Occlusion of Uterine Arteries Using Transcatheter Embolization

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Preauthorization is not required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: • With Uterine fibroids</td>
<td>Interventions of interest are: • Transcatheter uterine artery embolization</td>
<td>Comparators of interest are: • Hysterectomy • Myomectomy • Different uterine fibroid treatment</td>
<td>Relevant outcomes include: • Symptoms • Quality of life • Resource utilization • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With persistent uterine fibroids despite prior uterine artery embolization</td>
<td>Interventions of interest are: • Repeat transcatheter uterine artery embolization</td>
<td>Comparators of interest are: • Hysterectomy • Myomectomy</td>
<td>Relevant outcomes include: • Symptoms • Quality of life • Resource utilization • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With postpartum uterine hemorrhage</td>
<td>Interventions of interest are: • Transcatheter uterine artery embolization</td>
<td>Comparators of interest are: • Hysterectomy • Uterine-sparing surgery (e.g., balloon tamponade, compression sutures)</td>
<td>Relevant outcomes include: • Overall survival • Symptoms • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With cervical ectopic pregnancy</td>
<td>Interventions of interest are: • Transcatheter uterine artery embolization</td>
<td>Comparators of interest are: • Medication (e.g., methotrexate) • Surgery</td>
<td>Relevant outcomes include: • Resource utilization • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With uterine arteriovenous malformations</td>
<td>Interventions of interest are: • Transcatheter uterine artery embolization</td>
<td>Comparators of interest are: • Medication • Hysterectomy</td>
<td>Relevant outcomes include: • Symptoms • Resource utilization • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With adenomyosis</td>
<td>Interventions of interest are: • Transcatheter uterine artery embolization</td>
<td>Comparators of interest are: • Medication • Hysterectomy</td>
<td>Relevant outcomes include: • Symptoms • Resource utilization • Treatment-related morbidity</td>
</tr>
</tbody>
</table>

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, cervical ectopic pregnancy, and bleeding uterine arteriovenous malformation and adenomyosis.

**Summary of Evidence**

For individuals who have uterine fibroids who receive transcatheter UAE, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. The studies have generally found similar levels of symptoms and quality of life after UAE versus surgery. There were more reinterventions in the UAE group, but some women avoided surgery and maintained their uteruses. Moreover, studies have found lower complication rates after UAE versus surgery. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have persistent uterine fibroids despite prior uterine artery embolization who receive repeat transcatheter UAE, the evidence includes case series. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. Case series have shown that a high degree of symptom relief is possible after a repeat UAE for uterine fibroids. Moreover, evidence from RCTs on the safety and efficacy of UAE for initial treatment of uterine fibroids can be extrapolated to repeat procedures for the same indication. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have postpartum uterine hemorrhage who receive transcatheter UAE, the evidence includes case series and a systematic review. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. The systematic review of case series with over 1400 women found a rate of success of stopping bleeding. Postpartum uterine hemorrhage is an emergency situation with serious potential consequences (i.e., maternal mortality). Conducting RCTs is particularly difficult in this setting and may be unnecessary when there are sufficient uncontrolled data. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cervical ectopic pregnancy who receive transcatheter UAE, the evidence includes case series. Relevant outcomes are resource utilization and treatment-related morbidity. Only a few case series with a small number of patients have been published. Additional studies, especially controlled studies comparing UAE to medication or surgery, are needed to draw conclusions about the safety and efficacy of UAE in patients with cervical ectopic pregnancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have uterine arteriovenous malformations (AVM) who receive transcatheter UAE, the evidence includes case reports, case series, and a systematic review. Relevant outcomes are symptoms, resource utilization, and treatment-related morbidity. Only case reports and case series with a small number of patients have been published. A systematic review identified 54 women in 40 studies with uterine AVM treated using UAE. Additional studies, especially controlled studies comparing UAE to hysterectomy, are needed to draw conclusions about the safety and efficacy of UAE in patients with uterine AVM. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have adenomyosis who receive transcatheter UAE, the evidence includes case series and a systematic review. Relevant outcomes are symptoms, resource utilization, and treatment-related morbidity. A systematic review of case series data found short-term improvement in 83% of patients and long-term improvement in 65% of patients, suggesting possible recurrence of symptoms over time. All studies were case series and may have been subject to selection and/or observational biases. Controlled studies comparing UAE to medica-
tion or surgery and studies reporting long-term symptom recurrence rates are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Transcatheter embolization of uterine arteries as a treatment of uterine fibroids or as a treatment of postpartum uterus 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 Guidelines).

Transcatheter embolization for the management of all other indications, including cervical ectopic pregnancy, uterine arteriovenous malformation and adenomyosis 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 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 most patients reporting relief of symptoms.

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 (UAE) 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, treatment of cervical ectopic pregnancy, treatment of bleeding uterine arterio-venous malformation and adenomyosis.

**Regulatory Status**

In April 2000, Embosphere® Microspheres (Merit Medical, formerly 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. 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 arteriovenous malformations. In March 2004, the Contour SE™ (Boston Scientific) was cleared by FDA for treatment of uterine fibroids. In December 2008, Polyvinyl Alcohol Foam Embolization Particles (Cook Inc.) was cleared for marketing by FDA through the 510(k) process for use in uterine fibroid embolization. FDA product code: NAJ.

**Related Protocol**

Magnetic Resonance-Guided Focused Ultrasound

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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.


