PROVIDER POLICIES & PROCEDURES

TREATMENT AND/OR INTERVENTIONS FOR BENIGN PROSTATIC HYPERPLASIA (BPH)

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP Providers) with the information needed to support a medical necessity determination for treatment and interventions related to benign prostatic hyperplasia (BPH). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Benign prostatic hyperplasia (BPH) is a common condition in older individuals that can lead to lower urinary tract symptoms (LUTS) including urinary retention, frequency, urgency, and hesitancy. There are several treatment options to reduce symptoms related to BPH.

A temporarily implanted nitinol device (e.g., iTind) has been proposed as a minimally invasive alternative to traditional and standard methods of treatment for symptomatic BPH (i.e., prostatic urethral lift, transurethral resection of prostate, prostatectomy). The device is temporarily implanted into the obstructed prostatic urethra to facilitate tissue reshaping and improve urine outflow. The implant is typically removed after five to seven days of treatment.

Transurethral waterjet ablation "Aquablation" therapy is a minimally invasive, robotically controlled, heat-free waterjet procedure designed to remove excess prostate tissue in individuals diagnosed with BPH.

Drug-coated balloon catheter systems (e.g., Optilume®) is a minimally invasive treatment that combines mechanical dilation with simultaneous, localized drug delivery of paclitaxel for the treatment of BPH.

Transurethral ultrasound ablation (TULSA) and (TULSA- Pro) procedure is a minimally invasive treatment for BPH that uses MRI-guided, directional ultrasound energy delivered through the urethra to heat and destroy excess prostate tissue.

CLINICAL GUIDELINE

Coverage guidelines for treatments and/or interventions for BPH will be made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and his or her unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

The use of a temporarily implanted nitinol device (CPT codes **53865** and **53866**) for the treatment of LUTS secondary to BPH, may be considered medically necessary when:

A. The individual's prostate volume is between 25 grams and 80 grams; and
B. There is a lack of obstruction in the median lobe.

The use of transurethral waterjet ablation (CPT code **52597**) of the prostate for the treatment of LUTS

secondary to BPH may be considered medically necessary **ONCE** per lifetime for the following indications:

A. Prostate volume between 30 grams and 150 grams;
B. International Prostate Symptom Score (IPPS) ≥12;
C. Maximum urinary flow rate (Qmax) less than 15mL/s;
D. Failure, contraindication or an intolerance to conventional therapy (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) over a period of no less than three (3) months; and
E. The individual has none of the following conditions:
    a. BMI ≥ 42;
    b. Active infection, including urinary tract infection or prostatitis;
    c. Inability to safely stop anticoagulants or antiplatelet agents perioperatively;
    d. Known or suspected diagnosis of prostate cancer or prostate specific antigen (PSA) >10 ng/mL;
    e. Damaged external urinary sphincter;
    f. Diagnosis of a clinically significant urethral stricture or meatal stenosis, or bladder neck contracture; or
    g. Bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum.

Drug-coated balloon catheter systems (CPT code **52443**) are considered experimental/investigational and therefore NOT medically necessary as there is insufficient evidence in peer-reviewed, published, medical literature to support its safety and clinical efficacy for all indications.

Transurethral ablation of prostate tissue using thermal ultrasound with MRI guidance (CPT codes **55881** and **55882**) for the treatment of BPH is considered investigational and therefore not medically necessary as there is insufficient evidence in peer-reviewed, published, medical literature supporting its clinical efficacy and safety.

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Requests for coverage of treatments and/or interventions for BPH will be reviewed in accordance with procedures in place for reviewing requests for surgical procedures. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

Information required for review for a temporarily implanted nitinol device (CPT codes 53865 and 53866) and transurethral waterjet ablation (CPT code 52597)

1. Fully completed authorization request via on-line web portal; and
2. Documentation from the treating provider, written within the past three (3) months, as outlined in the *Clinical Guideline* section of this policy, supporting the medical need.

EFFECTIVE DATE

This Clinical Guideline is effective for prior authorization requests for individuals covered under the HUSKY A, B, C, and D programs on or after August 01, 2026.

LIMITATIONS
N/A

CODES:

Code	Description
52443	Examination of urethra and bladder with incision of opening of prostate gland and drug delivery using endoscope
52597	Transurethral robotic-assisted waterjet resection of prostate, including intraoperative planning, ultrasound guidance, control of postoperative bleeding, complete, including vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy, when performed
53865	Cystourethroscopy with insertion of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate
53866	Catheterization with removal of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate
55881	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation (more than one physician)
55882	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed (one physician)

*Code 55881 is used in conjunction with code 51721 (Insertion of transducer through urethra for delivery of heat ultrasound). 51721 does not require prior authorization.

DEFINITIONS

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain

the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

8. **Prior authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

Temporarily implanted nitinol device (iTind)

- Amparore D, De Cillis S, Schulman C, Kadner G, Fiori C, Porpiglia F. Temporary implantable nitinol device for benign prostatic hyperplasia-related lower urinary tract symptoms: over 48-month results. Minerva Urol Nephrol. 2023;75(6):743-751. doi:10.23736/S2724-6051.23.05322-3
- Elterman D, Aubé-Peterkin M, Evans H, et al. UPDATE – Canadian Urological Association guideline: Male lower urinary tract symptoms/benign prostatic hyperplasia. Can Urol Assoc J 2022;16(8):245-56. http://dx.doi.org/10.5489/cuaj.7906
- McVary KT. Surgical treatment of benign prostatic hyperplasia (BPH). In: UpToDate, O'Leary MP, Chen W (Eds.). Wolters Kluwer. Updated June 26, 2024.
- Porpiglia F, Fiori C, Bertolo R, et al. 3-Year follow-up of temporary implantable nitinol device implantation for the treatment of benign prostatic obstruction. BJU Int. 2018;122(1):106-112. doi:10.1111/bju.14141
- National Health Institute for Health and Care Excellence (NICE). Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia. Interventional procedures guidance. 21 September 2022. Available at: https://www.nice.org.uk/guidance/ipg737
- 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. 2024;211(1):11-19. doi:10.1097/JU.0000000000003698

Transurethral waterjet ablation "Aquablation"

- 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. 2023;210(1):143-153.
- Centers for Medicare & Medicaid Service. Transurethral Waterjet Ablation of the Prostate (L38682). 2025. Retrieved at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38682
- Desai M, Bidair M, Bhojani N et al. Aquablation® for benign prostatic hyperplasia in large prostate (80-150 cc): 2-year results *Can J Urol.* 2020; 27(2): 10147-10153
- Desai M, Bidair M, Bhojani N, et al. WATER II (80-150 mL) procedural outcomes. BJU Int. 2019;123(1):106-112. doi:10.1111/bju.14360

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- 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. PMID 30552937
- 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. Feb2020; 27(1): 10072-10079. PMID 32065861
- Gilling 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. PMID 35150215
- McVary KT. Surgical treatment of benign prostatic hyperplasia (BPH). In: *UpToDate*. O'Leary MP, Chen W (Eds.). Wolters Kluwer. Updated June 2024.
- National Institute for Health and Care Excellence (2023). Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. [IPG770]. https://www.nice.org.uk/guidance/ipg770.
- National Institute for Health and Care Excellence (NICE). Aquablation robotic therapy for lower urinary tract symptoms caused by benign prostatic hyperplasia. January 1, 2023. https://www.nice.org.uk/advice/mib315/chapter/Clinical-and-technical-evidence.
- Nguyen DD, Barber N, Bidair M, 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. doi:10.1111/bju.14917
- 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. 2023;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

Drug-coated Balloon Catheter Systems (Optilume®)

- Gauhar V, Yuen SKK, Gadzhiev N, et al. Optilume, a minimally invasive solution for BPH and urethral stricture: what we know, what we need? an EAU endourology scoping review. BMC Urol. 2025;25(1):196. Published 2025 Aug 9. doi:10.1186/s12894-025-01896-3
- Kaplan, SA, Moss, JL, Freedman, SJ. Two-year long-term follow-up of treatment with the Optilume BPH catheter system in a randomized controlled trial for benign prostatic hyperplasia (The PINNACLE Study). Prostate Cancer Prostatic Dis 27, 531–536 (2024). https://doi.org/10.1038/s41391-024-00833-z
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TULSA and TULSA-Pro

- Elterman D, Aubé-Peterkin M, Evans H, et al. UPDATE – Canadian Urological Association guideline: Male lower urinary tract symptoms/benign prostatic hyperplasia. Can Urol Assoc J 2022;16(8):245-56. http://dx.doi.org/10.5489/cuaj.7906
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PUBLICATION HISTORY

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