Kansas City
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# Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome

**Policy Number:** 4.01.18 **Last Review:** 11/2018
**Origination:** 11/2008 **Next Review:** 11/2019

## Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for ovarian and internal iliac vein embolization as a treatment of pelvic congestion syndrome. This is considered investigational.

## When Policy Topic is covered

Not Applicable

## When Policy Topic is not covered

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

## Description of Procedure or Service

| Populations | Interventions | Comparators | Outcomes |
|---|---|---|---|
| Individuals:<br>• With pelvic congestion syndrome | Interventions of interest are:<br>• Ovarian and/or internal iliac vein embolization | Comparators of interest are:<br>• Medical therapy (eg, analgesics, hormonal therapy)<br>• Surgical ovarian vein ligation | Relevant outcomes include:<br>• Symptoms<br>• Treatment-related morbidity |

Pelvic congestion syndrome is characterized by chronic pelvic pain that is often aggravated by standing; diagnostic criteria for this condition are not well-defined. Embolization of the ovarian and internal iliac veins has been proposed as a treatment for patients who fail medical therapy.

For individuals who have pelvic congestion syndrome who receive ovarian and/or internal iliac vein embolization, the evidence includes case series and a systematic review. Relevant outcomes are symptoms and treatment-related morbidity. According to a systematic review of case series data, approximately 80% of patients have reported some degree of symptom relief 12 months after ovarian and/or internal iliac vein embolization. It is difficult to draw conclusions from these

data because of a lack of a placebo control or comparative data from alternative interventions. Moreover, definitions of pelvic congestion syndrome vary, making it challenging to clearly define a patient population with symptoms arising from pelvic congestion. Randomized controlled trials using well-defined eligibility criteria are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Background

Pelvic congestion syndrome is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia and postcoital pain and aggravated by standing. 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. Because there are many etiologies of chronic pelvic pain, the pelvic congestion syndrome is often a diagnosis of exclusion, with the identification of varices using a variety of imaging methods, such as magnetic resonance imaging, computed tomography scanning, or contrast venography. However, the syndrome is still not well defined and it is unclear whether pelvic congestion syndrome causes chronic pelvic pain.[1] Although venous reflux is common, not all women with this condition experience chronic pelvic pain and, conversely, chronic pelvic pain is reported by women without pelvic congestion syndrome.

Initial treatment of pelvic congestion syndrome includes psychotherapy and medical therapy (eg, nonsteroidal anti-inflammatory drugs) and hormonal therapy. For patients who fail initial therapy, surgical ligation of the ovarian vein may be considered. Embolization therapy of the ovarian and internal iliac veins 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.

### 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.

Various materials (eg, coils, glue, gel foam) would be used to embolize the vein(s), and they would be subject to Food and Drug Administration regulation. Several products have been cleared for marketing by the Food and Drug Administration through the 510(k) process for uterine fibroid embolization (eg, Embosphere® Microspheres, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles) and/or embolization of hypervascular tumors and arteriovenous malformations (eg, Contour® Emboli PVA).

## Rationale

This evidence review was created in April 2004 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through June 7, 2018.

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 one or more intended clinical use 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 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

No randomized controlled trials have been published comparing embolization therapy for pelvic congestion syndrome with an alternative or sham/placebo treatment. The published evidence consists of case series, most of which were retrospective and conducted outside of the United States. Complicating the literature on this indication is a lack of standardized diagnostic criteria.

## Clinical Context and Therapy Purpose

The purpose of ovarian and/or internal iliac vein embolization in patients who have pelvic congestion syndrome is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of ovarian and/or internal iliac vein embolization improve the net health outcome in patients with pelvic congestion syndrome?

The following PICOTS were used to select literature to inform this review.

### *Patients*

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

### *Interventions*

The therapies being considered are ovarian and internal iliac vein embolization.

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

### *Outcomes*
The general outcomes of interest are symptom reduction (eg, pain related to varicose veins) and adverse events.

### *Timing*
Procedural follow-up ranges from 1 to 3 months.

### *Setting*
Ovarian and internal iliac vein embolization are minimally invasive procedures performed under sedation in the radiology inpatient or outpatient settings.

## Systematic Reviews
Tu et al (2010) published a systematic review of literature on the diagnosis and management of pelvic congestion syndrome.[2] They 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.

A systematic review by Mahmoud et al (2016) identified 20 case series (total N=1081 patients) assessing vein embolization for pelvic congestion syndrome.[3] Reviewers did not require any particular diagnostic criteria for pelvic congestion syndrome. The length of follow-up in the studies ranged from 1 month to 6 years. Seventeen studies (n=648 patients) reported on the proportion of patients who reported symptom relief. Overall, 571 (88.1%) patients reported short-term symptom relief and 77 (11.9%) reported little or no relief. Seventeen studies (n=721 patients) reported symptom relief at 12 months. A total of 88.6% had symptom improvement, and 13.4% reported little or no relief. 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.

## Case Series
Tables 1 and 2 summarize the characteristics and results of select case series that have reported on symptom improvements in patients with pelvic congestion syndrome treated with vein embolization.

**Table 1. Summary of Key Case Series Characteristics for Pelvic Congestion Syndrome**

| Study | Country | Participants | Treatment Delivery | Follow-Up, mo |
|---|---|---|---|---|
| **Hocquelet et al (2014)[4]** | France | 33 | Vein embolization | 26 |
| **Nasser et al (2014)[5]** | Brazil | 113 | Vein embolization | 12 |

| | | | | |
|---|---|---|---|---|
| **Laborda et al (2013)[6]** | Spain | 202 | Vein embolization | 60 |
| **Gandini et al (2008)[7]** | Italy | 38 | Vein embolization | 12 |
| **Kwon et al (2007)[8]** | Korea | 67 | Vein embolization | 45 |
| **Kim et al (2006)[9]** | U.S. | 127 | Vein embolization | 45 |

**Table 2. Summary of Key Case Series Results for Pelvic Congestion Syndrome**

| Study | Treatment | Clinical Outcome (at Least Substantial Improvement in Symptoms), % |
|---|---|---|
| **Hocquelet et al (2014)[4]** | Vein embolization | 94 (61 complete, 33 partial) |
| **Nasser et al (2014)[5]** | Vein embolization | 100 (53 complete, 47 partial) |
| **Laborda et al (2013)[6]** | Vein embolization | 94 (34 complete)[a] |
| **Gandini et al (2008)[7]** | Vein embolization | 100 |
| **Kwon et al (2007)[8]** | Vein embolization | 82 |
| **Kim et al (2006)[9]** | Vein embolization | 83 |

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

## Summary of Evidence

For individuals who have pelvic congestion syndrome who receive ovarian and/or internal iliac vein embolization, the evidence includes case series and a systematic review. Relevant outcomes are symptoms and treatment-related morbidity. According to a systematic review of case series data, approximately 80% of patients have reported some degree of symptom relief 12 months after ovarian and/or internal iliac vein embolization. It is difficult to draw conclusions from these data because of a lack of a placebo control or comparative data from alternative interventions. Moreover, definitions of pelvic congestion syndrome vary, making it challenging to define a patient population with symptoms arising from pelvic congestion. Randomized controlled trials using well-defined eligibility criteria are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Supplemental Information

### Practice Guidelines and Position Statements

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.[10]

### 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 trials that might influence this review are listed in Table 3.

### Table 3. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| **Ongoing** | | | |
| **NCT01909024[a]** | Pelvic Embolisation to Reduce Recurrent Varicose Veins - Recurrent | 270 | Dec 2018 |

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

References

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# Billing Coding/Physician Documentation Information

**36012** Selective catheter placement, venous system; second order, or more selective, branch (eg, left adrenal vein, petrosal sinus)

**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)

**ICD-10 Codes**

**N94.89** Other specified conditions associated with female genital organs and menstrual cycle.

There are no specific CPT codes for this procedure. The nonspecific CPT codes above may be used.

## Additional Policy Key Words

N/A

## Policy Implementation/Update Information

11/1/08 New policy; considered investigational.
11/1/09 No policy statement changes.
11/1/10 No policy statement changes.
11/1/11 No policy statement changes.
11/1/12 No policy statement changes.
11/1/13 No policy statement changes.
4/1/14 Removed deleted cpt code 37204.
11/1/14 No policy statement changes.
11/1/15 No policy statement changes.
11/1/16 No policy statement changes.
11/1/17 No policy statement changes.
11/1/18 No policy statement changes.