II 5-Year Clinical Trial Results. J Urol. 2023 Jul;210(1):143-153.
[3] National Institute for Health and Care Excellence. (2023). *Transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia* (Interventional procedures guidance IPG770).
[4] National Institute for Health and Care Excellence. (2023). *Aquablation robotic therapy for lower urinary tract symptoms caused by benign prostatic hyperplasia* (MedTech Innovation Briefing).

Three studies from the past year were open to all comers in contrast to the original inclusion/exclusion criteria from WATER and WATER II. Burton et al. (2023)[5] studied over 100 Aquablation patients to determine whether the procedure is safe and effective in retention patients. Zorn et al. (2024)[6] looked at a more focused set of Aquablation patients to see if same-day discharge of these patients is feasible.

The largest published real-world data set comes from Omidele et al. (2024)[7]. This was a study of 330 Aquablation patients with 4-year outcomes. The average age of patients treated was 65.2, 68% of the patients were in retention and the size of glands treated ranged from 38-330cc. The authors concluded Aquablation is safe and durable at 4 years outside of the narrow confines of current LCD indications and limitations.

Tables 2 and 3 below present the demographics and outcomes from the two, FDA clinical trials, WATER and WATER II, alongside those from data published from real-world studies.

Table 2. Demographics

	WATER	WATER II	Omidele (2024)	Zorn (2024)	Bach (2020)[8]	Burton (2023)		
						AUR	*CUR*	*NUR*
N	116	101	330	60	178	28	16	69
Avg. age	65.9	67.5	68.6	68.8	67.7	71	71	71
Follow-up	60	60	48	1	12	5.6	7.1	5
Gland size, range	25-80cc	80-150cc	38-330cc	41-270cc	27-223cc	96±54	68±45	65±30
% retention	0%	14%	68%	48%	20%	100%	100%	0%

AUR – Acute Urinary Retention; CUR – Chronic Urinary Retention; NUR – No Urinary Retention

Table 3. Effectiveness Outcomes

	WATER	WATER II	Omidele (2024)	Zorn (2024)	Bach (2020)	Burton (2023)		
						AUR	*CUR*	*NUR*
Qmax, pre	9.4	8.6	6.4	5.9	9.9	4.8	7.5	7.5
Qmax, post	17.3	17.1	17.4	26.3	20.8	17.3	17.9	16.3
% Impv	84%	99%	172%	346%	110%	260%	139%	117%
IPSS, pre	22.9	22.6	23.8	29.7	21.7	n/a	21.6	23.2
IPSS, post	7.8	6.8	6.9	6.6	6.4	7.5	10	6.9
% Impv	194%	232%	245%	350%	239%	n/a	116%	236%
QOL, pre	4.8	4.6	n/a	5.2	4.7	n/a	4.2	4.4
QOL, post	1.6	1.3	n/a	0.9	1.4	1.6	1.9	1.5
% Impv	200%	254%	n/a	478%	236%	n/a	121%	193%

AUR – Acute Urinary Retention; CUR – Chronic Urinary Retention; NUR – No Urinary Retention

[5] Burton, C. S., et al. (2023). Outcomes of Aquablation in Men With Acute and Chronic Urinary Retention. Urology, 180, 214–218.
[6] Zorn KC, et al. Safety and Efficacy of Same Day Discharge for Men Undergoing Contemporary Robotic-assisted Aquablation Prostate Surgery in an Ambulatory Surgery Center Setting-First Global Experience. Urology. Published online August 17, 2024.
[7] Omidele OO, et al. Aquablation at 4-years: Real World Data from the Largest Single-Center Study with Associated Outcomes Follow-Up. Urology. Published online July 30, 2024.
[8] Bach T, et al. First Multi-Center All-Comers Study for the Aquablation Procedure. J Clin Med. 2020;9(2):603.

This comparison illustrates that the real-world application of Aquablation in a much broader, more complex patient profile achieves the same outcomes as seen in the original clinical trials. The treated populations in the real-world studies enjoyed the same effectiveness outcomes in the key metrics – Qmax, IPSS, and QoL - as those from the more controlled populations in WATER and WATER II.

Combined with the recognition from such bodies as NICE, it can be concluded that the LCDs may be retired. Retiring the LCDs for Aquablation will bring the procedure into alignment with other resective BPH procedures like transurethral resection of the prostate (TURP), photoselective vaporization of the prostate (PVP), holmium laser enucleation of the prostate (HoLEP), and simple prostatectomy—none of which have an LCD.

Palmetto GBA Should Retire the Water Jet Ablation LCDs because the Clinical Evidence Now Supports Removal of the Key Limitations in Coverage Established under the Original LCDs, Rendering the LCDs Unnecessary.

The existing evidence is now sufficient to retire the LCDs pertaining to Transurethral Waterjet Ablation altogether. There is now compelling clinical evidence to remove the key limitations in coverage under the existing LCDs related to the "voided volume" parenthetical contained within the Qmax limitation, the prostate volume limitation, and the limitations related to prostate cancer and bladder calculus as detailed below.

PROCEPT is requesting four (4) revisions to remove the following key limitations:

1. **Clarify the limitation on urinary flow rate (Qmax) and volume voided.** This indication is being misinterpreted to prevent patients in urinary retention from receiving the procedure because those patients cannot hit the volume voided threshold. Real world evidence has proven that Aquablation is safe and effective for patients in urinary retention. The evidence is detailed below and is attached.
2. **Remove the limitation based on prostate volume.** Newly published clinical data supports the conclusion that transurethral waterjet ablation is reasonable and necessary for prostate volume size > 150 cc. The evidence is detailed below and is attached.
3. **Remove the limitation for known or suspected prostate cancer or prostate specific antigen (PSA) > 10 ng/mL.** The FDA removed the limitation on known prostate cancer or PSA > 10 ng/mL, effective 8/30/2023. The updated FDA 510k approval (K231024) is attached.
4. **Remove the limitation based on the presence of bladder calculus.** Bladder calculus, or stones, are often treated concomitantly with BPH as the underlying cause of the stones is often urinary retention/incomplete bladder emptying and urinary stasis secondary to BPH.

These indications and limitations are the anchors to the LCDs. The clinical literature and accepted urologic practice support their removal. Once removed, the LCDs lose much of their relevance and thus warrant retirement.

Urinary Flow Rate and Volume Voided

As a prerequisite for coverage, the LCDs require that patients have a low maximum urine flow rate. The requirement is expressed in terms of the Qmax flow rate. The Qmax flow rate is low in

individuals who have a significant obstruction of flow through the prostatic urethra due to benign prostatic hyperplasia (BPH). The LCD's requirement for a low flow rate is as follows:

- Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125cc).

The need for reconsideration of the LCDs' criterion for flow rate arises when individuals have urinary retention due to BPH that requires the use of either an indwelling catheter or intermittent catheterization. When a patient's BPH obstruction is so severe that they require the use of a catheter, the patient is unable to produce any meaningful flow of urine.

The LCD's flow rate requirement includes a parenthetical referring to the need to void at least 125cc of volume voided. This is a reference to flow rate testing that requires a minimum amount of urine to register a valid flow rate test. However, as mentioned above, in the case of patients who have catheter dependent urinary retention, the patients are not able to pass meaningful amounts of urine. The minimum volume requirement should not apply to someone who does not have adequate flow to undergo traditional flow rate testing.

AUA's BPH treatment guidelines[9] from 2021 address treating patients in retention. The guidelines state that "[i]ndications for surgery include a desire by the patient to avoid taking a daily medication, failure of medical therapy to sufficiently ameliorate bothersome LUTS, intolerable pharmaceutical side effects, and/or the following conditions resulting from BPH and for which medical therapy is insufficient: acute and/or chronic renal insufficiency, ***refractory urinary retention***, recurrent urinary tract infections (UTIs), recurrent bladder stones, and recalcitrant gross hematuria" (emphasis added). In these guidelines, Robotic Waterjet Treatment (Aquablation) is listed as a treatment option for patients with LUTS/BPH.

Summary of Clinical Outcomes for Patients in Urinary Retention

WATER II included cohorts of catheter-dependent patients who could not pass meaningful amounts of urine and who therefore could not undergo a flow rate test that requires 125cc of volume voided. There is additional peer-reviewed literature specifically demonstrating that Aquablation is medically necessary, clinically effective, and safe in patients with catheter-dependent urinary retention. Burton et al. compared outcomes of Aquablation in men with acute and chronic urinary retention. The authors found that 98 percent of these individuals achieved spontaneous voiding after Aquablation regardless of preoperative urodynamic status.

The real-world studies evidence in the previous section, like Burton et al., have included many patients in urinary retention and replicated the safety and efficiency outcomes as those from patients not in retention.

[9] Lerner LB, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART II-Surgical Evaluation and Treatment [published correction appears in J Urol. 2022 Mar;207(3):743.

Table 4. Retention patients in Real-World Evidence

	N	Avg. Age	Retention Patients
Omidele (2024)	330	65	224 (68%)
Zorn (2024)	60	69	29 (48%)
Bach (2020)	178	68	36 (20%)
Kasraeian (2020)[10]	55	67	24 (49%)
Marhamati (2024)[11]	812	69	113 (14%)

Unfortunately, the Qmax and volume voided criteria are being used to prevent catheter dependent patients from receiving Aquablation therapy when that is not what was intended when the procedure was first covered.

Of particular concern is that we are hearing reports that Recovery Audit Contractors (RAC) are focusing on the reference to the minimum 125cc voided volume reference in the flow rate requirement as a rationale for post-payment denials of claims for waterjet ablation of the prostate for patients with urinary retention that requires use of a catheter. We understand that the RACs are pursuing post-payment denials of legitimate claims, and these actions are having a chilling effect on Medicare beneficiaries with urinary retention that warrant access to waterjet ablation.

For the reasons described above, we request removal of the requirement to measure Qmax from the LCDs as shown below:

- ~~Maximum urinary flow rate (Qmax) of ≤15 mL/s (voided volume greater than 125 cc)~~

Prostate Volume

This section summarizes new evidence regarding the clinical outcomes for individuals with prostates greater than 150 cc at the time they received Aquablation for lower urinary tract symptoms (LUTS) due to BPH. The information is drawn from two studies in the peer-reviewed literature and unpublished reports from procedure information collected by the company. The FDA documentation for Aquablation does not contain any language limiting the use of the device based on prostate volume.

Summary of Clinical Outcomes for Individuals with Prostates Greater Than 150 cc

Aquablation in patients with prostates greater than 150cc has been well-researched, including several recent studies.

In a retrospective study by Helfand et. al (2021),[12] Aquablation was demonstrated as both safe and effective in men with very large (> 150 cc) prostates. In this study, the mean prostate size was 209 cc (range: 151 – 362) and the average age was 69 years (range: 54-83). At baseline, subjects reported severe LUTS as demonstrated by the mean pre-procedure IPSS of 19±6. At 6 months post Aquablation, the mean IPSS decreased to 7±5 ($p<0.001$). The maximum flow rate (QMax) increased from 7±4 cc/sec to 19.5 ± 5 at 6 months ($p<0.001$). This IPSS reduction and QMax increase are consistent with that observed in the WATER and WATER II studies of Aquablation which included

[10] Kasraeian A, et al. Aquablation for BPH. Can J Urol. 2020;27(5):10378-10381.
[11] Marhamati SH, et al. MP62-03 Aquablation Case Series of 812 Consecutive Men with LUTS due to BPH. Journal of Urology [Internet]. 2024 May 1 [cited 2024 Sep 5];211(5S):e1021.
[12] Helfand BT, et al.; Men with lower urinary tract symptoms secondary to BPH undergoing Aquablation with very large prostates (> 150 mL). Can J Urol. 2021 Dec;28(6):10884-10888.

men with prostates ranging from 30-80 cc and 80-150 cc, respectively. There were no reports of adverse events (incontinence, erectile dysfunction, or ejaculatory dysfunction) in the very large prostate group. Importantly, the authors reported that a statistically significantly lower rate of clinically significant bleeding within the very large cohort. Quality-of-life measures from the very large patient group were similarly in line with the outcomes reported in WATER and WATER II.

From efficacy, safety and quality-of-life standpoints, the compelling outcomes observed in WATER and WATER II, which only included prostates less than 150cc, have been reproduced in a population with prostate volumes greater than 150cc.

Operative time for the very large prostate patients was higher. However, the increase was not statistically significant, and the authors note that it was not proportional to the increase in prostate size. The study concluded that Aquablation provides reproducible results in relatively uniform time regardless of prostate size or shape.

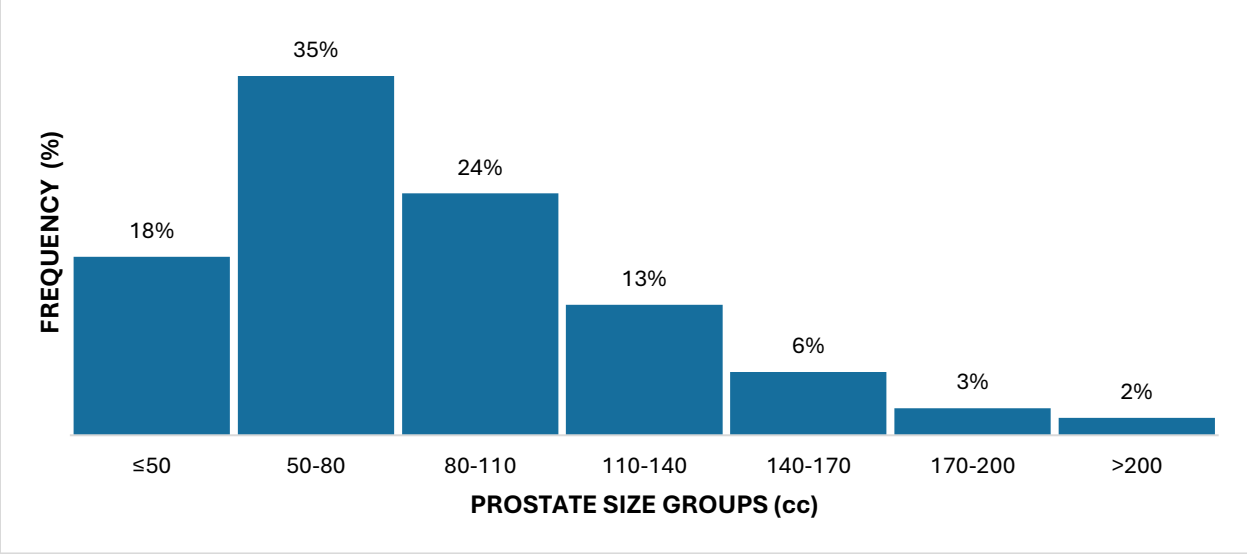
The real-world evidence referenced in the first section included many patients with gland sizes over 150cc and replicated the outstanding outcomes from WATER and WATER II.

Table 5. Prostate Volumes in Real-World Evidence

	N	Avg. Age	Prostate Volume, range
Omidele (2024)	330	65	38-330cc
Zorn (2024)	60	69	41-270cc
Kasraeian (2020)	55	67	27-233cc
Marhamati (2024)	812	69	22-263cc

Because most commercial insurers that cover Aquablation do not limit access based on prostate volume, many surgeons already treat these large glands. Over the last few years, PROCEPT has tracked the number of procedures performed along with the size of the prostate treated. See internal PROCEPT procedure data in Figure 1 below.

Figure 1: Prostate Size Distribution – U.S. Data
1/1/2021 – 6/30/2024
Avg: 89cc, Median: 80cc



Roughly 11% of Aquablation procedures were performed on very large prostates. In reviewing and discussing the outcomes of these procedures with the providers, the overall outcomes of improvement in symptom scores and peak urinary flow rates were reportedly comparable to those seen in Helfand et. al (2021), WATER and WATER II.

These findings for patients with prostates over 150 cc treated with Aquablation support the consistency with the outcomes obtained in smaller prostates. This consistency is exactly what one would expect for a surgical resection technique.

For the reasons described above, we request removal of the prostate size limitation on the LCDs as shown below:

- ~~Prostate volume 30-150cc by transrectal ultrasound (TRUS)~~

Prostate Cancer

The current LCDs, originally effective in 2020, reflect outdated FDA language that excluded patients with "diagnosed or suspected cancer of the prostate." A recent FDA clearance (K231024) removed this contraindication. This decision was predicated on a circulating tumor cell (CTC) study conducted in patients with BPH and prostate cancer undergoing Aquablation. The CTC results showed a small transient increase in CTCs post-operatively and reduced back to baseline status by day 2. We are requesting the Palmetto GBA update and align the LCD with the recent updated FDA label, which allows Aquablation therapy in patients that have known or suspected prostate cancer.

For many men diagnosed with prostate cancer, the disease does not threaten life expectancy or quality of life impairment, to the extent that there is an ongoing debate on whether low risk disease (Gleason Grade Group 1) should even be termed "cancer" due to its essentially non-existent

metastatic potential.[13] Within the NCCN guidelines[14] for prostate cancer, conservative management is a preferred or recommend course of treatment for all prostate cancer risk groups (and PSA levels) depending on life expectancy and symptomatology. See Table 6.

Table 6. Life expectancy for which active surveillance, observation and no imaging or treatment are indicated by risk group with the NCCN prostate cancer treatment guidelines.

NCCN Risk Group	Active Surveillance	Observation	No Imaging or Treatment
Very Low and Low	≥ 10 years*	5-10 years*	< 5 years*
Favorable Intermediate	≥ 10 years	5-10 years*	< 5 years*
Unfavorable Intermediate	NR	5-10 years*	< 5 years*
High or very high	NR	< 5 years	NR
Active surveillance includes regular follow-up with PSA measurement and biopsy. Observation involves monitoring with a history and physical exam no more often than every 12 months without surveillance biopsies.			

*Preferred treatment; NR=Not Recommend

Conservative management for localized prostate cancer has become more common in the United States. In the early 2000s, just 7% and 5% of men with low and intermediate risk disease, respectively, chose conservative management as their initial treatment. The utilization has grown substantially in recent years and the most recent data shows 60% and 20% of men with low risk and intermediate risk disease chose conservative management, respectively. These men tend to be older and, as such, are at increased risk from LUTS due to BPH but are currently, through NGS, unable to access to the symptom relief offered by Aquablation.

A body of evidence presented to FDA establishes a positive benefit to risk profile of Aquablation for men with diagnosed or suspected prostate cancer. The data addresses theoretical concerns, and provides compelling evidence leading the FDA to remove the contraindication:

- The American Urological Association (AUA) guidelines do not recommend against resective BPH therapies such as Aquablation in patients with diagnosed or suspected prostate cancer, as BPH treatment is not proven in literature to increase oncological risk.
- Many men with undiagnosed prostate cancer are treated with resective BPH therapies including Aquablation. but there is no evidence that this creates oncologic risk.[15]

[13] Eggener SE, et al. Low-Grade prostate Cancer: Time to stop calling It Cancer. J Clin Oncol. 2022 Sep 20;40(27):3110-3114.
[14] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Prostate Cancer Version 1.2023. National Comprehensive Cancer Network.
[15] Hilscher M, et al. Risk of prostate cancer and death after benign transurethral resection of the prostate-A 20-year population-based analysis. Cancer. 2022 Oct;128(20):3674-3680.

- The WATER study included men with undiagnosed prostate cancer and no adverse oncological outcomes were observed in the Aquablation arm.
- The theoretical routes for potential exposure to metastatic hazards during Aquablation therapy are demonstrated to pose negligible risk.
  - Physiological evidence through direct measurement of circulating tumor cells (CTCs) does not reveal increased potential for metastasis during Aquablation therapy.[16]
  - Tumor spill and CTC seeding of metastases from Aquablation is a theoretical concern that is not borne out by the scientific, clinical evidence or within the peer reviewed literature.[17]

Restricting access to men with suspicion of prostate cancer disproportionately impacts groups with certain demographic characteristics, such as older men and black men who have higher suspicion of prostate cancer.[18]

Dr.Helfand from Northshore in Chicago, IL presented a comparison of his data where approximately 60 patients with prostate cancer on active surveillance underwent Aquablation for BPH and compared that to his BPH only cohort (>400 patients) and the BPH outcomes were similar. He also compared the 60 patient BPH + prostate cancer cohort to his active surveillance cohort (>700 men) and noted a reduction in men undergoing radical prostatectomy due to cancer progression in the men who had Aquablation.

For these reasons, we request removal of the prostate cancer limitation on the LCDs as shown below:

- ~~Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) >10 ng/mL unless the patient has had a negative prostate biopsy within the last 6 months.~~

Bladder Calculus

The limitation of "bladder calculus" in the LCDs is restrictive and not aligned with appropriate clinical patient care or AUA guidelines. Similarly with the other limitations, comparative procedures for BPH, such as TURP, HoLEP and PVP do not stipulate this limitation as an indication for coverage.

Bladder stones are frequently treated concomitantly with BPH, and the underlying cause of bladder stones is often urinary retention/incomplete bladder emptying and urinary stasis secondary to BPH. In fact, the AUA guidelines recommend BPH surgery when bladder stones are forming.[19] According to AUA Guidelines published 2021 and amended 2023, "Surgery is recommended for patients who have renal insufficiency secondary to BPH, refractory urinary retention secondary to

[16] PROCEPT BioRobotics Corporation. Data on file.
[17] Eschwège P, et al. Prognostic value of prostate circulating cells detection in prostate cancer patients: a prospective study. Br J Cancer. 2009 Feb 24;100(4):608-10.
[18] Jahn JL, et al. The high prevalence of undiagnosed prostate cancer at autopsy: implications for epidemiology and treatment of prostate cancer in the Prostate-specific Antigen-era. Int J Cancer. 2015 Dec 15;137(12):2795-802. doi: 10.1002/ijc.29408. Epub 2015 Jan 8.
[19] Sandhu JS, Bixler BR, Dahm P, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023. *J Urol*. Jan 2024;211(1):11-19.

BPH, recurrent urinary tract infections (UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with LUTS/BPH refractory to or unwilling to use other therapies." Furthermore, this same guideline states "Cystolithalopaxy can be performed concomitantly with the surgical procedure used to remove the obstructing prostate tissue".

Patients who do *not* undergo concomitant BPH surgery with bladder stone removal are more likely to form recurrent stones and undergo additional surgery.[20] Thus, if concomitant BPH surgery and bladder stone removal is disallowed, as is currently stipulated by this LCD, patients are condemned to higher rates of additional surgery and morbidity, not to mention cost associated with a second procedure and anesthetic.

For these reasons, we request removal of the bladder calculus limitation on the LCDs as shown below:

- Bladder cancer, neurogenic bladder, ~~bladder calculus~~ or clinically significant bladder diverticulum.

Proposed LCD Edits

Should Palmetto GBA decide not to retire the Aquablation LCDs, we propose the following revisions:

Covered Indications

1. Indications including all of the following:
   ~~a. Prostate volume 30 – 150 cc by transrectal ultrasound (TRUS)~~
   a. Persistent moderate to severe symptoms despite maximal medical management including all of the following:
      i. International Prostate Symptom Score (IPSS) ≥ 12
      ~~ii. Maximum urinary flow rate (Qmax) of ≤ 15 mL/s (voided volume greater than 125 cc)~~
      ii. Failure, contraindication or intolerance to at least 3 months of conventional medical therapy for LUTS/BPH
2. Only treatment using an FDA approved/cleared device will be considered reasonable and necessary.

Limitations

1. Body mass index ≥42 kg/m^2.
~~2. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) >10 ng/mL unless the patient has had a negative prostate biopsy within the last 6 months.~~
2. Bladder cancer, neurogenic bladder, ~~bladder calculus~~ or clinically significant bladder diverticulum.
3. Active urinary tract or systemic infection.
4. Treatment for chronic prostatitis.
5. Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture.

[20] Chapelle C, Lavallée E, Vallée M, Descazeaud A. Bicentric retrospective study comparing the postoperative outcomes of patients treated surgically for bladder stones with or without concomitant surgery for BPH. *World J Urol*. Jan 8 2024;42(1):13.

6. Damaged external urinary sphincter.
7. Known allergy to device materials.
8. Inability to safely stop anticoagulants or antiplatelet agents preoperatively.

The existing evidence is now sufficient to retire the policy altogether. There is also compelling evidence to remove the prostate volume indication, the “voided volume” parenthetical contained within the Qmax indication, and the limitations prostate cancer and bladder calculus.

Thank you for your consideration of this formal request to retire or edit the LCDs regarding transurethral waterjet ablation. Please do not hesitate to contact us with any questions.

Sincerely,

Barry Templin
EVP, Technology and Clinical Development
PROCEPT BioRobotics