PHP_4.01.18	Ovarian and Internal Iliac Vein Endovascular Occlusion as a Treatment of Pelvic Congestion Syndrome		
Original Policy Date:	December 1, 2025	**Effective Date:**	December 1, 2025
Section:	4.0 OB/Gyn/Reproduction	**Page:**	Page 1 of 15

State Guidelines

As of the publication of this policy, there are no applicable Medi-Cal guidelines (Provider Manual or All Plan Letter). Please refer to the Policy Statement section below.

Policy Statement

In the absence of any State Guidelines, please refer to the criteria below.

I. Endovascular occlusion of the ovarian vein and internal iliac veins is considered **investigational** as a treatment of pelvic congestion syndrome.

Policy Guidelines

Endovascular occlusion of the internal iliac and ovarian veins has been performed on an outpatient basis but may require an overnight hospital stay.

Coding

See the Codes table for details.

Description

Pelvic congestion syndrome is characterized by chronic pelvic pain that is often aggravated by standing; diagnostic criteria for this condition are not clearly defined. Endovascular occlusion (e.g., embolization, sclerotherapy) of the ovarian and internal iliac veins has been proposed as a treatment for individuals who fail medical therapy.

Summary of Evidence

For individuals who have pelvic congestion syndrome who receive ovarian and/or internal iliac vein endovascular occlusion, the evidence includes randomized studies, comparative cohort studies, non-comparative cohort studies, case series, and systematic reviews. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Systematic reviews of prospective and retrospective data, as well as more recently published retrospective cohort studies, indicate consistently high clinical success rates (primarily in the form of significant pain reduction) ranging from 63.7% to 100% after ovarian and/or internal iliac vein endovascular occlusion at short-term, long-term, or overall follow-up. These data support guideline and international consensus recommendations for endovascular occlusion in this setting. In a randomized trial of embolization with vascular plugs or coils in patients with pelvic congestion syndrome, adverse events were reported in 22% and 10% of patients, respectively. 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. Differences between these procedures, particularly the need for general anesthesia with resection versus local anesthesia with embolization, suggest the possibility of selection bias in this study. Randomized controlled trials

using well-defined eligibility criteria and relevant comparators are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
Not applicable.

Related Policies

- Treatment of Varicose Veins/Venous Insufficiency

Benefit Application

Blue Shield of California Promise Health Plan is contracted with L.A. Care Health Plan for Los Angeles County and the Department of Health Care Services for San Diego County to provide Medi-Cal health benefits to its Medi-Cal recipients. In order to provide the best health care services and practices, Blue Shield of California Promise Health Plan has an extensive network of Medi-Cal primary care providers and specialists. Recognizing the rich diversity of its membership, our providers are given training and educational materials to assist in understanding the health needs of their patients as it could be affected by a member's cultural heritage.

The benefit designs associated with the Blue Shield of California Promise Medi-Cal plans are described in the Member Handbook (also called Evidence of Coverage).

Regulatory Status

Ovarian and internal iliac vein embolization 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 for uterine fibroid embolization (e.g., Embosphere® Microspheres, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles) and/or embolization of hypervascular tumors and arteriovenous malformations (e.g., Contour™ PVA Embolization particles). 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.

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).

Health Equity Statement

Blue Shield of California Promise Health Plan's mission is to transform its health care delivery system into one that is worthy of families and friends. Blue Shield of California Promise Health Plan seeks to advance health equity in support of achieving Blue Shield of California Promise Health Plan's mission.

Blue Shield of California Promise Health Plan ensures all Covered Services are available and accessible to all members regardless of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, or identification with any other persons

or groups defined in Penal Code section 422.56, and that all Covered Services are provided in a culturally and linguistically appropriate manner.

Rationale

Background

Pelvic Congestion Syndrome

Pelvic congestion syndrome 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 usually occurs before menopause, and pain is often greater before or during menses. The underlying etiology is thought to be related to varices of the pelvic 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]

Treatment

An initial conservative approach to the treatment of pelvic congestion syndrome may involve analgesics (e.g., short-term use of nonsteroidal anti-inflammatory drugs) and hormonal therapy, with or without psychotherapy.[3,4] The evidence base for medical management consists primarily of 5 clinical trials of hormonal therapy (sample sizes ranging from 22 to 102) in which medroxy-progesterone (in combination with psychotherapy), goserelin, and etonogestrel demonstrated significant improvements in pain scores with up to 13 months of follow-up.[4,5] Longer-term efficacy of these treatments has not been demonstrated, and the largest trial of medroxyprogesterone indicated rapid recurrence of symptoms with discontinuation.[6] Surgical ligation of pelvic veins may be considered, but is also supported by limited evidence and further limited by need for general anesthesia, duration of hospitalization, recovery time, and associated morbidity.[7] Embolization therapy and/or sclerotherapy of the ovarian and internal iliac veins has been proposed as an alternative to surgical vein ligation. Endovascular occlusion can be performed using a variety of materials including coils, vascular plugs, glue, liquid embolic agents, and gelatin sponge or powder (Gelfoam).

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 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.

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 review.

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 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 events, 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

Systematic Reviews

Tu et al (2010) published a systematic review of literature on the diagnosis and management of pelvic congestion syndrome.[5] The authors observed that studies have rarely specified explicit diagnostic criteria for pelvic congestion syndrome and that definitions of pelvic pain have varied widely across 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)[8]	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)[9]	1997-2014	20	Women with: • pelvic congestion syndrome** Studies with: • endovascular treatment of pelvic venous reflux	1081 (6 to 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)[8]	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 to 31.7%)		3.8% (NR)	0.8% (0 to 4.1%)
Median	95.1		4.6		NR	0
IQR_{Q3-Q1}	17.4		14.2		NR	0
Mahmoud et al (2016)[9]	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: 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 (N=1081) assessing endovascular treatment for pelvic congestion syndrome.[9] 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).[8] 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 to 6 months of treatment with medroxyprogesterone acetate (N=106).[10] However,

this study compared ovarian vein coil embolization to hysterectomy with bilateral or unilateral oophorectomy and was, therefore, not assessed separately as evidence.

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.[11] 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 (VAS). Clinical success was achieved in 89.7% of the FPC group and 90.6% of the VP group (p=.760). Improvement in VAS 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>.999). A total of 11 (22%) complications were seen in the FPC group and 5 (10%) in the VP group (p=.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=.004) and pre-treatment VAS pain score between groups (p=.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.[12] 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 to 10 in the surgical group, 8 to 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.[13] 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) versus standard coil embolization technique (control; n=53), both under local anesthesia, at 2 centers.[14] 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 non-comparative cohort studies and 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.[15] 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.[16] 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% to 80% reduction from baseline), or very successful (>80% reduction from baseline). Baseline mean VAS pain score (possible scores ranging from 0 to 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).[17] 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, mo
Shahat et al (2023)[15]	Egypt	40	Vein embolization (foam)	12
Sozutok et al (2022)[16]	Turkey	144	Vein embolization (coil ± plug or foam)	3
Jambon et al (2022)[17]	France	73	Vein embolization (foam)	Median 28
Liu et al (2019)[18]	China	12	Vein embolization (coil)	24 to 36
Hocquelet et al (2014)[19]	France	33	Vein embolization (foam, coil)	26
Nasser et al (2014)[20]	Brazil	113	Vein embolization (coil)	12
Laborda et al (2013)[21]	Spain	202	Vein embolization (coil)	60
Gandini et al (2008)[22]	Italy	38	Vein embolization (foam)	12
Kwon et al (2007)[23]	Korea	67	Vein embolization (coil)	45
Kim et al (2006)[24]	U.S.	127	Vein embolization (foam)	45

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

Study	Treatment	Clinical Outcome (at Least Substantial Improvement in Pain Symptoms), %
Shahat et al (2023)[15]	Vein embolization (foam)	97.5 without recurrence at 1 year

Sozutok et al (2022)[16]	Vein embolization (coil ± plug or foam)	63.7
Jambon et al (2022)[17]	Vein embolization (foam)	95.9 with complete or partial improvement in global impairment at 3 months
Liu et al (2019)[18]	Vein embolization (coil)	92; 68[a]
Hocquelet et al (2014)[19]	Vein embolization (foam, coil)	94 (61 complete, 33 partial)
Nasser et al (2014)[20]	Vein embolization (coil)	100 (53 complete, 47 partial)
Laborda et al (2013)[21]	Vein embolization (coil)	94 (34 complete)[b]
Gandini et al (2008)[22]	Vein embolization (foam)	100
Kwon et al (2007)[23]	Vein embolization (coil)	82
Kim et al (2006)[24]	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: 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.

Supplemental Information

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

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.[7] 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 Interventional Radiology
A fact sheet from the Society for Interventional Radiology on chronic pelvic pain in women endorsed ovarian vein embolization as an effective treatment option for pelvic congestion syndrome.[25]

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.[26,] Portions of these guidelines were updated most recently in 2023, although there was no mention of pelvic congestion syndrome.[27]

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).

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished and ongoing trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	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 (unknown)
Unpublished			

NCT04115137	Multicentric Spanish Record of Pelvic Varicose Veins Treated With Vascular Plugs Type Amplatzer - Pelvic Congestion Syndrome: Study of Efficacy and Safety (REPiVAC)	300	Jan 2021 (unknown)
NCT01909024[a]	A Randomised Controlled Trial Investigating The Use Of Pelvic Vein Embolisation To Reduce Recurrent Varicose Veins Of The Legs In Women With Recurrent Varicose Veins And Associated Pelvic Venous Reflux.	270	Dec 2018 (unknown)
NCT04358497	Endovascular Versus Medical Treatment for the Pelvic Congestion Syndrome (ENDPCS)	120	Oct 2022 (unknown; last reported as not yet recruiting)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Family history, if applicable
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history

  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

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

Type	Code	Description
CPT®	36012	Selective catheter placement, venous system: second order or more selective, branch
	37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)
HCPCS	None	

Policy History

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

Effective Date	Action
12/01/2025	New policy.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary or **Medical Necessity** means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I section 14059.5(a) and 22 CCR section 51303(a). Medically Necessary services must include services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.

For Members less than 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard of Medical Necessity set forth in 42

USC section 1396d(r)(5), as required by W&I sections 14059.5(b) and 14132(v). Without limitation, Medically Necessary services for Members less than 21 years of age include all services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support, or maintain the Member's current health condition. Contractor must determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the Child.

Criteria Determining Experimental/Investigational Status

In making a determination that any procedure, treatment, therapy, drug, biological product, facility, equipment, device, or supply is "experimental or investigational" by the Plan, the Plan shall refer to evidence from the national medical community, which may include one or more of the following sources:

1. Evidence from national medical organizations, such as the National Centers of Health Service Research.
2. Peer-reviewed medical and scientific literature.
3. Publications from organizations, such as the American Medical Association (AMA).
4. Professionals, specialists, and experts.
5. Written protocols and consent forms used by the proposed treating facility or other facility administering substantially the same drug, device, or medical treatment.
6. An expert physician panel selected by one of two organizations, the Managed Care Ombudsman Program of the Medical Care Management Corporation or the Department of Managed Health Care.

Feedback

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

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

Questions regarding the applicability of this policy should be directed to the Blue Shield of California Promise Health Plan Prior Authorization Department at (800) 468-9935, or the Complex Case Management Department at (855) 699-5557 (TTY 711) for San Diego County and (800) 605-2556 (TTY 711) for Los Angeles County or visit the provider portal at www.blueshieldca.com/en/bsp/providers.

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