RE: [PATIENT NAME]  
[ PATIENT ID]  
Request for coverage for Ovarian Vein Embolization (OVE) to treat Pelvic Congestion Syndrome (PCS)

[CARRIER MEDICAL DIRECTOR]:

On [INSERT DATE OF PRECERTIFICATION/COVERAGE REQUEST DENIAL], notice was received from your company that Ovarian Vein Embolization (OVE) is considered experimental and investigational and therefore, a non-covered service. This is a formal request for individual consideration to extend coverage for OVE for [PATIENT NAME], who is suffering from Pelvic Congestion Syndrome (PCS).

[ PATIENT NAME] has presented with symptoms consistent with pelvic congestion syndrome, which is a well defined condition. Namely, she has experienced longstanding [LIST RELEVANT SYMPTOMS: cyclical pelvic pain and pressure that correlates with her menses, pain during/after sexual intercourse, pelvic pain worse upon standing/sitting/walking] She has been seen by a physician, MD, and has undergone a rigorous clinical evaluation to determine the cause of her symptoms. Both Dr. [Referring MEDICINE PHYSICIAN NAME] and my findings are consistent; confirming that [PATIENT NAME] has physical findings that are commonly found with pelvic congestion syndrome, including recurrent varicose veins in the lower extremity(ies) [ADD OTHER RELEVANT SIGNS: vulvar varices, hemorrhoids]. Additionally, [LIST RELEVANT DIAGNOSTIC STUDY(IES)- FOR EXAMPLE- an MR venogram of the pelvis shows large ovarian and pelvic veins/ an ultrasound of the pelvis has been performed, which demonstrated enlarged pelvic varicosities, more prominent on the left than the right.- supporting a diagnosis of PCS for this patient. OVE has been found to be an effective minimally invasive procedure to treat the symptoms of PCS and is recommended for this patient.

PCS Symptoms  
[ PATIENT NAME] is not alone in suffering with the symptoms of PCS. It has been estimated that almost 40% of all women will experience chronic pelvic pain during their lifetime and that 15% of all women between the ages of 18-50 experience chronic pelvic pain. Of note, 15% of all hysterectomies and 35% of all diagnostic laparoscopies are performed due to chronic pelvic pain. Ovarian vein incompetence has been shown to
occur in approximately 10% of women. This phenomenon can lead to PCS and its associated symptoms in 60% of these patients. Despite this incidence, PCS is significantly under-diagnosed. It typically results in pelvic pain that is often described as dull and aching. The pain is typically worse in an upright position and becomes more severe with walking and postural changes. It may be associated with dyspareunia or a postcoital ache.

These symptoms of pelvic congestion syndrome (PCS) are typically caused by the development of varicosities in the infundibulopelvic and broad ligaments within the pelvis. The exact reason why these varicosities develop is unknown, but one important factor is the absence or incompetence of valves in the ovarian veins. Anatomy may also play a role: the left ovarian vein is more frequently incompetent than the right. Since the left ovarian vein drains vertically into the high-pressured left renal vein, it may be more prone to reflux than the right ovarian vein, which enters directly into the side of the inferior vena cava. Accordingly, symptoms are often more common or more severe on the left, as seen with [PATIENT NAME]. Hormones may also contribute since PCS mainly affects premenopausal women. Rarely, left-sided ovarian vein reflux can be caused by the “nutcracker” syndrome, in which the left renal vein is compressed between the superior mesenteric artery and the aorta. The back pressure in the renal vein is transmitted to the renal venules and ovarian vein, resulting in hematuria and pelvic congestion respectively. The pain associated with pelvic congestion syndrome has been directly attributed to the presence of these dilated veins within the pelvis.

**OVE Treatment Plan for PCS**

Once a patient such as [PATIENT NAME] has been diagnosed with PCS, it is important to direct treatment towards eliminating retrograde flow in the abnormal ovarian vein(s). Doing so reduces pressure in the pelvic veins, which in turn alleviates or improves symptoms. Ovarian vein embolization (OVE), a percutaneous, catheter-based procedure that results in occlusion of the abnormal ovarian vein(s), effectively eliminates retrograde flow in the ovarian vein. For the past 15 years, this treatment has been associated with good clinical outcomes in most women suffering from the symptoms of PCS. The procedure is technically successful in almost 100% of patients. Symptomatic improvement tends to be seen in >80% of patients undergoing OVE. The largest study with the longest follow up was just completed in Europe; 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. Gandini et al (2008) demonstrated statistically significant improvement in pelvic pain, dyspareunia, urinary urgency, and menstrual pain in 38 women treated with OVE. Kim, et al (2006) demonstrated an 83% success rate in 127 patients treated with OVE, with an impressive 4-year follow-up. Kwon, et al (2007) reported symptomatic improvement in 82% of 67 patients treated with OVE. Venbrux, et al (2002) reported symptomatic improvement in 96% of the 56 patients 12 months after being treated with OVE. Other reports by Mowatt, et al, Capasso, et al, Sichlar, et al, Tarazov, et al, Maleux, et al, and Cordts, et al have reported similar data to the studies outlined above. In select patients with the “nutcracker” syndrome described above, a less than 50% stenosis of the renal vein may be safely treated with OVE to relieve the pelvic
pain caused by reflux into the ovarian vein. In summary, patients that present with clinical signs and symptoms as well as, imaging findings consistent with PCS are excellent candidates for OVE.

OVE is performed on an outpatient basis. The OVE procedure begins with an ovarian venogram to confirm that retrograde flow is present. If reflux and retrograde flow is identified within the left and/or right ovarian vein, the vein is embolized to eliminate this reflux and reduce the pressure within pelvic varicosities.

**Body of Scientific Literature Supporting OVE is an Effective Treatment for PCS**

Attached is a comprehensive listing of the scientific literature available that supports OVE as an effective treatment for PCS (see Attachment A). Also, enclosed is a table (see Attachment B) summarizing the scientific articles available supporting ovarian vein embolization as an effective treatment for pelvic congestion syndrome. Of note, many of these articles support embolization of additional pelvic veins to maximize therapeutic benefit.

OVE emerged because of its safety, efficacy, and non-invasiveness compared with surgery: in a Korean study in which patients with documented PCS were randomized to hysterectomy (with either oopherectomy of ovary on the side of an incomplete gondal vein or bilateral oopherectomy) or OVE, OVE demonstrated significantly better results than surgery.

**Equitable Coverage Sought for Equivalent Treatments for Comparable Syndromes Found in Men and Women**

Painful dilated veins in the scrotum of men, caused by a refluxing testicular vein, result in varicoceles that are successfully treated with gonadal vein embolization. Painful dilated veins of the uterus and pelvis in women results in the Pelvic Congestion Syndrome. These are comparable syndromes with a common etiology. Given that the safety and efficacy of embolotherapy for both conditions are well-supported by the literature and that male varicoceles is routinely covered, it would not be fair to deny women coverage for the same condition. As such, we respectfully request that you re-consider and reverse this inappropriate determination. Please extend coverage to [PATIENT NAME] for ovarian vein embolization to treat pelvic congestion syndrome.

I hope that you will find this information helpful in reversing the previous denial [FOR PREAUTHORIZATION/OF COVERAGE]. Please feel free to contact me if you require any further information.

Sincerely,
[SIR MEMBER NAME], MD
[SIR MEMBER TITLE]

CC: [PATIENT NAME]
[STATE INSURANCE COMMISSIONER]
Robert White, Director of Reimbursement & Hospital Affairs, SIR