Healthy Blue

Medical Policy

Subject:	Vein Embolization as a Treatment for Pelvic Congestion Syndrome and Varicocele		
Document #:	SURG.00062	**Publish Date:**	12/16/2020
Status:	Revised	**Last Review Date:**	11/05/2020

Description/Scope

This document addresses ovarian and internal iliac vein embolization as a treatment for pelvic congestion syndrome (PCS) in women, and percutaneous testicular vein embolization for varicocele in men.

PCS, which is also referred to as pelvic venous incompetence (PVI), is a condition involving chronic pelvic pain (CPP) which is non-cyclic and of variable location and intensity. The CPP is usually aggravated by prolonged standing. The underlying etiology is thought to be related to varices of the ovarian veins, leading to pelvic congestion. As there are many etiologies for CPP, PCS is often a diagnosis of exclusion, when varices are identified using a variety of imaging methods, such as magnetic resonance imaging (MRI), computed tomography (CT) scanning or contrast venography. For those who do not respond to medical therapy with analgesics, embolization therapy of the ovarian and internal iliac veins has been proposed.

In men, testicular varicocele is a condition in which high hydrostatic pressure in the testicular veins (also called the spermatic veins) is thought to cause discomfort, pain and reduced fertility. Percutaneous embolization therapy has been used to treat varicocele as an alternative to surgical ligation (varicocelectomy) to improve symptoms, sperm count and sperm motility.

Position Statement

Investigational and Not Medically Necessary:

Embolization of the ovarian vein and internal iliac veins is considered **investigational and not medically necessary** as a treatment of pelvic congestion syndrome.

Embolization of the testicular (spermatic) veins is considered **investigational and not medically necessary** as a treatment of testicular varicocele.

Rationale

The literature regarding the clinical outcomes for embolization therapy for treatment of pelvic congestion syndrome (PCS) is limited to primarily case series and one randomized comparative trial. Several older small case series report pain relief in 50-80% of women (Cordis, 1998; Sichlau, 1994; Tarazov, 1997). In 2013, 5-year results were reported for a prospective, single center case series of 202 women suffering from chronic pelvic pain (CPP) who were being treated for lower limb varices. Inclusion criteria were: lower limb varices and CPP of greater than 6

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month duration; greater than 6 mm pelvic venous caliber on ultrasonography; and venous reflux or presence of communicating veins. Both ovarian and hypogastric veins were targeted for embolization. Pain level was assessed before and after embolotherapy and during follow-up using a visual analog scale (VAS). Technical and clinical success and recurrence of leg varices were studied. The study subjects completed a quality questionnaire, and clinical follow-up was performed at 1, 3, and 6 months and every year for 5 years. A total of 179 of 202 women (89%) completed the 5-year follow-up. The primary outcomes were pain improvement and individual post-procedure satisfaction. At baseline, the mean VAS was 7.34 (standard deviation [SD]: 0.7) and at 5 years the mean VAS was 0.78 (SD: 1.2). The decrease in the VAS score over time was statistically significant ($p<0.0001$). Mean individual satisfaction scores were 7.39 (SD: 1.5) on a 0 to 9 scale. There were 4 cases of coil migration (2%), which were considered to be a major complication; also groin hematoma occurred in 6 subjects. Post-procedure abdominal pain was reported in 23 subjects, and 24 subjects (12.5%) experienced recurrence of their leg varices within the follow-up period. Notably, this study was limited by the lack of a control group for clinical outcomes comparison and no clearly defined diagnostic criteria for use in trial subject selection (Laborda, 2013).

Additional small retrospective case series and single center chart reviews have reported favorable short-term outcomes (averaging 12-24 months) for embolization therapy related to VAS scores and symptomatic improvements. However, some investigators acknowledge difficulty in assessing subsequent recurrence rates, due to complexities associated with the pathophysiology of venous reflux disease and ongoing debate around the most effective embolic materials and techniques, as well as uncertainties about the most appropriate candidate selection (Hocquelet, 2014; Nasser, 2014).

Additional case series include Venbrux and colleagues who performed bilateral ovarian vein embolization therapy on 56 women, followed 3 to 10 weeks later by embolization of the internal iliac veins. The procedures were considered a technical success in all women, although in 2 women the coils inadvertently migrated to the pulmonary circulation where they were retrieved without incident. Recurrences of varices were noted in 3 women. In terms of pain control, the mean VAS score fell from 7.8 to 2.7 over a 12-month period (Venbrux, 2002).

In another case series of 41 women who underwent ovarian vein embolization, Maleux and colleagues (2000) reported a technical success rate of 98%. Partial or complete pain relief was reported by 68.3% of women. However, there was no formal assessment of pain prior to the procedure.

Chung compared the efficacy of embolization (n=52) to that of hysterectomy and bilateral oophorectomy (n=27) or hysterectomy and unilateral oophorectomy (n=27). Women were also stratified according to stress scores into three subgroups with normal, moderate-high and very high stress levels. A significant improvement in pain symptoms was observed in the three treatment groups. Women with normal to moderate-high stress levels who received embolization experienced superior symptom relief, compared to women who underwent hysterectomy with unilateral or bilateral oophorectomy. However, women with very high stress levels did not derive as much treatment benefit as women with normal to moderate-high stress levels (Chung, 2003).

Kim reported outcomes of internal iliac embolotherapy for chronic pelvic pain caused by ovarian and pelvic varices from 1998 to 2003. A total of 97 women completed long-term follow-up (mean 45 months ± 18). Long-term

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follow-up showed that 83% of these women exhibited clinical improvement, 13% had no significant change, and 4% exhibited worsened condition (Kim, 2006).

Kwon reported findings for 67 women who underwent ovarian vein coil embolization. Evaluation after coil embolization was performed within 3-6 months (n=3), 6 months to 1 year (n=7), 1-2 years (n=13), 2-3 years (n=7), 3-4 years (n=7), 4-5 years (n=13), or 5-6 years (n=17). Outcome analysis showed 82% (55/67) experienced pain reduction after coil embolization, were satisfied with the procedure, and did not pursue any further treatment. Twelve women (18%, 12/67) responded that their pain level had not changed, or had become more severe; 9 women were treated surgically, and the remaining 3 women remained under continuous drug therapy (Kwon, 2007).

In a 2005 Cochrane review, *Interventions for Treating Chronic Pelvic Pain in Women*, Stones and colleagues found that there is a "Very limited range of interventions that have been tested for the treatment of women with chronic pelvic pain." They concluded that, "Studies are currently needed to include trials of radiological embolization versus surgery for pelvic congestion" (Stones, 2005).

In a review, Smith discussed the current treatments for PCS, citing that the most common treatments used currently involve the embolization of pelvic and ovarian veins. Published outcomes of this treatment are available in a limited number of clinical series, usually with fairly short follow-up periods. The major complication of this treatment is migration of the materials (for example, coils) used to occlude veins. The longest duration of follow-up currently reported is 5 years. There is insufficient clinical evidence to support the use of embolization (embolotherapy) in the management of PCS (Smith, 2012).

Black commented on the paucity and quality of evidence supporting embolization treatment for PCS. In their publication, the authors outlined the research and reporting standards required to determine clinical efficacy of embolization for the treatment of PCS. The authors further proposed using pelvic venous insufficiency (PVI) to describe PCS because PVI is more specific to the pathophysiology and anatomy involved with compromised pelvic venous flow (Black, 2010).

A systematic review was conducted using 20 case series (total n=1081) of vein embolization for PCS. There were no randomized trials, and only one study included a control group. The immediate technical success rate in the occlusion of the affected veins was 99%, and 17 studies reported at 1 to 3 months for a total of 641 subjects. Results were reported as moderate to significant short-term, symptomatic relief in 88.1%, and 11.9% reported little or no relief. The total follow-up data varied between 7.3 months and 5 years. The authors concluded that in late follow-up, 86.6% reported relief of PCS symptoms and 13.6% experienced little or no relief (Maymoud, 2016).

Percutaneous embolization for gonadal venous insufficiency and varicocele in males has very limited evidence demonstrating safety and efficacy as compared to surgical repair. In 2018, a systematic review was performed to assess clinical outcomes for embolization treatment with different embolic materials for the management of testicular varicoceles. Study methodological quality was also analyzed. A total of 23 retrospective and 7 prospective clinical studies were included with a total of 3505 individuals. Although the technical success rates appeared high (above 90%) for all embolic materials used without significant differences, recurrence rates varied.

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Use of glue appeared to have the lowest recurrence rates, and sclerosant agents alone showed the highest rates. Recurrence rates were 4.2% for glue (11-3.08%; SD: 5.9) and 11.03% for sclerosants alone (18.8-5.15%; SD: 6.06) within an average follow-up period of 16.13 and 25.48 months respectively. Coils alone (n=898) had an average recurrence rate of 9.1% (17.8-1.4%; SD: 5.79) with a mean follow-up of 39.3 months. After an average of 12 months, the addition of sclerosants (n=1628) as an adjunct to coils did not improve recurrence rates (8.44%, 16.5-5.1%; SD: 3.4). At 1 year, glue appeared to be the most effective in preventing recurrence with coils being the second most effective. No differences were reported regarding the safety profile of the various embolic materials (Makris, 2018).

In 2014, the Practice Committee of the American Society for Reproductive Medicine, in conjunction with the Society for Male Reproduction and Urology, issued an updated opinion report on varicocele and infertility. This document discusses the evaluation and management of varicoceles in the male partners of infertile couples and provided the following:

> None of these methods (surgical repair and percutaneous embolization) has proven superior to the other in its ability to improve fertility, although there are differences in recurrence rates…Results are variable and depend on the experience and skill of the interventional radiologist performing the procedure.

To summarize the current state of the published evidence, randomized studies are needed to determine whether embolization of the internal iliac or gonadal veins is an effective treatment for PCS or male varicocele. Given that no randomized trials have been performed in this area, the safety and effectiveness of vein embolization as a treatment for PCS or gonadal venous insufficiency (varicocele) in males cannot be reliably distinguished from other management approaches, including medical therapy or watchful waiting.

Background/Overview

PCS is often associated with dyspareunia and postcoital pain and typically affects young multiparous women. The underlying etiology is thought to be related to varices of the ovarian veins, leading to pelvic congestion. Approximately 10-15% of women may have pelvic varicose veins but not all will have symptoms. As there are many etiologies of CPP, PCS is often a diagnosis of exclusion, that is confirmed when other conditions have been ruled-out. The presence of pelvic varices associated with the syndrome may be identified using a variety of imaging methods, such as MRI, CT scanning or contrast venography.

For those who fail medical therapy (for example, analgesics, vasoconstrictors and hormonal therapies), surgical ligation of the ovarian vein may be considered. More recently, catheter-based embolization therapy of the ovarian and internal iliac veins has been proposed. Catheter-based therapies may be performed on an inpatient or outpatient basis depending on the veins that are accessed and the technique that is used. Ovarian and internal iliac vein embolization is a therapy used to block blood flow to the veins that are causing pelvic congestion. It is performed by accessing the venous system via a catheter and injecting or deploying an inert material (for example, coils, solutions, plugs) to obstruct the affected veins. The embolization procedure may require multiple sessions. For example, one method involves use of gel foam and coils for embolization of the ovarian vein(s). This may be

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followed 3 to 10 weeks later by embolization of the internal iliac veins to reduce the risk of recurrence. Occasionally, the coils may migrate to another internal organ system, such as the pulmonary circulation, necessitating a retrieval procedure.

Definitions

Dysmenorrhea: Recurrent pelvic pain associated with menses and described as a painful cramping sensation in the lower abdomen, often accompanied by other symptoms, such as sweating, tachycardia, headaches, nausea, vomiting, diarrhea, and tremulousness. Primary dysmenorrhea begins at or shortly after menarche and is usually not accompanied by pelvic pathologic conditions. Secondary dysmenorrhea arises later in life and is usually associated with other pelvic conditions.

Dyspareunia: This term refers to painful sexual intercourse, due to medical or psychological causes. The symptom is significantly more common in women than in men, affecting up to one-fifth of women at some point in their lives. An extreme form, in which the woman's pelvic floor musculature contracts involuntarily, is termed vaginismus.

Embolization: A procedure in which targeted blood vessels are obstructed by delivering inert material (for example, coils, gels, foam) into the circulatory system.

Multiparous: The clinical term used for women with a history of one or more previous live births.

Pelvic congestion syndrome (PCS): A syndrome involving venous congestion and chronic pelvic pain that is generally associated with the veins in the pelvic area (for example, the ovarian veins).

Varices: Enlarged or twisted blood vessels.

Varicocele: A condition in which the testicular veins are enlarged within the scrotum caused by dilatation of the pampiniform plexus of spermatic veins and blood pooling. This condition results from incompetence of blood vessel leaflets, which leads to retrograde blood flow and increased pressure in the scrotal venous complex. This can result in testicular atrophy and decreased sperm quantity.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

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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 (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)

ICD-10 Procedure

06L03DZ	Occlusion of inferior vena cava with intraluminal device, percutaneous approach [includes right ovarian vein, right testicular vein]
06L04DZ	Occlusion of inferior vena cava with intraluminal device, percutaneous endoscopic approach [includes right ovarian vein, right testicular vein]
06LB3DZ	Occlusion of left renal vein with intraluminal device, percutaneous approach [includes left ovarian vein, left testicular vein]
06LB4DZ	Occlusion of left renal vein with intraluminal device, percutaneous endoscopic approach [includes left ovarian vein, left testicular vein]
06LH3DZ	Occlusion of right hypogastric vein with intraluminal device, percutaneous approach [includes internal iliac vein]
06LH4DZ	Occlusion of right hypogastric vein with intraluminal device, percutaneous endoscopic approach [includes internal iliac vein]
06LY3DZ	Occlusion of lower vein with intraluminal device, percutaneous approach
06LY4DZ	Occlusion of lower vein with intraluminal device, percutaneous endoscopic approach

ICD-10 Diagnosis

I86.1	Scrotal varices (varicocele)
I86.2	Pelvic varices [when indicated as ovarian and internal iliac vein varices]
I87.2	Venous insufficiency [when specified as gonadal or pelvic venous insufficiency]
N94.89	Other specified conditions associated with female genital organs and menstrual cycle [when indicated as chronic pelvic pain, female pelvic congestion]
R10.2	Pelvic and perineal pain

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. An INV and NMN statement for embolization for varicocele has been added to the Position Statement section. The Scope, Rationale, Definitions, References and Index sections were updated. The title has changed from: Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome to: Vein Embolization as a Treatment for Pelvic Congestion Syndrome and Varicocele. Updated Coding section; added ICD-10-CM I86.1 and ICD-10-PCS codes.

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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Historical

Reviewed	02/20/2020	MPTAC review. References were updated.
Reviewed	03/21/2019	MPTAC review. References were updated.
Reviewed	03/22/2018	MPTAC review. The document header wording was updated from "Current Effective Date" to "Publish Date." References were updated.
Reviewed	05/04/2017	MPTAC review. The Rationale and References were updated.
Reviewed	05/05/2016	MPTAC review. Rationale and References were updated. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. References were updated.
Reviewed	05/15/2014	MPTAC review. The Rationale and References were updated.
	01/01/2014	Updated Coding section with 01/01/2014 CPT changes; removed 37204 deleted 12/31/2013, and 75894.
Reviewed	05/09/2013	MPTAC review. The Rationale, Definitions and References were updated.
Reviewed	05/10/2012	MPTAC review. The Rationale and References were updated.
Reviewed	05/19/2011	MPTAC review. References were updated.
Reviewed	05/13/2010	MPTAC review. References were updated.
Reviewed	05/21/2009	MPTAC review. The Rationale and References were updated.
Reviewed	05/15/2008	MPTAC review. Description clarified by removing surgical ligation. References updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. References updated.
Reviewed	06/08/2006	MPTAC review. The Rationale and References were updated.
	11/22/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	10/28/2004	SURG.00062	Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome
WellPoint Health Networks, Inc.	06/24/2004	3.09.09	Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome

Historical

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