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Therapeutic Embolization and Vessel Occlusion to Treat Pelvic Conditions

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Related Policies (if applicable)
None

Disclaimer

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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 heavy, irregular and prolonged uterine bleeding, or iron deficiency; 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.

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; **AND**
- Evaluation by a gynecologist; **AND**
- Diagnostic venography, computed tomography or magnetic resonance imaging.

NOTE 1: Clinical signs and symptoms of pelvic congestion syndrome may include:

1. Worsening of symptoms with prolonged standing or sitting; or
2. Evening exacerbation; or
3. Relief of symptoms with rest in the lying down position; or
4. After raising of legs; or
5. Visible varicosities (e.g., perineal, vulvular, or gluteal).

NOTE 2: Transcatheter embolization for other indications not noted above are NOT addressed in this policy.

Policy Guidelines

None.

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.

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.

Therapeutic Embolization and Vessel Occlusion
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: 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.)

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., coils, 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.

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

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), quality of life, 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. (3) 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 1 and 2 summarize key characteristics and results.

Table 1. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Brown et al. (2018) (4)	1997-2014	14	Women with: • pelvic congestion syndrome with signs of pelvic vein incompetence on catheter-based venography** Studies with: • percutaneous intervention for pelvic congestion syndrome (e.g., sclerosis or embolization) • outcomes assessed pre- and post-treatment	828 (NR)	Quasi-randomized trial Prospective observational studies Case series*	1 to 288 months
Mahmoud et al. (2016) (5)	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 to 72 months

NR: not reported.
*Study design noted by author not consistent with design type.
**No specific diagnostic criteria specified for pelvic congestion syndrome.

Table 2. 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) (4)	**Overall relief**	**Overall relief**		

n (Total N)[1]	697 (762)		57 (697)		36 (944)[2]	6 (710)
% (Range)	91.5% (68.3 to 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) (5)	**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. (5) 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, which were deemed to be of poor quality.

Brown et al. (2018) evaluated patient outcomes following percutaneous treatment of pelvic congestion syndrome (N=828). (4) 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). (6) However, this study compared ovarian vein coil embolization to hysterectomy with bilateral or unilateral oophorectomy and was, therefore, not assessed separately as evidence.

<u>Randomized Studies</u>

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. (7) 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. (8) 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. (9) 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. (10) 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 3 and 4 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. (11) 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. (12) 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). (13) 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 3. Summary of Key Cohort Studies and Case Series Characteristics for Pelvic Congestion Syndrome

Study	Country	Participants	Treatment Delivery	Follow-Up, months
Shahat et al. (2023) (11)	Egypt	40	Vein embolization (foam)	12
Sozutok et al. (2022) (12)	Turkey	144	Vein embolization (coil ± plug or foam)	3
Jambon et al. (2022) (13)	France	73	Vein embolization (foam)	Median 28
Liu et al. (2019) (14)	China	12	Vein embolization (coil)	24-36
Hocquelet et al. (2014) (15)	France	33	Vein embolization (foam, coil)	26
Nasser et al. (2014) (16)	Brazil	113	Vein embolization (coil)	12
Laborda et al. (2013) (17)	Spain	202	Vein embolization (coil)	60
Gandini et al. (2008) (18)	Italy	38	Vein embolization (foam)	12
Kwon et al. (2007) (19)	Korea	67	Vein embolization (coil)	45
Kim et al. (2006) (20)	United States	127	Vein embolization (foam)	45

Table 4. Summary of Key Cohort Studies and Case Series Results for Pelvic Congestion Syndrome

Study	Treatment	Clinical Outcome (as Least Substantial Improvement in Pain Symptoms), %
Shahat et al. (2023) (11)	Vein embolization (foam)	97.5 without recurrence at 1 year
Sozutok et al. (2022) (12)	Vein embolization (coil ± plug or foam)	63.7
Jambon et al. (2022) (13)	Vein embolization (foam)	95.9 with complete or partial improvement in global impairment at 3 months
Liu et al. (2019) (14)	Vein embolization (coil)	92; 68[a]

Hocquelet et al. (2014) (15)	Vein embolization (foam, coil)	94 (61 complete, 33 partial)
Nasser et al. (2014) (16)	Vein embolization (coil)	100 (53 complete, 47 partial)
Laborda et al. (2013) (17)	Vein embolization (coil)	94 (34 complete)[b]
Gandini et al. (2008) (18)	Vein embolization (foam)	100
Kwon et al. (2007) (19)	Vein embolization (coil)	82
Kim et al. (2006) (20)	Vein embolization (foam)	83

[a] Rate of successful pregnancy following previous infertility.
[b] Based on 179 patients who completed the 5-year follow-up.

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.

Centers for Medicare and Medicaid Services (CMS)

Uterine arteries Embolization as Treatment of Post-partum Hemorrhage

National Coverage Determination

The National Coverage Determination (NCD) on Therapeutic Embolization indicates that there is coverage for a therapeutic embolization when done for hemorrhage and for other conditions amenable to treatment by the procedure, when reasonable and necessary for the individual patient. (21)

Practice Guidelines and Position Statements

Testicular/Gonadal Vein Embolization for Treatment of Varicocele

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.” (22)

An AUA Best Practice Policy and ASRM Practice Committee Report on Varicocele and Infertility-2001 (reviewed and validity confirmed 2012), is now an archived document, noted the following recommendations: Persistence or recurrence of a varicocele may be treated by either surgical ligation or percutaneous embolization of the refluxing veins. (23)

Cardiovascular and Interventional Radiological Society of Europe (24)
The Cardiovascular and Interventional Radiological Society of Europe addresses Standards of Practice on varicocele embolization. Although the Standards of Practice document provides up-to-date recommendations for the safe performance of varicocele embolization; it also notes that embolization has an established role in the successful management of male varicoceles.

Transcatheter Uterine Artery Embolization as a Treatment of Uterine Fibroids (leiomyomata)
Society of Obstetricians and Gynaecologists of Canada (25)
The Society of Obstetricians and Gynaecologists of Canada (SOGC) in their Guideline No. 461: The Management of Uterine Fibroids (July 2025) includes both a section addressing "Summary of Statements" as well as a section addressing "Recommendations."

- One of the "Summary Statements" notes that the presence of uterine fibroids can lead to a variety of clinical challenges, with abnormal uterine bleeding and bulk symptoms being the most common presentations. (high)
- The two following "Recommendations" address uterine artery embolization:
  - Uterine artery embolization may be offered as a minimally invasive technique that can reduce fibroid symptoms in patients wishing to preserve their uterus. (conditional, moderate)
  - Patients should be aware that uterine artery embolization maybe be associated with decreased fertility, higher miscarriage rate, and adverse pregnancy outcomes, and is not advised in patients wishing for future fertility. (conditional, moderate)

Embolization in Symptomatic Pelvic Congestion Syndrome
French Society of Cardiovascular Imaging (SFICV), Interventional Radiology Federation (FRI), College of French Radiology Teachers (CERF), and French Society of Women's Imaging (SIFEM)
The purpose of the expert consensus statement was to summarize the opinions of French radiologists, and gynecologists regarding the diagnosis, imaging, treatment and management of pelvic congestion syndrome (PCS). (26)

Several of the recommendations made in the consensus statement are noted below. (This is not the complete list of recommendations found in the document.) The first two recommendations below address aspects from the *Clinical impact and Symptom patterns and clinical signs* sections seen in the document acknowledging specific symptoms and length of pain characterized by pelvic congestion syndrome; while the last addresses the e*ndovascular treatment itself.*

- Recommendation (Class A): Identify chronic pelvic pain lasting more than six months with a venous pattern as pelvic congestion syndrome to facilitate clear communication and targeted treatment approaches.

- Recommendation (Class A): Document and evaluate common clinical signs of pelvic congestion syndrome, including pelvic heaviness, delayed and persistent deep dyspareunia, worsening in static positions, and symptom variations related to hormonal changes. Additionally, ensure that all patients undergo a gynecologic examination to exclude conditions requiring specific preoperative management.
- Recommendation (Class A): Use embolization as the primary treatment mode for pelvic congestion syndrome, after ensuring its validation through appropriate diagnostic correlations.

Society for Vascular Surgery and the American Venous Forum (27)
The Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) developed clinical practice guidelines for the care of patients with varicose veins of the lower limbs and pelvis. In the section focusing on Pelvic varicosity and pelvic congestion syndrome the following guideline numbers are included for treatment of pelvic varicose veins.

Table 5: Treatment of Pelvic Varicose Veins

Guide Number		GOR	LOE
14.1	We recommend noninvasive imaging with transabdominal and/or transvaginal ultrasonography, computed tomography or magnetic resonance venography in selected patients with symptoms of pelvic congestion syndrome or symptomatic varices in the distribution of the pubis, labia, perineum, or buttocks.	1	C
14.2	We recommend retrograde ovarian and internal iliac venography in patients with pelvic venous disease, confirmed or suspected by noninvasive imaging studies, in whom intervention is planned.	1	C
14.3	We suggest treatment of pelvic congestion syndrome and pelvic varices with coil embolization, plugs, or transcatheter sclerotherapy, used alone or together.	2	B
14.4	If less invasive treatment is not available or has failed, we suggest surgical ligation and excision of ovarian veins to treat reflux.	2	B

GOR: grade of recommendation; LOE: level of evidence; 1: Strong; 2: Weak; A: High quality; B: Moderate quality; C: Low or very low quality.

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®) ©2024 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 have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed 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
01/01/2026	Document updated. The following change was made to Coverage: 1) Revised criteria for embolization of uterine arteries for treatment of uterine fibroids; 2) Revised criteria for repeat embolization treatment for uterine fibroids; 3) Revised criteria for embolization for treatment of pelvic congestion syndrome; 4) Revised Note 1; 5) Replaced Note 2; 6) Removed Experimental investigational and/or unproven statements; 7) Added "Transcatheter embolization for other indications not noted above are NOT addressed in this policy." Added references 21, 23-27.
04/15/2025	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