LOUISIANA BLUE

Prostate Artery Embolization

Policy # 00957
Original Effective Date: 06/01/2026
Current Effective Date: 06/01/2026

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

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: 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 prostate artery embolization as a treatment for benign prostatic hyperplasia to be **investigational.***

Background/Overview

Benign prostatic hyperplasia (BPH) is a common condition in older men, affecting to some degree 40% of men in their 50s, 70% of those between ages 60 and 69, and almost 80% of those ages 70 years and older. BPH is a histologic diagnosis defined as an increase in the total number of stromal and glandular epithelial cells within the transition zone of the prostate gland. In some men, BPH results in prostate enlargement which can, in turn, lead to benign prostate obstruction and bladder outlet obstruction, which are often associated with lower urinary tract symptoms (LUTS) including urinary frequency, urgency, irregular flow, weak stream, straining, and waking up at night to urinate. LUTS are the most commonly presenting urological complaint and can have a significant impact on quality of life (QOL).

BPH does not necessarily require treatment. The decision on whether to treat BPH is based on an assessment of the impact of symptoms on QOL along with the potential side effects of treatment. Options for treatment include watchful waiting, medication, and minimally invasive surgical procedures. Patients with persistent symptoms despite medical treatment may be considered for surgical treatment. The traditional standard treatment for BPH is transurethral resection of the

prostate (TURP). TURP is generally considered the reference standard for comparisons of BPH procedures. A variety of minimally invasive surgical approaches are available as an alternative to TURP for management of LUTS in men with BPH. These methods include water vapor thermal therapy, prostatic urethral lift, and temporary implanted prostatic devices. Each of these approaches is discussed in detail in separate medical policies: 00480, 00684, and 00825, respectively (see noted policies at the top of page 1).

Prostate arterial embolization (PAE) is a minimally invasive treatment option that works by reducing blood supply to prostatic arteries. PAE differs from other minimally invasive surgical therapies in treatment approach (endovascular vs transurethral) and mechanism (embolic), and thus requires different considerations. An interventional radiologist injects microspheres through a catheter to the blood vessels around the prostate, reducing the blood supply to multiple different areas. No surgical intervention is required for this procedure and recovery times are often less than that of TURP. PAE requires significant clinician training and is associated with some common side effects such as post-PAE syndrome, blood in urine or semen, rare cases of prostatic or bladder spasms.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Prostate surgeries are procedures and, therefore, not regulated by the FDA. However, devices and instruments used during the surgery may require FDA approval. Refer to the following website for additional information:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

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.

Description

Prostate arterial embolization (PAE) has been investigated as a minimally invasive alternative to transurethral resection of the prostate (TURP), considered the traditional standard treatment for benign prostatic hyperplasia (BPH). PAE differs from other minimally invasive surgical therapies in treatment approach (endovascular vs transurethral) and mechanism (embolic), and thus requires different considerations. An interventional radiologist injects microspheres through a catheter to the blood vessels around the prostate, reducing the blood supply to multiple different areas. No surgical intervention is required for this procedure and recovery times are often less than that of TURP.

Summary of Evidence

For individuals who have benign prostatic hyperplasia (BPH) and lower urinary tract symptoms (LUTS) who receive prostate artery embolization (PAE), the evidence includes systematic reviews, randomized controlled trials (RCTs) and noncomparative studies. The outcomes of interest are symptoms, functional outcomes, quality of life, and procedure-related morbidity. A Cochrane meta-

analysis of 7 RCTs comparing PAE with transurethral resection of the prostate (TURP) or a sham procedure in men with LUTS due to BPH reported similar improvements in symptom scores and quality of life across procedures over both short-term (≤12 months) and long-term (13-24 months) follow-up. There remained significant uncertainty about major adverse events (very low-certainty evidence), but PAE was associated with a higher likelihood of retreatment (moderate-certainty evidence). The long-term effect on erectile function was minimal (low-certainty evidence), and PAE may continue to lower the incidence of ejaculatory disorders (low-certainty evidence). A qualitative systematic review of 5 RCTs and two observational studies found that PAE and TURP resulted in comparable symptom and quality of life improvements at 12 months. TURP offered greater increases in urine flow and prostate volume reduction, while PAE had shorter hospital stays and fewer complications. Three RCTs, published following the systematic reviews, have assessed the efficacy of PAE relative to conventional therapies for BPH. One RCT conducted in Switzerland (2024) reported that TURP demonstrated superior efficacy to PAE in improving LUTS and urinary flow rates at 5-years of follow-up, although erectile function outcomes favored PAE. Another RCT from Australia (2024) indicated that PAE, when utilized as a first-line therapy, resulted in greater reductions in prostate volume, improved symptom scores, and enhanced quality of life relative to medical therapy, with a lower incidence of adverse events. The third RCT, performed in France (2023), found that PAE was more effective than combined medical therapy for patients with moderate LUTS, yielding greater improvements in both symptoms and erectile function, with no major adverse events and a decreased need for retreatment. All three trials were open-label and characterized by high loss to follow-up and significant patient crossover between study arms. A retrospective, single-center study of 317 men with moderate to severe BPH found bilateral PAE had lower recurrence rates than a unilateral approach at over 2-years of follow-up. There is a paucity of direct comparative data between PAE and other minimally invasive therapies for BPH, such as transurethral water vapor thermal therapy, water jet ablation, prostatic urethral lift, and temporarily implanted nitinol devices; these modalities are addressed in separate medical policies. Future studies should specifically assess outcomes related to repeat interventions and unilateral PAE procedures. 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 LUTS attributed to BPH. An amendment to these guidelines was published in 2023.

The following recommendations are related to PAE based on a systematic review by Sandhu et al (2024) (discussed above) to support these updated AUA guidelines:

- PAE may be offered for the treatment of LUTS/BPH. PAE should be performed by clinicians trained in this interventional radiology procedure following a discussion of the potential risks and benefits. (Conditional Recommendation: Evidence level: Grade C)

Society of Interventional Radiology et al

In a 2019 multi-society, evidence-based position statement regarding PAE for the treatment of lower urinary tract symptoms due to BPH, the Society of Interventional Radiology (SIR) states that PAE is a safe and effective treatment, has good short and intermediate term efficacy and is a treatment option for the following:

- For appropriately selected men with BPH and moderate to severe LUTS. (Level of Evidence: B; strong recommendation)
- In patients with BPH and moderate to severe LUTS who have very large prostate glands (> 80 cm^3), without an upper limit of prostate size. (C; moderate recommendation)
- In patients with BPH and acute or chronic urinary retention in the setting of preserved bladder function as a method of achieving catheter independence. (C; moderate recommendation)
- In patients with BPH and moderate to severe LUTS who wish to preserve erectile and/or ejaculatory function. (C; weak recommendation)
- In patients with hematuria of prostatic origin as a method of achieving cessation of bleeding. (D; strong recommendation)
- In patients with BPH and moderate to severe LUTS who are deemed not to be surgical candidates for any of the following reasons: advanced age, multiple comorbidities, coagulopathy, or inability to stop anticoagulation or antiplatelet therapy. (E; moderate recommendation)
- PAE should be included in the individualized patient centered discussions regarding treatment options. (E; strong recommendation)

These recommendations were based on a review of 6 meta-analyses published between 2016 to 2019. SIR also gives a strong recommendation that interventional radiologists, given their knowledge of arterial anatomy, advanced microcatheter techniques, and expertise in embolization procedures, are the specialists best suited for the performance of PAE.

National Institute for Health and Care Excellence

In 2018, the NICE issued the following guidance on PAE for LUTS caused by BPH:

- "1.1 Current evidence on the safety and efficacy of prostate artery embolisation for benign prostatic hyperplasia is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
- 1.2 Patient selection should be done by a urologist and an interventional radiologist.
- 1.3 This technically demanding procedure should only be done by an interventional radiologist with specific training and expertise in prostatic artery embolisation."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Medicare has a general national coverage determination for Therapeutic Embolization (20.28).

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			
NCT07242807	Evaluation of Clinical and Functional Outcomes After Minimally Invasive Prostate Interventions: A Multicenter Prospective REDCap Registry (MIST Study)	2000	Dec 2030
NCT04084938	Prostatic Artery Embolization vs Transurethral Resection of the Prostate or Open Prostatectomy in Patients With Symptomatic Benign Prostatic Hyperplasia	140	Dec 2027
NCT04807010	PROARTE -PROstate ARTery to Reduce the Symptoms of Benign Prostatic Hyperplasia	108	Aug 2026
NCT04245566	Prostatic Artery Embolization vs. Pharmacotherapy for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: a Multicenter Randomized Controlled Trial	425	Dec 2025
NCT05531240	Transurethral Prostate Resection (TURP) vs. Prostate Artery Embolization (PAE): Open Multicentric Randomized Study for Evaluation of Outcomes, Complications, and Health Economics	104	Dec 2025

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

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Europe, Société Française de Radiologie, and the British Society of Interventional Radiology: Endorsed by the Asia Pacific Society of Cardiovascular and Interventional Radiology, Canadian Association for Interventional Radiology, Chinese College of Interventionalists, Interventional Radiology Society of Australasia, Japanese Society of Interventional Radiology, and Korean Society of Interventional Radiology. J Vasc Interv Radiol. May 2019; 30(5): 627-637.e1. PMID 30926185
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Policy History

Original Effective Date: 06/01/2026
Current Effective Date: 06/01/2026
03/05/2026 Medical Policy Committee review
03/11/2026 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 03/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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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	37243
HCPCS	No Code
ICD-10 Diagnosis	N40.0, N40.01

*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.

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.