Protocol

Ovarian and Internal Iliac Vein Endovascular Occlusion as a Treatment of Pelvic Congestion Syndrome

(40118)

Medical Benefit		**Effective Date**: 02/01/20	**Next Review Date**: 07/21
Preauthorization	No	**Review Dates**: 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18, 07/19, 11/19, 07/20	

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.

RELATED PROTOCOLS

Occlusion of Uterine Arteries Using Transcatheter Embolization

Treatment of Varicose Veins/Venous Insufficiency

Populations	Interventions	Comparators	Outcomes
Individuals: • With pelvic congestion syndrome	Interventions of interest are: • Ovarian and/or internal iliac vein embolization (e.g., embolization, sclerotherapy)	Comparators of interest are: • Medical therapy (e.g., analgesics, hormonal therapy) • Surgical ovarian vein ligation	Relevant outcomes include: • Symptoms • Treatment-related morbidity

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. Endovascular occlusion (e.g., embolization, sclerotherapy) 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 endovascular occlusion, the evidence includes case series and systematic reviews. 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 endovascular occlusion. It is difficult to draw conclusions from these data because of a lack of a placebo control or comparative data from current 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

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

POLICY GUIDELINES

Endovascular occlusion of the ovarian vein may require an overnight hospital stay. Endovascular occlusion 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.[1] 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 and/or sclerotherapy of the ovarian and internal iliac veins have been proposed as an alternative to surgical ovarian vein ligation. Endovascular occlusion can be performed using a variety of materials including coils, vascular plugs, glue, liquid embolic agents, and gelatin sponge or powder (Gelfoam).

REGULATORY STATUS

Ovarian and internal iliac vein embolizations are surgical procedures and, as such, are not subject to regulation by the U.S. Food and Drug Administration.

Various products (e.g., coils, vascular plugs, glue, liquid embolic agents, Gelfoam) and/or delivery-assist devices would be used to embolize the vein(s), and they would be subject to Food and Drug Administration regulation. Several products have been cleared for marketing by the Food and Drug Administration through the 510(k) process for uterine fibroid embolization (e.g., Embosphere® Microspheres, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles) and/or embolization of hypervascular tumors and arteriovenous malformations (e.g., Contour® Emboli PVA). Several embolization delivery systems have also been cleared via the 510(k) process for arterial and venous embolization in the peripheral vasculature featuring vascular plugs (e.g., ArtVentive Medical Group, Inc. Endoluminal Occlusion System [EOSTM]) or coils (e.g., Cook Incorporated MReye® Flipper®). FDA product code: KRD.

In November 2004, the sclerosant agent Sotradecol® (sodium tetradecyl sulfate injection) was approved by the U.S. Food and Drug Administration for use in the treatment of small uncomplicated varicose veins of the lower extremities that show simple dilation with competent valves (ANDA 040541).

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