August 23, 2024

Noridian JE/JF Part B
Attn: LCD Reconsideration
PO Box 6781
Fargo, ND 58103

RE: LCD Reconsideration Request for L38705 (JE) and L38707 (JF), Transurethral Waterjet Ablation of the Prostate

Greetings Medical Policy Team,

I am writing regarding LCD L38705/L38707 (Transurethral Waterjet Ablation of the Prostate) to request reconsideration of the maximum urinary flow rate (Qmax) indication under these LCDs.

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). I am pleased to provide this request for reconsideration as an interested party doing business within your jurisdictions.

Please accept this request for reconsideration of LCD L38705/L38707 to remove the "voided volume" parenthetical contained within the Qmax indication in the current LCD for transurethral waterjet ablation.

Background

As a prerequisite for coverage, the LCD requires 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 LCD 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.

Summary of Clinical Outcomes for Patients in Urinary Retention

WATER II[1], one of the pivotal studies used to establish Medicare coverage for waterjet ablation (Aquablation) 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.[2] 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.

I'd also like to highlight the AUA's BPH guidelines[3] from 2021. 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) – see "Treatment Indications" on page 819. In these guidelines, Robotic Waterjet Treatment (Aquablation) is listed as a treatment option for patients with LUTS/BPH – see pg. 823.

Noridian's own LCD/LCA archives contain history that illustrates intent for Noridian to allow Aquablation for catheter dependent patients. The attached Noridian article from Dec 2020 was released when Aquablation was first approved. See comment #2 on page 3. Multiple commenters submitted in response to the draft LCD which initially had a limitation on patients with PVR > 300cc highlighting that this limitation would disallow the procedure for patients with high PVR or who are otherwise catheter dependent. Noridian agreed and removed the limitation on PVR.

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

Of particular concern is that we are hearing reports that Recovery Audit Contractors (RAC) are focusing on the reference to 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.

[1] 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;210(1):143-153.
[2] Burton CS, et al. Outcomes of Aquablation in Men With Acute and Chronic Urinary Retention. Urology. 2023;180:214-218.
[3] 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.

Proposed Language

We propose the following revision to LCD L38705/L38707:

1. Indications including all of the following:
    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 "voided volume" parenthetical contained within the Qmax indication for Aquablation, and we have also attached the relevant clinical articles along with the referenced LCA for your review. We can facilitate a call with urologists in your jurisdiction to speak to their outcomes of Aquablation in this patient population.

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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