Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 172
Latest Review Date: September 2023
Category: Surgery
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **endovascular occlusion of the ovarian vein and internal iliac veins for the treatment of pelvic congestion syndrome** as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Pelvic congestion syndrome is characterized by chronic pelvic pain that often is 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.

Pelvic Congestion Syndrome

Pelvic congestion syndrome is a condition of chronic pelvic pain of variable location and intensity, which is associated with dyspareunia (possibly aggravated by standing) and symptoms suggestive of a venous origin, such as postcoital ache and tenderness over the ovarian point. 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 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. 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 of this syndrome 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 (e.g., 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).

KEY POINTS:

The most recent literature review was updated through June 29, 2023.

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. 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 outcomes.

Practice Guidelines and Position Statements

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, 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 forthe 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 of Interventional Radiology (SIR)
A fact sheet on chronic pelvic pain in women endorsed coil 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. The guideline 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

KEY WORDS:
Pelvic congestion syndrome (PCS), embolization therapy, ovarian vein, internal iliac vein, pelvic venous incompetence (PVI), Endovascular occlusion, Flipper, Embosphere, Contour, EOS

APPROVED BY GOVERNING BODIES:

Ovarian and internal iliac vein embolization is a surgical procedure and as such is not subject to regulation by FDA.

A variety of products including coils, vascular plugs, glue, liquid embolic agents, Gelfoam and/or delivery-assist devices would be used to embolize the vein(s), and those would be subject to FDA regulation. Several of these products have 510(k) marketing clearance 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®).

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).

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

There are no specific CPT codes for this procedure. The following nonspecific CPT codes may be used:

36012	Selective catheter placement, venous system: second order, or more selective, branch
37241	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)

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POLICY HISTORY:

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Medical Policy Group, June 2006
Medical Policy Group, June 2007
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Medical Policy Group, January 2014
Medical Policy Group, June 2014
Medical Policy Group, June 2015
Medical Policy Group, August 2016
Medical Policy Group, August 2017
Medical Policy Group, August 2018 **(4):** Updates to Key Points. Removed Previous Coding section (CPT code 37204 – deleted 2014).
Medical Policy Group, August 2019
Medical Policy Group, August 2020
Medical Policy Group, August 2021
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