Pelvic Congestion Syndrome Treatment

MEDICAL POLICY NUMBER: 174

Effective Date: 5/6/2025

Last Review Date: 5/2025

Next Annual Review: 7/2025

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial (self-funded groups only)** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Pelvic Congestion Syndrome: Guideline Note 26

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes:

- This policy and the criteria therein only apply to self-funded employer groups. For all other commercial groups, please refer to the Carelon Cardiovascular Guidelines.
- This policy only applies to pelvic congestion syndrome in females and does not apply to any other condition.

I. Vascular embolization with percutaneous catheter techniques of the ovarian and/or internal iliac vein is considered **not medically necessary** as a treatment of pelvic congestion syndrome**.**

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Pelvic Congestion Syndrome

According to the ECRI Institute:[1]

> "Pelvic congestion syndrome (PCS), also called chronic pelvic pain, is defined as continuous or intermittent noncyclic pain, localized to the pelvic region, which lasts for six or more months. PCS occurs when valves in the veins of the pelvic region leak and cause blood to flow backward and pool in the veins. Blood pooling in pelvic or ovarian veins may cause engorgement or thrombosis, causing pain and discomfort. Approximately one-third of all women will experience chronic pelvic pain in their lifetime; about 15% of outpatient gynecologist appointments are due to PCS, and the majority of patients are younger than 45 years of age. Risk factors associated with PCS include congestion of veins in the lower extremities, hormonal imbalance, multiple pregnancies, and polycystic ovarian syndrome.
>
> Symptoms of PCS include the following:
>
> - Pelvic pain that worsens toward the end of the day or after long periods of time standing
> - Persistent lower-back pain
> - Vaginal discharge
> - Continuous or recurring pain for at least six months
> - Initial sensation of fullness or heaviness, which can increase to severe pain, including during or after menstruation or intercourse
>
> Imaging is performed to document characteristic pelvic venous changes. However, the presence of these abnormalities is not diagnostic."[1]

Treatment

There is no standard treatment for PCS, and optimum treatment is uncertain. Instead, therapy may be individualized and based on symptoms. Medical therapy with medroxyprogesterone acetate, etonogestrel insert, or gonadotropin-releasing hormone (GnRH) agonist is generally used as first line therapies for treatment of PCS. These therapies are low risk and non-invasive. Invasive treatments may be considered for patients who are refractory to medications, but the optimal therapy remains unknown. Methods such as sclerotherapy or embolization have been proposed as alternatives to surgical treatment.

The ECRI Institute describes the process of embolization of ovarian and internal iliac below:[1]

> "Embolization of the ovarian vein and internal iliac veins, performed by interventional radiologists, is one procedure to treat these varicosities. During the embolization procedure, a catheter is guided to the affected vein and small coils are inserted to close off the vein. Blood flow is rerouted, reducing the pressure in the veins. Sclerosing agents, such as ethanol or sodium tetradecyl sulfate, may also be used to close the vein, either alone or in combination with the coils."

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of vascular embolization and occlusion procedures as a treatment for pelvic congestion syndrome. Below is a summary of the available evidence identified through June 2024. Due to the large number of studies that have evaluated the use of vascular embolization and occlusion procedures as a treatment for pelvic congestion syndrome, only recent systematic reviews and randomized controlled trials are described in detail below.

Systematic Reviews and Technology Assessment

- In 2020 (updated 2023), Hayes published a health technology assessment evaluating ovarian or internal iliac vein embolization for the treatment of pelvic congestion syndrome (PCS).[2] The authors identified 6 studies for the assessment: 1 randomized controlled trial (RCT) comparing ovarian venous embolization with hysterectomy and oophorectomy (n=106); 1 RCT comparing 2 devices used in embolotherapy, vascular plugs and fibered platinum coils (n=100); 2 pretest/posttest studies that compared baseline values prior to embolotherapy with follow-up values (n=127 and 202); 1 repeated measures time series (n=113); and 1 retrospective cohort study comparing embolotherapy alone with embolotherapy plus stenting, embolotherapy plus venoplasty, stenting alone, and venoplasty alone (n=227). Follow-up in this body of evidence ranged from 3 to 60 months.[2]

  Of the 6 studies, 4 reported clinical success rates from 83% to 100% and a fifth study reported rates from 35% to 58%. Five studies found that embolization was able to significantly reduce pain scores from baseline while one RCT found no difference in improvement of pain scores. Most studies also reported improvement in dyspareunia, dysmenorrhea, and urinary urgency. Overall complications rates ranged from 3.8% to 22%.

  Hayes concluded a **C rating (potential but unproven benefit)** due to a low-quality body of evidence, limited evidence comparing embolization with other treatments, and short follow-up periods. Study limitations included observational study design, lack of comparison with other treatments, limited follow-up duration, loss to follow-up, and some concerns regarding precision. The authors recommended "studies comparing embolotherapy with other minimally invasive PCS treatments, such as ovarian vein ligation, are needed to ascertain the role of embolotherapy in PCS."[2]

- In 2015, Hansrani et al. published a systematic review that evaluated the effectiveness of trans-venous occlusion as a treatment of chronic pelvic pain, including 12 case series and one randomized controlled trial (RCT) (N= 866 women).[3] Statistically significant improvements in pelvic pain were reported in nine of the 13 studies. Technical success was reported in 865 of 866 (99.8%) of women with low complication rates: coil migration in 14 women (1.6%), abdominal pain in ten women (1.2%) and vein perforation in five (0.6%). However, heterogeneous outcome measures prevented between-study comparisons or estimates of treatment effects. The one RCT included in the review, which reported that embolization resulted in significantly better pain reduction than hysterectomy, had significant limitations and was deemed of low quality. The authors noted that all 13 studies were of poor methodological quality, and most studies either lacked control groups or randomization, did not use objective outcome measures, and had inconsistent follow-up. The authors recommended that more high quality studies are needed that compare embolization, with other treatments.

- In 2016, Mahmoud et al. also published the results of a systematic review that evaluated vein embolization for PCS, including 20 case series (N=1081 patients).[4] The length of follow-up in the included studies ranged from one month to six years. Overall, 571 patients (88.1%) reported short-term symptom relief and 77 patients (11.9%) reported little or no relief. Seventeen studies (n=721 patients) reported symptom relief at 12 months. Only one study used a comparison group, but patients in it received conservative treatment because they were ineligible for vein embolization therapy, so outcomes based on intervention cannot be compared.

- In 2016, Champaneria et al. published a health technology assessment on behalf of the United Kingdom-based National Institute for Health Research Health Technology Assessment Programme that evaluated treatments for pelvic vein incompetence and chronic pelvic pain in women, including 21 case series and one poor-quality RCT.[5,6] Similar to the Hansrani review described above, the overall low quality and heterogeneity between included studies precluded a meta-analysis from being performed. However, the reviewers reported that approximately 75% of women who underwent embolization experienced substantial relief of pain that occurred early after treatment which was sustained. Adverse events noted included, transient pain following embolization and a <2% risk of coil migration.

Only key studies included in the systematic reviews are described in the following sections.

Randomized Controlled Trials (RCTs)

- In 2003, Chung and Huh published the results of an RCT that compared the efficacy of ovarian and/or internal iliac vein coil embolization to two different hysterectomy treatments (unilateral or bilateral ovary removal) for the treatment of PCS, including 106 patients refractory to medication.[7] Pain, as measured by visual analog scale (VAS) significantly improved 12 months post-procedure from 7.7 to 7.8 at baseline in all groups to: 3.2 in embolization patients (n=52); 4.6 in bilateral oophorectomy patients (n=27); and 5.6 in unilateral oophorectomy patients (n=27) ($p<0.05$ for the embolization group versus the surgical groups). Mean hospitalization times were 0.3 days for the embolization group versus 2.3 days for the surgery groups. To date, this RCT is the only RCT that has been published for embolization as a treatment for PCS and has a number of limitations including the following: the randomization protocol was not described, hysterectomy patients were not blinded to their treatment allocation; the sample sizes per

group were small, and there was a discrepancy between reported outcomes within the publication.

- In 2017, Guirola et al. published one-year outcomes from a single-center RCT which compared two different embolization devices, fibered platinum coils (FPC) versus vascular plugs (VP), in 100 women with PCS.[8] Patients were randomized to either FPC (n=50) or VP (n=50). Clinical success and subjective improvement were not significantly different between treatment groups at 1-year follow-up (89.7% for FPCs vs 90.6% for VPs; p = 0.760). The investigators acknowledged that there were significant differences between groups in age and pre-treatment VAS scores, both of which were slightly higher in the VP group despite randomization. Longer-term outcomes are needed to evaluate embolization procedures for the treatment of PCS.

Nonrandomized Studies

Additional prospective and retrospective case series have been published regarding the clinical outcomes of embolization therapy for patients with PCS. [9-28] However, these nonrandomized studies suffer from one or more of the following limitations:

- Small sample sizes
- Lack of comparator groups
- Retrospective study design
- Heterogeneity within and between studies with regards to:
    - Diagnostic criteria
    - co-treatments
    - patient selection
    - outcomes evaluating treatment "success"

Well-designed RCTs with larger patient populations and longer-term outcomes are needed to further evaluate the efficacy of embolization procedures for treatment of PCS.

CLINICAL PRACTICE GUIDELINES

Society for Vascular Surgery and the American Venous Forum

In 2011, the evidence-based clinical practice guidelines for the Society for Vascular Surgery and the American Venous Forum recommended the following:[29]

- Suggest treatment of pelvic congestion syndrome and pelvic varices with coil embolization, plugs, or transcatheter sclerotherapy, used alone or together. This recommendation was given a GRADE score of 2B: a weak recommendation indicating that the benefits closely balanced with risks and burden based on medium quality evidence.

EVIDENCE SUMMARY

There is insufficient evidence to consistently show that embolization and other occlusion techniques improves chronic pelvic pain or other health outcomes for people with pelvic congestion syndrome (PCS) compared to other treatments. Comparative studies, ideally randomized trials, comparing embolization to other surgical and nonsurgical treatments for PCS are needed to determine the

effectiveness of this treatment. Furthermore, the etiology of PCS is unclear and therefore there is no consensus for accurately diagnosing the condition, leading to high heterogeneity in the research. Therefore, occlusion techniques including but not limited to embolization of ovarian and/or internal iliac veins are considered not medically necessary for the treatment of pelvic congestion syndrome.

BILLING GUIDELINES AND CODING

CPT code 37241 is not specific for the treatment of pelvic congestion syndrome and may be billed for other conditions, which may have medical necessity. This medical policy only applies to pelvic congestion syndrome in females.

CPT code 36012 may be billed in conjunction with 37241 for treatment of pelvic congestion syndrome in females, and therefore would be considered not medically necessary per this policy.

The CPT code 75894 should not be billed in conjunction with 37241, as 75894 is considered a component of 37241. Therefore, if 75894 is requested with 37241 for pelvic congestion syndrome, then it will be denied as not separately reimbursable.

CPT code 37241 will be denied as not medically necessary if billed with any of the following ICD-10 diagnosis codes:

- I86.2 Pelvic varices
- I87.2 Venous insufficiency (chronic) (peripheral)
- N94.89 Other specific conditions associated with female genital organs and menstrual cycle
- R10.2 Pelvic and perineal pain

CODES*		
CPT	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)
HCPCS	None	

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for

Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
10/2023	Annual update. Removed Medicare lines of business, changed denial language from "investigational" to “not medically necessary”.
8/2024	Annual review. No changes.

5/2025	Interim update. Added note to criteria.