


<b>PROVIDENCE HEALTH PLANS AND PROVIDENCE HEALTH ASSURANCE MEDICAL POLICY</b>	<b>Pelvic Congestion Syndrome Treatment</b>	
<b>Effective Date: 5/1/2019</b>   <div style="text-align: right;">5/1/2019</div>	Section: SUR	Policy No: 340
	Medical Policy Committee Approved Date: 5/17; 10/17; 4/19	
Medical Officer	Date	

**See Policy CPT CODE section below for any prior authorization requirements**

**APPLIES TO:**

All lines of business

**BENEFIT APPLICATION**

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) for coverage determinations.

For other lines of business, refer to the Policy Criteria section below:

**POLICY CRITERIA**

Note: This policy only applies to pelvic congestion syndrome in females and does not apply to any other condition.

Vascular embolization with percutaneous catheter techniques of the ovarian and/or internal iliac vein is considered **investigational and is not covered** as a treatment of pelvic congestion syndrome.

Link to [Policy Summary](#)

**BILLING GUIDELINES**

CPT code 37241 is not specific for the treatment of pelvic congestion syndrome and may be billed for other conditions, which may have medical necessity. This medical policy only applies to pelvic congestion syndrome in females.

CPT code 36012 may be billed in conjunction with 37241 for treatment of pelvic congestion syndrome in females, and therefore would be considered investigational per this policy.

The CPT code 75894 should not be billed in conjunction with 37241, as 75894 is considered a component of 37241. Therefore, if 75894 is requested with 37241 for pelvic congestion syndrome, then it will be denied as not separately reimbursable.

ICD-10 Diagnosis codes that may apply to this policy, include, but are not limited to:

- I86.2 Pelvic varices
- I87.2 Venous insufficiency (chronic) (peripheral)
- N94.89 Other specific conditions associated with female genital organs and menstrual cycle
- R10.2 Pelvic and perineal pain

## CPT CODE

### All Lines of Business

#### Prior-authorization Required

Note: This policy only applies to pelvic congestion syndrome and does not apply to any other condition.

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 (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)
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## DESCRIPTION

### Pelvic Congestion Syndrome

According to the ECRI Institute:<sup>2</sup>

“Pelvic congestion syndrome (PCS), also called chronic pelvic pain, is defined as continuous or intermittent noncyclic pain, localized to the pelvic region, which lasts for six or more months. PCS occurs when valves in the veins of the pelvic region leak and cause blood to flow backward and pool in the veins. Blood pooling in pelvic or ovarian veins may cause engorgement or thrombosis, causing pain and discomfort. Approximately one-third of all women will experience chronic pelvic pain in their lifetime; about 15% of outpatient gynecologist appointments are due to PCS, and the majority of patients are younger than 45 years of age. Risk factors associated with PCS include congestion of veins in the lower extremities, hormonal imbalance, multiple pregnancies, and polycystic ovarian syndrome.

Symptoms of PCS include the following:

- Pelvic pain that worsens toward the end of the day or after long periods of time standing
- Persistent lower-back pain
- Vaginal discharge

- Continuous or recurring pain for at least six months
- Initial sensation of fullness or heaviness, which can increase to severe pain, including during or after menstruation or intercourse

Imaging is performed to document characteristic pelvic venous changes. However, the presence of these abnormalities is not diagnostic.”<sup>2</sup>

### Treatment

There is no standard treatment for PCS, and optimum treatment is uncertain. Instead, therapy may be individualized and based on symptoms. Medical therapy with medroxyprogesterone acetate, etonogestrel insert, or gonadotropin-releasing hormone (GnRH) agonist is generally used as first line therapies for treatment of PCS. These therapies are low risk and non-invasive. Invasive treatments may be considered for patients who are refractory to medications, but the optimal therapy remains unknown. Methods such as sclerotherapy or embolization have been proposed as alternatives to surgical treatment.

The ECRI Institute describes the process of embolization of ovarian and internal iliac below:<sup>2</sup>

“Embolization of the ovarian vein and internal iliac veins, performed by interventional radiologists, is one procedure to treat these varicosities. During the embolization procedure, a catheter is guided to the affected vein and small coils are inserted to close off the vein. Blood flow is rerouted, reducing the pressure in the veins. Sclerosing agents, such as ethanol or sodium tetradecyl sulfate, may also be used to close the vein, either alone or in combination with the coils.”<sup>2</sup>

## **REVIEW OF EVIDENCE**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of vascular embolization and occlusion procedures as a treatment for pelvic congestion syndrome. Below is a summary of the available evidence identified through January of 2019. Due to the large number of studies that have evaluated the use of vascular embolization and occlusion procedures as a treatment for pelvic congestion syndrome, only recent systematic reviews and randomized controlled trials are described in detail below.

### Systematic Reviews and Technology Assessment

In 2015 Hansrani et al. published a systematic review that evaluated the effectiveness of trans-venous occlusion as a treatment of chronic pelvic pain, including 12 case series and one randomized controlled trial (RCT) (N= 866 women).<sup>3</sup> Statistically significant improvements in pelvic pain were reported in nine of the 13 studies. Technical success was reported in 865 of 866 (99.8%) of women with low complication rates: coil migration in 14 women (1.6%), abdominal pain in ten women (1.2%) and vein perforation in five (0.6%). However, heterogeneous outcome measures prevented between-study comparisons or estimates of treatment effects. The one RCT included in the review, which reported that embolization resulted in significantly better pain reduction than hysterectomy, had significant limitations and was deemed of low quality. The authors noted that all 13 studies were of poor methodological quality, and

most studies either lacked control groups or randomization, did not use objective outcome measures, and had inconsistent follow-up. The authors recommended that more high quality studies are needed that compare embolization, with other treatments.

In 2016 Mahmoud et al. also published the results of a systematic review that evaluated vein embolization for PCS, including 20 case series (N=1081 patients).<sup>4</sup> The length of follow-up in the included studies ranged from one month to six years. Overall, 571 patients (88.1%) reported short-term symptom relief and 77 patients (11.9%) reported little or no relief. Seventeen studies (n=721 patients) reported symptom relief at 12 months. Only one study used a comparison group, but patients in it received conservative treatment because they were ineligible for vein embolization therapy, so outcomes based on intervention cannot be compared.

In 2016, Champaneria et al. published a health technology assessment on behalf of the United Kingdom-based National Institute for Health Research Health Technology Assessment Programme that evaluated treatments for pelvic vein incompetence and chronic pelvic pain in women, including 21 case series and one poor-quality RCT.<sup>5,6</sup> Similar to the Hansrani review described above, the overall low quality and heterogeneity between included studies precluded a meta-analysis from being performed. However, the reviewers reported that approximately 75% of women who underwent embolization experienced substantial relief of pain that occurred early after treatment which was sustained. Adverse events noted included, transient pain following embolization and a <2% risk of coil migration.

No additional studies, trials or otherwise, were identified since the publication of the systematic reviews described above. Only key studies included in the systematic reviews are described in the following sections.

#### Randomized Controlled Trials (RCTs)

In 2003, Chung and Huh published the results of an RCT that compared the efficacy of ovarian and/or internal iliac vein coil embolization to two different hysterectomy treatments (unilateral or bilateral ovary removal) for the treatment of PCS, including 106 patients refractory to medication.<sup>7</sup> Pain, as measured by visual analog scale (VAS) significantly improved 12 months post-procedure from 7.7 to 7.8 at baseline in all groups to: 3.2 in embolization patients (n=52); 4.6 in bilateral oophorectomy patients (n=27); and 5.6 in unilateral oophorectomy patients (n=27) (p<0.05 for the embolization group versus the surgical groups). Mean hospitalization times were 0.3 days for the embolization group versus 2.3 days for the surgery groups. To date, this RCT is the only RCT that has been published for embolization as a treatment for PCS and has a number of limitations including the following: the randomization protocol was not described, hysterectomy patients were not blinded to their treatment allocation; the sample sizes per group were small, and there was a discrepancy between reported outcomes within the publication.

In 2017, Guirola et al. published one-year outcomes from a single-center RCT which compared two different embolization devices, fibered platinum coils (FPC) versus vascular plugs (VP), in 100 women with PCS.<sup>8</sup> Patients were randomized to either FPC (n=50) or VP (n=50). Clinical success and subjective improvement were not significantly different between treatment groups at 1-year follow-up (89.7% for FPCs vs 90.6% for VPs; p = 0.760). The investigators acknowledged that there were significant differences between groups in age and pre-treatment VAS scores, both of which were slightly higher in

the VP group despite randomization. Longer-term outcomes are needed to evaluate embolization procedures for the treatment of PCS.

#### Nonrandomized Studies

In 2006, Richardson and Driver published the results of a retrospective study that compared patient-reported VAS scores from ovarian vein coil embolization and sclerosis to that of surgical ligation.<sup>9</sup> Seventy one patient surveys were conducted on average 69 months (range 2 to 156) post-procedure and were focused on VAS for pain. The surgical group included both a historical group and a group treated contemporaneously with the embolization group. Approximately 50% of the surgical group and 75% of the embolization group responded to the questionnaire. Because of the inclusion of the historical surgery group, the mean overall follow-up was 99 months for the surgical group and 22 months for the embolization group. Mean pain scores on VAS decreased significantly in both groups, from 6.5 to 4.0 at follow-up for embolization patients and from 6.8 to 4.0 for surgical patients; however, the difference between the treatment groups was not significant. There was also no difference in overall satisfaction with the procedure.

In 2006, Kim et al. published the results of a large prospective case series of 127 patients; the majority of which had bilateral ovarian vein embolization using coils and sclerosant, with subsequent embolization of internal iliac veins with sclerosant alone.<sup>10</sup> At a mean follow-up of 45 months, 30 patients were lost to follow-up and the mean overall pain VAS score of the remaining patients had decreased from 7.6 to 2.9 ( $p<0.01$ ). Treatment response was observed in 80/97 (83%) patients, while 13% of patients had no change and 4% had a worsening of symptoms post-treatment. Of patients with a treatment response, 64/80 (80%) reported significant improvement, 11 (14%) reported moderate improvement, and 5 (6%) reported only a slight improvement. In terms of adverse effects, two patients experienced migration of the coils that were retrieved with no lasting effects.

In 2007, Kwon et al. published the results of a retrospectively analysis of 67 patients treated with coil embolization of ovarian veins using medical records and phone interviews.<sup>11</sup> At 45 months follow-up, the authors reported a clinical success rate of 82%; five patients reported complete absence of symptoms, 50 patients reported significant reduction in symptoms, 10 had no change, and 2 reported worsening of symptoms. Similar to the Kim study above, adverse event rates were low, with two patients experienced migration of the coils.

Also in 2007, Creton et al. prospectively followed 24 patients treated with ovarian vein embolization using coils for 3 years.<sup>12</sup> The global symptom score (comprised of three 10-point VAS scores) decreased from 15.3 of a possible 30 points pre-treatment to 3.0 post-treatment. Improvement of symptoms was reported by all patients except one.

In 2009, Ascitutto et al. published the results of a small retrospective case series, including 35 patients with symptomatic PCS.<sup>13</sup> Patients were treated with coil embolization of the ovarian vein ( $n=28$ ), internal iliac vein ( $n=5$ ), or both ( $n=2$ ) and followed up to three years. Patients with isolated ovarian vein incompetence treated with embolization had a significant improvement in symptoms (mean symptom score 5.2 pre-treatment versus 1.2 post-treatment;  $p<0.0001$ ). Patients with isolated internal iliac vein incompetence who were treated with embolization also improved (mean symptom score 5.1 before and 2.1 after treatment) although the change was not statistically significant. In the two cases of combined

ovarian vein and internal iliac vein, isolated embolization of the affected ovarian vein did not improve symptoms (mean score 5.2 pre-treatment versus 5.1 post-treatment), while coiling of subsequent iliac vein resulted in symptom reduction (mean score 5.6 pre-treatment versus 3.2 post-treatment); however, this did not reach statistical significance due to the small numbers of patients.

Additional prospective and retrospective case series have been published regarding the clinical outcomes of embolization therapy for patients with PCS.<sup>14-28</sup> However, these nonrandomized studies suffer from one or more of the following limitations:

- Small sample sizes
- Lack of comparator groups
- Retrospective study design
- Heterogeneity within and between studies with regards to:
  - co-treatments
  - patient selection
  - outcomes evaluating treatment “success”

Well-designed RCTs with larger patient populations and longer-term outcomes are needed to further evaluate the efficacy of embolization procedures for treatment of PCS.

## **CLINICAL PRACTICE GUIDELINES**

Society for Vascular Surgery and the American Venous Forum

In 2011, the evidence-based clinical practice guidelines for the Society for Vascular Surgery and the American Venous Forum recommended the following:<sup>29</sup>

- Suggest treatment of pelvic congestion syndrome and pelvic varices with coil embolization, plugs, or transcatheter sclerotherapy, used alone or together. This recommendation was given a GRADE score of 2B: a weak recommendation indicating that the benefits closely balanced with risks and burden based on medium quality evidence.

## **CENTERS FOR MEDICARE & MEDICAID**

As of 02/05/2019, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which specifically addresses embolization or occlusion procedures as treatments for pelvic congestion syndrome.

## **POLICY SUMMARY**

There is not enough evidence to consistently show that embolization and other occlusion techniques improves chronic pelvic pain or other health outcomes for people with pelvic congestion syndrome (PCS) compared to other treatments. Comparative studies, ideally randomized trials, comparing embolization to other surgical and nonsurgical treatments for PCS are needed to determine the effectiveness of this treatment. In addition, there are no evidence-based clinical practice guidelines

which strongly support embolization as a treatment of PCS. Therefore, occlusion techniques including but not limited to embolization of ovarian and/or internal iliac veins are considered investigational for the treatment of pelvic congestion syndrome.

## **INSTRUCTIONS FOR USE**

Providence Health Plan (PHP) and Providence Health Assurance (PHA) Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. PHP and PHA Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. PHP and PHA reserve the right to determine the application of Medical Policies and make revisions to its Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

## **REGULATORY STATUS**

### Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

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