EMBOLIZATION OF THE OVARIAN AND ILIAC VEINS FOR PELVIC CONGESTION SYNDROME

Policy Number: SURGERY 105.6 T2  
Effective Date: May 1, 2017

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INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care 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.

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.
NON-COVERAGE RATIONALE

Embolization of the ovarian or internal iliac veins is considered unproven and not medically necessary for treating pelvic congestion syndrome.

The body of evidence in the peer-reviewed medical literature regarding embolization of the ovarian or internal iliac veins for the treatment of pelvic congestion syndrome is insufficient and poor quality. Additional well-designed randomized controlled trials are necessary to establish the relative safety and efficacy of the embolization procedure as a treatment of pelvic congestion syndrome.

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 may apply.

<table>
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<th>CPT Code</th>
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<td>37241</td>
<td>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)</td>
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*CPT® is a registered trademark of the American Medical Association*

Coding Clarification: According to the American Medical Association (AMA), CPT code 37241 is specific to venous embolization/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)

<table>
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<th>ICD-10 Diagnosis Code</th>
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<td>I86.2</td>
<td>Pelvic varices</td>
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<tr>
<td>N94.89</td>
<td>Other specified conditions associated with female genital organs and menstrual cycle</td>
</tr>
<tr>
<td>R10.2</td>
<td>Pelvic and perineal pain</td>
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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 and/or 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 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 and internal iliac veins are in close proximity, embolization of the iliac veins may also be necessary. (Nasser et al., 2014)

**CLINICAL EVIDENCE**

**Systematic Review**

Daniels et al. (2016) conducted a systematic review to evaluate the effectiveness of embolization of incompetent pelvic veins performed to reduce chronic pelvic pain (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.

Although results suggest positive treatment effects with low complication rates, majority of the studies had serious methodological limitations, and were considered poor quality. Studies were weakened by small patient populations, lack of randomization, lack of appropriate controls, and short duration of follow-up, all of which may lead to bias and reduce confidence in the study results. In addition, patient populations were heterogeneous, and some patients had confounding comorbidities that may have affected outcomes. The one available RCT had only quasi-randomization and lacked appropriate controls. In general, the available studies did not assess disease-specific outcomes, including quality of life (QOL) measures. The study authors concluded that additional well-designed RCTs with appropriate outcome measures and sufficient follow-up periods are necessary to definitively establish the safety and efficacy of embolization as a treatment for PCS.

**Primary Studies**

Several prospective and retrospective case series were also identified during an independent literature search that were not included in the systematic review (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). Many of these studies evaluated a small number of patients; hence, only the largest of these are included for discussion.

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.
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, Hocquelet 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.

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.

**Summary**

Results of a recent systematic review and three additional primary studies suggest favorable results of embolization for the treatment of PCS compared with pre-procedure symptoms for several patient-relevant outcomes, including pain reduction, overall patient satisfaction, and technical feasibility. Reported complication rates appeared relatively low. However, the overall body of evidence is low quality since the majority of the selected studies were substantially weakened by methodological flaws. These include a lack of randomization, lack of appropriate comparators of conventional treatments, heterogeneous patient populations, and absence of diagnostic criteria for PCS in the patient selection process, all of which may confound or bias study results. Additional well-designed RCTs or randomized comparative studies are necessary to confirm the safety and effectiveness of embolization procedures relative to traditional treatment approaches for PCS.

**Professional Societies**

**Society for Vascular Surgery (SVS) and American Venous Forum (AVF)**

In a guideline published by SVS and 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 January 10, 2017)

**REFERENCES**

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2017T0574E]


### POLICY HISTORY/REVISION INFORMATION

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<tr>
<td>07/01/2017</td>
<td>Updated list of related policies; added reference link to policy titled Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins</td>
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<tr>
<td>05/01/2017</td>
<td>Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or lists of applicable codes</td>
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