

EMBOLIZATION OF THE OVARIAN AND ILIAC VEINS FOR PELVIC CONGESTION SYNDROME

Policy Number: 2018T0574H

Effective Date: December 1, 2018

[Instructions for Use](#) ⓘ

Table of Contents	Page
COVERAGE RATIONALE	1
DEFINITIONS	1
APPLICABLE CODES	1
DESCRIPTION OF SERVICES	2
CLINICAL EVIDENCE	2
U.S. FOOD AND DRUG ADMINISTRATION	3
CENTERS FOR MEDICARE AND MEDICAID SERVICES	4
REFERENCES	4
POLICY HISTORY/REVISION INFORMATION	4
INSTRUCTIONS FOR USE	5

Related Commercial Policy

- [Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins](#)

Community Plan Policy

- [Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome](#)

COVERAGE RATIONALE

Embolization of the ovarian or internal iliac veins is unproven and not medically necessary for treating Pelvic Congestion Syndrome due to insufficient evidence of efficacy.

DEFINITIONS

Embolization: A procedure that allows for the blockage of blood flow in targeted blood vessels using clotting or sclerosing agents, such as coils, gel, or foam, applied directly to an area that is bleeding.

Fluoroscopy: A radiological imaging technique that converts real-time X-rays from an X-ray machine into video images, usual for guiding diagnostic and interventional procedures.

Internal Iliac Vein (Hypogastric Vein): Veins that originate deep in the pelvic region and extend to the lower portion of the abdomen, where they are joined with the right and left iliac veins, that together form the common iliac veins.

Ovarian Vein: One of a pair of veins that emerge from the broad ligament near the ovaries and the uterine tubes.

Pelvic Congestion Syndrome (PCS): A syndrome involving chronic pelvic pain usually associated with the Varices or Varicosities in the pelvic area.

Varices or Varicosities: Abnormally enlarged or twisted blood vessels.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

Coding Clarification:

- According to the American Medical Association (AMA), CPT code 37241 is specific to venous embolization or occlusion and excludes lower extremity venous incompetency. Coding instructions state that 37241 should not be used to report treatment of incompetent extremity veins.

- For sclerosis of veins or endovenous ablation of incompetent extremity veins, see 36468-36479 (CPT Assistant, 2014).

CPT Code	Description
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)

CPT® is a registered trademark of the American Medical Association

ICD-10 Diagnosis 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

DESCRIPTION OF SERVICES

Pelvic Congestion Syndrome (PCS), also known as pelvic venous incompetence (PVI), causes noncyclic pelvic pain and discomfort, lasting for at least 6 months, and typically affects women of reproductive age. Varicosities of the Ovarian Veins and/or Internal Iliac Veins are believed to lead to PCS. For those patients who fail to adequately respond to conventional treatments (i.e., pharmacological therapy or surgical intervention), embolization therapy of the Ovarian Vein and/or Internal Iliac Vein has been proposed as an alternative (Nasser et al., 2014).

Patients with PCS may be treated with Ovarian Vein embolization following venography to visualize the affected veins (Bittles et al., 2008; Nasser et al., 2014). Under fluoroscopic guidance, an interventional radiologist guides a catheter to the affected vein, and inserts inert embolic agents to completely seal the vein. As a result, blood flow is rerouted, thereby reducing pressure within the targeted veins. Several types of embolic agents may be used, and include, but are not limited to, metal coils, sclerosing agents, and gelatin sponges. These agents may either be temporary or permanent. Since the Ovarian Veins and Internal Iliac Veins are in close proximity, embolization of the Internal Iliac Veins may also be necessary (Nasser et al., 2014).

CLINICAL EVIDENCE

Guirola et al. (2017) provided one-year outcomes from a randomized, prospective, single-center study which compared fibered platinum coils (FPC) versus vascular plugs (VP) in 100 women with pelvic congestion syndrome (PCS). Patients were randomized to either FPC (n=50) or VP (n=50). Primary outcome (clinical success at 1 year using a VAS), number of devices, procedure and fluoroscopy times, radiation doses, costs, and complications were compared, and participants were followed at 1, 3, 6, and 12 months. Clinical success and subjective improvement were not significantly different at 1-year follow-up (89.7% for FPCs vs 90.6% for VPs; P = .760). The authors concluded that embolization for PCS resulted in pain relief in 90% of patients; clinical success was not affected by embolic device. Longer-term outcomes are needed to evaluate embolization procedures for the treatment of PCS.

In a single-center case series, Laborda et al. (2013) reported long-term results in 202 women with chronic pelvic pain (CPP). Inclusion criteria were: lower limb varices and CPP for more than 6 months, pelvic veins >6mm on ultrasonography, and either venous reflux or presence of communicating veins. The primary outcomes were pain assessment using a visual analog scale (VAS), and patient satisfaction. Technical and clinical successes were also evaluated as secondary outcomes. Follow-up evaluations were conducted at 1, 3, and 6 months, and each year thereafter for 5 years. At 5-years of follow-up, 11% of women were lost to follow-up, while 89% were available for evaluation. Study results demonstrated a significant improvement in pain symptoms (7.34±0.7 at baseline versus 0.78±1.2 at follow-up; P<0.0001). Technical success was considered 100%. Clinical success was observed in nearly 94% of all patients and approximately 33% experienced complete resolution of symptoms. Mean individual satisfaction scores were 7.39 [standard deviation (SD), 1.5; scale 0-9]. Major complications included four cases of coil migration and six cases of groin hematoma. Methodological limitations of this study include the case series design, the lack of appropriate controls for comparison, and the lack of diagnostic criteria during the patient selection process.

Nasser et al. (2014) conducted a retrospective review (n=113) in women with PCS who underwent embolization of the ovarian and pelvic varicose veins. The primary outcome was pain assessment using VAS. Patients were followed for a period of one year. Of the 113 included patients, 13 (10%) were lost to follow-up. At the end of follow-up, 37% had complete resolution of symptoms, 53% of patients had no pelvic pain and 47% had partial pain relief. There was also a significant reduction in the mean score of total associated symptoms at 12 months (2.69 at baseline to 0.92 at post-

procedure). Complications were considered relatively minimal, with four cases of coil migrations. No other serious complications were reported.

In a smaller case series, Hocquet et al. (2013) assessed the safety and efficacy of embolization for PCS (n=33). Average duration of follow-up was 26 months (range, 3-59). Patients experienced a significant reduction in pain following the procedure. The average VAS at baseline was 7.37 (SD, 0.99) compared with 1.36 (SD, 1.73) after embolization (P<0.0001). A total of 20 patients (~61%) had complete symptom resolution, 11 patients (~33%) had partial resolution, and 2 patients (6%) had no improvement.

Additional prospective and retrospective case series evaluated a small number of patients with PCS (Marcelin et al., 2017; Siqueira et al., 2016; Nasser et al., 2014; Castenmiller et al., 2013; Laborda et al., 2013; Meneses et al., 2013; Smith et al., 2012; Tinelli et al., 2012; Mallios et al., 2011). Well-designed randomized controlled trials with a larger patient population and longer term outcomes are needed to further evaluate embolization procedures for pelvic congestion syndrome.

In an evaluation of pelvic vein embolization indications, techniques and outcomes, Lopez (2015) summarized that evidence remains poor for its efficacy, and although initially anecdotal by way of case reports and small series, data is accumulating in larger series. There remains, however, a lack of robust evidence of its effectiveness, and this partly reflects the challenges of actually making the diagnosis clinically and radiologically, as well as the difficulty in assessing outcome. For pelvic congestion syndrome, symptomatic response is usually subjective but visual analogue scales (or variations thereof) have most often been used to attempt to identify a more objective outcome.

Daniels et al. (2016) conducted a systematic review to evaluate the effectiveness of embolization of incompetent pelvic veins performed to reduce CPP. Twenty-one prospective case series and one poor-quality randomized trial of embolization (involving a total of 1,308 women) were identified. The authors found that early substantial relief from pain was observed in approximately 75% of women undergoing embolization, and generally increased over time and was sustained. In addition, significant pain reductions following treatment were observed in all studies that measured pain on a visual analog scale. Repeat intervention rates were generally low. There were few data on the impact on menstruation, ovarian reserve, or fertility, but no concerns were noted. Transient pain was common following foam embolization, and there was a < 2% risk of coil migration. In the authors' opinion, embolization appears to provide symptomatic relief of CPP in the majority of women and is safe, although the quality of the evidence is low.

Hansrani et al. (2015) conducted a well-designed systematic review of the literature to evaluate the safety and effectiveness of transvenous occlusion of incompetent pelvic varicosities. Study authors selected 13 studies (n=866) that evaluated patients had CPP, PCS, or pelvic pain. The interventions generally consisted of transvenous occlusion of the ovarian and internal iliac veins (via the femoral or jugular veins) using metallic coils, sclerosants, or glue. A total of 10 studies were prospective uncontrolled, 2 were retrospective, and 1 was a randomized controlled trial (RCT) that included untreated controls. In 9 of 13 studies, patients experienced significant improvement in pelvic pain and other PCS symptoms following embolization of the pelvic varicosities when compared with baseline symptoms. One study reported 13% of recurrence at 5 years of follow-up. Embolization was generally considered technically successful, with 98 to 100% of veins occluded at first attempt. Adverse events included coil migration in 1.6% of patients, abdominal pain in 1.2%, and vein perforation in 0.6%. One serious complication was reported as coil migration to the lungs.

Professional Societies

Society for Vascular Surgery (SVS)/ American Venous Forum (AVF)

In a guideline published by the SVS and the AVF in 2011, guideline authors suggest "treatment of pelvic congestion syndrome and pelvic varices with coil embolization, plugs, or transcatheter sclerotherapy, used alone or together (2B)." The 2B recommendation indicates a "weak" recommendation based on moderate quality evidence, where the benefits of the technology are considered closely balanced with risks and burdens (Gloviczki et al., 2011).

Other professional society clinical guidelines that address embolization procedures for pelvic congestion syndrome were not identified.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Numerous products used for vascular embolization, including sclerosing agents, and other substances, have been approved by the FDA. These products are generally classified under the product code: KRD (device, vascular, for promoting embolization), indexed in the Center for Devices and Radiological Health (CDRH) 510(k) database or Premarket Search Strategy. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>. (Accessed February 7, 2018)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) specific to embolization of the ovarian and iliac veins for pelvic congestion syndrome. However, there is a general NCD for [Therapeutic Embolization \(20.28\)](#). Local Coverage Determinations (LCDs) do not exist at this time. (Accessed January 17, 2018)

REFERENCES

- American Medical Association. Current Procedural Terminology: CPT Professional Edition. AMA Press.
- Bittles M, and Hoffer E. Gonadal vein embolization: treatment of varicocele and pelvic congestion syndrome. *Semin Intervent Radiol*. 2008 Sep;25(3):261-70.
- Castenmiller PH, de Leur K, de Jong TE, et al. Clinical results after coil embolization of the ovarian vein in patients with primary and recurrent lower-limb varices with respect to vulval varices. *Phlebology*. 2013 Aug;28(5):234-8.
- Daniels JP, Champaneria R, Shah L, et al. Effectiveness of embolization or sclerotherapy of pelvic veins for reducing chronic pelvic pain: a systematic review. *J Vasc Interv Radiol*. 2016 Oct;27(10):1478-1486.
- Gloviczki P, Comerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg*. 2011; 53:2S-48S.
- Guirola JA, Sánchez-Ballester M, Sierre S, et al. A randomized trial of endovascular embolization treatment in pelvic congestion syndrome: fibered platinum coils versus vascular plugs with 1-year clinical outcomes. *J Vasc Interv Radiol*. 2017 Nov 22. [Epub ahead of print].
- Hansrani V, Abbas A, Bhandari S, et al. Trans-venous occlusion of incompetent pelvic veins for chronic pelvic pain in women: a systematic review. *European Journal of Obstetrics & Gynecology and Reproductive Biology*. 2015; 185:156-163.
- Hayes, Inc. Hayes Search & Summary. Percutaneous transcatheter coil embolization for pelvic congestion syndrome (PCS). Lansdale, PA: Hayes, Inc; March 2017.
- Hocquet A, Bras YL, Balian E, et al. Evaluation of the efficacy of endovascular treatment of pelvic congestion syndrome. *Diagnostic and Interventional Imaging*. 2014; 95:301-306.
- Laborda A, Medrano J, de Blas I, et al. Endovascular treatment of pelvic congestion syndrome: visual analog scale (VAS) long-term follow-up clinical evaluation in 202 patients. *Cardiovasc Intervent Radiol*. 2013 Aug;36(4):1006-14.
- Lopez, AJ. Female pelvic vein embolization: indications, techniques, and outcomes. *Cardiovasc Intervent Radiol* (2015) 38:806–820.
- Meneses L, Fava M, Diaz P. Embolization of incompetent pelvic veins for the treatment of recurrent varicose veins in lower limbs and pelvic congestion syndrome. *Cardiovasc Intervent Radiol*. 2013; 36(1):128-132.
- Mallios A, Laurian C, Houballah R, et al. Curative treatment of pelvic arteriovenous malformation--an alternative strategy: transvenous intra-operative embolisation. *Eur J Vasc Endovasc Surg*. 2011 Apr;41(4):548-53.
- Marcelin C, Izaaryene J, Castelli M, et al. Embolization of ovarian vein for pelvic congestion syndrome with ethylene vinyl alcohol copolymer (Onyx®). *Diagn Interv Imaging*. 2017 Jun 21. pii: S2211-5684(17)30152-3.
- Nasser F, Cavalcante RN, Affonso BB, et al. Safety, efficacy, and prognostic factors in endovascular treatment of pelvic congestion syndrome. *Int J Gynaecol Obstet*. 2014; 125(1):65-68.
- Siqueira FM, Monsignore LM, Rosa-E-Silva JC, et al. Evaluation of embolization for periuterine varices involving chronic pelvic pain secondary to pelvic congestion syndrome. *Clinics (Sao Paulo)*. 2016 Dec 1;71(12):703-708.
- Smith PC. The outcome of treatment for pelvic congestion syndrome. *Phlebology*. 2012; 27 Suppl 1:74-77.
- Tinelli A, Prudenzano R, Torsello M, et al. Suprapubic percutaneous sclero-embolization of symptomatic female pelvic varicocele under local anesthesia. *Eur Rev Med Pharmacol Sci*. 2012 Jan;16(1):111-7.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2018	<ul style="list-style-type: none">Simplified coverage rationale (no change to guidelines)Archived previous policy version 2018T0574G

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.