Name of Policy:  
Ovarian and Internal Iliac Vein Embolization as Treatment of Pelvic Congestion Syndrome

Policy #: 172  
Category: Surgery  
Latest Review Date: June 2014  
Policy Grade: C

Background/Definitions:  
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**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. Embolization of the ovarian and internal iliac veins has been proposed as a treatment for patients who fail medical therapy with analgesics.

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. For those who fail medical therapy with analgesics, surgical ligation of the ovarian vein has been considered. More recently, embolization therapy of the ovarian and internal iliac veins has been proposed. Vein embolization can be performed using a variety of materials including coils, glue, and gel foam.

**Policy:**
**Embolization of the ovarian vein and internal iliac veins for the treatment of pelvic congestion syndrome does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

*Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate 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.

**Key Points:**
No randomized controlled trials have been published comparing embolization therapy for pelvic congestion syndrome to an alternative or sham/placebo treatment. Randomized controlled trials are especially needed in situations such as this where the primary symptom is pain, a subjective outcome for which a placebo response to treatment is likely. The published studies consist of case series, most of which were retrospective and conducted outside of the United States. Case series have been discussed in several review articles, most recently in 2012.

A summary table of the largest case series published in the previous ten years that reported the proportion of patients with improvement in symptoms is as follows:
<table>
<thead>
<tr>
<th>Study</th>
<th>Location</th>
<th>No. of patients</th>
<th>Mean follow-up (months)</th>
<th>Clinical outcome (at least substantial improvement in symptoms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kim et al., 2006</td>
<td>U.S.</td>
<td>127</td>
<td>45</td>
<td>83%</td>
</tr>
<tr>
<td>Kwon et al., 2007</td>
<td>Korea</td>
<td>67</td>
<td>~44.8</td>
<td>82%</td>
</tr>
<tr>
<td>Gandini et al., 2008</td>
<td>Italy</td>
<td>38</td>
<td>12</td>
<td>100% (53% complete, 47% partial)</td>
</tr>
<tr>
<td>Nasser et al, 2014</td>
<td>Brazil</td>
<td>113</td>
<td>12</td>
<td>100%</td>
</tr>
<tr>
<td>Hocquelet et al, 2014</td>
<td>France</td>
<td>33</td>
<td>26</td>
<td>94% (61% complete, 33% partial)</td>
</tr>
</tbody>
</table>

Longer-term outcomes after coil embolization for pelvic congestion syndrome were reported by Laborda et al in 2013. The study included patients who were referred by a vascular surgeon. There were no clearly defined diagnostic criteria. A total of 179 of 202 women (89%) completed a five-year follow-up. Mean age at baseline was 43.5 years. The primary outcomes were pain improvement and patient satisfaction. Pain improvement was measured on a ten-point visual analog scale (VAS) with 0 defined as no pain at all and 10 defined as the worst pain imaginable. At baseline, mean VAS was 7.34 (standard deviation [SD]=0.7) and at five years mean VAS was 0.78 (SD=1.2). The decrease in the VAS score over time was statistically significant (p<0.0001). Mean patient satisfaction was 7.39 (SD=1.5) on a 0 to 9 scale. There were four cases of coil migration (2%), and these were considered major complications. As with the other case series previously discussed, this study is limited by the lack a control group with which to compare outcomes.

Another limitation in the literature on embolization therapy for the treatment of pelvic congestion syndrome is lack of standardization regarding diagnostic criteria. In 2010, Tu et al published a systematic review of literature on the diagnosis and management of pelvic congestion syndrome. The authors commented that studies have rarely specified explicit diagnostic criteria for pelvic congestion syndrome and that definitions of pelvic pain have varied widely among studies. Moreover, most studies have not used objective outcome measures. A 2012 review article by Ball et al stated that the issue of whether pelvic congestion syndrome causes chronic pelvic pain is still a matter of debate. The authors noted that although venous reflux is common, not all women with this condition experience chronic pelvic pain and, additionally, chronic pelvic pain is reported by women without pelvic congestion syndrome.

**Summary**

Randomized controlled studies using well-defined diagnostic criteria are required to establish the safety and efficacy of this procedure. The available literature regarding embolization therapy for the treatment of pelvic congestion syndrome consists of case series and is inadequate to draw clinical conclusions; thus the treatment is considered investigational.

**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.

American College of Obstetricians and Gynecologists (ACOG): No relevant policy positions on embolization for treating pelvic congestion syndrome were identified on the organization’s website.
**Key Words:**
Pelvic congestion syndrome (PCS), embolization therapy, ovarian vein, internal iliac vein, pelvic venous incompetence (PVI)

**Approved by Governing Bodies:**
While there is FDA approval for the various coil devices that may be used in this procedure, there are no devices designed and specifically labeled for this procedure that are FDA approved.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Current Coding:**
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) (effective 01/01/2014)

**Previous Coding:**
CPT Codes:

- **37204** Transcatheter occlusion or embolization (e.g., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck (deleted 01/01/2014)

**References:**


Policy History:
Medical Policy Group, June 2004 (4)
Medical Policy Administration Committee, July 2004
Available for comment July 12-August 25, 2004
Medical Policy Group, June 2005 (1)
Medical Policy Group, June 2006 (1)
Medical Policy Group, June 2007 (1)
Medical Policy Group, June 2009 (1)
Medical Policy Group, June 2010 (1)
Medical Policy Group, June 2011 (3): Updated Key Points and References; no change to policy statement
Medical Policy Group, June 2012 (4): Updated Key Points and References; no change to policy statement
Medical Policy Panel, May 2013
Medical Policy Group, September 2013 (1): Update to Key Points and References; no change to policy statement
Medical Policy Group, January 2014 (1): 2014 Coding Update: added new code 37241, effective 01/01/2014; moved deleted code 37204 to previous coding section, effective 01/01/2014
Medical Policy Panel, June 2014
Medical Policy Group, June 2014 (1): Update to Key Points and References; no change to policy statement

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.