Trent Haywood, M.D., J.D.
Senior Vice President and Chief Medical Officer
Blue Cross Blue Shield Association (BCBSA)
Attn: Office of Clinical Affairs
Evidence Street: Where the Market Meets Evidence
225 North Michigan Ave.
Chicago, IL 60601-7680
EvidenceStreet@bcbsa.com

Re: Policy Review 4.01.18 Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome

Dear Dr. Haywood,

Society of Interventional Radiology (SIR) thanks you for the opportunity to review and provide evidentiary support regarding Evidence Street Review Policy I.D # 4.01.18. SIR respectfully asks for the reconsideration of your designation of Ovarian and Internal Iliac Vein Embolization for the treatment of Pelvic Congestion Syndrome (PCS) as an investigational procedure. PCS is an underrecognized cause of debilitating pelvic pain in young women. Diagnosis depends on vigilant evaluation of symptoms and careful attention to imaging results. Transcatheter embolization is a safe and effective treatment that yields pain relief with few complications. For example, the safety and efficacy of embolotherapy for both gonadal vein embolization and ovarian and internal iliac vein embolization conditions are well supported by the several systematic reviews and other strong literature. These two syndromes are comparable with a common etiology. Given that male varicocele is routinely covered, it would not be fair to deny women coverage for the same condition. As such, we respectfully request that you reconsider Ovarian and Internal Iliac Vein Embolization as a medically necessary designation for the treatment of PCS.

For the past 20 years, this treatment has been associated with good clinical outcomes in most women suffering from the symptoms of PCS. Symptomatic improvement tends to be seen in >80% of patients undergoing Ovarian and Internal Iliac Vein Embolization. In a 2016 literature review, of the embolization procedure for PCS, Mahmoud et al analyzed 20 studies involving 1,081 total patients and found that 88.1% of patients reported “moderate to significant relief” within the first 90 days and 86.6% reported overall “relief of symptoms” in late follow-up. Another strong literature review conducted within the same year (2016) by Daniel et al analyzed 20 studies composed of 1,308 women, and the analysis reported that 75% of participants reported “substantial
relief” from pain “with low rates of repeated interventions.” In regard to randomized studies, Kim et al, in 2006, treated the ovarian veins in 127 patients followed by interval internal iliac vein embolization and 83% of patients showed clinical improvement 45 months after treatment, with no significant long-term complications. The largest study with the longest follow up was just completed in Europe; wherein Laborda et al (2013) prospectively followed 202 patients over 5 years and showed an astounding 93.9% clinical success rate and a significant reduction in the visual analog pain scale from 7.3 (out of 10) to 0.8. 4,8,11,12

BCBSA Evidence Positioning Systems indicates that the definition of the disease and defining a patient population is unclear. However, multiple studies referenced within the rationale clearly stipulate that the patient population are premenopausal women usually between the age of 20-45 years old, in the setting of ovarian or pelvic venous varicosities, with chronic pelvic pain with prolonged standing, after coitus, and during menstruation, with potential history of dysmenorrhea and menorrhagia.4,6,7,8,10,12,15

BCBSA has also indicated that there is no clear indication if the reporting of “relief of pain” is in turn a placebo effect and there is lack of comparative data to discern its true effect. Based on the pain associated with the condition, it would be inhuman to risk putting a patient into a randomized controlled placebo group. However, there are recent and updated randomized trials (Guirola et al, 2018) that have proven the efficacy of endovascular embolization with larger sample sizes compared to the reports referenced in the rationale.7

Lastly, the reviews provided by BSBSA in support of their rationale (Cochrane review, 2005, Stones Review, 2005, Smith, 2012 and Black, 2010)1,18,19, are all outdated information in comparison to the systematic reviews conducted by Daniels et al (2016) and Mahmoud et al (2016). In addition, these reviews focused on studies with very low sample populations whereas the 2016 reviews had a sample size greater than 1000 patients.4,12 Moreover, when comparing the complications associated with open pelvic surgical interventions, vs. endovascular interventions, embolotherpay patients had a far less significant negative outcomes compared to their counterparts.9,11,13

In addition to the articles referenced, SIR has also included a detail summary and analysis of the many more supporting evidence referenced in the BCBSA Evidence Street Submission Manual. The data, referenced in the BCBSA Evidence Street Submission Manual, is consistent with the findings outlined above and support embolization of additional pelvic veins to maximize therapeutic benefit. In summary, patients that present with clinical signs and symptoms as well as, imaging findings consistent with PCS are excellent candidates for Ovarian and Internal Iliac Vein Embolization.

As a professional medical association representing approximately 8,000 members, including most US physicians who are practicing in the specialty of vascular and interventional radiology, SIR is fully dedicated to improving the lives of all patients
through imaging and image-guided minimally invasive procedures. Pelvic Congestion Syndrome is a high priority for our patients, and current evidence-based research continuously supports Ovarian and Internal Iliac Vein Embolization as a medically necessary designated treatment. In addition, in comparison to other treatment alternatives, endovascular embolization has proven to have better clinical outcomes, faster recovery time, and lower rates of repeated interventions required.4,9,11,13

Thanks for the courtesy of your review of this request. If we can be of any future assistance, please do not hesitate to contact Susan Sedory, SIR’s Executive Director, at (703) 691 1805, or ssedory@sirweb.org.

Sincerely,

Laura Findeiss, MD, FSIR
SIR President
References: