Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome (for North Carolina Only)

Policy Number: CSNCT0574.02
Effective Date: July 1, 2025

Instructions for Use

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Related Policy

- Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for North Carolina Only)

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Embolization of the Ovarian Vein or Internal Iliac Vein is unproven and not medically necessary for treating Pelvic Congestion Syndrome due to insufficient evidence of efficacy.

Definitions

Embolization: A procedure that uses particles, such as tiny gelatin sponges or beads, to block a blood vessel. Embolization may be used to stop bleeding or to block the flow of blood to a tumor or abnormal area of tissue (National Cancer Institute).

Internal Iliac Vein (Hypogastric Vein): The primary artery supplying the pelvic viscera and an important contributor to structures of the pelvic wall, perineum, gluteal region, and thigh (Zaunbrecher).

Ovarian Vein: One of a pair of veins that emerge from the broad ligament near the ovaries and the uterine tubes (Mosby's Pocket Dictionary).

Pelvic Congestion Syndrome (PCS): A syndrome involving chronic pelvic pain usually associated with the varices or varicosities in the pelvic area (Merck Manual).

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 federal, state, or contractual requirements 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 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, refer to CPT codes 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)

Description of Services

Pelvic Congestion Syndrome (PCS), also known as pelvic venous incompetence (PVI) or Ovarian Vein reflux, 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 individuals 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 is being investigated (Nasser et al., 2014).

Individuals 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 fluoroscopy, 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

The body of evidence in the peer-reviewed medical literature regarding embolization of the ovarian vein or internal iliac veins for the treatment of pelvic congestion syndrome (PCS) is insufficient and poor quality. While some studies suggest favorable results of embolization for the treatment of PCS, additional well-designed randomized controlled trials are necessary to establish the relative safety and efficacy of the embolization procedure.

Hanna et al. 2024 conducted a systematic review to evaluate the safety and efficacy of embolotherapy for the treatment of pelvic congestion syndrome. The primary outcome was improvement in pelvic pain measured using a 0 to 10 visual analogue score (VAS). Secondary outcomes included other PCS symptom improvement, reintervention rate, recurrence rate, complication rate, and technical success. There were 25 studies included in the review with a combined total of 2,038 participants. Of the 25 studies included, 2 were randomized clinical trials, 13 were retrospective cohort studies, 8 were prospective cohort studies, and 2 were case series. Overall, 18 studies reported pre- and post-procedural pain outcomes using VAS and all but one showed statistically significant reduction in VAS post-procedure. The 7 studies that did not utilize VAS demonstrated subjective improvement in pain scores. Additionally, 17 of the studies reported a qualitative improvement in pain, however, 5 of these showed a proportion of participants whose symptoms worsened at the time of follow-up. There were qualitative improvements for a variety of symptoms including dyspareunia (8/25), dysmenorrhea (6/25), lower limb pain (2/25), post-coital pain (3/25), and urinary symptoms (5/25). Symptom recurrence during the follow-up period was reported in 17 of the studies and ranged from 0 to 42%. Technical success was reported in 20 studies and was achieved in 94% of patients. The most common complication was post-embolization syndrome. There were 183 complications of which the majority (89%) were self-limiting and did not require pharmacological, radiological, or surgical treatment including post-embolization syndrome and access site hematomas. Of the 183 complications that did require intervention, 13 were due to migrated coils, one was a common femoral artery injury, and one patient developed salpingitis. There are several limitations to this systematic review including the small number of studies with quantitative comparative data and the heterogeneity of the study designs which prevented meta-analysis, the majority of the studies were retrospective in design and did not control for other confounding factors, and the study time span of 25 years which brings into question the comparability of the data provided. The authors note that robust prospective, randomized controlled trials are needed to define treatment and diagnostic protocols. (The following publications previously cited in this policy, are included in this systematic review: Guirola 2018, Nasser 2014.)

In a 2023 single center retrospective observational study, Smak Gregoor et al. evaluated the efficacy of endovascular embolization of pelvic varicose veins in the treatment of pelvic venous disorders (PeVD). Ninety patients underwent a pelvic phlebography, 75 of which received embolization of pelvic varicose veins. Of these, 7 patients had an obstructive venous pathology, one presented with an anatomic anomaly, and in 7 patients no varicose veins could be found. The primary end point was resolution of symptoms classified as complete improvement (CI), partial improvement (PI) and no improvement (NI). The results showed that at the end of 13 month follow up, 26.6% of patients reported NI, 50.6% reported PI and 20% had CI of symptoms. There was a relatively high rate of recurrence of around 20%. The authors concluded that embolization of pelvic varicose veins can be an effective treatment for PeVD, however for most women, symptoms remain following treatment, and future research should focus on which patients are most likely to benefit, as well as treatment timing. This study is limited by its retrospective design and lack of objective outcome measures. Further high quality studies are needed to validate these findings.

A Hayes Health Technology Assessment (March 2020; updated April 2023) states that a low-quality body of evidence indicates that most individuals with PCS who are treated with ovarian or internal iliac vein embolization or sclerotherapy improve. However, very limited evidence comparing embolization with other treatments was identified, and most showed a follow-up of ≤ 1 year. There was a wide range of complication rates (3.8% to 22%) in the included studies. Studies comparing this treatment with other minimally invasive PCS treatments, such as ovarian vein ligation, are needed.

Sutanto et al. (2022) conducted a systematic review on isolated coil embolization. The authors searched MEDLINE and Embase databases from 1990 to July 20, 2020, for studies regarding isolated coil embolization (ICE) for pelvic venous reflux (PVR). A total of 970 individuals who received ovarian vein or mixed vein embolization from 20 studies were included. Collective analysis revealed mean improvements of 5.47 points on the VAS. Common symptoms such as urinary urgency and dyspareunia reported significant improvements of 78-100% and 60-89.5% respectively. Complications were rare, with coil migration being the most common. Recurrence in pain seen 1-2 years after CE ranging from 5.9-25%. Two randomized controlled trials revealed improved clinical outcomes with CE as compared with vascular plugs and hysterectomy. The limitations of the study are the large range of follow up period between patients, data on recurrence may be inaccurate, and small sample size. The authors concluded the current data suggests that isolated CE is technically effective and can result in clinical improvement among patients with PVR. However, further evidence in the form of larger registries of RCTs with longer follow up are required to ascertain its long-term effects.

Champaneria et al. (2016) conducted a systematic review of treatment to determine the effectiveness of treatment for PCS and concluded that the data supporting its diagnosis and treatment are limited and of variable methodological quality. Their assessment revealed that embolization appears to provide symptomatic relief in the majority of women and is safe; however, the majority of included studies of embolization were relatively small case series and only a single randomized controlled trial was considered at risk of potential biases. There is scope and demand for considerable further research in which adequately powered randomized trials are essential to provide evidence on the effectiveness of embolization.

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.

O'Brien and Gillespie (2015) conducted a systematic review of the diagnosis and treatment of PCS. Thirty-seven references were small series including fewer than 50 patients or individual case reports documenting medical, surgical, or endovascular treatment of PCS. The majority of these papers demonstrated successful treatment of symptoms from PCS with embolization of one or both ovarian veins in addition to treatment of refluxing internal iliac vein branches. In addition, open surgery and, more recently, endovascular stenting of LRV obstruction have shown some promise in alleviating symptoms attributed to nutcracker syndrome. Whereas a fairly large body of data regarding transcatheter ovarian vein embolization exists, the authors summarized that these studies are limited to relatively small clinical series and retrospective reviews. The success rates for the reduction of chronic pelvic pain (CPP) in these studies range from 47% to 94% with average follow-ups of 12 to 36 months. The authors concluded that ultimately, there remains an uncertainty as to the optimal technique for ovarian vein embolization, although a combination of coils and sclerosants has demonstrated clinical efficacy in a number of studies described before and is the most common published technique for ovarian vein

embolization. In addition, there is currently no evidence to suggest a difference in symptomatic relief with regard to unilateral vs bilateral ovarian vein embolization.

In an evaluation of pelvic vein embolization indications, techniques and outcomes, Lopez (2015, included in Hayes Health Technology Assessment) 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 PCS, 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.

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.

Clinical Practice Guidelines

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).

American College of Obstetricians and Gynecologists (ACOG)

In a 2020 practice bulletin on chronic pelvic pain, ACOG does not address embolization for treating chronic pelvic pain. With regard to PCS, ACOG states that it is a proposed cause of chronic pelvic pain related to pelvic venous insufficiency, and although venous congestion appears to be associated with chronic pelvic pain, evidence is insufficient to conclude that there is a cause-and-effect relationship. Furthermore, there is no consensus on the definition of this condition, and the diagnostic criteria are variable. Further research is needed to establish consistency in diagnosis and homogeneity of studies.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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 December 4, 2024)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2025	• Created state-specific policy version for the state of North Carolina (no change to coverage guidelines)
07/01/2025	**Definitions** • Updated definition of “Embolization” **Applicable Codes** • Removed list of ICD-10 diagnosis codes: I86.2, N94.89, and R10.2 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS139.P

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a

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