

7.01.55 Prostate Artery Embolization for Benign Prostatic Hyperplasia			
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Section:	7.0 Surgery	Page:	Page 1 of 16

Policy Statement

- I. Prostate artery embolization is considered **investigational** as a treatment for benign prostatic hyperplasia.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the [Codes table](#) for details.

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 evidence reviews. 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.

Additional Information

Not applicable.

Related Policies

- Prostatic Urethral Lift
- Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia
- Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

Regulatory Status

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

Background

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.¹ 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 Blue Shield of California Medical Policies: Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy; Prostatic Urethral Lift; and Temporarily Implanted Nitinol Device (iTind) for Benign Prostatic Hyperplasia, respectively (see Related Policies).

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.² 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Prostate Artery Embolization

Clinical Context and Therapy Purpose

The purpose of prostate artery embolization (PAE) in individuals who have benign prostatic hyperplasia (BPH) and lower urinary tract symptoms (LUTS) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with BPH and LUTS. Symptoms include urinary frequency, urgency, irregular flow, weak stream, straining, and getting up at night to urinate.

Interventions

The therapy being considered is PAE. PAE is an endovascular procedure to treat BPH, in which an interventional radiologist uses a catheter to insert tiny particles into the body to block blood flow in the prostatic arteries to the enlarged prostate, leading to prostate tissue shrinkage and symptom relief.

Comparators

The following practices are currently being used to treat BPH in this setting:

- Conservative treatment, including watchful waiting and lifestyle modifications;
- Pharmacotherapy;
- Transurethral resection of the prostate (TURP), which is generally considered the reference standard for comparisons of BPH procedures; and
- Prostatic urethral lift.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, health status measures, QOL, and procedure-related morbidity.

The International Prostate Symptom Score (IPSS) is used to assess the severity of BPH symptoms. The first 7 questions address urinary frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying, and urgency each on a scale of 0 to 5. The total score, summed across the 7 items measured, ranges from 0 (no symptoms) to 35 (most severe symptoms). A decrease in score indicates improvement.

A number of health status measures are used to evaluate symptoms relevant to BPH and adverse events of treatment for BPH, including urinary symptoms, urinary dysfunction measured by peak urinary flow rate (Q_{max}), ejaculatory dysfunction, overall sexual health, and overall QOL. Q_{max} is measured by uroflowmetry; low rates are associated with more voiding dysfunction and rates <10 mL/sec are considered obstructed. Urinary continence may be assessed via the Incontinence Symptom Index (ISI) questionnaire. Erectile and ejaculatory function is assessed in sexually active men only. Scales include the International Index of Erectile Function (IIEF) and the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD).

QOL is assessed with various scales including the IPSS-QoL.

Both short-term (up to 12 months) and long-term (12 months and longer) outcomes should be assessed. Treatment-related morbidity can also be assessed in the immediate post-procedure period.

Some validated patient-reported scales are summarized in Table 1.

Table 1. Patient-Reported Health Outcome Measures Relevant to Benign Prostatic Hyperplasia

Measure	Outcome Evaluated	Description	Clinically Meaningful Difference (If Known)
Male Sexual Health Questionnaire for Ejaculatory Dysfunction ³	Ejaculatory function and QOL	Patient-administered, 4-item scale. Symptoms rated as absent (15) to severe (0). QOL assessed as no problem (0) to extremely bothered (5).	NR
Sexual Health Inventory for Men ⁴	Erectile function	Patient-administered, 5-item scale. Erectile dysfunction rated as severe (1-7), moderate (8-11), mild to moderate (12-16), or mild (17-21). Fewest symptoms present for patients with scores 22-25.	5-point change ⁵

Measure	Outcome Evaluated	Description	Clinically Meaningful Difference (If Known)
American Urological Association Symptom Index; International Prostate Symptom Score^{6,7,8}	Severity of lower urinary tract symptoms	Patient-administered, 7-item scale. Symptoms rated as mild (0-7), moderate (8-19), or severe (20-35). IPSS asks an additional question, rating QOL as delighted (0) to terrible (6)	• Minimum of 3-point change^{8,6}, • Minimum of 30% change⁹
Benign Prostatic Hyperplasia Impact Index¹⁰	Effect of urinary symptoms on health domains	Patient-administered, 4-item scale. Symptoms rated as absent (0) to severe (13).	Minimum of 0.4-point change ⁸

IPSS: International Prostate Symptom Score; NR: Not reported; QOL: quality of life.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence Systematic Reviews

In a Cochrane systematic review, Jung et al. (2022) analyzed the effectiveness of PAE compared with other procedures for treating LUTS in men with BPH.¹¹ The analysis included 7 single-center, parallel RCTs (comprised of 8 publications including one trial published in Chinese) published up to November 2021. Of these, 6 trials compared PAE with TURP, while one trial evaluated PAE against a sham procedure (Pisco et al, 2020) (Table 1). The trials included 488 patients: 234 underwent PAE, 214 received TURP, and 40 were assigned to the sham group. The average patient age was 65 years, with a mean IPSS of 23.8, an average peak urine flow rate (Qmax) of 7.89 mL/second, and a mean prostate volume of 62.6 mL.

In short-term follow-up (≤ 12 months), studies demonstrated that PAE and TURP yielded similar improvements in urologic symptom scores measured by the IPSS, with little to no difference detected (mean difference [MD] 1.72; 95% confidence interval [CI], -0.37 to 3.81; 6 RCTs, 360 participants; $I^2 = 78\%$; low-certainty evidence). QOL outcomes were also comparable between the two procedures (MD 0.28; 95% CI, -0.28 to 0.84; 5 RCTs, 300 participants; $I^2 = 63\%$; low-certainty evidence). There was considerable uncertainty regarding the risk of major adverse events (risk ratio [RR] 0.75; 95% CI, 0.19 to 2.97; 4 RCTs, 250 participants; $I^2 = 24\%$; very low-certainty evidence), though PAE likely led to an increased need for retreatment procedures (RR 3.20; 95% CI, 1.41 to 7.27; 4 RCTs, 303 participants; $I^2 = 0\%$; moderate-certainty evidence). Regarding sexual health, PAE appeared to have minimal impact on erectile function compared to TURP in the short term (low-certainty evidence) and possibly reduced the risk of ejaculatory disorders (very low-certainty evidence). In long-term outcomes (13 to 24 months), PAE continued to show little to no difference in urologic symptom scores (MD 2.58; 95% CI, -1.54 to 6.71; 2 RCTs, 176 participants; $I^2 = 73\%$; low-certainty evidence) and QOL (MD 0.50 points, 95% CI -0.03 to 1.04; 2 RCTs, 176 participants; $I^2 = 29\%$; low-certainty evidence) compared to TURP. There remained significant uncertainty about major adverse events (very low-certainty evidence), but PAE was again associated with a higher likelihood of retreatments (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).

Ini' et al (2024) performed a qualitative systematic review to evaluate the clinical outcomes of patients treated with endovascular procedures for BPH, specifically comparing TURP and PAE.¹² The analysis included 7 studies (N=718) published up to January 2024, comprising 5 RCTs and two observational studies. Of these patients, 408 underwent PAE and 310 received TURP. The technical success rate for PAE ranged from 86% to 100%, whereas TURP achieved a 100% success rate. Over a 12-month follow-up, both procedures resulted in similar reductions in IPSS and improvements in QOL, but TURP led to greater enhancements in Qmax and more substantial decreases in prostate volume. PAE was associated with shorter hospital stays (mean length of hospitalization, 1.7 days (standard deviation (SD)=0.9) for PAE, and 3 days (SD=1.7) for TURP). The rate of complications and adverse events was higher in the TURP group compared to the PAE group (60.6% vs. 35.5%).

Sandhu et al. (2024) performed a systematic review and meta-analysis to support the updated AUA guidelines (2023) on evidence-based surgical management of male LUTS due to BPH.¹³ This guideline amendment led to revised statements and supporting text regarding combination therapy, photoselective vaporization of the prostate, water vapor thermal therapy, laser enucleation, and PAE. For the PAE section, five studies published up to October 2022 were reviewed. Among these studies, four were also analyzed in the Ini' et al. (2024) review. The fifth study refers to the initial 12-week outcome report from the Abt et al. RCT (2018), with the two-year results subsequently published by Abt et al. (2021) (Table 1). The authors made the following recommendations based on review of these studies:

- “The panel was unable to find substantial evidence to recommend PAE over more widely available minimally-invasive therapies for the routine treatment of LUTS, but there is evidence showing a short-term benefit of PAE compared to observation in a very select patient population. PAE is a technically demanding procedure, averaging fluoroscopy times of up to 50 minutes and procedure times up to 2 hours. Attainment of proficiency involves a challenging learning curve for physicians who - while trained in the performance of endovascular interventions - may be less familiar with core concepts of BPH pathophysiology, diagnosis, treatment, and follow-up which is why the Panel recommends that these procedures are only performed by physicians specifically trained in this technique. The Panel recommends continued investigation of PAE through trials involve multi-disciplinary teams of urologists and radiologists focused on further defining specific indications, including but not limited to gross hematuria recalcitrant to other therapies.”¹³,

Table 1. Comparison of Studies Included in Systematic Reviews & Meta-analyses

Study ²	Jung et al (2022) ¹¹	Ini et al (2024) ¹²	Sandhu et al (2024) ¹³
Abt et al, 2021 (RCT) ¹⁴	●	●	●
Pisco et al, 2020 (RCT) ¹⁵	●		●
Insausti et al, 2020 (RCT) ¹⁶	●	●	
Radwan et al, 2020 (RCT) ¹⁷	●	●	
Abt et al, 2018 (RCT) ³¹⁸	●		●
Carnevale et al, 2016 (RCT) ¹⁹	●	●	●
Gao et al, 2014 (RCT) ²⁰	●	●	●
Ray et al, 2018 (observational) ²¹		●	
Qiu et al, 2017 (observational) ²²		●	

¹Systematic reviews / meta-analyses across the columns; ² Primary studies across the rows; ³ Abt et al (2018) was the primary RCT; Abt (2021) was the follow-up report.

Randomized Controlled Trials

Müllhaupt et al (2024) conducted a randomized, open-label, trial at a Swiss tertiary care center to compare the efficacy and safety of PAE and TURP for LUTS/benign prostatic obstruction treatment at up to 5 years of follow-up.²³ The primary outcome was the change in IPSS after PAE versus TURP. Secondary outcomes included patient-reported outcomes, functional measures, and adverse events. Of the 103 patients with refractory disease, randomized between 2014 and 2017, 18 (of 48) who underwent PAE and 38 (of 51) who underwent TURP were available for analysis. The mean reduction in IPSS from baseline to 5 years was -7.78 points after PAE and -11.57 points after TURP (difference 3.79 points; 95% CI, -0.66 to 8.24; p=.092). TURP was superior for most patient-reported secondary outcomes except for erectile function. At 5 years, PAE was less effective than TURP regarding objective parameters, such as the improvement in maximum urinary flow rate (3.59 vs 9.30 ml/s, difference -5.71; 95% CI, -10.72 to -0.70; p=.027) and reduction in postvoid residual volume (28 vs 220 ml; difference 192; 95% CI, 84 to 300; p=.001).

Brown et al. (2024) conducted a single-center Australian trial to evaluate PAE versus medical therapy as initial treatment for obstructive BPH in men who had not previously received BPH treatment (P-EASY ADVANCE: Prostate Embolisation AS first-line therapY compAred to meDication in treatment naïVe men with prostAte eNlargement, a randomised ControllEd trial).²⁴Thirty-nine patients (recruited between between 2020 and 2022) with enlarged prostates and moderate-to-severe LUTS were randomized to receive either a combination of tamsulosin and dutasteride (n=17) or undergo PAE (n=22). Both groups had comparable baseline characteristics, including prostate volume (87.8 and 85.4 mL respectively) and urinary flow rates (Qmax, 6.5 and 6.6 mL/s, respectively). After treatment, both groups showed improvement in voiding and bladder outflow obstruction. However, a greater proportion of PAE patients were unobstructed (63%) compared to those on medication (28%) (p=.03), and PAE resulted in significantly greater reductions in prostate size (p<.001), incomplete bladder emptying (p=.002), IPSS scores (p=.032), Qmax (p=.006) and improved QOL (p=.001). Adverse effects such as altered ejaculation, erectile dysfunction, and nausea were reported more frequently among those receiving medication compared to PAE (13-20% vs. 0-5%).

Sapoval et al. (2023) performed a randomized, open-label superiority trial across 10 French hospitals to compare the effectiveness of PAE versus combined oral therapy (CT) for patients with moderate LUTS due to BPH.²⁵ The study enrolled 90 patients whose LUTS were defined by an IPSS >11, QOL score >3, and prostate volume of ≥50 ml, all resistant to alpha-blocker monotherapy. Patients were randomized in equal numbers to receive either PAE (n=44) or CT (n=43; dutasteride plus tamsulosin), with stratification based on center, IPSS, and prostate volume. The primary endpoint was the change in IPSS at 9 months, analyzed by the intention-to-treat approach. The 9-month change of IPSS was -10.0 (95% CI, -11.8 to -8.3) and -5.7 (95% CI, -7.5 to -3.8) in the PAE and CT groups, respectively. This reduction was significantly greater in the PAE group than in the CT group (-4.4; 95% CI, -6.9 to -1.9; p=.0008). The IIEF-15 score change was 8.2 (95% CI, 2.9 to 13.5) and -2.8 (95% CI, -8.4 to 2.8) in the PAE and CT groups, respectively. No treatment-related adverse events or hospitalization was noticed. After 9 months, 5 and 18 patients had invasive prostate re-treatment in the PAE and CT groups, respectively.

Table 2. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Müllhaupt et al (2024) ²³		5. Only unilateral PAE was possible in 20% of patients who required TURP because of unsatisfactory			

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
		results after PAE			
Brown et al (2024)²⁴	4. Small sample size in each group	5. 19% of patients had unilateral PAE	2. Lack of comparison with TURP as surgical option		1. Primary outcomes assessed between 7 to 12 months post-intervention
Sapoval et al (2023)²⁵			2. Lack of comparison with TURP as surgical option		1. Duration of combined treatment was 9 months.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 3. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Müllhaupt et al (2024)²³	4. Single-center design	1. Open-label Design		1. 37% of patients after PAE and 74% of patients after TURP were available for analysis, which limited the power and did not allow for detailed subgroup analyses. 3. 42% of patients in the PAE required TURP	4. Loss to loss to follow-up across groups limited the power and did not allow for detailed subgroup analyses.	
Brown et al (2024)²⁴	4. Single-center design	1. Open-label Design		3. High rate of patient crossover (87%) from medication group to PAE group		3. Confidence intervals not reported
Sapoval et al (2023)²⁵	4. PAE was performed in multiple centers with various level of expertise	1. Open-label Design		3. At 9 months, 23% of patients receiving medication were classified as non-adherent		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

Brown et al (2025) conducted a prospective study with 105 patients to assess the efficacy of PAE as a treatment for BPH thorough urodynamic testing.²⁶ The research took place during the same period and at the same Australian single-center as the above Brown et al. RCT (2023). Unlike the Brown RCT, a less proportion of patients underwent unilateral PAE (11%), with bilateral PAE ultimately achieved in 89%, with eight of these patients (8%) requiring a repeat PAE to achieve bilateral treatment. A total of 57 patients (54%) went on to complete urodynamic testing at a mean of 18 months post-PAE. Prostate volumes decreased by 31%, and significant improvements were seen in IPSS parameters, QOL scores, and other study outcomes. Bladder obstruction dropped from 67% to 30% post-procedure. Outcomes were closely linked to the amount of embolic material used. PAE was well tolerated; post-embolization symptoms resolved within a week on average. No major complications occurred, no urinary incontinence was reported, and only 2% experienced new retrograde ejaculation after the procedure.

Carnevale et al. (2020) conducted a retrospective, single-center study in Brazil to assess the efficacy, safety, and long-term outcomes of PAE for moderate to severe BPH.²⁷ The study included 317 men with a mean age of 65 years, followed for an average of 27 months (range, 3 to 96 months). Bilateral PAE was performed in 94% of patients, while 6% underwent unilateral PAE. Early clinical failure occurred in 2% of cases, and 23% experienced symptom recurrence at a median of 72 months. PAE led to significant improvements in IPSS, QOL scores, prostatic volume, Qmax, and postvoid residual volume ($p < .05$ for all). Unilateral PAE was linked to a higher recurrence rate than bilateral PAE (42% vs 21%; $p = .04$). None of the patients presented with urinary incontinence or erectile dysfunction.

Section Summary

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 evidence reviews. Future studies should specifically assess outcomes related to repeat interventions and unilateral PAE procedures.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.²⁸ An amendment to these guidelines was published in 2023.¹³

The following recommendations are related to PAE based on a systematic review by Sandhu et al (2024)¹³ (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:²⁹

- 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 cm³), 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:³⁰

- "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).³¹

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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.

References

1. UpToDate. Epidemiology and pathophysiology of benign prostatic hyperplasia. Literature review current through: Nov 2025. Accessed Dec 1, 2025.
2. Mouli S, Salem R, McClure TD. Prostate Artery Embolization for Benign Prostatic Hyperplasia. J Urol. Jul 2024; 212(1): 216-219. PMID 38703386
3. Rosen RC, Catania JA, Althof SE, et al. Development and validation of four-item version of Male Sexual Health Questionnaire to assess ejaculatory dysfunction. Urology. May 2007; 69(5): 805-9. PMID 17482908

4. Cappelleri JC, Rosen RC. The Sexual Health Inventory for Men (SHIM): a 5-year review of research and clinical experience. *Int J Impot Res*. 2005; 17(4): 307-19. PMID 15875061
5. Sønksen J, Barber NJ, Speakman MJ, et al. Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12-month results from the BPH6 study. *Eur Urol*. Oct 2015; 68(4): 643-52. PMID 25937539
6. Sarma AV, Wei JT. Clinical practice. Benign prostatic hyperplasia and lower urinary tract symptoms. *N Engl J Med*. Jul 19 2012; 367(3): 248-57. PMID 22808960
7. O'leary MP. Validity of the "bother score" in the evaluation and treatment of symptomatic benign prostatic hyperplasia. *Rev Urol*. 2005; 7(1): 1-10. PMID 16985801
8. Barry MJ, Williford WO, Chang Y, et al. Benign prostatic hyperplasia specific health status measures in clinical research: how much change in the American Urological Association symptom index and the benign prostatic hyperplasia impact index is perceptible to patients?. *J Urol*. Nov 1995; 154(5): 1770-4. PMID 7563343
9. Roehrborn CG, Wilson TH, Black LK. Quantifying the contribution of symptom improvement to satisfaction of men with moderate to severe benign prostatic hyperplasia: 4-year data from the CombAT trial. *J Urol*. May 2012; 187(5): 1732-8. PMID 22425127
10. Barry MJ, Fowler FJ, O'Leary MP, et al. Measuring disease-specific health status in men with benign prostatic hyperplasia. Measurement Committee of The American Urological Association. *Med Care*. Apr 1995; 33(4 Suppl): AS145-55. PMID 7536866
11. Jung JH, McCutcheon KA, Borofsky M, et al. Prostatic arterial embolization for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. *Cochrane Database Syst Rev*. Mar 29 2022; 3(3): CD012867. PMID 35349161
12. Ini' C, Vasile T, Foti PV, et al. Prostate Artery Embolization as Minimally Invasive Treatment for Benign Prostatic Hyperplasia: An Updated Systematic Review. *J Clin Med*. Apr 25 2024; 13(9). PMID 38731058
13. 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. PMID 37706750
14. Abt D, Müllhaupt G, Hechelhammer L, et al. Prostatic Artery Embolisation Versus Transurethral Resection of the Prostate for Benign Prostatic Hyperplasia: 2-yr Outcomes of a Randomised, Open-label, Single-centre Trial. *Eur Urol*. Jul 2021; 80(1): 34-42. PMID 33612376
15. Pisco JM, Bilhim T, Costa NV, et al. Randomised Clinical Trial of Prostatic Artery Embolisation Versus a Sham Procedure for Benign Prostatic Hyperplasia. *Eur Urol*. Mar 2020; 77(3): 354-362. PMID 31831295
16. Insausti I, Sáez de Ocáriz A, Galbete A, et al. Randomized Comparison of Prostatic Artery Embolization versus Transurethral Resection of the Prostate for Treatment of Benign Prostatic Hyperplasia. *J Vasc Interv Radiol*. Jun 2020; 31(6): 882-890. PMID 32249193
17. Radwan A, Farouk A, Higazy A, et al. Prostatic artery embolization versus transurethral resection of the prostate in management of benign prostatic hyperplasia. *Prostate Int*. Sep 2020; 8(3): 130-133. PMID 33102395
18. Abt D, Hechelhammer L, Müllhaupt G, et al. Comparison of prostatic artery embolisation (PAE) versus transurethral resection of the prostate (TURP) for benign prostatic hyperplasia: randomised, open label, non-inferiority trial. *BMJ*. Jun 19 2018; 361: k2338. PMID 29921613
19. Carnevale FC, Iscaife A, Yoshinaga EM, et al. Transurethral Resection of the Prostate (TURP) Versus Original and PERFECTED Prostate Artery Embolization (PAE) Due to Benign Prostatic Hyperplasia (BPH): Preliminary Results of a Single Center, Prospective, Urodynamic-Controlled Analysis. *Cardiovasc Intervent Radiol*. Jan 2016; 39(1): 44-52. PMID 26506952
20. Gao YA, Huang Y, Zhang R, et al. Benign prostatic hyperplasia: prostatic arterial embolization versus transurethral resection of the prostate--a prospective, randomized, and controlled clinical trial. *Radiology*. Mar 2014; 270(3): 920-8. PMID 24475799
21. Ray AF, Powell J, Speakman MJ, et al. Efficacy and safety of prostate artery embolization for benign prostatic hyperplasia: an observational study and propensity-matched comparison with transurethral resection of the prostate (the UK-ROPE study). *BJU Int*. Aug 2018; 122(2): 270-282. PMID 29645352

22. Qiu Z, Zhang C, Wang X, et al. Clinical evaluation of embolization of the superior vesical prostatic artery for treatment of benign prostatic hyperplasia: a single-center retrospective study. *Wideochir Inne Tech Maloinwazyjne*. Dec 2017; 12(4): 409-416. PMID 29362657
23. Müllhaupt G, Hechelhammer L, Graf N, et al. Prostatic Artery Embolisation Versus Transurethral Resection of the Prostate for Benign Prostatic Obstruction: 5-year Outcomes of a Randomised, Open-label, Noninferiority Trial. *Eur Urol Focus*. Sep 2024; 10(5): 788-795. PMID 38531756
24. Brown N, Kiosoglous A, Castree S, et al. The 'Prostate Embolisation AS first-line therapy compAred to meDication in treatment naïVe men with prostAte eNlargement, a randomised ControllEd trial' (P-EASY ADVANCE): a randomised controlled trial of prostate embolisation vs medication for BPH. *BJU Int*. Dec 2024; 134 Suppl 2(Suppl 2): 38-46. PMID 39139009
25. Sapoval M, Thiounn N, Descazeaud A, et al. Prostatic artery embolisation versus medical treatment in patients with benign prostatic hyperplasia (PARTEM): a randomised, multicentre, open-label, phase 3, superiority trial. *Lancet Reg Health Eur*. Aug 2023; 31: 100672. PMID 37415648
26. Brown N, Firouzmand S, Kiosoglous A, et al. Prostate artery EmbolisAtion Safety and efficacY: Preliminary and foLLow-Up urodynamic Studies (P-EASY PLUS). *BJU Int*. Oct 2025; 136 Suppl 2(Suppl 2): S54-S61. PMID 40501328
27. Carnevale FC, Moreira AM, de Assis AM, et al. Prostatic Artery Embolization for the Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia: 10 Years' Experience. *Radiology*. Aug 2020; 296(2): 444-451. PMID 32484416
28. American Urological Association (AUA). Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline (Published 2021; Amended 2023). Accessed Dec 8, 2025.
29. McWilliams JP, Bilhim TA, Carnevale FC, et al. Society of Interventional Radiology Multisociety Consensus Position Statement on Prostatic Artery Embolization for Treatment of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: From the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of 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
30. National Institute for Health and Care Excellence (NICE). Prostate artery embolisation for lower urinary tract symptoms caused by benign prostatic hyperplasia (Interventional procedures guidance; Reference number: IPG611; Published: 25 April 2018). Accessed December 2, 2025.
31. Centers for Medicare & Medicaid Services. NCD: Therapeutic Embolization (20.28). Accessed December 3, 2025.

Documentation for Clinical Review

- No records required

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
08/01/2026	New policy.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	AFTER
	<u>Blue font: Verbiage Changes/Additions</u>
New Policy Policy Statement: N/A	Prostate Artery Embolization for Benign Prostatic Hyperplasia 7.01.55 Policy Statement: I. Prostate artery embolization is considered investigational as a treatment for benign prostatic hyperplasia.