Local Coverage Determination (LCD): Transurethral Waterjet Ablation of the Prostate (L38705)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

LCD ID **Original Effective Date**

L38705

For services performed on or after 12/27/2020

LCD Title
Transurethral Waterjet Ablation of the Prostate

Revision Effective Date
N/A

Proposed LCD in Comment Period
N/A

Revision Ending Date
N/A

Source Proposed LCD
DL38705

Retirement Date
N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement
CPT codes, descriptions and other data only are copyright 2019 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Notice Period Start Date
11/12/2020

Notice Period End Date
12/26/2020

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Current Dental Terminology © 2019 American Dental Association. All rights reserved.

Copyright © 2013 - 2020, the American Hospital Association, Chicago, Illinois. Reproduced by CMS with permission. No portion of the American Hospital Association (AHA) copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an

express license from the American Hospital Association.
To license the electronic data file of UB-04 Data
Specifications, contact Tim Carlson at (312) 893-6816.
You may also contact us at ub04@aha.org.

CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for Transurethral Waterjet Ablation of the Prostate. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for Transurethral Waterjet Ablation of the Prostate and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*,
  - Chapter 14, Section 10 Coverage of Medical Devices
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*,
  - Chapter 23, Section 30 Services paid under the Medicare Physicians Fee Schedule
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Benign prostatic hyperplasia (BPH) is a histological diagnosis characterized by an increased number of epithelial and stromal cells in the prostate. It is common in men over the age of 40, and the incidence increases with age. In the United States, 8 million men older than 50 years old suffer from BPH. In many cases BPH is asymptomatic, however, symptoms may occur with prostate enlargement and compression of the urethra leading to bothersome lower urinary tract symptoms (LUTS), including voiding symptoms such as hesitancy, weak stream, straining, prolonged voiding, and storage symptoms (frequency, urgency, and nocturia). LUTS/BPH can have a significant impact on the quality of life and can cause serious complications such as infections, bleeding, calculus formation, urinary retention and decline of renal function when untreated.[1] First line treatment generally consists of treatment with medications such as alpha blockers, PDE5 Inhibitors, or finasteride/dutasteride. If treatment with medications is not successful, surgical options may then be considered. Transurethral resection of the prostate (TURP) and open simple prostatectomy (OSP) are the standard surgical treatments for LUTS/BPH and are highly effective and provide improved outcomes in urinary functions. However, neither TURP nor OSP are without considerable perioperative complication and morbidity.[2] Recently, new minimally invasive surgeries have emerged as alternatives for the resection of the prostate to manage LUTS in men with BPH. One such surgery is transurethral waterjet ablation which is minimally invasive; water based surgical therapy that combines image guidance and robotics to remove prostatic tissue.[3] The system works by pumping high pressure saline (500 to 8000 pounds per square [PSI]) through a probe nozzle to cut and dissect tissue at predetermined system parameters.[3]

Covered Indications

Treatment for LUTS/BPH treatment will be considered reasonable and necessary when performed **ONCE** in patients with the following:

1. Indications including **ALL** of the following:
    a. Age ≤80
    b. Prostate volume of 30-150 cc by transrectal ultrasound (TRUS)[4,5]
    c. Persistent moderate to severe symptoms despite maximal medical management

        including **ALL** of the following:

        i. International Prostate Symptom Score (IPSS) ≥12[4]
        ii. Maximum urinary flow rate (Qmax) of ≤15 mL/s[4] (voided volume greater than 125 cc)
        iii. Failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)

2. Only treatment using an FDA approved/cleared device will be considered reasonable and necessary.

Limitations

The following are considered not reasonable and necessary:

1. Body mass index ≥ 42kg/m2[6]
2. Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines[7]) or a prostate specific antigen (PSA) >10 ng/mL unless the patient has had a negative prostate biopsy within the last 6 months.
3. Bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum[6]
4. Active urinary tract or systemic infection[8]
5. Treatment for chronic prostatitis[6]
6. Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture[6]
7. Damaged external urinary sphincter[6]
8. Known allergy to device materials[8]
9. Inability to safely stop anticoagulants or antiplatelet agents preoperatively.[8]

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

Summary of Evidence

Year 1 Year 2 and Year 3 outcomes:

Initial clinical experience was reported in 2016, and the technology obtained FDA clearance in 2017 after the publication of the WATER trial, a PHASE III multicenter international, double-blind, randomized, non-inferiority study with 181 subjects comparing Aquablation (116/181) to TURP (65/181).[9] Men 45-80 years old with prostate size 30-80 cc (by TRUS), moderate-severe LUTS (International Prostate Symptom Score (IPSS) ≥ 12), and maximum urinary flow rate (Qmax) <15ml/s were included and stringent exclusion criteria applied. After randomization, although treatment was by an unblinded research team, a separate blinded team performed all follow-up. The primary endpoint was the change in the IPSS at six months; scores decreased by 16.9 points and points for Aquablation and 16.1 for TURP, respectively (noninferiority p<.0001 and superiority p=0.1347). The primary safety endpoint was the proportion of subjects with adverse events, defined as Clavien-Dindo grade 2 or higher or any grade 1 with persistent disability. The 3-month primary safety endpoint rate was lower in the Aquablation group than in the TURP group (26% vs 42%, p = 0.0149). At two years, IPSS score improvement was sustained (14.7 in Aquablation and 14.9 in TURP [p=0.834, 95% CI for difference -2.1 to 2.6]), and Qmax improvement was large in both groups (11.2 and 8.6 cc/s for Aquablation and TURP, respectively [p = 0.1880, 95% CI for difference -1.3 to 6.4])[10]. Two-year reduction in post-void residual (PVR) was 57 and 70 cc for Aquablation and TURP, respectively (p = 0.3894). Prostate specific antigen (PSA) decreased significantly in both groups by 1 point (p < 0.01). Retreatment rates were 4.3% and 1.5% (p = 0.42) in the Aquablation and TURP groups, respectively. Among the subset of sexually active men without the condition at baseline, anejaculation was less common after Aquablation (10% vs. 36%, p=0.0003). When post-Aquablation cautery was avoided rates of anejaculation were lower (7% vs. 16%, p=0.1774), and this resulted in the reduced grade 1 persistent events found in the Aquablation group. The authors hypothesize that Aquablation avoids damage to tissues involved in ejaculation though precise, image-based targeting, and robotic execution. Limitations of the study include the risk of performance bias as surgeons were not blinded and unknown generalizability to a broader population. Three-year results were essentially unchanged.[4]

A 2019 Cochrane Review based on 1-year Aquablation trial results, found evidence of similar results with TURP to be of moderate- certainty related to the urologic symptom score (IPSS) primary outcome measure. All other metrics

were graded low- certainty (QOL), to very low-certainty (adverse events, retreatments, erectile function, ejaculatory dysfunction).[3] Evidence was downgraded mainly due to study limitations (performance, reporting, and attrition bias), and imprecision (confidence intervals that crossed the assumed thresholds of clinically important differences or few events, or both). For example, both sexual outcome (erectile and ejaculatory function) results were downgraded two levels for a combination of imprecision and study limitations (high risk of performance and attrition bias). The authors recommend larger, more rigorously conducted, and transparently reported, studies comparing Aquablation to other techniques (laser enucleation, prostatic urethral lift, robotic-assisted simple prostatectomy) for which there is also increasing interest.

In a study by Nguyen DD, Barber N, Bidair M et al.[6] The authors looked to determine if the effectiveness of Aquablation is independent of prostate size by comparing its outcomes in two clinical trials. The first trial that was conducted was with men whose prostate was between 30 and 80 mL (WATER I) and the other trial was conducted with men whose prostates were between 80 and 150 mL (WATER II). Water I trial is a prospective, double-blind, multicenter, international clinical trial comparing the safety and ef?cacy of Aquablation and TURP as surgical treatments of LUTS due to BPH in men aged 45–80 years with a prostate volume between 30 and 80 mL, as measured by TRUS. Patients were enrolled at 17 centers. One hundred sixteen men participated. The Water II trial was a prospective, multicenter, international clinical trial of Aquablation for the surgical treatment of LUTS/BPH in men aged 45–80 years with a prostate volume between 80 and 150 mL, as measured by TRUS. Patients were enrolled at 13 US and three Canadian sites. One hundred one men participated. The studies parameters included patients who completed the IPSS. Patients completed questionnaires such as the Incontinence Severity Index (ISI), the International Index of Erectile Function (IIEF-5), and the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD). Patients received uro?owmetry, PVR measurements and underwent standard laboratory blood assessment. These questionnaires and measurements were provided at baseline. PVR and lab test were required postoperatively at 1 and 3 months. Adverse events were rated by the clinical events committee as possible, probably or definitely related to the study procedure and were classified using Clavien–Dindo grade for 3 months after treatment. The inclusion and exclusion criteria were the same for both studies. The Inclusion criteria included patients with moderate-to severe symptoms indicated by a baseline IPSS of ≥12 and a maximum urinary flow rate (Qmax) of <15 mL/s. Exclusion criteria included patients with a body mass index of ≥42 kg/m2, a history of prostate or bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum, active infection, treatment for chronic prostatitis, diagnosis of urethral stricture, meatal stenosis or bladder neck contracture, a damaged external urinary sphincter, stress urinary incontinence, post-void residual urine volume (PVR) >300 mL or urinary retention. The comparison between the two studies revealed the mean operative time for WATER I was 33 minutes and 37 minutes for WATER II. The actual treatment time was 4 minutes (WATER I) and 8 minutes (WATER II). For International Prostate Symptom Score, the mean change at 12 months averaged 15.1 for WATER I and 17.1 for WATER II (P = 0.605). Clavien–Dindo grade ≥II events at 3 months mark occurred in 19.8% of WATER I patients and 34.7% of WATER II patients (P = 0.468).[6] The authors conclude outcomes and effectiveness of Aquablation are comparable and are independent of prostate size with the expectation that with larger prostates a higher risk of complication is possible.

In an April, 2020 publication of WATER II data in the Canadian J Urol, Desai et. al.[5] report 2 year safety and effectiveness of the Aquablation procedure for treatment with men with symptomatic benign prostatic hyperplasia (BPH) and large volume 80-150 cc prostates. The study provides strong evidence that Aquablation provides excellent mid-term (2 year) long-term relief of LUTS related to BPH. The study is notable in that enrolled men (target range 80-150 cc, mean 107 cc, 83% with a large median lobe), a group that typically cannot undergo TURP, were included.

American Urological Association (AUA) amended guidelines now include Aquablation, but do not classify it as a minimally invasive surgical treatment (MIST) since general anesthesia is required. Based on 1-year WATER study results the AUA, found parity between Aquablation and TURP on IPSS, LUTS, and QOL scores (Quality of Evidence: Moderate). Their recommendation is: "Aquablation may be offered to patients with LUTS attributed to BPH provided prostate volume >30/<80g; however, patients should be informed that long term evidence of efficacy and

retreatment rates remains limited. (Conditional Recommendation; Evidence Level: Grade C)".[11]

Canadian Urological Association (CUA) 2018 guidelines also give a "conditional recommendation based on moderate-quality evidence" that Aquablation may be offered to men "interested in preserving ejaculatory function, with prostates <80 cc, with or without a middle lobe".[12]

A 2018 National Institute for Health and Care Excellence (NICE) systematic review based on 6-month WATER results concluded the procedure should only be used with "special arrangements," a defined designation meaning there are uncertainties about safety and effectiveness.[13]

Analysis of Evidence
(Rationale for Determination)

In summary, promising short-term, single study, Aquablation results have resulted in conditional recommendations in some guidelines (AUA, CUA, NICE). A conditional recommendation with Grade C evidence level (AUA) which translates to "Balance between Benefits & Risks/Burdens unclear Alternative strategies may be equally reasonable Better evidence likely to change confidence", echoing the Cochrane Review recommendation: "any recommendation for or against the use of Aquablation would be based on only very low-certainty evidence." However, these guideline recommendations predate publication of mid-term (3-year) results, which demonstrate persistent similar outcome with TURP.[4] These studies and recommendations demonstrate the safety and effectiveness of Aquablation as an option for men aged equal to or less than 80, with moderate to severe LUTS due to benign prostate hyperplasia as indicated by International Prostate Symptom Score (IPSS) equal to or greater than 12 and a 30-80 cc prostate. Also, the ability to preserve sexual function is a major consideration.

Further follow-up reports 2 year safety and effectiveness of the Aquablation procedure for treatment with men with symptomatic benign prostatic hyperplasia (BPH) and large volume 80-150 cc prostates.

Therefore, based on the 2 and 3 year results as well as recommendations from the AUA and CUA water jet treatment of LUTS/BPH is considered to be medically reasonable and necessary when performed as outlined in this LCD.

General Information

Associated Information

Please refer to the related Billing and Coding Article: Article Title (A58227) for documentation and utilization requirements as applicable.

Sources of Information

Contractor Medical Directors Waterjet Ablation Workgroup

Bibliography

1. Zorn KC, Goldenberg SL, Paterson R, So A, Elterman D, Bhojani N. Aquablation among novice users in Canada: A WATER II subpopulation analysis. *J Can Urol Assoc* 2019;13(5):E113-E118.
2. Chung ASJ, Woo HH. Update on minimally invasive surgery and benign prostatic hyperplasia. *Asian J Urol. 2018;5(1):22-27.*
3. Hwang_EC, Jung_JH, Borofsky_M, Kim_MH, Dahm_P. Aquablation of the prostate for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. *Cochrane Database of Systematic Reviews* 2019, Issue 2. Art. No.: CD013143.
4. Gilling P, Barber N, Bidair, M, et al. Three-year outcomes after Aquablation therapy compared to TURP: results from a blinded randomized trial. *Can J Urol*. February 2020; 27(1):10072-10079.
5. Desai M, Bidair M, Bhojani N et al. Aqablation for benign prostatic hyperplasia in large prostate (80-150 cc): 2-year results. *Can J Urol.* 2020; 27(2): 10147-10153.
6. Nguyen DD, Barber N, Bidair M, Gilling P, Anderson P, Zorn KC, et al. Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue trial (WATER) vs WATER II: comparing Aquablation therapy for benign prostatic hyperplasia in 30-80 and 80-150 mL prostates. *BJU Int.* 2020;125(1):112-122.
7. Carroll PR, Kellogg Parsons J, Andriole G, et al. NCCN Guidelines® Insights Prostate Cancer Early Detection, Version 2.2016 Featured Updates to the NCCN Guidelines J *Natl Compr Canc Netw* 2016;14(5):509–519.
8. FDA Approval: De *Novo* Classification Request for AQUABEAM System. Accessed 7/2/19].
9. Gilling P, Barber N, Bidair M, et al. Randomized Controlled Trial of Aquablation versus Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia: One-year Outcomes. *Urol.* 2019;125:169-173.
10. Gilling P, Barber N, Bidair M, et al. Two-Year Outcomes After Aquablation Compared to TURP: Efficacy and Ejaculatory Improvements Sustained. *Adv Ther*. March 8, 2019.
11. AUA Guidelines: Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms (2018, amended 2019). 2019.
12. Nickel JC, Aaron L, Barkin J, Elterman D, Nachabe M, Zorn KC. Canadian Urological Association guideline on male lower urinary tract symptoms /benign prostatic hyperplasia (MLUTS/BPH): 2018 update. *Can Urol Assoc J.* 2018; 12:303-312.
13. NICE Transurethral water jet ablation for LUTS caused by BPH. 2018
14. Taktak S, Jones P, Haq A, Rai BP, Somani BK. Aquablation: a novel and minimally invasive surgery for benign prostate enlargement. *Ther Adv Urol 2018, Vol. 10(6): 183–188.*
15. Desai M, Bidair M, Bhojani N, Trainer A, Arther A, Kramolowsky E, et al. WATER II (80–150 mL) procedural outcomes. *BJU Int* 2019;123(1):106-112.
16. Sturch P, Woo HH, McNicholas T, Muir G. Ejaculatory dysfunction after treatment for lower urinary tract symptoms: retrograde ejaculation or retrograde thinking? *BJU Int.* 2015;115(2):186-187.
17. Bjojani N, Bidair M, Zorn KC, et al. Aquablation for Benign Prostatic Hyperplasia in Large Prostates (80-150cc): 1-year Results. *Urology Gold Journal.* May 2019.
18. Misrai V, Rijo E, Zorn KC, Barry-Delongchamps N, Descazeaud A. Waterjet Ablation Therapy for Treating Benign Prostatic Obstruction in Patients with Small- to Medium-size Glands: 12-month Results of the First French Aquablation Clinical Registry. *Eur Urol* (2019).
19. Kasivisvanathan V, Hussain M. Aquablation versus transurethral resection of the prostate: 1 year United States - cohort outcomes. *Can J Urol.* 2018;25(3):9317-9322.

Revision History Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A58227 - Billing and Coding: Transurethral Waterjet Ablation of the Prostate

A58522 - Response to Comments: Transurethral Waterjet Ablation of the Prostate

Related National Coverage Documents

N/A

Public Version(s)

Updated on 11/06/2020 with effective dates 12/27/2020 - N/A

Keywords

N/A