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: 12/12/2022

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 ovarian vein may require an overnight hospital stay. Endovascular occlusion of the internal iliac veins has been performed on an outpatient basis.

Background/Overview
Pelvic Congestion Syndrome
Pelvic congestion syndrome is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia and postcoital pain and aggravated by standing. The syndrome occurs during the reproductive years, and pain is often greater before or during menses. The underlying etiology is thought to be related to varices of the ovarian veins, leading to pelvic vascular congestion. Because there are many etiologies of chronic pelvic pain, the pelvic congestion syndrome is often a diagnosis of exclusion, with the identification of varices using a variety of imaging methods, such as magnetic resonance imaging, computed tomography, or contrast

* ©2022 Blue Cross and Blue Shield of Louisiana
Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.
No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
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: 12/12/2022

venography. However, the syndrome is still not well-defined, and it is unclear whether pelvic congestion syndrome causes chronic pelvic pain. Although venous reflux is common, not all women with this condition experience chronic pelvic pain and, conversely, chronic pelvic pain is reported by women without pelvic congestion syndrome.

Treatment
Initial treatment of pelvic congestion syndrome includes psychotherapy and medical therapy (eg, nonsteroidal anti-inflammatory drugs) and hormonal therapy. For patients who fail initial therapy, surgical ligation of the ovarian vein may be considered. Embolization therapy and/or sclerotherapy of the ovarian and internal iliac veins has been proposed as an alternative to surgical ovarian 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.

In November 2004, the sclerosant agent Sotradeco®‡ (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).
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:  12/12/2022

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.

Pelvic congestion syndrome is characterized by chronic pelvic pain that is often aggravated by standing; diagnostic criteria for this condition are not well-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 studies, case series, and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. According to systematic reviews of case series data, approximately 86.6%, 88.1%, and 91.5% of patients have reported some degree of symptom relief 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 determined that resection is associated with significantly shorter times to postprocedural pain relief and avoidance of postembolization syndrome. Moreover, definitions of pelvic congestion syndrome vary, making it challenging to define a patient population with symptoms arising from pelvic congestion. 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.

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
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: 12/12/2022

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.

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.

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT04358497</td>
<td>Endovascular Versus Medical Treatment for the Pelvic Congestion Syndrome (ENDPCS)</td>
<td>120</td>
<td>Oct 2022 (not yet recruiting)</td>
</tr>
<tr>
<td>NCT03794466</td>
<td>Quantification of Pain Relief With Gonadal Vein Embolization for Pelvic Congestion Syndrome</td>
<td>30</td>
<td>Sep 2023 (recruiting)</td>
</tr>
</tbody>
</table>
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: 12/12/2022

### Unpublished

<table>
<thead>
<tr>
<th>NCT</th>
<th>Study Title</th>
<th>Participants</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT04115137</td>
<td>Multicentric Spanish Record of Pelvic Varicose Veins Treated With Vascular Plugs Type Amplatzer - Pelvic Congestion Syndrome: Study of Efficacy and Safety (REPiVAC)</td>
<td>300</td>
<td>Jan 2021</td>
</tr>
<tr>
<td>NCT01909024⁴</td>
<td>Pelvic Embolisation to Reduce Recurrent Varicose Veins - Recurrent</td>
<td>270</td>
<td>Dec 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
⁴ Denotes industry-sponsored or cosponsored trial.
* = NCT03165214 was withdrawn with no patients recruited and, therefore, deleted from the above table.

### References


©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
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: 12/12/2022


Policy History
Original Effective Date: 02/01/2020
Current Effective Date: 12/12/2022
11/07/2019 Medical Policy Committee review
11/05/2020 Medical Policy Committee review

©2022 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Page 6 of 9
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:   12/12/2022

11/04/2021   Medical Policy Committee review
11/03/2022   Medical Policy Committee review
Next Scheduled Review Date:  11/2023

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2021 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 Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana 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 Blue Cross Blue Shield of Louisiana 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 AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana 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.
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: 12/12/2022

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>36012, 37241, 75894</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>I86.2, I87.2, N94.89, R10.2</td>
</tr>
</tbody>
</table>

*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.
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: 12/12/2022

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.