Permanently Implanted Prostatic Devices for Benign Prostatic Hyperplasia

Policy # 00976
Original Effective Date: 10/01/2026
Current Effective Date: 10/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Transurethral Water Vapor Thermal Therapy (Rezum) and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy is addressed separately in medical policy 00684.

Note: Prostatic Urethral Lift is addressed separately in medical policy 00480.

Note: Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia is addressed separately in medical policy 00825.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of permanently implanted prostatic stent devices (eg, ProVee System, Zenflow Spring Implant) as a treatment of lower urinary tract symptoms due to benign prostatic hyperplasia to be **investigational.***

Background/Overview

Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH) is a common disorder among older individuals that results from hyperplastic nodules in the periurethral or transitional zone of the prostate. The clinical manifestations of BPH include increased urinary frequency, nocturia, urgency or hesitancy to urinate, and a weak stream when urinating. The urinary tract symptoms often progress with worsening hypertrophy and may lead to acute urinary retention, incontinence, renal insufficiency, and/or urinary tract infection. Benign prostatic hyperplasia prevalence increases with age and is present in more than 50% of individuals in their 60s, rising to 90% in their 90s.

Two scores are widely used to evaluate BPH-related symptoms: the American Urological Association Symptom Index (AUASI) and the International Prostate Symptom Score (IPSS). The AUASI is a self-administered 7-item questionnaire assessing the severity of various urinary

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symptoms. Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35). The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score."

Benign prostatic hyperplasia does not necessarily require treatment. The decision on whether to treat BPH is based on an assessment of the impact of symptoms on quality of life along with the potential side effects of treatment. For patients with moderate-to-severe symptoms (eg, an AUASI score of ≥8), bothersome symptoms, or both, a discussion about medical therapy is reasonable. Available medical therapies for BPH-related lower urinary tract dysfunction include α-adrenergic blockers (eg, alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5α-reductase inhibitors (eg, finasteride, dutasteride), combination α-adrenergic blockers and 5α-reductase inhibitors, anti-muscarinic agents, phosphodiesterase-5 inhibitors (eg, tadalafil), and beta-3 adrenergic receptor agonists (eg, mirabegron).

Patients who do not have sufficient response to medical therapy, or who are experiencing significant side effects with medical therapy, may be referred for surgical or ablative therapies. The American Urological Association (AUA) recommends surgical intervention for patients who have renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections, recurrent bladder stones or gross hematuria due to BPH, and/or lower urinary tract symptoms (LUTS) attributed to BPH refractory to and/or unwilling to use other therapies. Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH procedures. Minimally invasive surgical treatments (MISTs) including prostatic urethral lift (PUL), water vapor thermal therapy (WVTT), temporarily implanted nitinol devices (eg, iTind), and aquablation have been developed as alternatives to TURP with the aim of reducing procedure-related morbidity while preserving sexual function.

Permanently Implanted Prostatic Stent Devices
Permanently implanted prostatic stent devices represent a distinct category from temporarily implanted nitinol devices (eg, iTind, which is removed after 5–7 days). Unlike temporary devices that achieve their therapeutic effect through ischemic tissue remodeling, permanently implanted prostatic stent devices exert continuous radial expansion force against the prostatic lobes to maintain luminal patency indefinitely. These devices are designed to be retrievable at any time if clinically warranted.

Legacy Permanent Prostatic Stents
Earlier permanent prostatic stents, including the UroLume Wallstent (American Medical Systems; discontinued) and Memokath/Memotherm devices, were introduced in the 1990s but were subsequently abandoned due to high complication rates. A 2025 systematic review by Cerrato et al encompassing 2,618 patients across 38 studies reported an overall complication rate of 30.8% for legacy permanent stents, including encrustation rates of 12.6%, failure requiring removal or repositioning in 14.8%, urinary tract infection in 17.2%, and epithelial hyperplasia with tissue ingrowth. Importantly, these complications, particularly encrustation, tissue ingrowth, and migration, emerged predominantly beyond the first year of implantation, with progressive

accumulation over years of follow-up. This temporal pattern is clinically significant: initially acceptable short-term outcomes did not predict long-term device performance, and the UroLume was ultimately removed from the market by its manufacturer due to these delayed safety concerns. A newer generation of permanent prostatic stent devices has been developed with design features intended to address these historical failure modes, including non-crossing strut configurations to minimize encrustation, nitinol superelasticity for atraumatic radial force, and retrievability via standard endoscopic equipment.

Comparative Landscape
A 2026 network meta-analysis by Shin et al (N=21,078 across 103 randomized controlled trials) compared the efficacy and safety of MISTs for BPH, confirming TURP as the highest-ranked treatment for symptom improvement and the lowest for surgical reintervention. Neither the ProVee System nor the Zenflow Spring Implant was included in the analysis. The results provide landscape context for established alternatives, but do not allow direct comparison with the devices under review.

ProVee System
The ProVee System for BPH (ProVerum Limited, Dublin, Ireland) consists of the ProVee Expander and Generation II Delivery System. The ProVee Expander is a permanent nitinol implant with 3 apices intended to correspond with the 3 dominant lobes of the prostate (2 lateral lobes and the median lobe). The device applies radial expansion force to the dominant lobes and is available in one universal size. The Generation II Delivery System is a 16 Fr single-use steerable device with integrated imaging (CMOS sensor) and irrigation, facilitating targeted deployment under direct visualization via a transurethral approach. The system allows for staged deployment, enabling the user to visualize the partially deployed expander relative to anatomical landmarks prior to full deployment.

Zenflow Spring Implant
The Zenflow Spring Implant and Delivery System (Zenflow, Inc., South San Francisco, CA) consists of a permanent nitinol spring coil implant constructed from a single wire strand formed into ring elements connected by spine sections. The implant is available in multiple sizes (15–21 mm length) to accommodate prostate lengths between 25 and 45 mm. The device is delivered via a proprietary single-use flexible cystoscope (Spring Scope) with an 11.5 Fr delivery catheter and balloon-anchored positioning system. The ends of the implant have rounded balls to assist in grasping for potential retrieval.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In December 2025, the ProVee System for BPH (ProVerum Limited) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process (P250011; product code: MER). The ProVee System is indicated for the treatment of obstructive lower urinary tract

symptoms secondary to BPH in men with prostatic urethral lengths greater than or equal to 3.75 cm and prostatic volumes between 30 cc and 80 cc.

In December 2025, the Zenflow Spring Implant and Delivery System (Zenflow, Inc.) was approved by the FDA through the PMA process (P250007; product code: MER). The Zenflow Spring Implant is indicated for the treatment of obstructive lower urinary tract symptoms secondary to BPH in men with prostatic urethral lengths between 25 and 45 mm and prostate volumes between 25 and 80 cc. Both devices received PMA approval, the highest regulatory bar requiring demonstrated safety and effectiveness through clinical trial data. Neither device has been previously marketed in the United States or any foreign country. The FDA required 60-month post-approval studies for both devices, explicitly citing the precedent that a prior device of this type was removed from the market by its manufacturer due to long-term safety concerns.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Benign prostatic hyperplasia (BPH) is a common condition in older individuals that can lead to lower urinary tract symptoms (LUTS) including increased urinary frequency, urgency, hesitancy, nocturia, and a weak urinary stream. Permanently implanted prostatic stent devices have been proposed as a minimally invasive treatment for LUTS secondary to BPH. These devices are permanently placed in the prostatic urethra where they exert continuous radial expansion force to maintain luminal patency and improve urine outflow. Unlike temporarily implanted nitinol devices that facilitate tissue reshaping through short-term ischemic remodeling, permanently implanted prostatic stent devices remain in situ indefinitely.

Summary of Evidence

For individuals who have moderate-to-severe benign prostatic hyperplasia (BPH) with lower urinary tract symptoms who receive a permanently implanted prostatic stent device (eg, ProVee System, Zenflow Spring Implant), the evidence includes 2 manufacturer-sponsored randomized controlled trials (RCTs) with sham controls, multiple single-arm pilot studies, and systematic reviews of legacy prostatic stents and minimally invasive surgical treatments (MISTs) for BPH. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, sexual function, treatment-related morbidity, and long-term device complications. One double-blind, sham-controlled RCT of the ProVee System (N=221) met both co-primary effectiveness endpoints, demonstrating a mean International Prostate Symptom Score (IPSS) improvement of 9.5 versus 5.6 for sham at 3 months (p=.001) and a mean percent IPSS improvement of 38.3% from baseline at 12 months (p=.002), with no device- or procedure-related serious adverse events (SAEs). One single-blind, sham-controlled RCT of the Zenflow Spring Implant (N=205 randomized) failed to meet

either co-primary effectiveness endpoint in the intent-to-treat (ITT) population; U.S. Food and Drug Administration (FDA) approval was based on a post-hoc modified ITT/intended use (mITT/IU) population that retrospectively excluded 38 erroneously enrolled participants with obstructive median lobe anatomy, in which the responder rate was 59.6% versus 33.3% for sham at 3 months and the mean percent IPSS change was -37.2% at 12 months. One systematic review of prostatic stents (N=2,618 across 38 studies) found high complication rates for legacy permanent stents including encrustation (12.6%), failure requiring removal or repositioning (14.8%), and urinary tract infection (17.2%). No studies have directly compared permanently implanted prostatic stent devices to active treatment alternatives such as transurethral resection of the prostate or prostatic urethral lift. Both devices received FDA premarket approval in December 2025 with required 60-month post-approval studies, explicitly citing the historical precedent of a prior permanent prostatic stent removed from the market due to long-term safety concerns. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association

In 2021, the American Urological Association (AUA) published guidelines on the surgical evaluation and treatment of lower urinary tract symptoms (LUTS) attributed to benign prostatic hyperplasia (BPH). A 2023 amendment to these guidelines introduced a category for temporarily implanted prostatic devices (TIPD), noting that iTind may be offered for men with BPH, LUTS, prostate volume of 25 to 75 grams, and who lack an obstructive median lobe (Conditional recommendation; Grade C, based on expert opinion). The AUA guidelines address legacy prostatic stents as a historical category but do not include ProVee or Zenflow, which received U.S. Food and Drug Administration (FDA) premarket approval after the guideline evidence cutoff.

No professional society guideline has evaluated either ProVee or Zenflow as of April 2026.

National Institute for Health and Care Excellence

In 2022, NICE issued guidance on prostatic urethral temporary implant insertion for LUTS caused by BPH. This guidance addresses the iTind device only and states that the evidence is limited in quantity and quality; the procedure should only be used with special arrangements for clinical governance, consent, and audit or research. NICE has not issued guidance for permanently implanted prostatic stent devices.

U.S. Preventive Services Task Force Recommendations
None.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05186740[a]	The ProVee Urethral Expander System Clinical Study	221	Dec 2028
NCT06236802[a]	ProVIDE II Bridging Study for the ProVee System for BPH	40	Jun 2029
NCT04987138[a]	Safety and Effectiveness Study of the Zenflow Spring System - A Minimally Invasive Treatment for LUTS Associated With BPH	279	Jun 2026
NCT06849258[a]	A Prospective, Multicenter, Double Blind, Randomized, Clinical Study to Evaluate the Safety and Efficacy of The FloStent in Men Suffering From Benign Prostatic Hyperplasia Symptoms	215	Dec 2032

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 10/01/2026
Current Effective Date: 10/01/2026
07/02/2026 Medical Policy Committee review
07/08/2026 Medical Policy Implementation Committee review.
07/16/2026 Medical Quality Management Committee approval. New policy.
Next Scheduled Review Date: 07/2027

Policy # 00976
Original Effective Date: 10/01/2026
Current Effective Date: 10/01/2026

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0941T, 0942T, 0943T, 52282, 53899
HCPCS	C1889, L8699
ICD-10 Diagnosis	N40.1

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.