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### Corporate Medical Policy

## Ovarian and Internal Iliac Vein Embolization, Ablation and Sclerotherapy

File Name: ovarian\_and\_internal\_iliac\_vein\_embolization

Origination: 12/2004 Last Review: 3/2024

#### **Description of Procedure or Service**

Therapeutic intervention to treat varicose veins/venous insufficiency may be performed using embolization, ablation or sclerotherapy.

This medical policy addresses the treatment of pelvic varices:

- 1. For pelvic congestion syndrome and
- 2. As part of treatment of lower extremity venous insufficiency.

Varices in the veins that originate in the pelvis may include the ovarian and iliac veins. The ovarian veins in women are also referred to as the gonadal veins. The gonadal veins in men are known as testicular or internal spermatic veins. Gonadal veins drain into the renal vein and inferior vena cava from the testicle or ovary. This policy does not address treatment of the gonadal vein in men for varicose veins of the scrotum (varicocele).

#### 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. 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.

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).

#### Treatment of pelvic varices for lower extremity venous insufficiency

Pelvic venous reflux into lower extremity leg varices has been suggested as a cause of recurrent varicose veins in the lower extremity, often in the setting of pelvic congestion syndrome. It has been proposed that in certain patients, the treatment of lower extremity varicose veins should also include treatment of the pelvic varices.

#### **Regulatory Status**

Vein embolization is a surgical procedure and, as such, is 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<sup>TM</sup> 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<sup>TM</sup>]) or coils (eg, Cook Incorporated MReye® Flipper®).

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.

This policy does not address isolated treatment of male gonadal veins or varicose veins of the lower extremities. Refer to policy titled "Varicose Veins of the Lower Extremities, Treatment for".

\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

#### Policy

Ovarian and internal iliac vein embolization, ablation or sclerotherapy is considered investigational as a treatment of pelvic congestion syndrome and as part of treatment of lower extremity varicose veins. BCBSNC does not provide coverage for investigational services or procedures.

#### **Benefits Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

#### When Ovarian and Internal Iliac Vein Embolization is covered

Not applicable.

#### When Ovarian and Internal Iliac Vein Embolization is not covered

Embolization, ablation or sclerotherapy of ovarian veins and internal iliac veins is considered investigational as a treatment of pelvic congestion syndrome and as part of treatment of lower extremity varicose veins.

Embolization, ablation or sclerotherapy of any other pelvic veins is considered investigational as a treatment of pelvic congestion syndrome and as part of treatment of lower extremity varicose veins.

#### **Policy Guidelines**

There are no generally accepted, well-defined clinical criteria for the diagnosis of pelvic congestion syndrome, reflecting the residual uncertainty that there is a causal relationship between pelvic vein incompetence and chronic pelvic pain. Since it is predominantly observed in multiparous women of reproductive age, it suggests both a mechanical and a hormonal mechanism. The data supporting the diagnosis and treatment of pelvic vein incompetence in the presence of chronic pelvic pain are limited and of variable quality, and higher quality research is required to thoroughly address the research question. Although some research has shown that treatment of pelvic varices provides symptomatic relief in some women, the studies are small case series from which conclusions cannot be drawn with certainty.

Likewise, there is insufficient good quality research to show that embolization, ablation, or sclerotherapy of pelvic varices improves long term health outcomes in the treatment of lower extremity varicose veins.

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, noncomparative 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 postprocedure 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.

#### **Billing/Coding/Physician Documentation Information**

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

There are no specific CPT codes for this procedure. The following nonspecific CPT codes may be used: 36012, 37241, 37243, 37244, and 75894.

ICD-10 diagnosis codes: I86.2, N94.89

CPT provides clarification regarding the intended use for 37241 as follows:

- For sclerosis of veins or endovenous ablation of incompetent extremity veins, use 36468–36479
- Do <u>not</u> report 37241 in conjunction with 36468, 36470, 36471, 36475–36479, 75894, 75898 in the same surgical field

Examples of intended use of 37241 (not an all-inclusive list):

- Embolization/occlusion of gastric/esophageal varices;
- Embolization/occlusion of varicoceles;
- Embolization/occlusion of incompetent ovarian vein for pelvic congestion syndrome;
- Embolization/occlusion of patent perforators siphoning flow from dialysis access fistula;
- Embolization/occlusion of patent perforators siphoning flow from lower extremity venous bypass grafts;
- Injection/occlusion/embolization of vascular malformations that are primarily venous;
- Injection/occlusion/embolization of vascular malformations that are primarily lymphatic.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

#### Scientific Background and Reference Sources

ECRI Hotline Response - Coil Embolization of the Ovarian Vein for Pelvic Congestion Syndrome (12/12/2003) retrieved on 10/6/04 from http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?doc\_id=7214&q=%22pelvic+congestion+syndrome&anm

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 4/16/04. Specialty Matched Consultant Advisory Panel -12/2004.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 3/7/06.

Specialty Matched Consultant Advisory Panel -12/13/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 8/2/07.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 8/14/08.

Specialty Matched Consultant Advisory Panel - 12/2008

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 5/13/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 5/12/2011

Specialty Matched Consultant Advisory Panel – 3/21/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 5/10/2012

Specialty Matched Consultant Advisory Panel – 3/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 5/9/2013

Specialty Matched Consultant Advisory Panel – 3/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 6/12/2014

Specialty Matched Consultant Advisory Panel – 3/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 6/11/2015

Specialty Matched Consultant Advisory Panel – 3/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 8/11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 8/10/2017

Champaneria R, Shah L, Moss J, et al. The relationship between pelvic vein incompetence and chronic pelvic pain in women: systematic reviews of diagnosis and treatment effectiveness. *Health Technol Assess*. 2016 Jan:20(5):1-108. Available at: https://www.journalslibrary.nihr.ac.uk/hta/hta20050/#/full-report

Bittles M, Hoffer E. Gonadal vein embolization: treatment of varicocele and pelvic congestion syndrome. *Semin Intervent Radiol* 2008;25:261-270.

Medical Director review - July 2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 8/9/2018

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BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.18, 8/13/2020

Specialty Matched Consultant Advisory Panel – 3/2021

Specialty Matched Consultant Advisory Panel – 3/2022

Medical Director review 3/2022

Ball E, Khan KS, Meads C. Does pelvic venous congestion syndrome exist and can it be treated?. Acta Obstet Gynecol Scand. May 2012; 91(5): 525-8. PMID 22268663

Specialty Matched Consultant Advisory Panel – 3/2023

Medical Director review 3/2023

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Meissner MH, Khilnani NM, Labropoulos N, et al. The Symptoms-Varices-Pathophysiology classification of pelvic venous disorders: A report of the American Vein Lymphatic Society International Working Group on Pelvic Venous Disorders. J Vasc Surg Venous Lymphat Disord. May 2021; 9(3): 568-584. PMID 33529720

Borghi C, Dell'Atti L. Pelvic congestion syndrome: the current state of the literature. Arch Gynecol Obstet. Feb 2016; 293(2): 291-301. PMID 26404449

Bendek B, Afuape N, Banks E, et al. Comprehensive review of pelvic congestion syndrome: causes, symptoms, treatment options. Curr Opin Obstet Gynecol. Aug 2020; 32(4): 237-242. PMID 32487799

Tu FF, Hahn D, Steege JF. Pelvic congestion syndrome-associated pelvic pain: a systematic review of diagnosis and management. Obstet Gynecol Surv. May 2010; 65(5): 332-40. PMID 20591203

Farquhar CM, Rogers V, Franks S, et al. A randomized controlled trial of medroxyprogesterone acetate and psychotherapy for the treatment of pelvic congestion. Br J Obstet Gynaecol. Oct 1989; 96(10): 1153-62. PMID 2531611

Antignani PL, Lazarashvili Z, Monedero JL, et al. Diagnosis and treatment of pelvic congestion syndrome: UIP consensus document. Int Angiol. Aug 2019; 38(4): 265-283. PMID 31345010

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#### **Policy Implementation/Update Information**

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2/23/04	Specialty Matched Consultant Advisory Panel review 12/9/04. Notification of new policy indicating that ovarian and internal iliac vein embolization for pelvic congestion syndrome is investigational. Notification given 12/23/04. Effective date 3/3/05.	
1/17/07	Specialty Matched Consultant Advisory Panel review 12/13/2006. No changes to criteria. Reference sources added. (pmo)	
1/12/09	Reference sources added. No changes to criteria. Specialty Matched Consultant Advisory Panel review 12/2008. (pmo)	
6/8/10	Coding information added to the Billing/Coding section. There is no specific CPT code for this procedure, however CPT 75894 and 37204 might be used. (adn)	
6/22/10	Policy Number(s) removed (amw)	
1/18/11	Description section revised. Policy statement reworded but intent is unchanged. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 12/16/2010. Policy accepted as written. (adn)	
4/17/12	Specialty Matched Consultant Advisory Panel review 3/21/12. Added Related Guideline. Updated Policy Guidelines. No change to policy intent. (sk)	
4/16/13	Specialty Matched Consultant Advisory Panel review 3/20/13. No change to Policy statement. (sk)	
7/1/13	Reference added. Updated Billing/Coding section, adding code 36012. No change to Policy statement. ICD-10 diagnosis codes added to Billing/Coding section. (sk)	
12/31/13	Coding update. CPT 37204 deleted. CPT 37243 added. (sk)	
4/29/14	Specialty Matched Consultant Advisory Panel review 3/25/14. Senior Medical Director review. Deleted CPT 37243 and added CPT 37241 to Billing/Coding section. Added ICD-9 code 625.5 to Billing/Coding section. No change to Policy statement. (sk)	
8/26/14	Reference added. No change to Policy statement. (sk)	
4/28/15	Specialty Matched Consultant Advisory Panel review 3/25/15. (sk)	

7/28/15	Reference added. Related Guideline removed. (sk)
4/29/16	Specialty Matched Consultant Advisory Panel review 3/30/2016. Policy statement unchanged. (an)
4/28/17	Updated Policy Guidelines. Added reference. Specialty Matched Consultant Advisory Panel review meeting 3/29/2017. No change to policy statement. (an)
4/27/18	Updated Description section. Deleted ICD-9 codes from Billing/Coding section. Reference added. Specialty Matched Consultant Advisory Panel review meeting 3/28/2018. No change to policy statement. (an)
9/7/18	Policy name changed from "Ovarian and Internal Iliac Vein Embolization" to "Ovarian, Internal Iliac and Gonadal Vein Embolization, Ablation and Sclerotherapy". Description section updated with revisions for pelvic congestion syndrome and addition of information regarding varicocele. NOTE: This policy does not address varicose veins of the lower extremities. Refer to policy titled "Varicose Veins of the Lower Extremities, Treatment for". Policy statement revised to read: <b>Ovarian, Internal Iliac and Gonadal Vein Embolization, Ablation and Sclerotherapy is considered investigational as a treatment of Pelvic Congestion Syndrome or Varicoceles.</b> When Not Covered section revised to read: Embolization, ablation or sclerotherapy of ovarian veins, internal iliac veins, or gonadal veins is considered investigational as a treatment of pelvic congestion syndrome or varicoceles. Policy Guidelines updated. Added codes <i>186.1</i> , <i>186.2</i> to Billing/Coding section. Additional coding instructions added to Billing/Coding section. References added. (an)
11/9/18	Policy statement clarified to read: "Ovarian, Internal Iliac and Gonadal Vein Embolization, Ablation or Sclerotherapy is considered investigational as a treatment of Pelvic Congestion Syndrome and as part of treatment of lower extremity varicose veins." (an)
4/16/19	Reference added. Specialty Matched Consultant Advisory Panel review 3/20/2019. No change to policy statement. (an)
12/31/19	Policy name changed from "Ovarian, Internal Iliac and Gonadal Vein Embolization, Ablation and Sclerotherapy" to "Ovarian and Internal Iliac Vein Embolization, Ablation and Sclerotherapy". Policy guideline and description section updated. Policy updated to no longer address treatment of the gonadal vein in men with varicocele. Removed <i>186.1</i> from coding section. (eel)
3/24/20	Description section updated with definition of gonadal veins. When not covered section clarified with pelvic veins. No change to policy statement. (eel)
5/26/20	Reference added. Specialty Matched Consultant Advisory Panel review 3/18/2020. No change to policy statement. (eel)
3/31/21	Regulatory status updates. Reference added. Specialty Matched Consultant Advisory Panel review 3/9/2021. No change to policy statement. (bb)
3/31/22	References updated. Specialty Matched Consultant Advisory Panel review 3/2022. Medical Director Review 3/2022. No change to policy statement (tt)
3/31/23	Description updated for clarity. References updated. Specialty Matched Consultant Advisory Panel review 3/2023. Medical Director Review 3/2023. No change to policy statement (tt)

- 4/1/24 Description and Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 3/2024. Medical Director Review 3/2024. No change to policy statement. (tt)
- 5/1/24 Updated Billing/Coding section to include CPT codes 37243, 37244, and 75894. (tt)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.