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

Policy # 00691
Original Effective Date: 02/01/2020
Current Effective Date: 12/14/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Occlusion of Uterine Arteries Using Transcatheter Embolization is addressed separately in medical policy 00130.

Note: Treatment of Varicose Veins/Venous Insufficiency is addressed separately in medical policy 00034.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers endovascular occlusion of the ovarian vein and/or internal iliac veins as a treatment of pelvic congestion syndrome to be **investigational.***

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/Overview

Pelvic Congestion Syndrome

Pelvic congestion syndrome is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia and post coital 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. 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 (eg, 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 has 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).

FDA or Other Governmental Regulatory Approval

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

Various products (eg, 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 (eg, Embosphere®‡ Microspheres, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles) and/or embolization of hypervascular tumors and arteriovenous malformations (eg, 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 (eg, ArtVentive Medical Group, Inc. Endoluminal Occlusion System [EOS™‡]) or coils (eg, 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).

Rationale/Source

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 (eg, embolization, sclerotherapy) of the ovarian and internal iliac veins has been proposed as a treatment for patients who fail medical therapy.

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 86.6%, 88.1%, and 91.5% of patients have reported some degree of symptom relief after ovarian and/or internal iliac vein endovascular occlusion at short-term, long-term, or overall follow-up. In a randomized trial of embolization with vascular plugs or coils in patients with pelvic congestion syndrome, adverse events were reported in 22% and 10% of patients, respectively. A retrospective analysis comparing coil embolization to endoscopic resection determined that resection is associated with significantly shorter times to postprocedural pain relief and avoidance of post embolization syndrome. 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 and relevant comparators are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

A fact sheet from the Society for Interventional Radiology on chronic pelvic pain in women endorsed ovarian vein embolization as an effective treatment option for pelvic congestion syndrome.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04358497	Endovascular Versus Medical Treatment for the Pelvic Congestion Syndrome (ENDPCS)	120	Oct 2022 (not yet recruiting)
NCT04115137	Multicentric Spanish Record of Pelvic Varicose Veins Treated With Vascular Plugs Type Amplatzer - Pelvic Congestion Syndrome: Study of Efficacy and Safety (REPiVAC)	300	Jan 2021 (recruiting)
NCT03794466	Quantification of Pain Relief With Gonadal Vein	30	Sep 2020 (recruiting)

	Embolization for Pelvic Congestion Syndrome		
NCT03165214	Effectiveness of Embolization of Pelvic Veins in Treatment of Pelvic Congestion Syndrome	52	Sep 2019 (unknown)
NCT01909024[a]	Pelvic Embolisation to Reduce Recurrent Varicose Veins - Recurrent	270	Dec 2018 (unknown)

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

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11/07/2019 Medical Policy Committee review
11/13/2019 Medical Policy Implementation Committee approval. New policy.
11/05/2020 Medical Policy Committee review
11/11/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 11/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	36012, 37241, 75894
HCPCS	No codes
ICD-10 Diagnosis	I86.2, I87.2, N94.89, R10.2

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.