LOUISIANA BLUE

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: 12/09/2024

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

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

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 internal iliac and ovarian veins has been performed on an outpatient basis but may require an overnight hospital stay.

Background/Overview

Pelvic Congestion Syndrome

Pelvic congestion syndrome is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia (which may be aggravated by standing) and symptoms suggestive of a venous origin, such as postcoital ache and tenderness over the ovarian point. The syndrome usually occurs before menopause, and pain is often greater before or during menses. The underlying etiology is thought to be related to varices of the pelvic veins, leading to pelvic vascular congestion. The lack of clear diagnostic criteria and overlapping clinical presentation of pelvic congestion syndrome with other potentially related pelvic venous disorders has hindered research progress and contributed to underdiagnosis of these disorders as causes of chronic pelvic pain.[1,] In 2021, a multidisciplinary, intersociety working group convened by the American Vein and Lymphatic Society published the Symptoms-Varices-Pathophysiology (SVP) classification of pelvic venous disorders which, in conjunction with the established Clinical-Etiologic-Anatomic-Physiologic classification for lower extremity venous disorders when applicable, places patients in homogeneous populations based on standardized definitions of presenting symptoms, involved

variceal reservoirs, and underlying pathophysiology (including anatomic, hemodynamic, and etiologic disease features). The term pelvic venous disorder, accompanied by the patient-specific SVP classification, has been proposed to replace pelvic congestion syndrome and other historical nomenclature for related diseases (such as May-Thurner syndrome and nutcracker syndrome). As diagnostic criteria remain lacking, pelvic venous disorder as a cause of chronic pelvic pain amounts to a diagnosis of exclusion; evaluation may involve a variety of physical assessments, laboratory measurements, and/or imaging studies to eliminate other etiologies of chronic pelvic pain, such as cystitis or gynecologic malignancy.

Treatment

An initial conservative approach to the treatment of pelvic congestion syndrome may involve analgesics (eg, short-term use of nonsteroidal anti-inflammatory drugs) and hormonal therapy, with or without psychotherapy. The evidence base for medical management consists primarily of 5 clinical trials of hormonal therapy (sample sizes ranging from 22 to 102) in which medroxyprogesterone (in combination with psychotherapy), goserelin, and etonogestrel demonstrated significant improvements in pain scores with up to 13 months of follow-up. Longer-term efficacy of these treatments has not been demonstrated, and the largest trial of medroxyprogesterone indicated rapid recurrence of symptoms with discontinuation. Surgical ligation of pelvic veins may be considered, but is also supported by limited evidence and further limited by need for general anesthesia, duration of hospitalization, recovery time, and associated morbidity. Embolization therapy and/or sclerotherapy of the ovarian and internal iliac veins has been proposed as an alternative to surgical 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 (FDA).

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 FDA regulation. Several products have been cleared for marketing by the FDA 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™‡ PVA Embolization particles). 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.

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In November 2004, the sclerosant agent Sotradecol®‡ (sodium tetradecyl sulfate injection) was approved by the FDA 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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Pelvic congestion syndrome is characterized by chronic pelvic pain that is often aggravated by standing; diagnostic criteria for this condition are not clearly 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.

Summary of Evidence

For individuals who have pelvic congestion syndrome who receive ovarian and/or internal iliac vein endovascular occlusion, the evidence includes randomized studies, comparative cohort studies, non-comparative cohort studies, case series, and systematic reviews. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. Systematic reviews of prospective and retrospective data, as well as more recently published retrospective cohort studies, indicate consistently high clinical success rates (primarily in the form of significant pain reduction) ranging from 63.7% to 100% after ovarian and/or internal iliac vein endovascular occlusion at short-term, long-term, or overall follow-up. These data support guideline and international consensus recommendations for endovascular occlusion in this setting. 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 indicated significantly greater improvement in pain 1 month post-procedure with resection, but similar improvements in pain between the procedures at 5-year follow-up. Differences between these procedures, particularly the need for general anesthesia with resection versus local anesthesia with embolization, suggest the possibility of selection bias in this study. Randomized controlled trials using well-defined eligibility criteria and relevant comparators are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

International Union of Phlebology

An international consensus document on the diagnosis and treatment of pelvic congestion syndrome (which acknowledged the suboptimal nature of this terminology and noted that new nomenclature was being proposed at the time of publication) was published by a task force of the International Union of Phlebology in 2019. Key consensus statements include:

- Symptomatic (pain-relief) therapies include analgesics, nonsteroidal anti-inflammatory drugs, and psychotropic drugs, but the effect of such therapy is transient.
- Hormonal therapy seems to have therapeutic effect, but long-term usage is not recommended because of the high risk of osteoporosis.
- Current surgical treatment includes open or laparoscopic surgery to ligate the insufficient veins. However, these procedures are rarely performed as they are more invasive than endovascular embolization procedures, and require a general anesthetic and a longer recovery period. Surgery of the reproductive organs is not advised as a treatment option.
- Injecting foam or liquid sclerosant could be used for occlusion of gonadal veins and for the treatment of atypical varicose veins of perineal, vulval, gluteal, or posterior thigh localization.
- Transcatheter embolization therapy is the method of choice for the treatment of pelvic congestion syndrome. The aim of embolization is to occlude insufficient venous axes as close as possible to the origin of the leak. In pelvic venous disorders these will be the gonadal axes, pelvic varicose veins, and insufficient tributary branches of the internal iliac veins. However, published evidence of its effect has been criticized for the lack of validated clinical and imaging criteria for the disorders responsible for pelvic venous disease.
- Treatment of choice for pelvic congestion syndrome is pelvic vein embolization, in the absence of obstructions. Serious complications after this kind of treatment are very rare.

Society for Interventional Radiology

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.

Society for Vascular Surgery and American Venous Forum
A clinical practice guideline for the care of patients with varicose veins and related chronic venous disorders was jointly published by the Society for Vascular Surgery and American Venous Forum in 2011. Portions of these guidelines were updated most recently in 2023, although there was no mention of pelvic congestion syndrome.

The 2011 guidelines included the recommendations below related to treatment of pelvic congestion syndrome. Medical management is not included among recommendations; the guideline states that "Pharmacologic agents to suppress ovarian function, such as medroxyprogesterone or gonadotropin-releasing hormone, may offer short-term pain relief, but their long-term effectiveness has not been proven."

- We suggest treatment of pelvic congestion syndrome and pelvic varices with coil embolization, plugs, or transcatheter sclerotherapy, used alone or together (grade 2B: weak recommendation, moderate quality of evidence).
- If less invasive treatment is not available or has failed, we suggest surgical ligation and excision of ovarian veins to treat reflux (grade 2B: weak recommendation, moderate quality of evidence).

U.S. Preventive Services Task Force Recommendations
Not applicable.

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 and ongoing 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			
NCT03794466	Quantification of Pain Relief With Gonadal Vein Embolization for Pelvic Congestion Syndrome	30	Jun 2024

NCT05553158[a]	Study to Investigate the Influence of Compression Treatment in Patients with Pelvic Congestion Syndrome (PCS)	172	Nov 2024
Unpublished			
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 (unknown)
NCT01909024[a]	A Randomised Controlled Trial Investigating The Use Of Pelvic Vein Embolisation To Reduce Recurrent Varicose Veins Of The Legs In Women With Recurrent Varicose Veins And Associated Pelvic Venous Reflux.	270	Dec 2018 (unknown)
NCT04358497	Endovascular Versus Medical Treatment for the Pelvic Congestion Syndrome (ENDPCS)	120	Oct 2022 (unknown; last reported as not yet recruiting)

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

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Policy History

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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.
11/04/2021	Medical Policy Committee review
11/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 11/2025

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 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.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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

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*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 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.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.