

A. Documentation Required:

To facilitate the authorization process, referral requests must include the following:

1. History and physical exam, laboratory results (urinalysis, PSA) and radiology imaging (usually transrectal prostate ultrasound, possibly MRI) results supporting the diagnosis of benign prostatic hypertrophy without evidence of cancer.
2. Patient history of any pelvic surgery, pelvic radiation therapy, bleeding diatheses or immune compromising conditions.
3. A physician order from a Urology specialist for the prostate artery embolization procedure with a statement that this procedure is the only procedural alternative to control BPH symptoms or unremitting hematuria.
4. The embolization procedure will be performed by an Interventional Radiologist physician(s) who have received appropriate interventional embolization training in the prostate region to perform highly selective embolization.
5. The embolization procedure uses Embosphere microspheres.
6. The ordering physician has documented that the patient is not planning to father children in the future or has discussed with the patient that the effects of the procedure on fertility have not been determined and they agree to proceed.

B. Criteria for Medical Necessity:

1. Prostate Artery Embolization is considered medically necessary in men for treatment of **benign prostatic hypertrophy** who meet **ALL** the following criteria:

- a. Aged 40 years or older, **AND**
- b. Have a diagnosis of symptomatic benign prostatic hypertrophy (BPH) that is refractory to medical therapy consistent with **ALL** the following:
 - i. Patient score of 13 or higher on the IPSS scale, **AND**
 - ii. Prostate size > 80grams; **AND**
 - iii. Trial of at least two drugs to treat BPH symptoms without significant improvement of IPSS score, e.g., alpha blockers (alfuzosin, doxazosin, silodosin, tamsulosin, terazosin), 5-alpha-reductase inhibitors (dutasteride, finasteride) or tadalafil, **OR** contraindication to medication therapy; **AND**
- c. Have undergone testing including urinalysis, PSA lab testing, and prostate imaging to exclude active infection and prostate cancer; **AND**
- d. The procedure is the only procedural treatment available to the patient, i.e., patient is not a candidate for TURP, laser prostate therapy, or the Urolift procedure or those procedures are not available.

2. Prostate artery embolization is considered medically necessary in men for treatment of **refractory hematuria of prostate origin** in whom other conservative therapy and medical procedures have been unsuccessful at controlling the hematuria.

C. Indications Considered Experimental/Investigational or not of Medical Necessity:

1. Prostate arterial embolization with embosphere microspheres are contraindicated in patients with:
 - a. Active urinary tract infection or prostatitis;
 - b. Prostate cancer–related urinary dysfunction as source of symptoms;

- c. Bladder cancer–related urinary dysfunction as source of symptoms;
- d. Bladder atonia, neurogenic bladder disorder, or other neurological disorder impacting bladder function as the sole etiology of urinary dysfunction symptoms;
- e. Urinary obstruction due to causes other than BPH, including urethral stricture.

CPT/HCPCS Codes

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
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REFERENCES

Abt D, 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* 2018; 361 doi: <https://doi.org/10.1136/bmj.k2338> (Published 19 June 2018).

American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH), Published 2010. Available at: [https://www.auanet.org/guidelines/benign-prostatic-hyperplasia/lower-urinary-tract-symptoms-\(2018\)](https://www.auanet.org/guidelines/benign-prostatic-hyperplasia/lower-urinary-tract-symptoms-(2018)) Assessed October 29, 2018.

American Urological Association Guideline: Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia. Published 2018. Available at: [https://www.auanet.org/guidelines/benign-prostatic-hyperplasia/lower-urinary-tract-symptoms-\(2018\)](https://www.auanet.org/guidelines/benign-prostatic-hyperplasia/lower-urinary-tract-symptoms-(2018)) Assessed October 29, 2018.

Antunes AA, Carnevale FC, da Motta Leal Filho JM, et al. Clinical, laboratorial, and urodynamic findings of prostatic artery embolization for the treatment of urinary retention related to benign prostatic hyperplasia. A prospective single-center pilot study. *Cardiovasc Intervent Radiol* 2013; 36(4):978-86.

Carnevale FC, da Motta Leal Filho JM, Antunes AA, et al. Midterm follow-up after prostate embolization in two patients with benign prostatic hyperplasia. *Cardiovasc Intervent Radiol* 2011; 34(6):1330-3.

Carnevale FC, da Motta Leal Filho JM, Antunes AA, et al. Quality of life and clinical symptom improvement support prostatic artery embolization for patients with acute urinary retention caused by benign prostatic hyperplasia. *J Vasc Interv Radiol* 2013; 24(4):535-42.

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* 2016; 39(1):44-52.

Food and Drug Administration. De novo classification request for Embosphere microspheres. Available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160040.pdf Accessed on: September 24, 2018.

Hayes, Inc. Search & Summary. Prostate artery embolization (PAE) for treatment of benign prostatic hypertrophy. Publication date: August 24, 2017. Archived on: September 24, 2018. Accessed October 24, 2018.

Kably I, Pereira K, Chong W, et al. Prostate artery embolization (PAE) in the management of refractory hematuria of prostatic origin secondary to iatrogenic urological trauma: a safe and effective technique. Urology 2016; 88:218-21.

National Institute of Health and Care Excellence. Prostate artery embolization for benign prostatic hyperplasia. Published date: April 2013. Available at: <https://www.nice.org.uk/Guidance/IPG453> Accessed: October 24, 2018.

Pereira K, Halpern JA, McClure TD, et al. Role of prostate artery embolization in the management of refractory haematuria of prostatic origin. BJU Int. 2016; 118:359-365.

UpToDate.

- Medical treatment of benign prostatic hyperplasia. Last updated: July 10, 2018. Accessed October 24, 2018.
- Transurethral procedures for treating benign prostatic hyperplasia. Last updated: July 23, 2018. Accessed October 24, 2018.

Zumstein V, et al. Prostatic Artery Embolization versus Standard Surgical Treatment for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Systematic Review and Meta-analysis. European Urology Focus. 2018: