

# Protocol

## Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome

(40118)

Medical Benefit		Effective Date: 01/01/11	Next Review Date: 07/19
Preauthorization	No	Review Dates: 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18	

***This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"><li>• With pelvic congestion syndrome</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Ovarian and/or internal iliac vein embolization</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Medical therapy (e.g., analgesics, hormonal therapy)</li><li>• Surgical ovarian vein ligation</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Treatment-related morbidity</li></ul>

### DESCRIPTION

Pelvic congestion syndrome is characterized by chronic pelvic pain that is often aggravated by standing; diagnostic criteria for this condition are not well-defined. Embolization of the ovarian and internal iliac veins has been proposed as a treatment for patients who fail medical therapy.

### SUMMARY OF EVIDENCE

For individuals who have pelvic congestion syndrome who receive ovarian and/or internal iliac vein embolization, the evidence includes case series and a systematic review. Relevant outcomes are symptoms and treatment-related morbidity. According to a systematic review of case series data, approximately 80% of patients have reported some degree of symptom relief 12 months after ovarian and/or internal iliac vein embolization. It is difficult to draw conclusions from these data because of a lack of a placebo control or comparative data from alternative interventions. Moreover, definitions of pelvic congestion syndrome vary, making it challenging to define a patient population with symptoms arising from pelvic congestion. Randomized controlled trials using well-defined eligibility criteria are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

### POLICY

Embolization of the ovarian vein and internal iliac veins is considered **investigational** as a treatment of pelvic congestion syndrome.

**POLICY GUIDELINES**

Embolization of the ovarian vein may require an overnight hospital stay. Embolization of the internal iliac veins has been performed on an outpatient basis.

**BACKGROUND****PELVIC CONGESTION SYNDROME**

Pelvic congestion syndrome is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia and postcoital pain and aggravated by standing. The syndrome occurs during the reproductive years, and pain is often greater before or during menses. The underlying etiology is thought to be related to varices of the ovarian veins, leading to pelvic vascular congestion. Because there are many etiologies of chronic pelvic pain, the pelvic congestion syndrome is often a diagnosis of exclusion, with the identification of varices using a variety of imaging methods, such as magnetic resonance imaging, computed tomography, or contrast venography. However, the syndrome is still not well defined, and it is unclear whether pelvic congestion syndrome causes chronic pelvic pain.<sup>1</sup> Although venous reflux is common, not all women with this condition experience chronic pelvic pain and, conversely, chronic pelvic pain is reported by women without pelvic congestion syndrome.

**Treatment**

Initial treatment of pelvic congestion syndrome includes psychotherapy and medical therapy (e.g., nonsteroidal anti-inflammatory drugs) and hormonal therapy. For patients who fail initial therapy, surgical ligation of the ovarian vein may be considered. Embolization therapy of the ovarian and internal iliac veins has been proposed as an alternative to surgical ovarian vein ligation. Vein embolization can be performed using a variety of materials including coils, glue, and gel foam.

**REGULATORY STATUS**

Ovarian and internal iliac vein embolization is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Various materials (e.g., coils, glue, gel foam) would be used to embolize the vein(s), and they would be subject to FDA regulation. Several products have been cleared for marketing by FDA through the 510(k) process for uterine fibroid embolization (e.g., Embosphere® Microspheres [South Jordan, UT], Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles [Bloomington, IN]) and/or embolization of hypervascular tumors and arteriovenous malformations (e.g., Contour® Emboli PVA [Marlborough, MA]).

**RELATED PROTOCOL**

Occlusion of Uterine Arteries Using Transcatheter Embolization

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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10. Society of Interventional Radiology (SIR). Diseases and conditions: Chronic pelvic pain (pelvic congestion syndrome) [Patient Center]. n.d.; <https://www.sirweb.org/patient-center/pelvic-congestion-syndrome--chronicpelvic-pain/>. Accessed August 2, 2017.