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

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Instructions for Use

Table of Contents **Page**

Application 1
Coverage Rationale 1
Definitions 1
Applicable Codes 2
Description of Services 2
Clinical Evidence 2
U.S. Food and Drug Administration 4
References 4
Policy History/Revision Information 5
Instructions for Use 6

Related Policy

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

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

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. Types of Embolization are arterial Embolization, chemoembolization, and radioembolization. (National Cancer Institute)

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. (Merriam-Webster)

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)

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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 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)

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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 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.

A Hayes Health Technology Assessment (March 2020; updated March 2022) states there is a lack of robust evidence regarding the efficacy on the use of ovarian or internal iliac vein embolization for the treatment of PCS. The overall low quality of evidence primarily reflects individual study limitations, lack of comparison treatments, limited follow up, loss to follow-up and concerns regarding precision.

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Sutanto et al. (2021) 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.

Guirola et al. (2018) 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 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.

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) 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

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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 ten studies were prospective uncontrolled, two were retrospective, and one 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.

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 single-center case series, Laborda et al. (2013) reported long-term results in 202 women with 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.

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).

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 October 20, 2022)

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Policy History/Revision Information

Date	Summary of Changes

02/01/2024	**Application**
	• Added language to indicate any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using *Ohio Administrative Code 5160-1-01*
	Definitions
	• Removed definition of:
	  ○ Fluoroscopy
	  ○ Varices or Varicosities

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Date	Summary of Changes
	Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CS139OH.K – P

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]), or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC), or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC), or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC), or contractual requirements for benefit plan coverage. 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 uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines 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.

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