

Medical Coverage Policy | Prostate Artery Embolization for Benign Prostatic Hypertrophy



EFFECTIVE DATE: 01|01|2023

POLICY LAST UPDATED: 09|07|2022

OVERVIEW

Prostatic arterial embolization (PAE) is proposed as a minimally invasive procedure and as an alternative to transurethral resection of the prostate (TURP) or open prostatectomy for the treatment of benign prostatic hypertrophy (BPH). PAE has been proposed to reduce the blood supply of the prostate gland, causing some of it to undergo necrosis with subsequent shrinkage. The arterial occlusion may be achieved through the use of polyvinyl alcohol particles, coil embolizers, or microspheres

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Prostatic arterial embolization for benign prostatic hyperplasia is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Prostatic arterial embolization for benign prostatic hyperplasia is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

BACKGROUND

Prostatic arterial embolization (PAE) is being evaluated as a minimally invasive procedure for benign prostatic hyperplasia that may help improve urinary symptoms caused by an enlarged prostate without the risk of sexual side effects. Using x-ray guidance, interventional radiologists insert a catheter into an artery in the groin or wrist and advanced it to the arteries supplying blood to the prostate gland. Tiny round particles (microspheres) are injected into the arteries, partially blocking the blood flow to the prostate. This procedure is called embolization. Areas of the prostate which are most affected by BPH are deprived of oxygen which results in necrosis of targeted areas. Over months the body's immune system reabsorbs the dead tissue and replaces it with scar tissue which slowly contracts and results in shrinkage of the prostate which alleviates some of the symptoms associated with BPH.

Given the strong association between BPH, lower urinary tract symptoms, sexual dysfunction, and the current standard of care (TURP), minimally invasive therapies, including PAE have been evaluated with the intention to increase voiding domains while minimizing adverse sexual effects in men with BPH.

Regulatory Status

In 2017, Embosphere microspheres (BioSphere Medical, S.A.) was reclassified by the U.S. Food & Drug Administration (FDA) into a Class II device. To classify the Embosphere Microspheres into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. The FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. As a result of this order, immediate marketing of the device, as described in the De Novo request - subject to the general control provisions of the FD&C Act and the special controls identified in the order, was granted.

Indications for use: Embolization of arteriovenous malformation, hypervascular tumors, including symptomatic uterine fibroids, and prostatic arteries for symptomatic benign prostatic hyperplasia (BPH). DEN160040. Product code: NOY

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when used for treating benign prostatic hyperplasia. When CPT code(s) are being used for liver or uterine fibroids, refer to the Prior Authorization via Web-Based Tool for Procedures policy.

- 37242** Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)
- 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

RELATED POLICIES

Prior Authorization via Web-Based Tool for Procedures

Prostatic Urethral Lift

Transurethral Water Vapor Thermal Therapy and Transurethral Water Jet Ablation (Aquablation) for Benign Prostatic Hypertrophy

PUBLISHED

Provider Update, November 2022

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12. U.S. Food & Drug Administration. Device Classification Under Section 513(f)(2)(De Novo). Agents, Embolic for treatment of benign prostatic hyperplasia. 2017. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN160040>. Accessed November 16, 2021.

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