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June 21, 2024

National Government Services, Inc.
Medical Policy Unit
Attn: LCD Reconsideration Requests
P.O. Box 7108
Indianapolis, IN 46207-7108

Dear Members of the National Government Services,

We hope this letter finds you well. We are writing on behalf of urologists across the country to formally request a review and reconsideration of the contraindications listed for Transurethral Waterjet Ablation of the Prostate (LCD ID: L38682), an innovative treatment for benign prostatic hyperplasia (BPH). We believe that the current contraindications warrant reassessment, as advances in medical research and clinical evidence have emerged since the initial recommendations were made. We also believe current limitations do not align with similar therapies for BPH.

As medical professionals who have been actively involved in the treatment of BPH, we have encountered numerous cases that challenge the current contraindications of Transurethral Waterjet Ablation of the Prostate. We humbly submit the following four indications and limitations for your reconsideration and have attached separate letters with relevant data for each contraindication.

1. Known or suspected prostate cancer (Limitation #2 in LCD Policy):

While it is important to exercise caution in patients with a history of prostate cancer or elevated prostate-specific antigen (PSA) levels, eliminating any man with prostate cancer from treatment of their urinary symptoms goes against current urology practice patterns. Low grade, low risk prostate cancer is not considered clinically significant, should be managed with active surveillance rather than radical prostatectomy or radiation, and does not influence the treatment of symptomatic BPH. Therefore, Transurethral Waterjet Ablation of the Prostate may still be a viable treatment option for select patients in this category. Furthermore, requiring men over the age of 70 or even 80 to undergo PSA testing and biopsy is unnecessary and inconsistent with other national guidelines.

2. Maximum Urinary Flow Rate (Qmax) \geq 15 mL/s (Indication 1.b.II in LCD Policy):

While the current LCD excludes patients with maximum urinary flow rates (Qmax) above 15 mL/s from receiving Transurethral Waterjet Ablation of the Prostate, evidence suggests that Qmax alone may not be the most reliable predictor of successful outcomes. Additional factors such as prostate size and patient symptoms should be considered to ensure that the treatment is appropriately offered to patients who may benefit from it.

3. Bladder stones (Indication 1.b.II in LCD Policy):

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. 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.

4. Requirement for at least 3 months of medical therapy (Indication 1.b.III in LCD Policy):

This requirement restricts patient autonomy, is not evidence-based, is in contradiction with the AUA guidelines, exposes patients to possible side effects, and is not a requirement for analogous BPH procedures. Alpha blockers, 5ARIs, and PDE5 inhibitors have side effects, only improve patient-reported outcome measures and urinary flow rates slightly (compared to surgery which results in a greater degree in improvement in symptoms and flow rates), and there are concerns with long-term use of these medications including risks of depression and dementia. We encourage the LCD to align with AUA guidelines which support an indication for surgery which includes “a desire by the patient to avoid taking a daily medication”.

We wish to emphasize that our foremost commitment and guiding ethos is the diligent and compassionate care of our patients combined with the commitment to provide high quality, evidence-based care. It is our earnest hope that the comprehensive data and cogent arguments elucidated here will prove to be enlightening and beneficial. The goal of this discourse is to broaden the scope of available medical care for those patients under the protection of federal health insurance through Medicare, and to align coverage for Transurethral Waterjet Ablation of the Prostate with coverage for other accepted, standard treatments for BPH. This endeavor is not merely a professional obligation but a moral imperative to enhance the health and well-being of those we are privileged to serve.

Our team would be more than willing to contribute to any review process and provide relevant data and clinical experiences to support the case for reconsideration. We understand the importance of maintaining high standards in healthcare, and we are committed to ensuring that patients receive the most appropriate and effective treatments based on the latest evidence.

Thank you for considering our request. We eagerly await your response and hope that the National Government Services will take the lead in promoting evidence-based, patient-centric healthcare practices.

Sincerely,

Arpeet Shah, MD



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Executive Leadership Team at Associated
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Physician Petition

Amendment to NGS LCD Policy for Transurethral Waterjet Ablation of the Prostate

Action Petitioned For: Amendment to the NGS LCD Policy for Transurethral Waterjet Ablation of the Prostate by removing the following contraindications noted in the letters included:

1. Known or suspected prostate cancer / PSA >10 ng/mL unless the patient has had a negative prostate biopsy within the last 6 months (Limitation 2 in LCD Policy)
2. Maximum Urinary Flow Rate (Q_{max}) ≥ 15 mL/s (Indication 1.b.II in LCD Policy)
3. Bladder stones (Indication 1.b.II in LCD Policy)
4. Requirement for at least 3 months of medical therapy (Indication 1.b.III in LCD Policy)

Physician Name	Physician Practice	Physician Email Address
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June 21, 2024

National Government Services, Inc.
Medical Policy Unit
Attn: LCD Reconsideration Requests
P.O. Box 7108
Indianapolis, IN 46207-7108

Dear Members of the National Government Services,

We are writing to you today to request a consideration for a revision to the NGS LCD policy Transurethral Waterjet Ablation of the Prostate (LCD L38682). In this letter, we have included relevant data from peer-reviewed publications, as well as a petition from relevant expert physicians to support this change.

The limitation of "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" in the current LCD Policy is restrictive and not aligned with appropriate clinical patient care and current FDA labeling. Furthermore, comparative procedures for benign prostatic hyperplasia (BPH; CPTs 52648, 52649, 52441, 52601, 53854) do not include this as a contraindication for Medicare coverage.

Transurethral Waterjet Ablation of the Prostate, also known as robotic waterjet treatment (RWT) or Aquablation, is a treatment for BPH, not prostate cancer. Prostate cancer affects the peripheral zone of the prostate in 98% of cases and thus does not meaningfully contribute to urinary obstruction. BPH occurs in the transitional and central zones which results in obstruction and causes lower urinary tract symptoms (LUTS). Transurethral Waterjet Ablation of the Prostate for BPH is not intended to treat the peripheral zone of the prostate.

More fundamentally, eliminating any man with prostate cancer from treatment of their urinary symptoms goes against current urology practice patterns. Low grade, low risk prostate cancer is not considered clinically significant, should be managed with active surveillance rather than radical prostatectomy or radiation, and does not influence the treatment of symptomatic BPH. The NCCN Clinical Practice Guidelines in Oncology v4.2024 preferred management for low risk prostate cancer is active surveillance.¹ Furthermore, there is a reasonable argument that Grade Group 1 prostate cancer should not be called "cancer".^{2,3} This topic has even been discussed in the lay press.⁴ The exclusion of men with incidental or clinically insignificant prostate cancer from BPH treatment is not a criteria for any other BPH surgery (CPTs 52648, 52649, 52441, 52601, 53854).

Furthermore, requiring men over the age of 70 or even 80 to undergo PSA testing and biopsy prior to any outlet procedure is unnecessary. The AUA and NCCN guidelines recommend shared decision making, rather than prescribed mandatory screening.^{1,5} Moreover, the US Preventive Services Task Force recommends against PSA-based screening for prostate cancer in men 70 years and older.⁶ Statistically, at least 30% of men over age 80 have prostate cancer as evidenced in autopsy studies.⁷ Requiring these men to undergo biopsy for a disease that has no bearing on their 10 year survival is unnecessary and may result in overdiagnosis and overtreatment, something that the urologic community has worked to reverse over the last few decades.⁸⁻¹⁰ As such, setting mandatory prostate cancer, PSA, and biopsy

cutoffs in this LCD is unreasonable and will only add risk, cost, and waste while we “treat the numbers” instead of treating patients.

Our clinical practice supports the use of Transurethral Waterjet Ablation of the Prostate for patients with bladder outlet obstruction and prostate cancer and/or a prostate specific antigen (PSA) > 10ng/ml. The data referenced herein supports that Transurethral Waterjet Ablation of the Prostate is indicated to treat BPH for patients, regardless of diagnosis of prostate cancer. Finally, like the other BPH procedures referenced above, there is no data that suggests the diagnosis of prostate cancer, or an elevated PSA (>10ng/ml) has a negative impact on the safety or procedural efficacy of Transurethral Waterjet Ablation of the Prostate.

We request that this contraindication is removed from the NGS LCD Policy.

Thank you for your consideration.

Arpeet Shah, MD



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Dear Members of the National Government Services,

We are writing to you today to request consideration for a revision to the NGS LCD policy for Transurethral Waterjet Ablation of the Prostate (CPT 0421T). In this letter, we have included relevant data from peer-reviewed publications, as well as a petition from relevant expert physicians to support this change.

The indication of "maximum urinary flow rate (Qmax) of ≤ 15 mL/s (voided volume greater than 125 cc)" in the current LCD Policy is restrictive and not aligned with appropriate clinical patient care and FDA labeling. Comparative procedures for BPH (CPT 52648, 52649, 52441, 52601, 53854) do not require "maximum urinary flow rate (Qmax) of ≤ 15 mL/s (voided volume greater than 125 cc)" as an indication for Medicare coverage.

We also wish to provide our expert opinion regarding this required indication. Our clinical practices support the use of Transurethral Waterjet Ablation of the Prostate for patients independent of urinary flow rate (Qmax), including for patients in urinary retention for whom a Qmax is zero or not obtainable. Testing for Qmax is additional diagnostic test that is not always accurate or able to be obtained in patients with BPH. Also, waiting for the disease to progress to a point where Qmax is ≤ 15 mL/s may negatively impact long-term bladder health and the outcome of any BPH treatment (medications or procedures). We suspect this is why a Qmax limitation is not required for other BPH procedures listed above.

We request that this required indication is removed from the NGS LCD Policy.

Thank you for your consideration.

Arpeet Shah, MD



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The limitation of "bladder calculus" in the current LCD Policy is restrictive and not aligned with appropriate clinical patient care or AUA guidelines. Comparative procedures for BPH (CPT 52648, 52649, 52441, 52601, 53854) do not stipulate this limitation as an indication for Medicare 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.¹ 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 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 "Cystolitholapaxy 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.² 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.

We request that this required indication is removed from the NGS LCD Policy.

Thank you for your consideration.

Arpeet Shah, MD



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The indication of "Failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 inhibitor, finasteride/dutasteride)" in the current LCD Policy is restrictive and not aligned with appropriate clinical patient care and FDA labeling. Comparative procedures for BPH (CPTs 52648, 52649, 52441, 52601, 53854) do not require this as an indication for Medicare coverage.

Furthermore, mandating use of medications restricts patient autonomy, is not evidence-based, and conflicts with the American Urological Association (AUA) guidelines. AUA guidelines state "*indications for these procedures [BPH surgeries] 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 UTIs, recurrent bladder stones, and recalcitrant gross hematuria. Acute and chronic adverse events are associated with each class of medical therapy and can include cardiovascular and sexual effects.*"¹

Alpha blockers, 5ARIs, and PDE5 inhibitors have side effects, only improve patient-reported outcome measures and urinary flow rates slightly (~4-6 point IPSS improvement and 1-2mL/sec improvement, respectively)²⁻⁴ compared to surgery which results in a much greater degree in improvement in symptoms and flow rates (~10-15 point IPSS improvement and 10-20mL/sec improvement, respectively)⁵⁻⁸, and there are concerns with long-term use of these medications including risks of depression and dementia.⁹ In addition, alpha blockers act rather rapidly, generally in 5-7 days, and assessment for treatment response should not wait for 3 months of usage. Finally, AUA guidelines state that if patients report any degree of bother from BPH (not a specific IPSS cutoff) that management of symptoms should be pursued by any means, including surgery.

We request that this required indication is removed from the NGS LCD Policy.

Thank you for your consideration.

Arpeet Shah, MD



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