



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 09/19/22
LAST REVIEW DATE: 08/06/24
CURRENT EFFECTIVE DATE: 08/06/24
LAST CRITERIA REVISION DATE: 08/01/23
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NEXT ANNUAL REVIEW DATE: 3RD QTR 2025

TRANSURETHRAL WATER VAPOR THERMAL THERAPY AND TRANSURETHRAL WATER JET ABLATION (AQUABLATION) FOR BENIGN PROSTATIC HYPERTROPHY

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Transurethral water vapor thermal therapy and transurethral waterjet ablation (aquablation) have been investigated as minimally invasive alternatives to transurethral resection of the prostate, considered the traditional standard treatment for benign prostatic hyperplasia. Transurethral water vapor thermal therapy uses radiofrequency-generated water vapor (~103°C) thermal energy based on the thermodynamic properties of convective versus conductive heat transfer to ablate prostate tissue. Aquablation cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra.

The Rezum™ System (NxThera, Inc, acquired by Boston Scientific in 2018) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K150786). The FDA determined that this device was substantially equivalent to existing devices (Medtronic Prostiva devices). Rezum is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia. It is indicated for men > 50 years of age with a prostate volume >30 cm³ and <80 cm³. The Rezum System is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

The Aquabeam® System (Procept Robotics Corporation) was cleared for marketing by the FDA through the 513(f)(2) (de novo) classification process (DEN170024). The device is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia.

Criteria:

- Transurethral water vapor thermal therapy as a treatment of benign prostatic hyperplasia is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting
- Transurethral waterjet ablation (aquablation) as a treatment of benign prostatic hyperplasia is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or

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2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
3. Insufficient evidence to support improvement of the net health outcome; or
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
5. Insufficient evidence to support improvement outside the investigational setting

Resources:

Literature reviewed 08/06/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 08/06/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Bach T, Gilling P, El Hajj A, Anderson P, Barber N. First Multi-Center All-Comers Study for the Aquablation Procedure. *J Clin Med*. Feb 24 2020;9(2)doi:10.3390/jcm9020603
2. Bhojani N, Bidair M, Kramolowsky E, 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*. Jul 2023;210(1):143-153. doi:10.1097/ju.0000000000003483
3. Elterman D, Gilling P, Roehrborn C, et al. Meta-analysis with individual data of functional outcomes following Aquablation for lower urinary tract symptoms due to BPH in various prostate anatomies. *BMJ Surg Interv Health Technol*. 2021;3(1):e000090. doi:10.1136/bmjst-2021-000090
4. Food and Drug Administration. Aquabeam System Device Classification Under Section 513(f)(2) (De Novo). 2017. Accessed April 17, 2024. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN170024>
5. Gilling P, Barber N, Bidair M, et al. WATER: A Double-Blind, Randomized, Controlled Trial of Aquablation(®) vs Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia. *J Urol*. May 2018;199(5):1252-1261. doi:10.1016/j.juro.2017.12.065
6. 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*. Feb 2020;27(1):10072-10079.
7. Gilling PJ, Barber N, Bidair M, et al. Randomized Controlled Trial of Aquablation versus Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia: One-year Outcomes. *Urology*. Mar 2019;125:169-173. doi:10.1016/j.urology.2018.12.002

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8. Gillig PJ, Barber N, Bidair M, 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.* Feb 2022;29(1):10960-10968.
9. 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 Syst Rev.* Feb 13 2019;2(2):Cd013143. doi:10.1002/14651858.CD013143.pub2
10. Kang TW, Jung JH, Hwang EC, Borofsky M, Kim MH, Dahm P. Convective radiofrequency water vapour thermal therapy for lower urinary tract symptoms in men with benign prostatic hyperplasia. *Cochrane Database Syst Rev.* Mar 25 2020;3(3):Cd013251. doi:10.1002/14651858.CD013251.pub2
11. Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART II-Surgical Evaluation and Treatment. *J Urol.* Oct 2021;206(4):818-826. doi:10.1097/ju.0000000000002184
12. McVary KT, El-Arabi A, Roehrborn C. Preservation of Sexual Function 5 Years After Water Vapor Thermal Therapy for Benign Prostatic Hyperplasia. *Sex Med.* Dec 2021;9(6):100454. doi:10.1016/j.esxm.2021.100454
13. McVary KT, Gange SN, Gittelman MC, et al. Minimally Invasive Prostate Convective Water Vapor Energy Ablation: A Multicenter, Randomized, Controlled Study for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *J Urol.* May 2016;195(5):1529-1538. doi:10.1016/j.juro.2015.10.181
14. McVary KT, Gittelman MC, Goldberg KA, et al. Final 5-Year Outcomes of the Multicenter Randomized Sham-Controlled Trial of a Water Vapor Thermal Therapy for Treatment of Moderate to Severe Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *J Urol.* Sep 2021;206(3):715-724. doi:10.1097/ju.0000000000001778
15. McVary KT, Roehrborn CG. Three-Year Outcomes of the Prospective, Randomized Controlled Rezūm System Study: Convective Radiofrequency Thermal Therapy for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia. *Urology.* Jan 2018;111:1-9. doi:10.1016/j.urology.2017.10.023
16. McVary KT, Rogers T, Roehrborn CG. Rezūm Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study. *Urology.* Apr 2019;126:171-179. doi:10.1016/j.urology.2018.12.041

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17. 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*. Nov 2019;76(5):667-675. doi:10.1016/j.eururo.2019.06.024
18. National Institute for Health and Care Excellence (NICE). Aquablation robotic therapy for lower urinary tract symptoms caused by benign prostatic hyperplasia. January 1, 2023. Accessed April 15, 2024. <https://www.nice.org.uk/advice/mib315/chapter/Clinical-and-technical-evidence>
19. National Institute for Health and Care Excellence (NICE). Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia. 2020. Accessed April 16, 2024. <https://www.nice.org.uk/guidance/mtg49/chapter/1-Recommendations>
20. National Institute for Health and Care Excellence (NICE). Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. [IPG770]. 2023. Accessed April 17, 2024. <https://www.nice.org.uk/guidance/ipg770>
21. 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. doi:10.1097/ju.0000000000003698
22. UpToDate. Medical treatment of benign prostatic hyperplasia. Updated January 2024. <https://www.uptodate.com/contents/medical-treatment-of-benign-prostatic-hyperplasia>
23. Westwood J, Geraghty R, Jones P, Rai BP, Somani BK. Rezum: a new transurethral water vapour therapy for benign prostatic hyperplasia. *Ther Adv Urol*. Nov 2018;10(11):327-333. doi:10.1177/1756287218793084

Coding:

CPT: 0421T, 53854, 55899
HCPCS: C2596

History:

Date:

Activity:

Medical Policy Panel	08/06/24	Review with revisions
Medical Policy Panel	08/01/23	Review with revisions
Medical Policy Panel	08/30/22	Approved guideline (Effective 09/19/22)
Medical Director (Dr. Deering)	06/13/22	Development



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Policy Revisions:

08/06/24	Updated:	Resource section
08/01/23	Added:	"Insufficient evidence to support improvement of the net health outcome; or", and "Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or" to experimental or investigational criteria.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíłkídkgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíłkídkgo beehaz'áanii hółq díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíłnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

