

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	Ovarian and Internal Iliac Vein Endovascular Occlusion as a Treatment of Pelvic Congestion Syndrome
Policy Number	4.01.10
Category	Technology Assessment
Original Effective Date	03/15/22
Committee Approval Date	11/18/21, 09/15/22, 09/21/23, 09/19/24
Current Effective Date	09/19/24
Archived Date	N/A
Archive Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> • Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. • If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. • If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. • If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY STATEMENT

Based upon our criteria and the lack of peer-reviewed literature, endovascular occlusion of the ovarian and/or internal veins has not been medically proven to be effective and, therefore, is considered **investigational** for the treatment of pelvic congestion syndrome.

Refer to Corporate Medical Policy #7.01.47 Varicose Vein Treatments

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

The American College of Obstetricians and Gynecologists (ACOG) defines chronic pelvic pain as “pain symptoms perceived to originate from pelvic organs/structures typically lasting more than six months. It is often associated with negative cognitive, behavioral, sexual and emotional consequences as well as with symptoms suggestive of lower urinary tract, sexual, bowel, pelvic floor, myofascial, or gynecological dysfunction.” Therefore, diagnostic criteria may be difficult to discern, as well as multifactorial in nature.

Pelvic congestion syndrome (PCS) has also been known as pelvic venous disorder, pelvic venous insufficiency, pelvic venous incompetence, or pelvic venous reflux, with the nomenclature often being used interchangeably. PCS is proposed to be a cause of chronic pelvic pain, deriving from varicosities in the ovarian or internal iliac veins. It is described as a syndrome of variable pain location and intensity, associated with dyspareunia and postcoital pain, is aggravated by standing or exercise and typically occurs during the reproductive years. It is estimated that up to 47% of women have pelvic varicosities, and although common, not all women with pelvic varicosities experience chronic pelvic pain, and conversely, chronic pelvic pain is reported by women without evidence of pelvic congestion. The diagnosis of PCS is

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typically one of exclusion, utilizing different imaging methods such as magnetic resonance imaging (MRI), computed tomography (CT), laparoscopy or contrast venography.

Conservative treatment options for PCS include psychotherapy, non-steroidal anti-inflammatories, and hormonal therapy. For patients who do not respond to these initial therapies, surgical ligation of the ovarian vein may be considered.

Embolization and sclerotherapy are two treatments that have been proposed as less-invasive alternatives which consist of accessing the vasculature via catheter through the jugular or femoral arteries. Under imaging guidance, the catheter is directed through the femoral vein to the veins in question. Once in place, the vein will either be injected with medication (sclerotherapy), and/or coils, plugs, glue, liquid embolic agents, gelatin sponge or powder (Gelfoam) will be inserted to occlude the impacted veins (embolization). The procedure is typically performed on an outpatient basis.

Surgical procedures are not subject to regulation by the United States Food and Drug Administration (FDA), however various products used in vein embolization (e.g., coils, vascular plugs, glue, liquid embolic agents, Gelfoam) and their delivery assist devices are subject to regulation. Several products have been cleared through the 510 (k) process for uterine fibroid embolization and/or embolization of hypervascular tumors and arteriovenous malformations (e.g., Embosphere Microspheres, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles, Contour Emboli PVA).

RATIONALE

The literature regarding outcomes of individuals with PCS who receive pelvic vein embolization consists of randomized studies, comparative studies, case series, and systematic reviews, however, has been described by the Journal of Vascular and Interventional Radiology (Black et al, 2010) as, and still remains, “limited due to nonstandardized reporting, incomplete follow-up, and the use of variable measures of outcome”.

In a systematic review by Daniels et al. (2016) with a search of databases dating from inception to November of 2013, authors aimed to critically review the effectiveness of embolization of incompetent pelvic veins. No language or study design restrictions were applied in the search criteria. Of the studies identified, 140 full texts were retrieved, and 22 articles were included in the final review. Of those included, 20 were case series, one study was unable to be reliably assessed after translation, and only one was a randomized trial, which was deemed poor quality by the authors (Chung and Huh, 2003), as it compared embolization to hysterectomy and was likely subject to several biases. Authors state that all estimates of effectiveness come from what they believe to be prospective case series of 1,308 women, with early relief of pain noted in approximately 75% of 162 women in six case series, which was sustained. One-third of the studies that were selected did not clearly describe intended outcome measures or the collection process, had no report of symptoms at two time points, and few stated the impacts on menstruation and fertility. Although the data supported the safety and efficacy of embolization, the quality of the evidence is poor.

In a retrospective study of 617 patients diagnosed with pelvic venous disorders, DeGregorio et al. (2020) aimed to determine the efficacy and safety of pelvic vein embolization. A total of 520 women were included in the analysis. Inclusion criteria involved a diagnosis of varicose veins in the pelvis with a diameter of 6 mm or more based on doppler ultrasound (US), and symptoms greater than six months. Patients underwent embolization of the four main pelvic veins when possible, and follow-up consisted of VAS survey and doppler US. Technical success was defined as embolization of the four main pelvic veins, and occurred in 84.4% of patients. Of the total patients treated, 261 women underwent embolization using coils and 259 with Amplatzer vascular plugs (AVP). The average follow-up time frame was 58.7 months and a total of 484 patients (93.07%) completed five years of follow-up. VAS improved from 7.63 to 0.91 at the five-year mark. Results showed 26 patients (5%) experienced symptom recurrence. There were nine cases of coil migration (1.9 %). The authors state late migration of metallic devices to the lung can be seen in routine chest radiographs, and could be an important concern. Discussion remains as to the homogeneity of endovascular therapeutic modalities, the selection of the embolic agents, and the number of veins needed to be treated.

To date, no randomized controlled trials have been published comparing endovascular occlusion for PCS with a relevant comparator or sham/placebo treatment. Hindering the development of clinical trials with sound methodology are the varying definitions of pelvic pain, as well as the lack of specified explicit diagnostic criteria for PCS. Several consensus panels have been funded over time attempting to identify research priorities (Black et al., 2010; Champaneria et al., 2016;

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Khilnani et al., 2019) to address these limitations. International panels have met to create a discriminative classification instrument for PCS, but to date, the tools have not been validated or widely accepted.

There is insufficient evidence to conclude that there is a cause-effect relationship between venous congestion and chronic pelvic pain. Randomized controlled trials using well-defined eligibility criteria and relevant comparators or sham/placebo treatments are needed to determine the effects of the treatment on health outcomes.

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN).

CPT Codes

Code	Description
37241 (E/I)*	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). (*E/I for the ICD-10-CM diagnosis codes listed below)
75894 (E/I)*	Transcatheter therapy, embolization, any method, radiological supervision and interpretation. (*E/I for the ICD-10-CM diagnosis codes listed below)

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ICD10 Codes

Code	Description
I86.2	Pelvic varices
N94.89	Other specified conditions associated with female genital organs and menstrual cycle
R10.2	Pelvic and perineal pain

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*Key Article

KEY WORDS

Pelvic venous disorder, Pelvic congestion syndrome, pelvic reflux, pelvic venous incompetence, pelvic vein insufficiency, ovarian vein, iliac vein, ligation, embolization.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon review, ovarian and internal iliac vein endovascular occlusion as a treatment of pelvic congestion syndrome is not specifically addressed in a National or Local Medicare coverage determination or policy. However, there is currently a National Coverage Determination (NCD) for Therapeutic Embolization (20.28). Please refer to the following NCD website for Medicare Members:

<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=52&ncdver=1&Keyword=Therapeutic%20emboli&KeywordLookUp=Title&KeywordSearchType=Exact&bc=CAAAAAAAAAAAAA> accessed 07/31/24.