BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 172
Category: Surgery

Latest Review Date: August 2020
Policy Grade: C

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:

Effective for dates of service on or after July 1, 2005:

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 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 congestion. As 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 scanning, or contrast 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 (e.g., 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).

KEY POINTS:

The most recent literature review was updated through May 28, 2020.

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. It is difficult to draw conclusions from these data because of a lack of a placebo control or comparative data from current alternative interventions. 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 clearly 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 the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
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.

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

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:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, June 2006
Medical Policy Group, June 2007
Medical Policy Group, June 2009
Medical Policy Group, June 2010
Medical Policy Group, June 2011
Medical Policy Group, June 2012
Medical Policy Group, September 2013
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