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Therapeutic Embolization and Vessel Occlusion to Treat Pelvic Conditions

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Transcatheter therapeutic embolization or vessel occlusion **may be considered medically necessary** for the following:

1) Uterine arteries as a treatment of uterine fibroids (leiomyomata) that meet **one** of the following criteria:
   a) Excessive uterine bleeding as evidenced by either profuse bleeding lasting more than 8 days, or anemia due to acute or chronic blood loss; or
   b) Pelvic discomfort caused by leiomyomata, either acute severe pain, chronic lower abdominal pain, or low back pressure or bladder pressure with urinary frequency not due to urinary tract infection; or
   c) Asymptomatic fibroids of such size that they are palpable abdominally and are of concern to the patient; **OR**
2) Uterine arteries as treatment of post-partum hemorrhage; **OR**
3) Testicular vein embolization (gonadal vein embolization) as a treatment of symptomatic varicocele.

One repeat transcatheter therapeutic embolization or vessel occlusion of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization **may be considered medically necessary** when there is documentation of continued symptoms such as bleeding or pain, in combination with findings on imaging of an incomplete initial procedure, as evidenced by continued blood flow to the treated regions.

Embolization (e.g., utilizing metallic coils or foam/gel sclerotherapy) of the ovarian veins, with or without internal iliac veins, as a treatment of pelvic congestion syndrome (PCS)/pelvic vein incompetence **may be considered medically necessary** when **ALL** the following criteria is met and documented in the individual's medical records:

- Continuous chronic pelvic pain (CPP) (see **NOTE 1**) for 6 months or more that interferes with activities of daily living; **AND**
- Failure to respond to at least 6 months of pharmacotherapy that includes analgesics, anti-inflammatories **and** hormonal treatments; **AND**
- Evaluation by an Obstetrics and Gynecology physician-which may or may not include a pelvic laparoscopy and/or open exploratory laparotomy (pre- or post-hysterectomy) without identifiable pathology (see **NOTE 2**); **AND**
- Definitive diagnostic venography, computed tomography **or** magnetic resonance imaging.

NOTE 1: Documented history of continuous CPP includes **at least 3** of the following indications or examination findings:

1. Postural pain that is exacerbated by standing or heavy activity, absent or nearly absent on awakening, and improved with supine positioning;
2. Painful upper and/or posterior thigh, buttock, or vulvoperineal varicosities;
3. Post-coital discomfort or dyspareunia (painful sexual intercourse);
4. Dysmenorrhea (painful menses);
5. Ovarian point tenderness on abdominal examination **or** tenderness and cervical motion on pelvic examination.

NOTE 2: Documented objective history of a laparoscopic procedure performed during concurrent menstrual function or withdrawal to pharmacologic estrogen administration that yielded negative findings.

Embolization of the ovarian vein and internal iliac veins as a treatment of PCS **is considered experimental, investigational and/or unproven** when the above criteria have not been met.

Transcatheter embolization **is considered experimental, investigational and/or unproven** for the following, including but not limited to:

- Cervical ectopic pregnancy;
- Uterine arteriovenous malformation (AVM);
- Adenomyosis;
- Benign prostatic hyperplasia (BPH);

- Hemorrhoidal embolization.

Policy Guidelines

There are no specific CPT codes for ovarian and internal iliac vein embolization. The nonspecific CPT code 36012 might be billed.

Description

Therapeutic occlusion or embolization is defined as the intravascular deposition of particulate liquid, mechanical agents, or autologous blood clot to produce intentional vessel blockage. Embolic vascular occlusion may be performed at any level from large arteries or veins to the capillary beds, and it may be temporary or permanent in nature.

Background

Pelvic Conditions and Customary Treatments

Uterine Leiomyomata

Uterine leiomyomata (i.e., fibroids) are extremely common benign tumors that can be submucosal (located primarily within the uterine cavity below the endometrium), intramural (within the uterine wall or myometrium), or subserosal in location. Patient symptomatology, physical examination findings, and imaging results are related to the location of the fibroids. Individuals may have fibroids in any or all of these locations within the uterus. Treatment for uterine fibroids is usually sought when they are associated with menorrhagia, pelvic pain, urinary symptoms (i.e., frequency), or are suspected to cause infertility. Treatment options include medical therapy with gonadotropin agonists or progestins or various types of surgical therapy. Hysterectomy (removal of uterus) is considered the definitive surgical treatment for those who no longer want to maintain fertility. Various types of myomectomies (the removal of fibroids with retention of the uterus) have also been described. Hysteroscopic myomectomy involves removal of submucosal fibroids using a resectoscope or a laser. Subserosal fibroids can be removed via an open abdominal or laparoscopic approach.

Postpartum Hemorrhage

Postpartum hemorrhage, defined as the loss of more than 500 mL of blood after delivery, occurs in up to 18 percent of births. Blood loss exceeding 1,000 mL is considered physiologically significant and can result in hemodynamic instability. Even with appropriate management, approximately 3 percent of vaginal deliveries will result in severe post-partum hemorrhage. It is the most common maternal morbidity in developed countries and a major cause of death worldwide. Postpartum hemorrhage may last up to 6 weeks following delivery. Complications from postpartum hemorrhage include orthostatic hypotension, anemia, and fatigue. Uterine atony (muscular weakness) is responsible for most cases and can be managed with uterine massage in conjunction with oxytocin, prostaglandins, and ergot alkaloids. Retained placenta is a less common cause and requires examination of the placenta, exploration of the uterine cavity, and manual removal of retained tissue. Rarely, an invasive placenta causes postpartum

hemorrhage and may require surgical management. Traumatic causes include lacerations, uterine rupture, and uterine inversion. Coagulopathies require clotting factor replacement for the identified deficiency. In some cases, hysterectomy is required.

Ectopic Pregnancies
Ectopic pregnancies (i.e., fallopian tubal pregnancy) account for up to 2% of pregnancies and are the leading cause of first-trimester maternal mortality. Patients present with pelvic pain and vaginal bleeding. First-line treatment for patients with minimal symptoms is systemic methotrexate. In patients with high β-human chorionic gonadotrophin, response to methotrexate may not be adequate, and the patient is susceptible to complications such as hemorrhaging, resulting in the need for a hysterectomy.

Uterine Arteriovenous Malformations
Uterine arteriovenous malformations (AVMs) are rare but may cause severe genital hemorrhaging. There are two types: low-flow AVM is characterized by an abnormal vascular network without visible early venous drainage and high-flow AVM, which has early venous drainage. Uterine AVMs may be congenital or acquired. Risk factors for acquired AVMs are prior uterine surgery such as dilatation and curettage, myomectomy, and cesarean section. Treatment options include hysterectomy and uterine artery ligation.

Adenomyosis
Adenomyosis is characterized by the diffuse or focal growth of endometrial glandular and stromal tissue in the muscular layer of the uterus. The etiology of adenomyosis is unknown. Symptoms include dysmenorrhea, menorrhagia, infertility, and an enlarged uterus may be found on physical examination. Treatment options include surgery and hormone therapy.

Pelvic Congestion Syndrome
Pelvic congestion syndrome (PCS) is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia (which may be aggravated by standing) and symptoms suggestive of a venous origin, such as postcoital ache and tenderness over the ovarian point. The syndrome occurs during the reproductive years, and pain is often greater before or during menses. The underlying etiology is thought to be related to varices of the ovarian veins, leading to pelvic vascular congestion. The lack of clear diagnostic criteria and overlapping clinical presentation of pelvic congestion syndrome with other potentially related pelvic venous disorders has hindered research progress and contributed to underdiagnosis of these disorders as causes of chronic pelvic pain. (1) In 2021, a multidisciplinary, intersociety working group convened by the American Vein and Lymphatic Society published the Symptoms-Varices-Pathophysiology (SVP) classification of pelvic venous disorders which, in conjunction with the established Clinical-Etiologic-Anatomic-Physiologic classification for lower extremity venous disorders when applicable, places patients in homogeneous populations based on standardized definitions of presenting symptoms, involved variceal reservoirs, and underlying pathophysiology (including anatomic, hemodynamic, and etiologic disease features). (2) The term pelvic venous disorder, accompanied by the patient-specific SVP classification, has been proposed to replace pelvic congestion syndrome and other historical nomenclature for related

diseases (such as May-Thurner syndrome and nutcracker syndrome). As diagnostic criteria remain lacking, pelvic venous disorder as a cause of chronic pelvic pain amounts to a diagnosis of exclusion; evaluation may involve a variety of physical assessments, laboratory measurements, and/or imaging studies to eliminate other etiologies of chronic pelvic pain, such as cystitis or gynecologic malignancy. (1)

Varicocele

Varicocele is a condition that causes the veins in the scrotum to become dilated or enlarged and can occur in 20% of males. Symptoms of a varicocele may include visible or palpable (able to be felt) enlarged vein, aching pain within scrotum, feeling of heaviness in the testicle(s), atrophy (shrinking) of the testicle(s), changes in testosterone levels, benign prostatic hyperplasia and related urinary problems, or infertility issues. Treatment options include open or laparoscopic varicocelectomy. Robotic surgery and microsurgical varicocelectomy have been used as an alternative surgical option for varicocelectomy.

Benign Prostatic Hyperplasia (BPH)

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. Initial treatment for BPH is usually drug therapy, however patients often require surgical intervention.

<u>Therapeutic Embolization and Vessel Occlusion</u>

Embolization involves the selective occlusion of blood vessels (arteries or veins) to devascularize, preventing or slowing blood supply to the intended region or organ. When embolizing arteries, such as uterine artery embolization (UAE) – interrupting the uterine arteries, small embolization particles are selectively catheterized by injecting into the uterine arteries to block blood supply to the uterus and the uterine fibroids. Doing UAE potentially serves as alternative to hysterectomy.

UAE has also been used to control bleeding in situations such as severe postpartum hemorrhage, cervical ectopic pregnancy, bleeding uterine AVM, and adenomyosis.

Embolization therapy of the ovarian and internal iliac veins (gonadal vein embolization) has been proposed as an alternative to surgical ovarian vein ligation. Vein embolization can be performed using a variety of materials including coils, glue, and gel foam. Gonadal vein embolization is used to treat PCS when the patient fails medical treatment.

Testicular vein embolization (gonadal vein embolization) has been proposed as an alternative to surgical intervention. This involves passing a small wire through a peripheral vein and into the abdominal veins that drain the testes. Through a small flexible catheter, the physician can obstruct the gonadal vein so that the increased pressures from the abdomen are no longer

transmitted to the testicles. The obstruction is often performed with many small metal coils. The testicles then drain through smaller collateral veins. (**NOTE 3:** The recovery period is significantly less than with surgery and the risk of complications is minimized with overall effectiveness similar to surgery, yet with fewer recurrence rates. However, radiation exposure to the testicles can often not be avoided with this technique.)

Prostatic arterial embolization (PAE) has been proposed as a minimally invasive procedure for the treatment of BPH. Performed under local anesthetic and sedation by a interventional radiologist, PAE is thought to reduce the blood supply of the prostate gland, causing some of it to undergo necrosis with subsequent shrinkage.

Laparoscopic Coagulation of Uterine Fibroids

Laparoscopic coagulation of uterine fibroids is a unique approach in that the fibroid is not physically removed, but instead multiple (up to 75) laparoscopic punctures of the uterine fibroid are performed to devascularize the fibroid and induce atrophy.

Hemorrhoidal Embolization

Hemorrhoidal artery embolization (HAE) is a minimally invasive procedure, usually performed by an interventional radiologist, that treats internal hemorrhoids by reducing blood flow to the hemorrhoidal arteries. Hemorrhoid embolization is performed by using femoral or radial access. The inferior mesenteric artery and then the superior rectal arteries are catheterized with a microcatheter.

Regulatory Status

Embolization and vessel occlusion are surgical procedures and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

Various products (e.g., vascular plugs, glue, liquid embolic agents, Gelfoam) and/or delivery-assist devices would be used to embolize the vein(s), and they would be subject to FDA regulation. Several products have been cleared for marketing by the FDA through the 510(k) process.

In April 2000, Embosphere® Microspheres (Merit Medical, formerly BioSphere Medical) was cleared by the FDA for treatment of hypervascularized tumors and AVMs. In 2002, this product was cleared for marketing specifically for use in uterine fibroid embolization. Since then, several other devices have been cleared for marketing and a sampling of those are listed herein. In 2003, Contour® Emboli PVA (Boston Scientific) was cleared for marketing by the FDA through the 510(k) process for the embolization of peripheral hypervascular tumors and peripheral AVMs. In March 2004, the Contour SE™ (Boston Scientific) was cleared for marketing by the FDA through the 510(k) process for the treatment of uterine fibroids. In November 2004, the sclerosant agent Sotradecol® (sodium tetradecyl sulfate injection) was approved by the FDA for use in the treatment of small uncomplicated varicose veins of the lower extremities that show simple dilation with competent valves (ANDA 040541). In 2008, Polyvinyl Alcohol Foam Embolization Particles (Cook Inc.) was cleared for marketing by the FDA through the 510(k)

process for use in uterine fibroid embolization. In 2016, Bead Block™ microspheres (Biocompatibles UK) were cleared for marketing by the FDA for embolization of uterine fibroids and AVMs. In 2020, Hydropearl® Microspheres (MicroVention, Inc.) was cleared for marketing by the FDA for the embolization of AVMs and hypervascular tumors, including uterine fibroids. FDA product code: NAJ.

Several embolization delivery systems have also been cleared via the 510(k) process for arterial and venous embolization in the peripheral vasculature featuring vascular plugs (e.g., ArtVentive Medical Group, Inc. Endoluminal Occlusion System [EOS™]) or coils (e.g., Cook Incorporated MReye® Flipper®). FDA product code: KRD.

Refer to <https://www.accessdata.fda.gov> for a complete list of U.S. FDA approved products.

Rationale

Medical policies 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, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical uses 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 (RCT) 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.

Uterine Fibroids

Clinical Context and Therapy Purpose

The purpose of transcatheter uterine artery embolization (UAE) in individuals who have uterine fibroids 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 policy.

Populations
The relevant population of interest is individuals with uterine fibroids.

Treatment for uterine fibroids is typically recommended when accompanied by menorrhagia, pelvic pain, or urinary symptoms (i.e., frequency), or when the fibroids are suspected to cause infertility. Treatment options include medical therapy with gonadotropin agonists or progestins or various types of surgical therapy. Hysterectomy is considered the definitive surgical treatment for those who no longer want to maintain fertility. Various types of myomectomy (the removal of fibroids with retention of the uterus) are recommended to maintain fertility. Hysteroscopic myomectomy involves removal of submucosal fibroids using a resectoscope or a laser. Subserosal fibroids can be removed via an open abdominal or laparoscopic approach. Laparoscopic laser coagulation of uterine fibroids is a unique approach in which the fibroid is not physically removed; instead, multiple (up to 75) laparoscopic laser punctures of the uterine fibroid are performed to devascularize the fibroid and induce atrophy.

Interventions
The intervention of interest is transcatheter UAE, which is a minimally invasive technique in which a catheter is used to inject small embolic agents into the uterine arteries and block the blood supply. With the blood supply to uterine fibroids and the uterus blocked, the fibroids will shrink. Transcatheter UAE is administered in a tertiary care setting.

Comparators
The following therapies, most of which are more invasive, are currently being used to make decisions about uterine fibroids: hysterectomy, myomectomy, and other uterine fibroid treatments, most of which are conducted in a tertiary care setting.

Outcomes
The general outcomes of interest include patient satisfaction (quality of life, in years), live birth rates (when the comparison is a uterine-sparing procedure), uterine volume reduction (in months), fibroid volume reduction (in months), and reintervention rates (in years). The following table describes the questionnaires used to measure the quality of life.

Table 1. Outcomes of Interest for Individuals with Uterine Fibroids Treated With UAE

Measure	Outcome Evaluated	Description	Follow-up Timing
Defecation Distress Inventory	Quality of life	Scores for constipation, fecal incontinence, painful defecation, and flatus incontinence in patients with and without enterocele	Up to 5 years
36-Item Short-Form Health Survey, physical	Quality of life	A survey of 8 health concepts that rely on patient self-reporting. All items are scored so that a high	Up to 5 years (2-4)

and mental component summary		score indicates a more favorable health state (0-100).	

UAE: uterine artery embolization.

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 effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Initial Uterine Artery Embolization (UAE) for Uterine Fibroids

A number of RCTs evaluating UAE for the treatment of uterine fibroids and several systematic reviews of these RCTs have been published. RCTs have compared UAE with hysterectomies, myomectomies, laparoscopic occlusion of uterine arteries, and focused ultrasound.

Systematic Reviews

A Cochrane review by Gupta et al. (2014) included 7 RCTs comparing UAE with other surgical interventions in women with symptomatic uterine fibroids. (3) Four of the RCTs excluded women who desired pregnancy in the future. The comparator intervention was hysterectomy in 3 trials, hysterectomy or myomectomy in 2 trials, and myomectomy in 2 trials. Reviewers' primary outcomes were patient satisfaction and live birth rates (the latter analysis limited to studies where the comparison intervention was a uterine-sparing procedure). Pooled analyses did not find statistically significant differences in patient satisfaction with UAE or other interventions after 2 years (6 trials; odds ratio [OR], 094; 95% confidence interval [CI], 0.59 to 1.48) or 5 years (2 trials; OR=0.90; 95% CI, 0.45 to 1.80). A single study reported live birth rates, so a meta-analysis was not possible. UAE was associated with a higher rate of minor complications at 1 year (6 trials; OR=1.99; 95% CI, 1.41 to 2.81), and there was no statistically significant difference between groups in the rate of major complications. Moreover, the UAE group was significantly less likely to require a blood transfusion than the surgery group (2 trials; OR=0.07; 95% CI, 0.01 to 0.52). The rate of further surgical interventions within 2 years was significantly increased in the UAE group (6 trials; OR=3.72; 95% CI, 2.28 to 6.04).

In a systematic review and meta-analysis, Das et al. (2014) identified 10 studies comparing the efficacy of 1 embolic agent used in UAE with another intervention or comparing 2 embolic agents. (4) Five studies were RCTs, and 5 were controlled trials that were not randomized. Embosphere microspheres were used in all of the RCTs. In a pooled analysis of data from 2 studies comparing microspheres with spherical polyvinyl alcohol for the treatment of uterine fibroids, there were no statistically significant between-group differences in outcomes (uterine volume reduction, dominant fibroid volume reduction). Data from other studies were not

pooled, but a qualitative analysis of study findings did not suggest that any agent was superior or inferior to any other agent.

A systematic review and meta-analysis by Martin et al. (2013) assessed complications and reintervention rates following UAE and surgery for symptomatic uterine fibroids. (5) Surgery was not defined in this meta-analysis, so it is unclear whether myomectomies were also included with hysterectomies. Outcomes for UAE and surgery were stratified by study design (RCTs, nonrandomized studies, case series). Eight RCTs comparing UAE with a surgical intervention were included, for a total of 350 patients undergoing UAE and 346 patients undergoing surgery. Among the UAE cases in the RCTs, the most common complications were discharge and fever (4%), postembolization syndrome (2.9%), pain (2.9%), and groin complications (2.9%). The most common complications among patients undergoing surgery were urinary stress incontinence (3.8%), pressure symptoms (2.9%), and menorrhagia (2.6%). Three trials presented reintervention data and, in a meta-analysis of these studies, there was a significantly higher risk of reintervention after UAE than after surgery, but a wide confidence interval indicates imprecision in the risk estimate (OR=6.04; 95% CI, 2.0 to 18.1).

van der Kooij et al. (2011) published a systematic review and meta-analysis of RCTs comparing UAE with surgery (hysterectomy/myomectomy) for treating symptomatic uterine fibroids and presenting up to 5 years of follow-up data. (6) Reviewers identified 11 articles reporting on 5 RCTs. The overall intraprocedural and early postprocedural complication rates were similar with both procedures. However, hospital length of stay, need for blood transfusion, and febrile morbidity was significantly lower in the UAE group than in the surgery group. At 12 months, a pooled analysis of 2 studies found a significantly higher reintervention rate in the UAE group than in the surgery group (OR=5.78; 95% CI, 2.14 to 15.58). Pooled analyses of quality of life (QOL) variables at 12 months found no significant differences between groups. Results were similar after 5 years.

Randomized Controlled Trials

Uterine Artery Embolization versus Hysterectomy or Myomectomy

The EMbolization versus HysterectoMY (EMMY) trial (2005) from the Netherlands included 177 women with uterine fibroids and heavy menstrual bleeding who were scheduled to undergo hysterectomy. (7, 8) They were randomized to UAE (n=88) or hysterectomy (n=89). By the 2-year follow-up, 19 (23%) of the 81 women who received UAE had undergone a hysterectomy. An analysis of health related QOL outcomes at 2 years found similar improvement in both groups. The Defecation Distress Inventory score improved significantly in only the UAE group starting at 6 months. A report of 5-year outcomes data from the EMMY trial was published in 2010. (9) At 5 years, 70 (79%) of 89 patients originally randomized to the hysterectomy group and 75 (85%) of 88 patients in the UAE group completed questionnaires. In an intention-to-treat analysis, 23 (28.4%) of 81 patients who had received UAE underwent hysterectomy during the 5 years. Including patients who had subsequent hysterectomies, 58 (71.6%) of 81 patients in the UAE group no longer had menorrhagia. There were no significant differences between groups in health-related QOL at 5 years, as assessed by the Physical and Mental Component scores of the 36-Item Short-Form Health Survey. Ten-year outcomes were reported by de Bruijn

et al. in 2016. (10) Completed questionnaires were available for 131 (75%) of 177 randomized patients at 10 years. An additional 5 hysterectomies were performed between the 5- and 10-year follow-ups, for a total of 28 (35%) hysterectomies in the UAE group. At 10 years, there were no statistically significant differences between groups in health related QOL or in urinary and defecation function.

Mara et al. (2008) conducted a controlled trial focusing on pregnancy outcomes. This trial randomized 121 women with uterine fibroids who desired future pregnancies to UAE or myomectomy. (11) Participants were followed for a mean of 25 months; they were advised to wait for at least 6 months post-procedure before attempting to conceive. At final follow-up, 13 (50%) of 26 women in the UAE group who tried to conceive became pregnant compared with 31 (76%) of 40 in the myomectomy group; the difference between groups was not statistically significant. Among women in the UAE group who became pregnant, the spontaneous abortion rate was 64%, and the live birth rate was 19%. In the myomectomy group, the spontaneous abortion rate was 23%, and the live birth rate was 48%.

The multicenter Randomized Trial of Embolization versus Surgical Treatment for Fibroids (REST) assigned patients 2:1 to undergo UAE (n=106) or surgery (n=43 hysterectomies, n=8 myomectomies). (12) The UAE group had lower postoperative pain (3.0 versus 4.6, respectively) and faster recovery (e.g., median length of hospitalization, 1-day versus 5-day, respectively). Of 7 identified pregnancies in the UAE group, 2 resulted in successful live births. Five-year follow-up data from the REST trial were published by Moss et al. (2011). (13) A total of 144 (92%) of 157 randomized patients were included in the 5-year analysis. QOL and symptom scores were similar in both groups at 5 years: mean symptom score was 4.5 in the UAE group and 4.8 in the surgery group (scores ranged from 15 [markedly worse] to 5 [markedly better]). At 5-year follow-up, 27 (25%) of 106 in the UAE group and 2 (4%) of 51 in the surgery group had received an additional intervention for continued or recurrent symptoms. The total rate of further intervention for symptoms or adverse events over the 5-year period was 32% in the UAE group and 4% after surgery. In the UAE group, there were 3 procedural failures, 8 repeat UAEs, and 18 hysterectomies. Note that a woman had both a repeat UAE and a hysterectomy, and 2 women were not embolized after randomization and subsequently underwent surgery.

Findings of the Fibroids of the Uterus: Myomectomy versus Embolization (FUME) Trial from the U.K. were published by Manyonda et al. (2012). (14) The investigators randomized women with symptomatic fibroids to UAE (n=82) or myomectomy (n=81). Mean hospital stay was significantly shorter after UAE (2 days) than after surgery (4 days; $p<0.001$). There were no significant differences in minor or major complications. A total of 120 (74%) of 163 women were available for the analysis of the primary outcome measure (i.e., QOL). There were no significant differences between groups in change in QOL scores from baseline to 1 year. Nine (11%) patients in the UAE group required additional intervention (6 hysterectomies, 2 myomectomies, 1 repeat embolization) and 3 (4%) patients in the myomectomy group later underwent hysterectomy.

Sirkeci et al. (2023) published an RCT comparing myomectomy versus uterine artery embolization (UAE) for women who were wanting to avoid hysterectomy. (15) The present study is the largest ever randomized clinical trial to report on the treatment of symptomatic fibroids by UAE and any surgery. Data on fibroid-specific quality of life (UFS-QOL), loss of menstrual blood and pregnancy was collected from 254 women. At 4 years, the mean difference in the UFS-QOL was 5.0 points (95% confidence interval (CI) -1.4 to 11.5; P = 0.13) in favor of myomectomy. This was not statistically significant as it was at 2 years. There were no differences in bleeding scores, rates of amenorrhea, or heavy bleeding. Of those who were still menstruating, the majority reported regular or fairly regular periods: 36 of 48 (75%) in the UAE group and 30 of 39 (77%) in the myomectomy group. Twelve women after UAE and six women after myomectomy became pregnant (4 years) with seven and five live births, respectively (hazard ratio 0.48, 95% CI 0.18-1.28). There was no difference between the levels of hormones associated with the uterine reserve in each group. There were, however, substantially more surgical re- interventions in the UAE group within 2 years of follow- up, possibly reflecting the higher residual impact on QOL observed in the UAE group and the marginal patient- reported preference for myomectomy.

Uterine Artery Embolization versus Laparoscopic Occlusion of Uterine Arteries

An RCT by Hald et al. (2007) in Norway evaluated clinical outcomes in 66 premenopausal women (mean age, 43 years) with symptomatic uterine fibroids who were assigned to laparoscopic occlusion of uterine arteries (with coagulation) or UAE. (16) Women who wanted to bear children in the future, had a large uterus, had undergone multiple open abdominal surgeries, and who had bleeding disorders were excluded. The primary outcome was a reduction in blood loss at 6 months postintervention, as measured by a pictorial blood loss assessment chart. Fifty-eight women underwent treatment, 29 in each group. The proportion of women who had a reduction in blood loss after 6 months did not differ between the treatment groups (52% after UAE versus 53% after laparoscopy; p=0.96). Follow-up data were reported in 2009 at a median of 48 months posttreatment (range, 8-73 months). (17) The cumulative clinical failure and recurrence rate was significantly lower in the UAE group (17% [n=5]) than in the laparoscopy group (48% [n=17]; p=0.02). Moreover, fewer patients in the UAE group (7% [n=2]) had a hysterectomy than in the laparoscopy group (28% [n=8]; p=0.41). The authors concluded that UAE is superior to laparoscopic occlusion of uterine arteries for treatment of uterine fibroids.

Uterine Artery Embolization versus Focused Ultrasound

Barnard et al. (2017) published an RCT and a cohort study comparing the use of UAE with magnetic resonance imaging-guided focused ultrasound surgery (MRgFUS) for the treatment of uterine fibroids. (18) Premenopausal women with symptomatic uterine fibroids were randomized to MRgFUS (n=27) or UAE (n=22). Women who declined randomization were enrolled in a nonrandomized cohort study; 43 underwent MRgFUS, and 40 underwent UAE. The outcome of interest was recovery during the first 6 weeks post-procedure, captured in symptom diaries that included information on return to work, return to normal activities, medication use, symptoms, and adverse events. Separate multivariate analyses of the RCT and the cohort populations found similar conclusions: opioid use was significantly higher in the UAE

group, and length of time to first day fully back to work and first day back to normal activities were also significantly longer for patients treated with UAE. Treatment time was significantly longer in the MRgFUS group.

Jian et al. (2020) conducted a retrospective analysis on women who underwent high intensity focused ultrasound (HIFU) or uterine artery embolization (UAE) for retained placenta accreta. (19) A total of 63 and 31 patients who underwent HIFU and UAE followed by hysteroscopic resection, respectively, were analyzed. The baseline characteristics, including age, gravidity, parity, previous cesarean section rate, previous curettage rate, previous intrauterine adhesions rate, and delivery mode, were similar between the two groups. Vaginal bleeding was the major complaint in patients with retained placenta accreta. The number of hysteroscopy sessions, amount of intraoperative blood loss, and the length of hospital stays were also similar between the groups. No further hysterectomy was needed in either group. Both HIFU and UAE combined with hysteroscopic resection seem to be safe and effective procedures in cases of retained placenta accreta. The only limitation identified in this study was its retrospective design.

Section Summary: Initial Uterine Artery Embolization Procedures for Uterine Fibroids

Most of the current evidence, including a number of RCTs, systematic reviews, and a retrospective review, has compared UAE with surgery (hysterectomy or myomectomy) for treating uterine fibroids. A Cochrane review found similar levels of patient satisfaction after UAE and surgery. A potential benefit of UAE over hysterectomy is that, depending on the location of the fibroids, the uterus and fertility may be preserved. Other benefits of UAE over hysterectomy and/or myomectomy include lower blood transfusion rates and lower complication rates. However, studies with long-term follow-up have shown that patients undergoing UAE have higher reintervention rates. Single RCTs have compared UAE with laparoscopic occlusion and MRgFUS. UAE had higher clinical success rates and lower reintervention rates than laparoscopic occlusion. Recovery was longer and opioid use higher among patients undergoing UAE compared with MRgFUS. Additional research comparing other uterus-sparing procedures with UAE are needed. The available evidence from RCTs does not suggest that any one embolization agent is superior to another.

Repeat Uterine Artery Embolization (UAE) Procedures for Recurrent or Persistent Uterine Fibroid Symptoms

Clinical Context and Therapy Purpose

Treatment for uterine fibroids is typically recommended when accompanied by menorrhagia, pelvic pain, or urinary symptoms (i.e., frequency), or when the fibroids are suspected to cause infertility. Treatment options include medical therapy with gonadotropin agonists or progestins or various types of surgical therapy. Hysterectomy is considered the definitive surgical treatment for those who no longer want to maintain fertility. Various types of myomectomy (the removal of fibroids with retention of the uterus) are recommended to maintain fertility. Hysteroscopic myomectomy involves removal of submucosal fibroids using a resectoscope or a laser. Subserosal fibroids can be removed via an open abdominal or laparoscopic approach. Laparoscopic laser coagulation of uterine fibroids is a unique approach in which the fibroid is

not physically removed; instead, multiple (up to 75) laparoscopic laser punctures of the uterine fibroid are performed to devascularize the fibroid and induce atrophy.

The purpose of transcatheter UAE in individuals who have persistent uterine fibroids despite prior UAE 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 policy.

Populations
The relevant population of interest is individuals with uterine fibroids who have undergone prior UAE.

Interventions
The intervention of interest is transcatheter UAE, which is a minimally invasive technique in which a catheter is used to inject small embolic agents into the uterine arteries and block the blood supply. With the blood supply to uterine fibroids and the uterus blocked, the fibroids will shrink. Transcatheter UAE is administered by a physician in a tertiary care setting.

Comparators
The following therapies, most of which are more invasive, are currently being used to make decisions about persistent uterine fibroids despite prior UAE: hysterectomy and myomectomy, both of which are administered by a physician in a tertiary care setting.

Outcomes
The general outcome of interest includes symptom control, with follow-up from months to years.

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 effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
No RCTs focusing on repeat UAE were identified; there are published case series. In 2009, McLucas and Reed published a study in which the charts of 1058 women who had undergone initial bilateral UAE at several U.S. centers were reviewed. (20) Forty-two (4%) patients had documented persistent symptoms, and they were offered a second bilateral UAE. Thirty-nine patients had repeat procedures, and 34 (87%) of them completed a follow-up questionnaire at

least 6 months postembolization. Before the second UAE procedure, 27 (79%) of the 34 women reported severe bleeding, with only 2 (6%) women reported severe bleeding post-procedure. Similarly, the number of women with severe pain decreased from 20 (59%) to 2 (6%), and with severe pressure decreased from 18 (53%) to 2 (6%). Four women experienced severe levels of 1 or more symptoms after the second UAE.

Yousefi et al. (2006) reported on 24 patients who underwent repeat embolization for recurrent or persistent symptoms 6 to 66 months after the initial UAE. (21) The most common symptoms were pressure and/or bulk symptoms (n=15), recurrent heavy bleeding (n=12), and pelvic pain or cramping (n=7). Follow-up data were available on 21 (87.5%) of 24 after the second UAE; 19 (90%) reported symptom control.

Section Summary: Repeat UAE Procedures for Recurrent or Persistent Uterine Fibroid Symptoms

There is a lack of RCTs on repeat UAE for the treatment of symptoms associated with recurrent uterine fibroids. However, there are data from case series showing high rates of success after a second UAE for recurrent or persistent symptoms.

Postpartum Uterine Hemorrhage

Clinical Context and Therapy Purpose

The purpose of transcatheter UAE in individuals who have postpartum uterine hemorrhage 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 policy.

Populations

The relevant population of interest is individuals with postpartum uterine hemorrhage.

Interventions

The intervention of interest is transcatheter UAE, which is a minimally invasive technique in which a catheter is used to inject small embolic agents into the uterine arteries and block the blood supply. UAE is performed by a physician in a tertiary care setting.

Comparators

The following therapies, most of which are more invasive, are currently being used to make decisions about postpartum uterine hemorrhage: hysterectomy or uterine-sparing surgery, which are performed by a physician in a tertiary care setting.

Outcomes

The general outcomes of interest include control of bleeding (post-procedure) and live births.

Study Selections 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 effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

A systematic review and meta-analysis by Liu et al. (2020) assessed the safety and effectiveness of UAE compared with hysterectomy in studies of refractory postpartum hemorrhage. (22) This review searched various bibliographic databases through October 2017 and included 6 RCTs and 9 comparative observational studies published between 2008 and 2017. Primary outcomes included blood loss, operating time, hemostatic effective rate, and length of stay. The meta-analysis included 1142 women (n range, 31 to 200). While hemostatic effective rate was similar for UAE compared with hysterectomy (10 studies; OR 1.58, 95% CI, 0.80 to 3.12), UAE resulted in less intraoperative blood loss (9 studies; pooled weighted mean difference [WMD] -893.39 ml; 95% CI, -1205.65 to -581.13), a shorter mean operative time (14 studies; WMD, -37.19 minutes; 95% CI, -44.42 to -29.96) and length of stay (6 studies; WMD -5.36; 95% CI, -5.76 to -4.97). Pain was the most commonly reported adverse event, reported by 15.28% of participants in the UAE groups and 23.60% in the hysterectomy groups (P-value not reported). Only one study reported rates of serious adverse events, which were 2% for UAE (2/100) and 5% for hysterectomy (5/100).

Sathe et al. (2016) reported that rates of successful bleeding control with UAE in uncontrolled studies ranged from 58% to 98%, with a total of 1251 (87%) of 1435 patients in 15 studies achieving successful control of bleeding. (23)

Previously, Rath et al. (2012) published a systematic review of the literature on second-line treatment of postpartum hemorrhage (PPH). (24) Success rates of UAE for PPH reported in uncontrolled studies ranged from 70% to 100% and from 60% to 83% when the hemorrhage was associated with placenta accreta.

Randomized Controlled Trials

A randomized controlled trial by Radaelli et al. (2023) aimed to verify if prophylactic intraoperative uterine artery embolization in patients with placenta previa and at least one additional risk of bleeding (major placenta previa), can reduce hemorrhage, need for blood transfusions, peripartum hysterectomy and maternal morbidity. (25) Seventy-six patients with major placenta previa were treated with elective cesarean section, 32 patients (embolized group or EMB) underwent selective catheterization of bilateral uterine arteries before cesarean section and subsequent uterine embolization. Significant differences were found in term of intraoperative blood loss (CTR: 1431 mL; EMB: 693 mL); despite a high percentage of CTR patients had a bleeding greater than 1000 mL (56%), the need for blood transfusion was not significantly different between the two groups. Time of surgery was higher in the EMB group,

considering that embolization procedure required approximatively 30 min. Three patients from the CTR group needed hysterectomy and ICU admission, compared to none in the EMB group. Preventative uterine embolization in patients with placenta previa demonstrated feasibility and safety in establishing a prophylactic role in the prevention of peripartum hemorrhage.

Case Series

Among the representative, larger case series included in the systematic review published by Sathe et al. (2016) described above, is the retrospective evaluation by Kim et al. (2013) who analyzed data on 121 women with PPH, 60 women of whom underwent UAE and 61 of whom underwent a cesarean hysterectomy at a single center in Korea. (26) The clinical success rate for UAE (which was not explicitly defined) was reported as 96%. Eleven patients treated with UAE experienced transient fever after the procedure, and there was a case of ovarian failure. Two patients were subsequently treated with cesarean hysterectomy. Among the 61 patients at the same center who underwent cesarean hysterectomy, the success rate was 93%. Four patients in this group underwent UAE immediately following cesarean hysterectomy due to arterial hemorrhage at extrauterine sites (2 cases) and bleeding from uterine collateral vessels (2 cases).

In addition to the case series included in the systematic reviews described above, a retrospective study was published by Lee et al. (2019) which analyzed data on 381 women with postpartum hemorrhage from the CHA Bundang Medical Center in Korea. (27) Among women with postpartum hemorrhage who were unresponsive to conservative management between January 2007 and April 2017, 333 underwent UAE and 48 underwent cesarean hysterectomy. An important study conduct limitation is that women in the UAE group were younger (33.3 years versus 34.9 years; P=.017) and had a lower mean parity (0.55 versus 0.85; P=.012). This baseline difference has the potential to increase risk of confounding and bias in study outcomes. Compared to the hysterectomy group, the UAE group received fewer transfusions and had a shorter mean operative time. However, an important relevance limitation is that the key outcome of clinical success was not reported. Various complications were evaluated, but the comparative effects were not calculated. The most common early postprocedural complication in both groups was pneumonia and pulmonary edema (14.1% versus 18.8%). Rates of maternal expire were 2.1% (4/333) in the UAE group and 4.2% (2/48) in the hysterectomy group.

Pregnancy Outcomes with Postpartum Hemorrhage

Doumouchtsis et al. (2014) identified 17 studies (total n=675 participants) reporting on fertility outcomes after UAE for PPH. (28) To be selected, studies had to report on 5 or more cases. None identified was an RCT. A total of 168 (25%) of the 675 patients wanted a pregnancy following UAE and 126 (75%) of the 168 women who desired pregnancy conceived. There were 136 term live births and 30 cases of pregnancy loss (ectopic pregnancy, miscarriage, elective abortion).

Mohan et al. (2013) identified 21 studies reporting pregnancy outcomes and/or pregnancy complications after UAE for the treatment of uterine fibroids or PPH. (29) Reviewers reported

that the cumulative pregnancy and miscarriage rates among women trying to conceive following UAE for uterine fibroids were 59% and 28%, respectively, and the cumulative live birth rate was 65%. The term delivery rate was 61%. In the studies on UAE for PPH, the cumulative pregnancy rate, based on a small number of pregnancies, was 87.2%. Rates of miscarriage and live births were not reported following UAE for PPH.

Section Summary: Postpartum Uterine Hemorrhage

A systematic review of multiple RCTs and comparative observational studies has compared UAE with hysterectomy in refractory postpartum hemorrhage in 1142 women. This review found similar hemostatic effective rates for UAE and hysterectomy but found several benefits of UAE including reduced blood loss, operating time and length of stay. Additionally, case series involving over 1400 patients have shown a high rate of success stopping the bleeding.

Cervical Ectopic Pregnancy

Clinical Context and Therapy Purpose

Ectopic pregnancies account for up to 2% of pregnancies and are the leading cause of first-trimester maternal mortality. Patients present with pelvic pain and vaginal bleeding.

First-line treatment for patients with minimal symptoms is systemic methotrexate. In patients with high β-human chorionic gonadotrophin, response to methotrexate may not be adequate, and the patient is susceptible to complications such as hemorrhaging, resulting in the need for a hysterectomy.

The purpose of transcatheter UAE in individuals who have cervical ectopic pregnancy 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 policy.

Populations

The relevant population of interest is individuals with cervical ectopic pregnancy.

Interventions

The intervention of interest is transcatheter UAE, which is a minimally invasive technique in which a catheter is used to inject small embolic agents into the uterine arteries and block the blood supply. UAE is performed in a tertiary care setting.

Comparators

The following therapies, most of which are more invasive, are currently being used to make decisions about cervical ectopic pregnancy: medication (e.g., methotrexate) or surgery. Surgery is performed in a tertiary care setting.

Outcomes

The general outcomes of interest include clinical and technical success (post-procedure) and stopping recurrent bleeding (up to 6 months). (30)

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 effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Retrospective Studies and Case Series

No RCTs or other comparative studies evaluating the UAE for treating cervical ectopic pregnancy were identified. The published literature consists of small case series. Sample sizes range from 2 to 20 patients, and most studies had fewer than 10 patients.

Kwon et al. (2017) retrospectively reviewed the charts of 13 women who had ectopic pregnancies that were refractory to systemic methotrexate who were then treated with UAE. (30) Locations of the ectopic implantation were cesarean scar (n=6), cervix (n=5), fallopian tube (n=1), and uterine cornua (n=1). Outcomes were technical success, clinical success, and complications. Results were reported for all patients, regardless of the ectopic implantation site. Mean gestational age at the time of diagnosis was 8.5 weeks (range, 3-14 weeks). Median follow-up was 25 weeks (range, 4-85 weeks). Technical success was 100%. Clinical success was achieved in 10 (77%) patients. Three patients experienced recurrent vaginal bleeding (2 instances of which occurred in patients who had cervical ectopic pregnancies) and underwent repeat embolization. The uteri of all 13 patients were preserved.

Hu et al. (2016) retrospectively reviewed the charts of 19 women who had cervical pregnancies and were treated with UAE followed by curettage. (31) The median gestational age of the fetuses at the time of UAE was 7.4 weeks (standard deviation, 1.6). One procedure was deemed an emergency due to profuse bleeding; the remaining 18 were nonemergency procedures. There were no reports of further vaginal bleeding following UAE. None of the patients underwent a hysterectomy due to the cervical pregnancy. Nine patients were followed for up to 39 months. Eight of the nine resumed normal menstruation. Only one attempted to conceive, and she had an uncomplicated pregnancy and a vaginal delivery.

A prospective series was conducted in China by Xiaolin et al. (2010). (32) Patients received methotrexate injections before, during, and after the UAE procedure. Median follow-up was 12 months (range, 1-50 months). Two (10%) of 20 patients had recurrent vaginal bleeding; the other 18 had no significant bleeding after UAE. Five (25%) patients had an additional curettage procedure due to bleeding and/or high levels of β-human chorionic gonadotropin. The uterus was preserved in all patients, and normal menses resumed after 2 to 4 months. Eight (50%) of 16 women who attempted to conceive achieved a normal pregnancy within 1 year. There were 2 miscarriages and 6 live births at term.

Section Summary: Cervical Ectopic Pregnancy

Cervical ectopic pregnancy is an emergent, rare, and clinically complex situation that may preclude gathering controlled data for evidence. However, because there are only a few case series available, the largest of which included 20 patients, additional case series are needed to inform a determination of efficacy. The limited noncomparative evidence is insufficient to determine the effect of UAE on health outcomes.

Uterine Arteriovenous Malformation

Clinical Context and Therapy Purpose

Uterine arteriovenous malformations (AVMs) are rare but may cause severe genital hemorrhaging. There are 2 types: low-flow AVM is characterized by an abnormal vascular network without visible early venous drainage, and high-flow AVM, which has early venous drainage. Uterine AVMs may be congenital or acquired. Risk factors for acquired AVMs are prior uterine surgery such as dilatation and curettage, myomectomy, and cesarean section.

The purpose of transcatheter UAE in individuals who have a uterine AVM 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 policy.

Populations

The relevant population of interest is individuals with uterine AVM.

Interventions

The intervention of interest is transcatheter UAE, which is a minimally invasive technique in which a catheter is used to inject small embolic agents into the uterine arteries and block the blood supply. Transcatheter UAE is administered by a physician in a tertiary care setting.

Comparators

The following therapies, most of which are more invasive, are currently being used to make decisions about AVM: medication or hysterectomy. Hysterectomy is performed by a physician in a tertiary care setting.

Outcomes

The general outcomes of interest, by indication, include symptom control (up to 3 years) and reintervention rates (up to 3 years). (30)

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 effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

No RCTs or other comparative studies evaluating UAE for treating uterine AVMs were identified. The published literature consists of case reports, small case series, and a systematic review.

Systematic Reviews

A systematic review by Yoon et al. (2016) of literature on acquired uterine AVMs identified 54 women treated with UAE in 40 studies published between 2003 and 2013, primarily case reports. (33) There were 22 unilateral and 32 bilateral procedures. Thirty-three (61%) of 54 patients had symptoms controlled with the initial embolization procedure. Nine of 13 patients who underwent repeat UAE experienced resolution of symptoms. No major complications were reported after UAE.

Case Series

The following case series were published after the Yoon et al. (2016) systematic review. Barral et al. (2017) described using ethylene vinyl alcohol copolymer (Onyx) as the embolic agent for UAE in the treatment of uterine AVMs. (34) Records from 12 women, mean age 33 years, were reviewed. After a mean follow-up of 29 months, 11 of the 12 women achieved clinical success, defined as the absence of bleeding at 1 month following embolization.

The largest series, published by Kim et al. (2014) in Korea, retrospectively reviewed data from a single center on 19 patients who underwent UAE as first-line treatment of bleeding uterine AVMs. (35) All patients presented with intermittent or progressive vaginal bleeding after gynecologic procedures or obstetric events. The UAE procedures were bilateral, and a variety of embolization agents were used. Seventeen (89.5%) of 19 patients had immediate clinical success following the UAE, defined as cessation of bleeding without symptom recurrence and resolution of the uterine AVMs on postoperative imaging studies.

Retrospective Studies

Kulshrestha et al. (2022) conducted a retrospective study to examine the outcome of patients with symptomatic AVM, formed following pregnancy and managed by UAE. (36) This study was conducted after ethical approval and included 15 patients presenting with abnormal uterine bleeding following pregnancy, who were suspected to have an AVM which later was confirmed by angiography and managed with UAE. Presenting symptoms, post-UAE complications and subsequent fertility outcomes were noted. Follow-up period ranged from 6 months to 2.5 years. The mean age was 28.4±3.82 years and mean parity was 1.3. Out of 15 cases, 9 (60%) presented after abortion, 4 (26.6%) after normal vaginal delivery and 2 (13.3%) after cesarean delivery; of these 10/15 (66.7%) patients had a history of curettage. The most common presenting symptom was continuous bleeding per-vaginum since the antecedent pregnancy in 9/15 (60%) patients and 6/15 (40%) patients had irregular bleeding. The mean duration of symptoms was 91±85.7 (30-360) days. For UAE, embolic agents used were polyvinyl alcohol

(PVA) particles (300-500 μm) in 2 (13.3%), 30% glue injection in 3 (20%), the combination of PVA with glue injection in 4 (26.6%) and PVA with gelfoam in 6 (40%) patients. After UAE, bleeding responded within 3.6±0.97 (3-6) days in all but one patient who required repeat UAE one month later. All women resumed their normal menstrual cycle in 31.3±5.2 (24-42) days. Ten patients desired conception, of whom 5 (50%) conceived within 13.2±5.1 (6-19) months after UAE. Two women carried pregnancy to term, one underwent preterm cesarean. One patient had postpartum hemorrhage, which was managed medically. One had spontaneous abortion at 6 weeks gestation and the other is 13 weeks pregnant at present. In this study, UAE was successful in the symptomatic management of all fifteen patients presenting with post pregnancy AVM with no significant complications, and half of the woman desiring pregnancy conceived. Further studies, in the form of RCT's with larger sample sizes, and longer term follow-up are needed to validate the results.

Section Summary: Uterine Arteriovenous Malformation

The limited noncomparative and retrospective evidence is insufficient to determine the effect of UAE on health outcomes in patients with bleeding associated with uterine AVMs. Additional data, ideally controlled trials comparing UAE with alternative uterine-sparing treatments, are needed to determine the safety and efficacy of UAE for treating uterine AVMs.

Adenomyosis

Clinical Context and Therapy Purpose

The purpose of transcatheter UAE in individuals who have adenomyosis 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 policy.

Populations

The relevant population of interest is individuals with adenomyosis.

Adenomyosis is characterized by the diffuse or focal growth of endometrial glandular and stromal tissue in the muscular layer of the uterus. The etiology of adenomyosis is unknown. Symptoms include dysmenorrhea, menorrhagia, infertility, and an enlarged uterus, which may be found on physical examination.

Interventions

The intervention of interest is transcatheter UAE, which is a minimally invasive technique in which a catheter is used to inject small embolic agents into the uterine arteries and block the blood supply. Transcatheter UAE is administered by a physician in a tertiary care setting.

Comparators

The following therapies, most of which are more invasive, are currently being used to make decisions about adenomyosis: medication or hysterectomy. Hysterectomy is performed in a tertiary care setting.

Outcomes

The general outcomes of interest include QOL (up to 5 years) and symptom control (up to 5 years).

Table 2. Outcomes of Interest for Individuals with Adenomyosis Treated With UAE

Measure	Outcome Evaluated	Description	Follow-up Timing
Uterine Fibroid Symptom & Health Related Quality of Life (UFS-quality of life) questionnaire	Symptoms/Quality of Life	A 37-question questionnaire that evaluates symptoms of uterine fibroids and their impact on health-related quality of life; patients answer questions on a Likert-type scale of 1- 5 (1 = None of the time, 5 = All of the time) (37)	During previous 3 months

UAE: uterine artery embolization

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 effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

No RCTs or other comparative studies evaluating UAE for treating adenomyosis were identified.

Systematic Reviews

In a systematic review of publications from 1999 through 2010, Popovic et al. (2011) evaluated the literature on UAE for patients with adenomyosis, alone or in conjunction with uterine fibroids. (38) Reviewers identified 8 case series reporting short-term follow-up in patients with adenomyosis alone. After a median follow-up of 9.4 months (range, 3-12 months), 85 (83%) of 102 patients had marked or complete improvement in clinical symptoms. Six case series reported long-term follow-up (median, 40.6 months; range, 17-60 months). Marked or complete improvement occurred in 135 (65%) of 208 patients, suggesting recurrence of symptoms over time in some patients. No deaths or serious adverse events were reported.

Case Series

Additional case series have been published since the Popovic et al. (2011) review. de Bruijn et al. (2017) provided 7-year QOL data on 28 women with adenomyosis treated with UAE. (39) Outcomes were Uterine Fibroid Symptom Quality of Life (UFS-QOL) questionnaire and Symptom Severity Score (SSS). A higher UFS-QOL score indicates a better QOL and a lower SSS

indicates an improvement in symptoms. Patients were considered asymptomatic if their SSS was less than 20 and their UFS-QOL score was greater than 80. At 7 years posttreatment, 3 women had undergone a second UAE, and 5 women had undergone a secondary hysterectomy. Median SSS at baseline was 72 (range, 23-100) and improved to 17 (range, 0-44). Median UFS-QOL score at baseline was 31 (range, 20-88) and improved to 98 (range, 9-100).

Zhou et al. (2016) evaluated short- (12-month) and long-term (5-year) outcomes for 252 women following UAE treatment for adenomyosis. (37) Outcomes of interest were dysmenorrhea and menorrhagia. Subgroup analyses were conducted by lesion vascularity: 1) blood supply equality of the uterus ("equal" if left and right uterine arteries supplied blood equally, otherwise "unequal") and 2) vascularity degree ("hypervascular" if vessels abundant at margin and center of lesions, "isovascular" if vessels abundant at margin but not core, and "hypovascular" if vessels lacking at margin and core). Following UAE, both short- and long-term rates of dysmenorrhea improvement and menorrhagia improvement were statistically similar among the equal and unequal blood supply groups, with improvement rates reported between 68% and 77%. However, improvement rates in dysmenorrhea and menorrhagia differed statistically among the vascularity groups, with patients in the hypervascular group experiencing higher rates of improvement than the other groups.

Wang et al. (2016) prospectively reported on 117 premenopausal patients with adenomyosis who underwent UAE. (40) A total of 115 (98%) of 117 patients who successfully underwent bilateral UAE were included in the analysis. At 12 months, patients were queried about change in dysmenorrhea symptoms. Thirteen (11.3%) patients reported slight symptom improvement, 64 (55.7%) reported moderate improvement, and 31 (27.0%) reported marked improvement. Seven (6%) patients reported no change.

Bae et al. (2015) retrospectively reviewed outcomes for 50 women who underwent UAE for symptomatic adenomyosis and were followed for at least 18 months. (41) At baseline, 41 (82%) of 50 women had both heavy menstrual bleeding and dysmenorrhea; the remainder reported only 1 of these 2 symptoms. The extent of post-procedure necrosis of adenomyosis imaged with MRI was significantly associated with the likelihood of experiencing symptoms at follow-up. In receiver operating characteristic curve analysis, a cutoff of 34.3% necrosis was the most predictive of symptom recurrence (area under the curve, 0.721; 95% CI, 0.577 to 0.839; p=0.004). Among 12 patients with less than 34.3% necrosis, 58% were symptom-free at 18 months; among 40 patients with greater than 34.3% necrosis, 94% were symptom-free at 18 months.

<u>Retrospective Studies</u>

Hu et al. (2024) examined the improvement of dysmenorrhoea and menorrhagia after UAE in women with symptomatic adenomyosis and identified factors that could predict the improvement of dysmenorrhoea and menorrhagia. (42) This was a retrospective study of 48 women with adenomyosis who underwent bilateral uterine artery embolization. All procedures were conducted by the same experienced interventional radiologist with >10 years of experience in UAE. The percentage of the volume of the absence of contrast enhancement on

T1-weighted images was evaluated 5-7 days after UAE. A receiver operating characteristic (ROC) analysis was used to determine a cut-off point and predict the improvement of dysmenorrhoea and menorrhagia. At 24 and 36 months after UAE, the improvement rates for dysmenorrhoea and menorrhagia were 60.4% (29/48) and 85.7% (30/35), and the recurrence rates were 19.4% (7/36) and 9.1% (3/33), respectively. Only the percentage of the volume of the absence of contrast enhancement on T1-weighted images was associated with the improvement of dysmenorrhoea ($p = 0.001$, OR = 1.051; 95% CI: 1.02-1.08) and menorrhagia ($p = 0.006$, OR = 1.077; 95% CI: 1.021-1.136). When the cut-off value of the ROC analysis was 73.1%, sensitivity, specificity, positive predictive value, and negative predictive value for the improvement of dysmenorrhoea were 58.6%, 94.7%, 94.4%, and 60%, while they were 58.9%, 80%, 100%, 100%, and 45.5% for the improvement of dysmenorrhoea. Bilateral uterine artery embolization for symptomatic adenomyosis led to good improvement while larger, multi center studies are needed to further study recurrence.

Section Summary: Adenomyosis

There is a lack of RCTs or other controlled comparative studies on UAE for the treatment of adenomyosis. Several case series, a systematic review, and a retrospective review are available. The systematic review found short-term symptom improvement in 83% of patients and long-term improvement in 65% of patients. Preliminary evidence from case series published after the systematic review showed that patients with greater necrosis of adenomyosis and patients with higher vascularity of lesions had higher response rates to UAE. A case series with 7 years of follow-up reported that 5 (18%) of 28 patients underwent a subsequent hysterectomy. Additional data from controlled trials are needed, especially on long-term efficacy and recurrence rates.

Ovarian and Internal Iliac Vein Embolization for Treatment of Pelvic Congestion Syndrome

No randomized controlled trials have been published comparing endovascular occlusion for pelvic congestion syndrome with a relevant alternative comparator or sham/placebo treatment. A randomized, prospective trial comparing embolization with coils versus vascular plugs is discussed. The remaining published evidence consists of case series, most of which were retrospective and conducted outside of the United States. Complicating the literature on this indication is a lack of standardized diagnostic criteria.

Clinical Context and Therapy Purpose

The purpose of ovarian and/or internal iliac vein endovascular occlusion in individuals who have pelvic congestion syndrome 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 policy.

Populations

The relevant population of interest is individuals with pelvic congestion syndrome.

Interventions

The therapies being considered are ovarian and internal iliac vein endovascular occlusion.

Comparators
The following therapies are currently being used to make decisions about pelvic congestion syndrome: medical therapy (e.g., analgesics, hormonal therapy) and surgical ovarian vein ligation.

Outcomes
The general outcomes of interest are symptom reduction (e.g., pain related to varicose veins) and adverse events. Procedural follow-up ranges from 1 to 3 months.

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 effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Tu et al. (2010) published a systematic review of literature on the diagnosis and management of pelvic congestion syndrome. (43) They observed that studies have rarely specified explicit diagnostic criteria for PCS and that definitions of pelvic pain have varied widely among studies. Moreover, most studies have not used objective outcome measures.

Two systematic reviews assessing endovascular occlusion for pelvic congestion syndrome were published between 2016 and 2018. Tables 3 and 4 summarize key characteristics and results.

Table 3. Systematic Review Characteristics

Study	Dates	Trials	Participants[1]	N (Range)	Design	Duration
Brown et al. (2018) (44)	1997-2014	14	Women with: • pelvic congestion syndrome with signs of pelvic vein incompetence on catheter-based venography** Studies with:	828 (NR)	Quasi-randomized trial Prospective observational studies Case series*	1-288 months

			• percutaneous intervention for pelvic congestion syndrome (e.g., sclerosis or embolization) • outcomes assessed pre- and post-treatment			
Mahmoud et al. (2016) (45)	1997-2014	20	Women with: • pelvic congestion syndrome** Studies with: • endovascular treatment of pelvic venous reflux	1081 (6-218)	Prospective observational studies Case series	1-72 months

[1] Key eligibility criteria.

*Study design noted by author not consistent with design type.

**No specific diagnostic criteria specified for pelvic congestion syndrome.

Table 4. Systematic Review Results

Study	Patients with Symptomatic Improvement		Patients with Little to No Symptomatic Improvement		Procedural Complications	Reports of Worsening Symptoms
Brown et al. (2018) (44)	**Overall relief**		**Overall relief**			
N (Total N)[1]	697 (762)		57 (697)		36 (944)[2]	6 (710)
% (Range)	91.5% (68.3 - 100%)		8.2% (0-31.7%)		3.8% (NR)	0.8% (0-4.1%)
Median	95.1		4.6		NR	0
IQR_{Q3-Q1}	17.4		14.2		NR	0
Mahmoud et al. (2016) (45)	**Short-term relief**	**Long-term relief**	**Short-term relief**	**Long-term relief**		
N (Total N)	571 (648)	624 (721)	77 (648)	97 (721)	120 (1041)	NR
% (Range)	88.1% (NR)	86.6% (NR)	11.9% (NR)	13.4% (NR)	11.5% (NR)	NR
Median	NR	NR	NR	NR	NR	NR
IQR_{Q3-Q1}	NR	NR	NR	NR	NR	NR

IQR_{Q3-Q1}: interquartile range. NR: not reported.

[1]Proportion of patients with outcome from population completing all relevant follow-up.

[2]Proportion of procedures with outcome from total number of procedures performed.

A systematic review by Mahmoud et al. (2016) identified 20 case series (total n=1081 patients) assessing endovascular treatment for pelvic congestion syndrome. (45) Reviewers did not require any particular diagnostic criteria for pelvic congestion syndrome. Only a single study used a comparison group, but patients in it received conservative treatment because they were ineligible for vein embolization therapy; as a result, outcomes following the 2 interventions cannot be compared. The authors included a quality assessment for the included studies.

Brown et al. (2018) evaluated patient outcomes following percutaneous treatment of pelvic congestion syndrome (N=828). (44) Study inclusion criteria required symptom(s) of pelvic congestion syndrome and the presence of pelvic venous incompetence on catheter-based venography - criteria which were not specified or defined. This review also includes a randomized trial published by Chung and Huh (2003) that evaluated the efficacy of various treatments for pelvic congestion syndrome that had failed 4-6 months of treatment with medroxyprogesterone acetate (N=106). (46)

Randomized Studies

A randomized, prospective trial by Guirola et al. (2018) in Spain compared the safety and efficacy of embolization with vascular plugs (VPs) or fibered platinum coils (FPCs) in women with pelvic congestion syndrome. (47) Patients were enrolled (N=100) and randomly assigned to each treatment group via block randomization (N=50). Diagnosis of pelvic congestion syndrome was accomplished through a symptom screening questionnaire followed by an ultrasound study. Patients with 3 or more positive symptom responses advanced to the ultrasound screening, and patients with pelvic veins >6 mm in diameter and/or venous reflux or dilated midline communicating veins were advanced to randomization. Follow-up screening occurred at 1, 3, 6, and 12 months. The primary outcome was clinical success assessed subjectively through patient responses regarding relief of symptoms and pain scores assessed with the visual analog scale. Clinical success was achieved in 89.7% of the FPC group and 90.6% of the VP group (P=0.760). Improvement in visual analog scale pain scores at the end of 12 months was 90.2% overall and improvement was seen in 95.9% of the FPC group and 96% of the VP group (P>0.999). A total of 11 (22%) complications were seen in the FPC group and 5 (10%) in the VP group (P=0.059). Minor adverse events included access site hematoma and ovarian vein extravasation. Device migrations were considered major complications. A major limitation in the study is the significant difference in age (P=0.004) and pre-treatment visual analog scale pain score between groups (P=0.004), both of which were higher in the VP group despite randomization.

Emad El Din et al. (2023) performed a randomized trial comparing surgical ovarian vein ligation under spinal or general anesthesia (n=25) with endovascular coil embolization under spinal or local anesthesia (n=25) in patients with pelvic congestion syndrome (criteria included chronic pelvic pain with an ovarian vein diameter >6 mm and moderate to severe congestion of the ovarian plexus) who had not experienced improvement with unspecified (non-surgical/ embolization) medical management. (48) Patients who were nulliparous, aged >55 years, or deemed unfit for surgery were excluded. Outcomes including VAS pain score (possible responses ranging from 0 to 10) and ultrasound assessment of varicosities and reflux were

evaluated. No differences between groups in baseline characteristics were reported; median VAS pain score at pre-operative baseline was 9 in both groups (range, 7-10 in the surgical group, 8-10 in the embolization group; p=.71). At 1 week post-operatively, median VAS pain score was reduced to 2 in the surgical group and 1 in the embolization group (p≤.001 for within-group pre-post comparison; p=.006 for between-group comparison). However, although patients were followed for 3 months, subsequent clinical outcomes and complication rates were not reported; the authors stated that no procedural complications were recorded.

Comparative Studies

A multicenter, retrospective, cohort study by Gavrilov et al. (2023) compared the efficacy of gonadal vein coil embolization under local anesthesia (n=177) with open or endoscopic (transperitoneal or retroperitoneal) gonadal vein resection under general anesthesia (n=184) in patients with pelvic venous disorder-associated chronic pelvic pain. (49) Patients with signs and symptoms of pelvic venous disease (chronic pelvic pain, dyspareunia, discomfort and/or heaviness in the hypogastric region, vulvar varicose veins) and pelvic reflux (>1 second in the gonadal, parametrial, and/or uterine veins on duplex ultrasound) were included. Patients who had ultrasound or venographic evidence of nutcracker syndrome or May-Thurner syndrome or who underwent hybrid interventions on the gonadal and iliac or pelvic veins and organs were excluded. The authors stated that no special criteria dictated choice between resection and embolization for most patients; however, patients with a gonadal vein diameter ≥10 mm only underwent resection. Outcomes included patient-reported relief from chronic pelvic pain and change in post-operative VAS pain scores from pre-operative baseline at various time points, as well as rate of recurrence of signs/symptoms of pelvic venous disorder accompanied by imaging evidence of reflux at the site of intervention. Pre-operative characteristics were similar between groups, with the exception of clinical-etiologic-anatomic-pathophysiologic class 2 to 3 chronic lower extremity venous disease, which was more prevalent in the resection group (22%) than the embolization group (11%; p<.001). The rate of reported relief from chronic pelvic pain at 1 month was higher in the resection group (100%) than the embolization group (74%; p<.001). At 1 month post-operatively, VAS pain score was significantly lower in the resection group (mean 1.1 from baseline 6.1) than in the embolization group (mean 4.1 from baseline 6.3; p<.001 for between-group comparison). The authors attributed the initial differences in chronic pelvic pain relief and VAS pain scores to patients in the embolization group who experienced post-embolization syndrome. At 5 years post-operatively, VAS pain scores were not significantly different between the resection (mean 1.7) and embolization groups (mean 2.1; p=.8). Complications within 30 days of the procedure were reported in 14% of resection patients and consisted primarily of pelvic vein thrombosis (11%), with 2 cases of deep vein thrombosis and 1 case of post-operative ileus reported. In the embolization group, Society of Interventional Radiology class C/D (major) complications were reported in 5%, including pelvic or uterine vein thrombosis, deep vein thrombosis, and coil protrusion; class A/B (minor) complications were reported in 37%. Post-embolization syndrome, characterized by pain over the embolized vein, fever, fatigue, and malaise, was reported in 20% of embolization patients, lasting between 5 and 23 days. Recurrence was reported in 6% of the resection group and 16% of the embolization group over the course of the study (p<.05), with mean time to recurrence of 29.2 months and 17.1 months, respectively.

Chen et al. (2022) performed a retrospective cohort study of patients with pelvic congestion syndrome (based on symptom screening and transvaginal ultrasound or computed tomography venography demonstrating pelvic vein diameter >6 mm and/or venous reflux or communicating veins) who underwent proximal coil occlusion of the refluxing vein followed by distal foam sclerotherapy (PCODS; n=94) vs standard coil embolization technique (control; n=53), both under local anesthesia, at 2 centers. (50) The primary endpoint was clinical remission (defined as relief of dysmenorrhea, dyspareunia, and/or urinary urgency, and a decrease in VAS pain score of ≥4 points from baseline) at 12 months post-procedure. The authors' per-protocol analysis (which excluded 3 and 2 patients who were lost to follow-up prior to 12 months in the PCODS and control groups, respectively) is reported for this review based on the small difference in sample size compared to the intention-to-treat analysis (N=147 vs 152), similar reported results between analyses, and a lack of description of how missing data were treated in the intention-to-treat analysis. No significant differences were identified in baseline characteristics between groups. At 12 months post-operatively, clinical remission rates in the PCODS and control groups were 86.2% and 71.7%, respectively (p=.032). The authors reported coil migration that did not require intervention in 2 patients in the control group; no other safety outcomes were reported.

Non-comparative Studies and Case Series

Tables 5 and 6 summarize the characteristics and results of select case series that have reported on symptom improvements in patients with pelvic congestion syndrome treated with endovascular occlusion. Additional details of select studies are described below.

Shahat et al. (2023) reported a single-center, retrospective study of patients with pelvic congestion syndrome (N=40) treated via ovarian vein foam embolization under local anesthesia between 2019 and 2021. (51) Premenopausal patients with chronic pelvic pain attributed to pelvic congestion syndrome (based on relation to menses, sexual intercourse, prolonged sitting/standing, and relief when lying down, as well as venographic evidence of ovarian vein incompetency) were included. Endpoints included pre- and post-operative VAS pain scores for 6 domains (up to 12 months) and pelvic congestion syndrome recurrence (defined as ultrasound evidence of pelvic varices and/or return of VAS pain score to pre-operative baseline). Compared to pre-operative baseline, statistically significant reductions in VAS pain score for pelvic and leg pain (both scored separately when lying and standing), dyspareunia, and pain with menses were noted at 12 months (specific p-values not reported); significant changes were noted as early as 1 month for most pain domains, except for pelvic pain when lying and leg pain when lying. One recurrence was reported during 12-month follow-up. Complications were reported in 20%, including post-procedural pain (15%), contrast allergy (2.5%), and segmental and subsegmental pulmonary embolism (2.5%).

Sozutok et al. (2022) reported a single-center, retrospective study of patients with chronic pelvic pain with imaging evidence of pelvic congestion syndrome (enlarged [>6 mm] pelvic veins and/or significant reflux on abdominal computed tomography, or pelvic venous dilatation and/or reflux on diagnostic angiography; N=144) who underwent ovarian vein embolization via

coil (n=47) with or without other materials (VP and/or foam; n=97) between 2012 and 2020. (52) The study endpoint was change from pre-operative baseline in VAS pain scores up to 12 months, defined as unsuccessful (<50% reduction from baseline), successful (50-80% reduction from baseline), or very successful (>80% reduction from baseline). Baseline mean VAS pain score (possible scores ranging from 0-100) was 35.46; at 3-month follow-up (n=131), mean VAS pain score was 14.68, corresponding to rates of successful and very successful pain management of 38.1% and 25.6%, respectively. At 12-month follow-up (n=84), mean VAS pain score was 14.14, but success rates were not reported at this timepoint. The authors found that patients who underwent coil embolization alone were significantly more likely to achieve successful pain reduction than those undergoing procedures involving additional embolization materials (p=.036). Complication rates were not reported.

Jambon et al. (2022) reported a single-center, prospective study of patients with imaging diagnoses of non-compressive (non-nutcracker or Crockett syndrome) pelvic venous disorders (N=73) who underwent foam embolization of incompetent pelvic veins (defined by reflux and dilatation with diameter >5 mm). (53) Endpoints included clinical efficacy, defined as partial (VAS global impairment score improvement by ≥50% from pre-operative baseline to a score <40 out of 100) or complete improvement (VAS impairment score of 0) at 3-month follow-up, and improvement in VAS global impairment score from baseline at the end of follow-up. Median duration of follow-up was 28 months (range, 18.1 to 34.5 months). At 3 months post-operatively, clinical efficacy was achieved in 95.9%, with complete and partial improvement in 30.1% and 65.8%, respectively. Mean VAS global impairment score at the end of follow-up was significantly improved compared to pre-operative baseline (6.52 vs 37.93; p<.0001). Significant improvements were also noted in mean VAS score at the end of follow-up compared to baseline for chronic pelvic pain (1.01 vs 6.07; p<.0001) and dyspareunia (0.81 vs 3.84; p<.0001). No complications were reported during the procedure, while 4 mild complications (3 patients with post-embolization syndrome lasting up to 1 month and 1 case of transitory radiculalgia) were reported post-operatively; no major post-operative complications occurred.

Table 5. Summary of Key Cohort Series Characteristics for Pelvic Congestion Syndrome

Study	Country	Participants	Treatment Delivery	Follow-Up, months
Shahat et al. (2023) (51)	Egypt	40	Vein embolization (foam)	12
Sozutok et al. (2022) (52)	Turkey	144	Vein embolization (coil ± plug or foam)	3
Jambon et al. (2022) (53)	France	73	Vein embolization (foam)	Median 28
Liu et al. (2019) (54)	China	12	Vein embolization (coil)	24-36
Hocquelet et al. (2014) (55)	France	33	Vein embolization (foam, coil)	26

Nasser et al. (2014) (56)	Brazil	113	Vein embolization (coil)	12
Laborda et al. (2013) (57)	Spain	202	Vein embolization (coil)	60
Gandini et al. (2008) (58)	Italy	38	Vein embolization (foam)	12
Kwon et al. (2007) (59)	Korea	67	Vein embolization (coil)	45
Kim et al. (2006) (60)	U.S.	127	Vein embolization (foam)	45

Table 6. Summary of Key Cohort Series Results for Pelvic Congestion Syndrome

Study	Treatment	Clinical Outcome (as Least Substantial Improvement in Pain Symptoms), %
Shahat et al. (2023) (51)	Vein embolization (foam)	97.5 without recurrence at 1 year
Sozutok et al. (2022) (52)	Vein embolization (coil ± plug or foam)	63.7
Jambon et al. (2022) (53)	Vein embolization (foam)	95.9 with complete or partial improvement in global impairment at 3 months
Liu et al. (2019) (54)	Vein embolization (coil)	92; 68[a]
Hocquelet et al. (2014) (55)	Vein embolization (foam, coil)	94 (61 complete, 33 partial)
Nasser et al. (2014) (56)	Vein embolization (coil)	100 (53 complete, 47 partial)
Laborda et al. (2013) (57)	Vein embolization (coil)	94 (34 complete)[b]
Gandini et al. (2008) (58)	Vein embolization (foam)	100
Kwon et al. (2007) (59)	Vein embolization (coil)	82
Kim et al. (2006) (60)	Vein embolization (foam)	83

[a] Rate of successful pregnancy following previous infertility.

[b] Based on 179 patients who completed the 5-year follow-up.

Laborda et al. (2013) reported pain outcomes on 202 patients who underwent coil embolization for PCS. (57) There were no clearly defined diagnostic criteria; patients were referred by a vascular surgeon. A total of 179 (89%) of 202 women completed 5-year follow-up. Pain was measured on a 10-point visual analog scale (VAS). At baseline, mean VAS (standard deviation; SD) was 7.34 (0.7), and at 5 years mean VAS was 0.78 (1.2). The decrease in mean VAS score over time was statistically significant ($p<0.001$). There were 4 (2%) cases of coil migration, and they were considered major complications. As with the other case series previously reported, this study lacked a control group with which to compare outcomes.

In 2015, Khilnani and Rosenblatt published a study of 33 patients having intermittent or continuous lower abdominal pain that has lasted more than 6 months that intensified during

menses or following a day's work. (61) Seventy-two percent of the patients took analgesics on a regular basis and 66% had continuous pain. Following embolization for PCS, using sclerosant, the follow-up was completed by utilizing an ultrasound and questionnaire at 1-, 6-, and 12-month(s). At the 1-month follow-up, chronic pelvic pain (CPP) was present in 13 patients (39%); the pain was continuous in 3 and intermittent in 10 patients. At the follow-up after 6/12 months the symptoms were unchanged. Ultrasound revealed a reduction in periovarian varicosities. The authors concluded that embolization is still a "first-choice" treatment for bilateral PCS.

Section Summary: Ovarian and Internal Iliac Vein Embolization for Treatment of Pelvic Congestion Syndrome

In regard to the treatment of pelvic congestion syndrome, the evidence consists of systematic reviews, randomized studies, comparative studies, non-comparative cohort studies, and case series. Inclusion and exclusion criteria varied among studies. One randomized study compared different embolization techniques without a non-embolization control; the other compared embolization with surgical ligation but did not report clinical endpoints more than 7 days post-operatively. A retrospective analysis comparing coil embolization to endoscopic resection indicated significantly greater improvement in pain 1-month post-procedure with resection, but similar improvements in pain between the procedures at 5-year follow-up. The study design suggests risk of selection bias; the authors noted there were not specific criteria for undergoing 1 procedure or the other, but resection was performed under general anesthesia whereas embolization was performed under local anesthesia. Non-comparative retrospective cohort studies and case series, as well as systematic reviews combining prospective and retrospective data, indicate high rates of clinical success (primarily in the form of pain reduction) with ovarian and/or internal iliac vein endovascular occlusion, with success rates ranging from 63.7% to 100% at follow-up ranging from 3 months to 5 years.

Testicular/Gonadal Vein Embolization for Treatment of Varicocele

Randomized Controlled Trials (RCTs)

In 2015, Wang et al. (62) systematically reviewed 35 randomized controlled trials and observational studies from 1966 to August 5, 2013, which compared any of the following treatments for varicocele: laparoscopic, retroperitoneal, open inguinal and subinguinal varicocelectomy, microsurgical subinguinal and inguinal varicocelectomy, percutaneous venous embolization, Tauber antegrade sclerotherapy, retrograde sclerotherapy, and expectant therapy (no treatment). In patients with subfertility or abnormal sperm parameters, various surgical approaches and embolization/sclerotherapy have led to improvements in pregnancy rates, and sperm counts and motility. Inguinal and subinguinal micro-varicocelectomy had the highest pregnancy rates, and significant increases in sperm parameters. In all patients after various varicocelectomy or embolization/sclerotherapy, inguinal and subinguinal micro-varicocelectomy were associated with low odds of recurrence, hydrocele formation and overall complications. Tauber antegrade sclerotherapy was associated with lower odds of hydrocele formation. Radiologic embolization (balloon or coil) or sclerotherapy of spermatic veins was found to have a failure rate of 19.8%. Larger properly conducted RCTs of varicocele treatment in men with varicocele and sperm defects are needed to confirm these results.

Case Series

In 2009, Bechara et al. published a comparative case series of 84 patients with testicular varicocele. (63) This study compared the treatment outcome of percutaneous coil embolization treatment versus laparoscopic varicocelectomy in patients with symptomatic varicoceles. The 5-year period results were analyzed. Forty-one patients underwent percutaneous coil embolization of the testicular vein, which were compared with a cohort of 43 patients who underwent laparoscopic varicocelectomy. Technical success in interventional and laparoscopic treatment was 95% and 100%, respectively. Embolization treatment resulted in two recurrent varicoceles (4.8%) compared to 1 patient following laparoscopic repair (2.3%, not significant). Embolization treatment was associated with a lower complication rate than laparoscopic repair (9.7% versus 16.3%, p = .03). The reviewers concluded coil embolization of the testicular vein offers treatment advantage compared with laparoscopic repair in patients with varicoceles.

A retrospective analysis of a consecutive series of varicocele embolization procedures comparing metallic coils and glue (n-butyl-2 cyanoacrylate) were published in 2017 by Bileiro et al. (64) A total of 129 procedures were performed, 26 using glue (20.2%; 26 men with a mean age of 32.6 years) and 103 using coils (79.8%; 103 men with a mean age of 32.3 years). A total of 89 procedures (69%) were motivated by infertility (glue=20, coils=69) and 40 (31%) by testicular pain (glue=6, coils=34). The mean procedure time was 35.58±13.44 minutes for glue and 45.97±17.46 minutes for coils (P=0.0054). Immediate technical success rate was 100% using glue and 99% using coils (p=1.0000). Both materials showed significant improvement of semen parameters, with similar clinical success rates. For patients referred for testicular pain, clinical success rate was 66.67% using glue and 88.24% using coils (p=0.2147). Recurrence rate was 11.54% with glue and 5.83% with coils (p=0.4000). Procedure time was significantly shorter with glue (p=0.0054). Glue and coils are both safe and effective for varicocele embolization.

An earlier case series reported by Cassidy et al. in 2012 from Canada, revealed that surgical correction is the most commonly performed technique to treat varicoceles with a technical failure rate of less than 5%. (65) An attractive alternative to surgery is the selective catheterization and embolization of the gonadal vein. A total of 158 patients underwent embolization for clinical varicoceles and male factor infertility between 2004 and 2008. Of these, 56% underwent attempted bilateral embolization, 43% unilateral left-sided embolization and 1.3% unilateral right-sided embolization. Of these patients who underwent attempted bilateral embolization, 19.3% did not experience a successful obliteration of the right gonadal vein and 2.3% (2/88) experienced a failure rate in the embolization of the left gonadal vein. Of the 2 attempts at unilateral right-sided embolization, there were no failures. For the 68-unilateral left-sided embolization attempts, there was a 4.4% failure rate. All of the right-sided embolization attempts, 18.9% failed, while 3.2% of the left-sided attempts failed. The reviewers' conclusion is that 19.3% technical failure rate for bilateral varicocele embolization is higher than the current published rate of 13% and is largely related to failure to successfully occlude the right gonadal vein. Men with unilateral left-sided varicoceles should be offered both options as they have similar failure rates, but with embolization offering some clear advantages to the patient.

In 2012, Kim et al. published a case series over a period of 10 years of 28 patients requiring percutaneous transcatheter embolization of postsurgical, recurrent/persisting varicoceles. (66) The patients had undergone laparoscopic varicocelectomy (39.3%), high retroperitoneal ligation (25%), or inguinal ligation (25%). Subjective symptoms were scrotal pain (60.7%) and a palpable scrotal mass (50%) exclusively on the left side. Embolization was technically successful in all but 2 cases, thus yielding an occlusion rate of 93%; a single case of suspected thrombophlebitis was the only complication. After excluding 2, technically unsuccessful cases and 1 patient who was lost to follow-up, 25 patients underwent scrotal examination after embolization, which revealed complete resolution in 20 cases (80%), partial improvement in 4 cases (16%), and no improvement in 1 case (4%). Among the follow-up group of patients, of the 12 who initially presented with scrotal pain, 6 (50%) were symptom-free and 4 (33.3%) had partial improvement.

Wong et al. (2022) conducted a retrospective review of review of 40 patients referred for varicocele embolization over a 10-year period (February 2010-March 2020). (67) Technical embolization success was achieved in 36/40 patients (90%), with 4 procedures abandoned due to an inaccessible vein. 32/36 patients completed short term follow-up at a median interval of 2.8 months. There was a significant reduction in peritesticular vein size following embolization (pre-3.70 vs post-2.56 mm, $p = 0.00017$) and a significant relationship between varicocele grade and early clinical success ($\chi 2 = 4.2$, $p = 0.04$). No post procedural complications including hydroceles were identified. This study demonstrated technical success, matching rates described in adult patients which is reassuring and in support of embolization in the younger patient cohort. More importantly, the overall clinical success rate is comparable with previous embolization studies. Although this study has the longest follow-up for varicocele embolization in children, it is limited by a few patients being lost to early and long-term follow-up. In summary, paediatric varicocele embolization is a successful alternative to surgical ligation, with no complications and good clinical outcomes over a long-term follow-up.

Section Summary: Testicular/Gonadal Vein Embolization For Treatment of Varicocele
Embolization to the gonadal/testicular vein is the alternative to surgical correction or as a salvage embolization following surgical treatment. This has been confirmed from several case series. More recently, studies have focused on types of materials used (i.e., coils, glue, gel foam) with success compared to ligation.

Prostatic Artery Embolization for Treatment of Benign Prostatic Hyperplasia
Gao et al. (2014) compared prostatic arterial embolization (PAE) and transurethral resection of the prostate (TURP) in the care of patients with benign prostatic hyperplasia (BPH). (68) A total of 114 patients provided written informed consent and were randomly assigned to undergo PAE (n = 57) or TURP (n = 57). The groups were compared regarding relevant adverse events and complications. Functional results--including improvement of International Prostate Symptom Score (IPSS), quality of life (QOL), peak urinary flow, postvoiding residual urine volume, prostate-specific antigen (PSA) level, and prostate volume--were assessed at 1-, 3-, 6-, 12-, and 24-month follow-up between January 20, 2007, and January 31, 2012. Student t test,

X^2 test, Fisher exact test, and repeated measures analysis of variance were used, as appropriate.

Overall technical success rates for TURP and PAE were 100% and 94.7%, respectively; the clinical failure rates were 3.9% and 9.4%, respectively. The six functional results showed improvements after TURP and PAE at all follow-up time points when compared with preoperative values (P = .001). However, the TURP group showed greater degrees of improvement in the IPSS, QOL, peak urinary flow, and postvoiding residual urine volume at 1 and 3 months, as well as greater reductions in the PSA level and prostate volume at all follow-up time points, when compared with the PAE group (P < .05). The PAE group showed more overall adverse events and complications (P = .029), mostly related to acute urinary retention (25.9%), postembolization syndrome (11.1%), and treatment failures (5.3% technical; 9.4% clinical).

Authors concluded that although both procedures resulted in significant clinical improvements in the treatment of BPH, the advantages of the PAE procedure must be weighed against the potential for technical and clinical failures in a minority of patients.

Russo et al. (2015) evaluated 1-year surgical and functional results and morbidities of PAE vs. open prostatectomy (OP). (69) Researchers undertook a 1:1 matched-pair analysis (IPSS, peak flow [PF], postvoid residual [PVR], and prostate volume) of 287 consecutive patients treated for benign prostatic obstruction, including 80 OP and 80 PAE. Inclusion criteria were as follows: lower urinary tract symptoms or benign prostatic obstruction, IPSS ≥12, PSA <4 ng/mL, or PSA between 4 and 10 ng/mL but negative prostate biopsy, total prostate volume >80 cm(3), and PF <15 mL/s. Follow-up was performed at 1 month, 6 months, and 1 year at clinic. Primary end points of the study were the comparison regarding IPSS, International Index of Erectile Function-5, PF, PVR, and IPSS quality of life (IPSS-QOL) after 1 year of follow-up. Regarding primary end points, OP group had lower IPSS (4.31 vs 10.40; P <.05), 1-year PVR (6.15 vs 18.38; P <.05), 1-year PSA (1.33 vs 2.12; P <.05), IPSS-QOL (0.73 vs 2.78; P <.05), International Index of Erectile Function-5 (10.88 vs 15.13; P <.05), and greater PF (23.82 vs 16.89; P <.01). The matched-pair comparison showed higher value of postoperative hemoglobin level (mg/dL) and shorter hospitalization (days) and catheterization (days) for PAE group. At the multivariate logistic regression, PAE was associated with persistent symptoms (IPSS ≥8; odds ratio, 2.67; 95% CI, 0.96-7.4; P <.01) and persistent PF ≤15 mL/s (odds ratio, 4.95; 95% CI, 1.73-14.15; P <.05) after 1 year. Researchers concluded that PAE could be considered a feasible minimally invasive technique but failed to demonstrate superiority to OP because of the increased risk of persistent symptoms and low PF after 1 year.

In 2016, Wang et al. conducted a systematic review to evaluate the efficacy and safety of PAE on lower urinary tract symptoms (LUTS) related to BPH. (70) Twelve studies involving 840 participants were included. Compared with baseline, the International Index of Erectile Function (IIEF-5; IPSS) scores, the quality-of-life scores, peak urinary flow rate (Qmax) and postvoid residual volume all had significant improvements during the 24-month follow-up (all *P*<0.00001). Both prostate volume (PV) and PSA had significant decrease during the 12-

month follow-up (*P*<0.00001 and *P*=0.005, respectively), except postoperative 24 months (*P*=0.47 and *P*=0.32, respectively). The IIEF-5 short form scores had significant increase at postoperative 6 months (*P*=0.002) and 12 months (*P*<0.0001), except postoperative 1 month (*P*=0.23) and 24 months (*P*=0.21). For large volume (PV ≥80 mL) BPH, the results were similar. There were no life-threatening complications. Reviewers concluded that PAE is an effective, safe, and well-tolerable treatment for LUTS related to BPH, including large volume (PV ≥80 mL) BPH, with a good short-term follow-up. Studies with large number of cases and longer follow-up time are needed to validate our results.

Teoh et al. (2017) systematically reviewed the current evidence on PAE in treatment men with BPH. (71) A total of 987 records were identified through database searching. After removing duplicates, screening and reviewing full-length texts, a total of five records remained, with two RCTs and three non-randomized cohort studies. TURP resulted in better IPSS than PAE. Open prostatectomy had better IPSS, QOL score, Qmax and PVR, but worse IIEF score than PAE at 1 year. Unilateral PAE had higher rate of poor clinical outcome than bilateral PAE, but the difference became statistically insignificant after adjusting for age; IPSS, QOL score, Qmax, PVR, IIEF score, PV and PSA did not differ between the two groups. PAE with 100 µm PVA particles resulted in greater reduction in PSA level, but worse IIEF score than PAE with 200 µm PVA particles; IPSS, QOL score, Qmax, PVR, PV and poor clinical outcome did not differ between the two groups. Reviewers concluded that evidence on different aspects of PAE was limited. Further studies are warranted to investigate the role of PAE as compared to other forms of medical and surgical treatment.

Zumstein et al. (2018) performed a systematic review and meta-analysis of clinical trials comparing efficacy and safety of PAE versus established surgical therapies. (72) Five studies including 708 patients met the selection criteria. Risk of bias was rated high for most of the studies. Mean reduction in the International Prostate Symptom Score was lower after PAE compared with standard surgical therapies (mean difference 3.80 points [95% CI: 2.77-4.83]; p<0.001). PAE was less efficient regarding improvements in all functional parameters assessed including maximum urinary flow, post void residual, and reduction of prostate volume. In contrast, patient-reported erectile function (International Index of Erectile Function 5) was better after PAE and significantly fewer adverse events occurred after PAE. Reviewers concluded that moderately strong evidence confirms efficacy and safety of PAE in the treatment of BPH-LUTS in the short term. Significant advantages regarding safety and sexual function, but clear disadvantages regarding all other patient-reported and functional outcomes were found for PAE. Large-scale randomized controlled trials including longer follow-up periods are mandatory before PAE can be considered as a standard therapy and to define the ideal indication for PAE in the management of BPH-LUTS.

Malling et al. (2019) conducted a systematic review studying the efficacy of prostate artery embolization to treat LUTS with more than ten participants and follow-up longer than 6 months were included by two independent authors. (73) Outcomes investigated were International Prostate Symptom Score (IPSS), QOL, International Index of Erectile Function (IIEF-5), PV, PSA, Qmax, PVR and complications. To summarize mean change from baseline, a meta-analysis was

done using the random-effects model. The search returned 210 references, of which 13 studies met the inclusion criteria, representing 1,254 patients. Patients in the included studies with data available for meta-analysis had moderate to severe LUTS and a mean IPSS of 23.5. Statistically significant ($p< 0.05$) improvements of all investigated outcomes were seen at 12-month follow-up. Major complications were reported in 0.3% of the cases. Findings suggested that PAE can reduce moderate to severe LUTS in men with BPH with a low risk of complications.

Jiang et al. (2019) conducted a systematic review comparing the efficiency and safety of TURP with PAE. (74) A total of four studies involving 506 patients were included in our meta-analysis. The pooled data showed that the Qmax was higher in TURP group than PAE with a significant difference (WMD:4.66, 95% CI 2.54 to 6.79, $P < 0.05$). The postoperative QOL was lower in the TURP than PAE group (WMD: -0.53, 95% CI -0.88 to -0.18, $P < 0.05$). The postoperative prostate volume was significantly smaller in the TURP than PAE group (WMD: -8.26, 95% CI -12.64 to -3.88, $P < 0.05$). The operative time was significantly shorter in the TURP than PAE group (WMD: -10.55, 95% CI, -16.92 to -4.18, $P < 0.05$). No significant difference was found in the postoperative IPSS and complications between TURP and PAE ($P > 0.05$, WMD: 1.56, 95% CI -0.67 to 3.78, p = 0,05, OR: 1.54, 95% CI, 1.00 to 2.38, respectively). Reviewers concluded that TURP could achieve improved Qmax and QOL compared to PAE. Therefore, for patients with BPH and LUTS, TURP was superior to PAE.

In 2020, Pisco et al. sought to assess the safety and efficacy of PAE compared with a sham procedure in the treatment of LUTS/BPH. (75) A randomized, single-blind, sham-controlled superiority clinical trial was conducted in 80 males ≥45 years with severe LUTS/BPH refractory to medical treatment from 2014 to 2019 in a private clinic, with efficacy assessments at 6 and 12 months after randomization. One patient in the PAE group and three in the sham group did not complete the study. Patients were randomized 1:1 upon successful catheterization of a prostatic artery to either PAE or a sham PAE procedure without embolization. After 6 months all 38 patients randomized to the sham group who completed the single-blind period underwent PAE, and both groups completed a 6-mo open period. Mean age was 63.8±6.0yr, baseline IPSS 26.4±3.87, and QOL score 4.43±0.52. At 6 months, patients in the PAE arm had a greater improvement in IPSS, with a difference in the change from baseline of 13.2 (95% CI 10.2-16.2, $p<0.0001$), and a better QOL score at 6 months (difference: 2.13; 95% CI 1.57-2.68, $p<0.0001$) than the patients in the sham arm. The improvements in IPSS and QOL in the sham group 6 months after they performed PAE were, respectively, 13.6±9.19 ($p<0.0001$) and 2.05 ± 1.71 ($p<0.0001$). Adverse events occurred in 14 (35.0%) patients after PAE and in 13 (32.5%) after sham, with one serious adverse event in the sham group during the open period. No treatment failures occurred. Limitations include a single-center trial, only severe LUTS/BPH, and follow-up limited to 12 months. Researchers found superior efficacy of PAE compared with a sham procedure.

Insausti et al. (2020) compared clinical and functional outcomes of PAE with those of TURP for the treatment of LUTS secondary to BPH. (76) A noninferiority randomized trial was conducted involving men over 60 years of age with LUTS secondary to BPH. From November 2014 to January 2017, 45 patients were randomized to PAE (n = 23) or to TURP (n = 22). PAE was

performed with 300- to 500-µm microspheres with the patient under local anesthesia, whereas bipolar TURP was performed with the patients under spinal or general anesthesia. Primary outcomes were changes in Qmax and IPSS from baseline to 12 months. QO
L, and PV changes from baseline to 12 months were secondary outcomes. Adverse events were compared using the Clavien classification. Mean Qmax increased from 6.1 mL/s in the PAE group and from 9.6 mL/s in the TURP patients (P = .862 for noninferiority), and mean IPSS reduction was 21.0 points for PAE and 18.2 points for TURP subjects (P = .080) at 12 months. A greater QOL improvement was reported in the PAE group (3.78 points for PAE and 3.09 points for TURP; P = .002). Mean PV reduction was 20.5 cm^3 (34.2%) for PAE subjects and 44.7 cm^3 (71.2%) for TURP subjects (P < .001). There were fewer adverse events reported in the PAE group than in the TURP group (n = 15 vs n = 47; P < .001). Researchers concluded that reduction of LUTS in the PAE group was similar to that in the TURP group at 12 months, with fewer complications secondary to PAE. Long-term follow-up is needed to compare the durability of the symptomatic improvement from each procedure.

Abt et al. (2018) compared PAE with TURP in the treatment of LUTS secondary to BPH in terms of patient reported and functional outcomes. (77) A noninferiority randomized trial involving 103 patients aged ≥40 years with refractory LUTS secondary to BPH were randomized between February 11, 2014, and May 24, 2017; 48 and 51 patients reached the primary endpoint 12 weeks after PAE and TURP, respectively. Mean reduction in IPSS from baseline to 12 weeks was −9.23 points after PAE and −10.77 points after TURP. Although the difference was less than 3 points (1.54 points in favor of TURP [95% CI −1.45 to 4.52]), non-inferiority of PAE could not be shown (P=0.17). None of the patient reported secondary outcomes differed significantly between treatments when tested for superiority; IPSS also did not differ significantly (P=0.31). At 12 weeks, PAE was less effective than TURP regarding changes in maximum rate of urinary flow (5.19 v 15.34 mL/s; difference 10.15 (95% CI −14.67 to −5.63); P<0.001), postvoid residual urine (−86.36 vs −199.98 mL; 113.62 (39.25 to 187.98); P=0.003), PV (−12.17 vs −30.27 mL; 18.11 (10.11 to 26.10); P<0.001), and desobstructive effectiveness according to pressure flow studies (56% vs 93% shift towards less obstructive category; P=0.003). Fewer adverse events occurred after PAE than after TURP (36 vs 70 events; P=0.003). Researchers concluded that the improvement in LUTS secondary to BPH seen 12 weeks after PAE is close to that after TURP. PAE is associated with fewer complications than TURP but has disadvantages regarding functional outcomes, which should be considered when selecting patients. Further comparative study findings, including longer follow-up, should be evaluated before PAE can be considered as a routine treatment.

Knight et al. (2020) conducted a systematic review and meta-analysis comparing PAE and TURP for the management of BPH. Six studies with 598 patients were included (78). TURP was associated with significantly more improvement in maximum urinary flow rate (Q) (mean difference = 5.02 mL/s; 95% CI [2.66,7.38]; p < 0.0001; I^2 = 89%), prostate volume (mean difference = 15.59 mL; 95% CI [7.93,23.25]; p < 0.00001; I^2 = 88%), and PSA (mean difference = 1.02 ng/mL; 95% CI [0.14,1.89]; p =0.02; I^2= 71%) compared to PAE. No significant difference between PAE and TURP was observed for changes in International Prostate Symptoms Score (IPSS), IPSS quality of life (IPSS-QOL), International Index of Erectile Function (IIEF-5), and post-

void residual (PVR). PAE was associated with fewer adverse events (AEs) (39.0% vs. 77.7%; p < 0.00001) and shorter hospitalization times (mean difference = -1.94 days; p < 0.00001), but longer procedural times (mean difference = 51.43 min; p = 0.004). Study results concluded subjective symptom improvement was equivalent between TURP and PAE. While TURP demonstrated larger improvements for some objective parameters, PAE was associated with fewer AEs and shorter hospitalization times.

Pisco et al. (2016) sought to confirm that PAE has a positive medium- and long-term effect in symptomatic BPH. (79) Between March 2009 and October 2014, 630 consecutive patients with BPH and moderate-to-severe LUTS refractory to medical therapy for at least 6 months or who refused any medical therapy underwent PAE. Outcome parameters were evaluated at baseline; 1, 3, and 6 months; every 6 months between 1 and 3 years; and yearly thereafter up to 6.5 years. Mean patient age was 65.1 years ± 8.0 (range, 40-89 y). There were 12 (1.9%) technical failures. Bilateral PAE was performed in 572 (92.6%) patients and unilateral PAE was performed in 46 (7.4%) patients. The cumulative clinical success rates at medium- and long-term follow-up were 81.9% (95% CI, 78.3%-84.9%) and 76.3% (95% CI, 68.6%-82.4%). There was a statistically significant (P < .0001) change from baseline to last observed value in all clinical parameters: IPSS, QOL, PV, PSA, urinary maximal flow rate, postvoid residual, and International Index of Erectile Function. There were 2 major complications without sequelae. Researchers found that PAE had a positive effect on IPSS, QOL, and all objective outcomes in symptomatic BPH. The medium- (1-3 y) and long-term (> 3-6.5 y) clinical success rates were 81.9% and 76.3%, with no urinary incontinence or sexual dysfunction reported.

Ray et al. (2018) sought to assess the efficacy and safety of PAE for LUTS secondary to BPH and to conduct an indirect comparison of PAE with TURP. (80) As a joint initiative between the British Society of Interventional Radiologists, the British Association of Urological Surgeons and the National Institute for Health and Care Excellence, the UK Register of Prostate Embolization (UK-ROPE) study, which recruited 305 patients across 17 UK urological/ interventional radiology centers, 216 of whom underwent PAE and 89 of whom underwent TURP. The results showed that PAE was clinically effective, producing a median 10-point IPSS improvement from baseline at 12 months post-procedure. PAE did not appear to be as effective as TURP, which produced a median 15-point IPSS score improvement at 12 months post-procedure. These findings are further supported by the propensity score analysis, in which 65 closely matched pairs of patients who underwent PAE and patients who underwent TURP. In terms of IPSS and QOL improvement, there was no evidence of PAE being non-inferior to TURP. Patients in the PAE group had a statistically significant improvement in maximum urinary flow rate and prostate volume reduction at 12 months post-procedure. PAE had a reoperation rate of 5% before 12 months and 15% after 12 months (20% total rate), and a low complication rate. Of 216 patients, one had sepsis, one required a blood transfusion, four had local arterial dissection and four had a groin hematoma. Two patients had non-target embolization that presented as self-limiting penile ulcers. Results indicate that PAE provides a clinically and statistically significant improvement in symptoms and QOL, although some of these improvements were greater in the TURP arm. The safety profile and quicker return to normal activities may be seen as highly beneficial by patients considering PAE as an alternative treatment to TURP, with the

concomitant advantages of reduced length of hospital stay and need for admission after PAE. PAE is an advanced embolization technique demanding a high level of expertise and should be performed by experienced interventional radiologists who have been trained and proctored appropriately. The use of cone-beam computed tomography is encouraged to improve operator confidence and minimize non-target embolization. PAE was clinically effective producing a median 10-point IPSS improvement from baseline at 12 months post-procedure, which was NOT as effective as TURP which produced a median 15-point IPSS score improvement at 12 months post-procedure. In terms of IPSS and QOL improvement, there was no evidence of PAE being non-inferior to TURP.

Section Summary: Prostatic Artery Embolization for Treatment of Benign Prostatic Hyperplasia
Embolization of the prostatic artery has been proposed as an alternative to TURP or open prostatectomy for the treatment of BPH. Short and limited mid-term data in the published, peer-reviewed literature demonstrate improved outcomes with PAE, however additional large, well-designed studies with longer follow-up are needed to validate these results.

Hemorrhoidal Embolization
Stecca et al. (2021) conducted a prospective, non-randomized, non-controlled study, phase I/II clinical trial examining the technical and clinical success rates of superior rectal artery embolization (SRAE) in the treatment of symptomatic grades-II and grade-III hemorrhoidal disease. (81) A total of 43 patients (24 men and 19 women; mean age of 52 years) with symptomatic hemorrhoidal disease were treated and completed the 6-month follow-up with anamnestic questionnaire and disease scores, including French bleeding score (FBS), Goligher prolapse, VAS for pain, and QOL. Clinical success was evaluated at 7 days, 1 month, and 6 months of follow-up. The reduction in the FBS in grade-III prolapse was statistically significant ($p = 0.001$) and improvement in the QOL was significant in both groups ($p < 0.05$). No serious complications were observed. The study concluded that hemorrhoidal embolization was a safe and effective technique in the treatment of symptomatic hemorrhoidal disease. However, further comparative, multi-center studies with longer follow-up periods and larger cohorts of patients are needed to confirm the clinical success rates.

De Gregorio et al. (2023) conducted a prospective study to examine the safety and effectiveness of catheter-directed hemorrhoidal embolization (CDHE) for rectal bleeding due to hemorrhoids. (82) All 80 subjects had symptomatic bleeding hemorrhoids; they were classified according to Goligher classification: grade-I (13.7%), grade-II (71.1%), grade-III (15%), and no grade-IV. Micro-coils were employed for embolization and microspheres if recurrence of bleeding occurred. Follow-up evaluation (1, 3, 6, and 12 months) included clinical examination and an anoscopy. A questionnaire was carried out to determine improvement regarding bleeding, QOL before, and the degree of patient satisfaction of each participant. Technical success was achieved in 100% of the cases; 55 (68.7%) subjects had the absence of rectal bleeding after 12 months of embolization; visual analog score (VAS) and QOL improved 4 points and 1.5, respectively, after embolization. A total of 25/80 (31.3%) had a recurrence in rectal bleeding; 17 (21.3%) patients underwent a 2nd embolization, and 4 patients (5%) were treated with open hemorrhoidectomy. No major complications were observed; 16 subjects had minor

complications. Subjective post-treatment symptom and QOL surveys showed significant differences from the baseline survey and the degree of satisfaction in the telephone survey at 12 months revealed a high degree of patient satisfaction (8.3 ± 1.1). The study concluded that the findings of this study showed that CDHE's safety profile was acceptable. The study showed that CDHE has provided encouraging outcomes in patients with hemorrhoids and mild prolapse Goligher grade-I to grade-III with persistent rectal bleeding. These preliminary findings, however, need to be validated by well-designed studies.

Section Summary: Hemorrhoidal Embolization

Rectal artery hemorrhoidal embolization has been proposed as an alternative to a surgical procedure for the treatment of symptomatic hemorrhoidal disease. Short term data in the form of non-randomized, non-controlled studies and prospective studies have been published showing positive outcomes with embolization. Further large, well-designed studies with longer follow-up are needed to confirm these results.

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists (ACOG)

In June 2021, ACOG issued a Practice Bulletin on management of symptomatic uterine leiomyomas. (83) This Practice Bulletin (No. 228-replaces Practice Bulletin No. 96, August 2008) stated that: "Uterine artery embolization (UAE) is recommended as an interventional procedure for the treatment of uterine leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes." Some medical therapies for uterine leiomyomas are indicated for long-term use, whereas others are meant to be a bridge to surgical treatments, interventional procedures, or menopause. Treatment decisions should be guided by an individual patient's symptoms and treatment goals.

In 2013, ACOG issued a committee opinion on the management of acute abnormal uterine bleeding in nonpregnant reproductive aged women. (84) This opinion was reaffirmed in 2020. The committee listed UAE among the surgical options for acute abnormal uterine bleeding and stated that the need for surgical treatment, including UAE, is based on the clinical stability of the patient, the severity of bleeding contraindications to medical management, the patient's lack of response to medical management, and the underlying medical condition of the patient.

In 2017, the ACOG published a practice bulletin (No. 183) on postpartum hemorrhage. (85) UAE was recommended when less invasive techniques (uterotonic agents, uterine massage, uterine compression, manual removal of clots) failed. Studies have shown that the median success rate is 89% (range, 58%-98%).

Society of Obstetricians and Gynecologists of Canada

In 2015, the Society of Obstetricians and Gynecologists of Canada published clinical guidelines on the management of uterine leiomyomas. (86) The guidelines stated: "Of the conservative interventional treatments currently available, uterine artery embolization has the longest track record and has been shown to be effective in properly selected patients."

In 2019, an addendum to the 2015 recommendations was published. (87) The addendum stated: “The selected treatment should be directed towards an improvement in symptomatology and quality of life. The cost of the therapy to the health care system and to women with fibroids must be interpreted in the context of the cost of untreated disease conditions and the cost of ongoing or repeat investigative or treatment modalities.” No new changes were mentioned with regards to UAE.

Society of Interventional Radiology (SIR)

The 2009 (reviewed and unchanged in 2014) quality improvement guidelines from the SIR stated that UAE is indicated in women with uterine leiomyomas that are causing significant symptoms. (88) Absolute contraindications to UAE included a viable pregnancy, active infection, and suspected uterine, cervical, or adnexal malignancy (unless the procedure is being performed for palliation or in conjunction with surgery). A desire to maintain fertility was deemed a relative contraindication.

A SIR fact sheet on infertility in men endorsed catheter-directed embolization as an effective treatment option for varicocele. (89)

In 2019, the SIR updated their position statement on PAE for BPH. (90) “The data supporting PAE for BPH have advanced since the SIR Position Statement was published in 2014, confirming that PAE is a safe and effective treatment for BPH with good short- and midterm durability.” Based on comprehensive review, SIR, the Cardiovascular and Interventional Radiological Society of Europe, Societe Française de Radiologie, and the British Society of Interventional Radiology jointly conclude that current evidence is adequate to support the use of PAE for BPH in appropriately selected patients.

A fact sheet from the SIR on chronic pelvic pain in women endorsed ovarian vein embolization as an effective treatment option for pelvic congestion syndrome. (91)

American Urological Association (AUA) and American Society for Reproductive Medicine (ASRM).

The AUA Clinical Guideline on Diagnosis and Treatment of Infertility in Men: AUA/ASRM Guideline (2020, amended 2024) states: “Surgical varicocelectomy should be considered in men attempting to conceive who have palpable varicocele(s), infertility, and abnormal semen parameters, except for azoospermic males; Evidence Level: Grade B.” (92)

The AUA Clinical Guideline on Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: (2021, amended 2023) states: “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).” They also went on to state; “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.” (93)

European Association of Urology (EAU)

In 2024, the EAU updated their guideline on the management of non-neurogenic male LUTS. (94) The guidelines state: "Offer Aquablation* to patients with moderate-to-severe LUTS and a prostate volume of 30-80 mL as an alternative to transurethral resection of the prostate. *Aquablation remains under investigation as evidence levels has not been reached." Strength rating: Weak.

The guidelines go on to state: "Offer prostatic artery embolisation (PAE)* to men with moderate-to-severe LUTS who wish to consider minimally invasive treatment options and accept less optimal outcomes compared with transurethral resection of the prostate. *PAE remains under investigation. Strength rating: Weak.

International Union of Phlebology

An international consensus document on the diagnosis and treatment of pelvic congestion syndrome (which acknowledged the suboptimal nature of this terminology and noted that new nomenclature was being proposed at the time of publication) was published by a task force of the International Union of Phlebology in 2019. (95) Key consensus statements include:

- Symptomatic (pain-relief) therapies include analgesics, nonsteroidal anti-inflammatory drugs, and psychotropic drugs, but the effect of such therapy is transient.
- Hormonal therapy seems to have therapeutic effect, but long-term usage is not recommended because of the high risk of osteoporosis.
- Current surgical treatment includes open or laparoscopic surgery to ligate the insufficient veins. However, these procedures are rarely performed as they are more invasive than endovascular embolization procedures and require a general anesthetic and a longer recovery period. Surgery of the reproductive organs is not advised as a treatment option.
- Injecting foam or liquid sclerosant could be used for occlusion of gonadal veins and for the treatment of atypical varicose veins of perineal, vulval, gluteal, or posterior thigh localization.
- Transcatheter embolization therapy is the method of choice for the treatment of pelvic congestion syndrome. The aim of embolization is to occlude insufficient venous axes as close as possible to the origin of the leak. In pelvic venous disorders these will be the gonadal axes, pelvic varicose veins, and insufficient tributary branches of the internal iliac veins. However, published evidence of its effect has been criticized for the lack of validated clinical and imaging criteria for the disorders responsible for pelvic venous disease.
- Treatment of choice for pelvic congestion syndrome is pelvic vein embolization, in the absence of obstructions. Serious complications after this kind of treatment are very rare.

Society for Vascular Surgery and American Venous Forum

A clinical practice guideline for the care of patients with varicose veins and related chronic venous disorders was jointly published by the Society for Vascular Surgery and American Venous Forum in 2011. (96) Portions of these guidelines were updated most recently in 2023, although there was no mention of pelvic congestion syndrome. (97)

The 2011 guidelines included the recommendations below related to treatment of pelvic congestion syndrome. Medical management is not included among recommendations. The guideline states that "Pharmacologic agents to suppress ovarian function, such as medroxyprogesterone or gonadotropin-releasing hormone, may offer short-term pain relief, but their long-term effectiveness has not been proven."

- We suggest treatment of pelvic congestion syndrome and pelvic varices with coil embolization, plugs, or transcatheter sclerotherapy, used alone or together (grade 2B: weak recommendation, moderate quality of evidence).
- If less invasive treatment is not available or has failed, we suggest surgical ligation and excision of ovarian veins to treat reflux (grade 2B: weak recommendation, moderate quality of evidence).

Summary of Evidence

For individuals who have uterine fibroids who receive transcatheter uterine artery embolization (UAE), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, quality of life (QOL), and treatment-related morbidity. The majority of studies have compared UAE with hysterectomy and myomectomy and found similar levels of symptoms and QOL across all treatment groups. Benefits for women undergoing UAE included avoiding surgery and maintaining their uterus, lower complication rates, and lower blood transfusion rates. However, patients undergoing UAE had higher reintervention rates compared with patients who had surgery. Smaller trials have compared UAE with laparoscopic occlusion and magnetic resonance image (MRI)-guided focused ultrasound surgery. Additional trials with larger sample sizes comparing UAE with these and other uterus-preserving procedures are needed. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have persistent uterine fibroids despite prior UAE who receive repeat transcatheter UAE, the evidence includes case series. Relevant outcomes are symptoms, QOL, and treatment-related morbidity. Case series have shown that a high degree of symptom relief is possible after a repeat UAE for uterine fibroids. Moreover, evidence from RCTs on the safety and efficacy of UAE for initial treatment of uterine fibroids may indicate a benefit for patients in need of repeat procedures for the same indication. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have postpartum uterine hemorrhage who receive transcatheter UAE, the evidence includes case series and a systematic review. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. The systematic review of case series assessing over 1400 women reported success rates of stopping bleeding that ranged from 58% to 98%. PPH is an emergency situation with serious potential consequences (i.e., maternal mortality). Conducting RCTs is particularly difficult in this setting and may be unnecessary when there are sufficient uncontrolled data. Though from case series, there is evidence reporting on over 1400 women. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a cervical ectopic pregnancy who receive transcatheter UAE, the evidence includes case series. Relevant outcomes are treatment-related morbidity. Only a few case series with a small number of patients have been published. Additional studies, especially controlled studies comparing UAE with medication or surgery, are needed to assess the safety and efficacy of UAE in patients with cervical ectopic pregnancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have uterine arteriovenous malformations (AVMs) who receive transcatheter UAE, the evidence includes case reports, case series, a systematic review, and a retrospective review. Relevant outcomes are symptoms, and treatment-related morbidity. Only case reports and case series with a small number of patients have been published. A systematic review identified 54 women in 40 studies with uterine AVMs treated with UAE. Additional controlled studies comparing UAE with hysterectomy are needed to assess the safety and efficacy of UAE in patients with uterine AVMs. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have adenomyosis who receive transcatheter UAE, the evidence includes case series, a systematic review, and a retrospective review. Relevant outcomes are symptoms, and treatment-related morbidity. A systematic review of case series data found short-term improvement in 83% of patients and long-term improvement in 65% of patients, suggesting possible recurrence of symptoms over time. All studies were case series, which might have been subject to selection and/or observational biases. Additional case series published after the review have reported that patients with greater necrosis of adenomyosis and patients with higher vascularity of lesions may experience higher response rates to UAE. Controlled studies comparing UAE with medication or surgery and studies reporting long-term symptom recurrence rates are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pelvic congestion syndrome who receive ovarian and/or internal iliac vein endovascular occlusion, the evidence includes randomized studies, comparative studies, case series, and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. According to systematic reviews of case series data, approximately 86.6%, 88.1%, and 91.5% of patients have reported some degree of symptom relief after ovarian and/or internal iliac vein endovascular occlusion at short-term, long-term, or overall follow-up. There are an increasing number of case series with positive outcomes for patients experiencing pelvic congestion syndrome (PCS) for greater than 6 months following failed pharmacological treatment, which has been confirmed by radiological evidence, and negative diagnostic evidence of other pathology causing the chronic pelvic pain (CPP). RCTs using well-defined eligibility criteria and relevant comparators would be useful. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who have benign prostatic hypertrophy (BPH) who receive prostatic artery embolization (PAE), the evidence includes randomized studies, comparative studies, and

systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Short and limited mid-term data in the published, peer-reviewed literature demonstrate improved outcomes with PAE, however additional large, well-designed studies with longer follow-up are needed to validate these results. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with symptomatic hemorrhoidal disease who receive transcatheter embolization, the evidence includes a prospective, non-randomized, non-controlled study, phase I/II clinical trial, and a prospective study. Relevant outcomes are symptoms and treatment-related morbidity. Short-term data (6 months or less) published in peer-reviewed literature demonstrated a reduction in the French bleeding scores and improved quality of life with hemorrhoidal embolization. No serious complications were observed. Larger studies with longer follow-up times are needed to further validate the results found in the short-term studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished and ongoing trials that might influence this policy are listed in Table 7.

Table 7. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03794466	Quantification of Pain Relief With Gonadal Vein Embolization for Pelvic Congestion Syndrome	30	Dec 2025
NCT05553158[a]	Study to Investigate the Influence of Compression Treatment in Patients with Pelvic Congestion Syndrome (PCS)	172	Nov 2024
NCT02163525[a]	Post Market TRUST - U.S.A. Study	114	Jun 2024
NCT04856306	Myomectomy vs Uterine Artery Embolization vs GnRh Antagonist for AUB-L	300	Aug 2025
Unpublished			
NCT02819609[a]	Comparing Patient-Centered Outcomes after Treatment for Uterine Fibroids	12,234	Jan 2015 (completed)
NCT02884960[a]	Safety and Efficacy of Embozene® Microspheres for Uterine Fibroid Embolization Compared to Embosphere® Microspheres for Symptomatic Relief from Uterine Fibroids	118	Oct 2018 (unknown)

NCT04115137	Pelvic Varicose Veins Treated With Vascular Plugs Type Amplatzer - (REPiVAC)	300	Jan 2021 (unknown)
NCT01909024[a]	Pelvic Embolisation to Reduce Recurrent Varicose Veins - Recurrent	270	Dec 2018 (unknown)
NCT04358497	Endovascular Versus Medical Treatment for the Pelvic Congestion Syndrome (ENDPCS)	120	Oct 2022 (unknown)
NCT02942537	Study of Volume Reduction of Uterine Fibroids after Embolization or Microwave Treatment (MYOMIC1)	36	Feb 2020 (unknown)

NCT: National Clinical Trial

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	36012, 36245, 36246, 36247, 37241, 37242, 37243, 37244, 75894
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change

TBD	Document updated with literature review. The following change was made to Coverage: Added hemorrhoidal embolization to the list of procedures that are considered experimental, investigational and/or unproven for transcatheter embolization. References 1, 2, 15, 19, 36, 42, 67, 81-82, 88, 91 and 97 added; others updated.
05/15/2024	Document updated with literature review. The following change was made to Coverage: Updated criteria on embolization of the ovarian veins for pelvic congestion syndrome specific to pelvic laparoscopy/exploratory laparotomy. References 41-46 and 84-86 added.
12/01/2022	Reviewed. No changes.
01/15/2022	Document updated with literature review. Coverage statement removed: Laparoscopic occlusion of the uterine arteries using bipolar coagulation is considered experimental, investigational and/or unproven. References 51, 65-69, 72, 76, and 79 added; others removed.
05/01/2021	Document updated with literature review. The following change was made to Coverage: Added "Benign prostatic hyperplasia (BPH)" as an experimental, investigational and/or unproven indication for transcatheter embolization. References 19, 23, 38, 41-49, 56-64, 67, 73 and 76 added, others removed.
10/15/2019	Reviewed. No changes.
05/01/2018	Document updated with literature review. The following criteria was added to the medically necessary coverage statement for uterine artery embolization: "Asymptomatic fibroids of such size that they are palpable abdominally and are of concern to the patient." The following criteria was added to the medically necessary coverage statement for testicular vein embolization: "Testicular vein embolization (gonadal vein embolization) as a treatment of symptomatic varicocele." Treatment using embolization (e.g., utilizing metallic coils or foam/gel sclerotherapy) of the ovarian veins, with or without internal iliac veins, as a treatment of pelvic congestion syndrome/pelvic vein incompetence has changed from experimental, investigational and/or unproven TO medically necessary when meeting specific diagnostic criteria. Title changed from "Therapeutic Embolization and Vessel Occlusion", with the addition of "to Treat Pelvic Conditions." References added were 15, 26-27, 30, 33-34, 40-43, 47, 50-52, 54-56, and 58; no references removed.
04/01/2017	Document updated with literature review. The following additions were made to the transcatheter embolization experimental, investigational and/or unproven coverage statement: 1) Uterine arteriovenous malformation; and, 2) Adenomyosis. The following indications were removed from the transcatheter therapeutic embolization or vessel occlusion medically necessary coverage statement: 1) Congenital or acquired vascular anomaly; 2) Acute or recurrent hemorrhage; and, 3) Devascularization of neoplasms for palliation.
01/15/2015	Reviewed. No changes.

08/01/2013	Document updated with literature review. The following changes were made: 1) Transcatheter therapeutic embolization or vessel occlusion of the uterine arteries as may be considered medically necessary for treatment of post-partum hemorrhage; 2) One repeat transcatheter therapeutic embolization or vessel occlusion of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization may be considered medically necessary when there is documentation of continued symptoms such as bleeding or pain, in combination with findings on imaging of an incomplete initial procedure, as evidenced by continued blood flow to the treated regions; 3) Transcatheter embolization for the management of cervical ectopic pregnancy is considered experimental, investigational and unproven.
03/01/2011	Document updated with literature review. The following change was made: 1) reference to American College of Obstetrics and Gynecology was removed from the coverage section; 2) “asymptomatic fibroids” was removed from the medical necessity criteria. Description and Rationale sections were completely rewritten.
07/15/2008	Revised/Updated Entire Document
07/15/2004	Position statement converted to Medical Policy
10/01/2002	Medical Policy converted to Position Statement
03/01/2000	Revised/Updated Entire Document
11/01/2000	Revised/Updated Entire Document
01/01/2000	New medical document