PROCEPT BioRobotics

January 31, 2023

CGS Administrators, LLC
Attn: Robert D. Hoover, Jr., MD, MPH
DME LCD Reconsiderations
26 Century Blvd, STE ST610
Nashville, TN 37241-3865

RE: LCD Reconsideration Request - Fluid Jet System in the Treatment of Benign Prostatic Hyperplasia (BPH) (L38378)

Greetings Dr. Hoover & Medical Policy Team:

I am writing regarding LCD L38378 (Fluid Jet System in the Treatment of BPH) to request reconsideration of the age limitation under this policy and to provide information supporting the conclusion that transurethral waterjet ablation (also called "Aquablation") is reasonable and necessary for individuals who are over 80 years old.

PROCEPT BioRobotics is an innovative U.S.-based medical device company that manufacturers the AQUABEAM® System, which is a transurethral waterjet ablation system for treating individuals with symptomatic benign prostatic hyperplasia (BPH). We are pleased to provide this request for reconsideration as an interested party doing business within your jurisdictions.

The requested revision will update and align your LCD with the recently finalized revision to Palmetto GBA's corresponding LCD (L38549), as well as with the clinical evidence in octogenarians summarized below and the FDA-cleared indications for use (that do not include any age limitation).

Please accept this request for reconsideration of LCD L38378 to remove the age limitation from the current coverage criteria for transurethral waterjet ablation by deleting the phrase "age $\leq$ 80" under the indications required by the LCD.

This letter summarizes new evidence regarding the clinical outcomes for individuals who were over 80 years old 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 The information is drawn from two studies in the peer-reviewed literature and unpublished reports recently obtained from three independent urology practices in the United States.

Background

Age is likely the most significant contributor to the prevalence of LUTS in BPH patients with reports showing that the prevalence of LUTS increases to 80% in men at 70 years of age. Given that the incidence and severity of LUTS generally increases with age, the age limitation in the current LCD warrants reevaluation to determine whether retaining this limitation on patient access is fair and truly necessary.

Transurethral waterjet ablation of the prostate is a robotic technology that promotes safety and provides highly reproducible, consistent results. Waterjet ablation uses real-time transrectal ultrasound imaging guidance to allow the surgeon to define the target anatomic resection contour on a computer console. Contours are selected to avoid damage to the bladder neck, ejaculatory ducts, and urinary sphincter. In addition, apical treatment can be planned to ensure that no injury occurs to the verumontanum and its underlying ejaculatory ducts. Tissue is resected using an automated, robotic-executed, high-velocity waterjet with up to 2.4 cm treatment depth.

Summary of Clinical Outcomes for Individuals Over 80 Years Old

Aquablation therapy has been well-researched, including two landmark studies that are commonly referred to as "WATER" (Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue) and "WATER II."[1,2] As summarized in LCD L38378, the two prospective trials demonstrated excellent safety and effectiveness in men with smaller (30 – 80 mL) and larger (80 – 150 mL) prostates. Both studies were limited to men between the ages of 45 and 80. The age inclusion criteria for WATER and WATER II were similar to many clinical trials evaluating other BPH surgical techniques.

After the conclusion of the enrollment of the WATER and WATER II studies, investigators initiated two "real-world" registries to evaluate the outcomes of Aquablation in the community-based setting. Accordingly, many of the exclusion criteria observed in the WATER and WATER II studies were removed, including the age restrictions. The OPEN WATER study and the Kasraeian study were published in April and October of 2020, respectively.

The OPEN WATER study is a multi-center, prospective, all-comers study of Aquablation therapy in a real-world setting enrolling 178 patients in five community-based sites.[3] This study evaluated Aquablation with prostates ranging in size from 20 to 150 mL with patients ranging in age from 39 to 88 years.

The Kasraeian study is a single-center, retrospective analysis of prospectively collected data to evaluate the safety and efficacy of Aquablation therapy in a community-based setting. The study included 55 patients treated between July 2018 and December 2019 and compared outcomes in

patients with prostates less than 100 mL and greater than 100 mL.[4] This study included prostates ranging from 27 to 252 mL in volume (mean of 100 mL) with patient ages ranging from 50 to 84 years.

The OPEN WATER and Kasraeian studies included 13 patients (8 and 5 patients, respectively) with ages greater than 80 at the time of the transurethral waterjet ablation procedures. Three-month follow up on 12 of the 13 patients demonstrated a 14-point decline in the International Prostate Symptom Score (IPSS), which is consistent with the overall findings across all ages in both the OPEN WATER and Kasraeian studies (as well as consistent with the findings in the WATER and WATER II studies). In addition, the maximum urinary flow rate (Qmax) more than doubled in the patients over 80 where 12-month follow up data are available.

We also received clinical information on Aquablation patients over 80 years old at the time of treatment from three independent urology practices in the United States. This information was provided by:

- Potomac Urology (Alexandria, Virginia) – Dr. Inderjit Singh (isingh@potomacurology.com)
- Georgia Urology (Georgia) – Dr. Lewis Kriteman (lkriteman@gaurology.com)
- Northshore University Urology (Evanston, Illinois) – Dr. Brian Helfand (bhelfand@northshore.org)

The three private practices treated a total of 30 patients who were over 80 years old with Aquablation between June 2018 and December 2021. The mean age was 82.7 years, and the average prostate volume was 90.4 mL. For the patients with available baseline demographic information, the clinical variables (other than age) were similar to WATER and WATER II (see chart below).

	>80 years data set	WATER	WATER II
Prostate volume (mL)	90.4	54.1	107.4
Baseline IPSS	20	22	23
Baseline Qmax	8.8 mL/s	9.4 mL/s	8.7 mL/s

All 30 cases were completed successfully, and no cases were aborted or converted to another surgical resection technique. In reviewing and discussing the outcomes with the providers noted above, the overall outcomes of improvement in symptom scores and peak urinary flow rates were comparable to those seen in WATER and WATER II. Twenty-seven of the 30 patients were treated in the outpatient setting with three patients treated in the inpatient setting. Two adverse events were reported with one patient contracting sepsis and one patient requiring clot evacuation following the Aquablation procedure. There were no transfusions, ICU admissions, or deaths within 30 days.

These findings for patients over 80 years old treated with Aquablation (described above) are noteworthy and compelling in light of the consistency with the outcomes demonstrated in younger patients, and this consistency is exactly what one would expect for a surgical resection technique. This same consistency exists with other surgical resection techniques. As one example, TURP is the gold-standard resection technique for treating younger patients for LUTS dues to BPH, and TURP has also demonstrated clinically acceptable results for patients over 80 years old.[5]

In summary, we have obtained data on 43 patients who underwent Aquablation when over 80 years old, and the results demonstrate outstanding clinical efficacy and safety consistent with reports in the peer-reviewed literature for younger patients.

Additional Considerations

As you consider the new information regarding the use of Aquablation in patients over 80, we also urge you to consider the potential that the lack of age limitations for other BPH interventions could skew treatment decisions, even if Aquablation provides a superior safety profile for patients over 80 years old. By removing the age limitation for transurethral waterjet ablation (Aquablation), CGS can better ensure that each patient and treating physician can select the best possible treatment option without counterproductive discrepancies between Medicare beneficiaries who happen to be, for example, 78 years old versus 81 years old.

The published data on Aquablation demonstrates the procedure is safe, reproducible and an effective treatment of LUTS due to BPH. More important, Aquablation is feasible and effective for the large prostates for which treatment options are limited. For most practicing urologists (greater than 98%) who do not perform HoLEP, Aquablation can be a reasonable choice to avoid the need for open simple prostatectomy on larger prostates. Other documented advantages include a short learning curve, procedure reproducibility through image guidance and robotic execution, shorter operative time (less than one hour) and shorter length of stay, all of which are potentially associated with decreased procedure-related morbidity — factors that are highly relevant to patients over 80 years old.

Considering the new data involving the treatment of individuals over 80 (described above), policymakers should take steps to remove any age-based limitations on Aquablation treatments for BPH. Individuals over 80 years old need access to the full spectrum of treatment options, especially given the direct association that exists between age and the disease burden of BPH. Elderly individuals with LUTS due to BPH often have a very limited set of clinical options, and transurethral waterjet ablation can provide a safer, less-invasive clinical option for patients suffering from LUTS due to BPH. Individuals who are over 80 years old should have access to this important therapy under the same clinical criteria that would apply to a similarly situated 79 year old.

In addition to the clinical data described above, please consider the following observations relating to the rationales for removing the age limitation in LCD L38378 as soon as possible.

- Palmetto GBA modified their LCD L38549 to remove the age restriction effective January 29, 2023. The presentation provided to Palmetto GBA is attached for reference.

- The Defense Health Agency recently updated TRICARE's systemwide coverage policy to cover transurethral waterjet ablation of the prostate for the treatment of BPH without any limitation based on age.[6]

- Aquablation provides a superior safety profile for patients who are both over and under 80 years old. Currently, the LCD limits access to Aquablation for patients under 80, but other clinical options are not subject to age limitations, even if Aquablation provides a safer clinical option. By removing the age limitation for transurethral waterjet ablation, CGS can better ensure that each patient and treating physician can select the best possible treatment option without counterproductive discrepancies between Medicare beneficiaries who happen to be, for example, 78 years old versus 81 years old.

- There are two commercial health plans — Humana and Anthem Blue Cross Blue Shield — with positive coverage policies for Aquablation that have been effective for over 24 months with no age restrictions,[7,8] as well as additional commercial health plans that have added coverage of transurethral waterjet ablation without age restrictions since CGS finalized its policy, including Health Care Service Corporation,[9] Cigna,[10] CareFirst,[11] and Blue Cross Blue Shield Massachusetts.[12]

- There is nothing in the FDA-cleared labeling to support or require an age-based restriction. The FDA cleared the AQUABEAM® Robotic System for the resection and removal of prostate tissue in males suffering from LUTS due to BPH under a *de novo* request in December 2017 following completion of a randomized, double-blind clinical trial (WATER), which is detailed in this letter and included in the accompanying clinical package.[13] The labeling reviewed and cleared by the FDA has no restrictions or limitations based on age, prostate size, or prostate shape.

- Recent publication of the five-year follow up data for the WATER study further highlights the benefits of Aquablation, including the potential benefits that one would expect to apply to patients over 80 years of age. For example, the five-year follow up revealed that 12.3 percent of patients treated with TURP required a subsequent intervention (procedure or medication) while only 6.0 percent of Aquablation patients required subsequent interventions over five years.[14]

Proposed Language

We propose the following revision to LCD L38378:

1. Indications including all of the following:
    ~~a. Age ≤ 80~~
    a. Prostate volume 30 – 150 cc by transrectal ultrasound (TRUS)
    b. 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)
        iii. Failure, contraindication or intolerance to at least 3 moths of conventional medical therapy for LUTS/BPH

The existing evidence is now sufficient to remove the age limitation for Aquablation, and we have also attached the relevant clinical articles (the published evidence) for your review. We can facilitate a call with the urologists noted above to speak to their outcomes of Aquablation in this patient set. Thank you for your consideration of this formal request for coverage of transurethral waterjet ablation. Please do not hesitate to contact me with any questions.

Sincerely,

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