The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

Transcatheter uterine artery embolization (UAE) is a minimally invasive technique that involves the injection of small particles into the uterine arteries to block the blood supply to the uterus and uterine fibroids. It potentially serves as an alternative to hysterectomy. UAE has also been used to treat other conditions including postpartum hemorrhage (PPH) and cervical ectopic pregnancy.

Background

Uterine leiomyomata (i.e., fibroids) are extremely common benign tumors that can be located primarily within the uterine cavity (submucosal fibroids) or on the serosal surface of the uterus. Treatment for uterine fibroids is usually sought when they are associated with menorrhagia, pelvic pain, urinary symptoms (i.e., frequency), or are suspected to be the cause of infertility. Treatment options include medical therapy with gonadotropin agonists or gestagen suppression or various types of surgical therapy. Hysterectomy is considered the definitive surgical treatment for those who no longer wish to maintain fertility. Various types of myomectomy, which describes removal of the fibroid with retention of the uterus, have also been described. Hysteroscopic myomectomy involves removal of submucosal fibroids using either a resectoscope or a laser. Subserosal fibroids can be removed via an open abdominal or laparoscopic approach. Laparoscopic laser coagulation of uterine fibroids is a unique approach in that the fibroid is not physically removed, but instead multiple (up to 75) laparoscopic laser punctures of the uterine fibroids are performed in an effort to devascularize the fibroid and induce atrophy. There is interest in techniques to directly devascularize the uterine fibroid by interrupting the uterine arteries. One technique, uterine artery embolization involves selective catheterization of the uterine arteries with injection of embolization material.

UAE has also been used to control bleeding in other situations such as severe postpartum hemorrhage or in the treatment of cervical ectopic pregnancy.

Regulatory Status

In April 2000, Embosphere® Microspheres (Biosphere Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for hypervascularized tumors and arteriovenous malformations (AVMs). In November 2002, this product was cleared for marketing specifically for use in uterine fibroid embolization. Since that time, several other devices have been cleared for marketing. In 2003, Contour® Emboli PVA (Boston Scientific) was cleared for the embolization of peripheral hypervascular tumors and peripheral AVMs. In March 2004, the Contour SE™ (Boston Scientific) was cleared by the FDA for treatment of uterine fibroids. In December 2008, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles received FDA marketing clearance for use in uterine fibroid embolization.
Corporate Medical Guideline

Transcatheter embolization of uterine arteries as a treatment of uterine fibroids or as a treatment of postpartum uterine hemorrhage may be considered medically necessary.

One repeat transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization may be considered medically necessary (see Policy Guideline).

Transcatheter embolization for the management of cervical ectopic pregnancy is considered investigational.

Policy Guidelines

Patient Selection Criteria

Initial procedure

There are no specific criteria for uterine artery embolization regarding the size, location, or multiplicity of fibroid tumors. The American College of Obstetricians and Gynecologists (ACOG) has suggested the following general criteria for treatment of fibroid tumors:

- Asymptomatic fibroids of such size that they are palpable abdominally and are a concern to the patient; OR
- Excessive uterine bleeding as evidenced by either profuse bleeding lasting more than eight days, or anemia due to acute or chronic blood loss; OR
- Pelvic discomfort caused by myomata, either acute severe pain, chronic lower abdominal pain, or low back pressure or bladder pressure with urinary frequency not due to urinary tract infection.

Repeat procedure

One repeat UAE may be performed when there is documentation of continued symptoms such as bleeding or pain. Repeat procedures may be most appropriate when there are persistent symptoms in combination with findings on imaging of an incomplete initial procedure, as evidenced by continued blood flow to the treated regions. Limited data from case series suggest a high rate of success following repeat procedures for this purpose, with the majority of patients reporting relief of symptoms.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.
References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


