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OVERVIEW

Wireless sensors implanted in an aortic aneurysm sac after endovascular repair are being investigated to measure post-procedural pressure. It is thought that low pressures may correlate with positive prognoses, and high pressures may indicate the need for revision.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Use of wireless pressure sensors is considered not covered in the management (intraoperative and/or postoperative) of patients having endovascular aneurysm repair as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Use of wireless pressure sensors is considered not medically necessary in the management (intraoperative and/or postoperative) of patients having endovascular aneurysm repair as the evidence is insufficient to determine the effects of the technology on health outcomes.

BACKGROUND

The goal of abdominal aortic aneurysm (AAA) repair is to reduce pressure in the aneurysm sac and thus prevent rupture. Failure to exclude the aneurysm completely from the systemic circulation results in continued pressurization. An endoleak (persistent perfusion of the aneurysmal sac) may be primary (within the first 30 days) or secondary (after 30 days). Endoleaks are reported to vary from 10% to 50% of cases, and there are 5 types of endoleaks.¹ Type I endoleaks result from ineffective fixation at either end of the graft; while these can seal spontaneously, risk of rupture is high and intervention is often indicated. Type II endoleaks result from retrograde filling of the aneurysm mainly from lumbar and/or inferior mesenteric arteries. Risk of rupture is less than with types I and III, and type II endoleaks can often be monitored when the aneurysm is shrinking. Type III endoleaks are caused by failure of the implanted graft and include development of holes, which need to be treated aggressively. Type IV endoleaks are caused by the porosity of the graft fabric. Type V endoleaks are referred to as endotension and correspond to continued aneurysm expansion in the absence of a confirmed endoleak. Endoleaks, particularly types I and III, lead to continued sac pressurization and therefore may be considered technical failures of endovascular aneurysm repair (EVAR).

The completeness of exclusion or absence of endoleaks is evaluated by intraoperative angiography. However, interpretation of images can be problematic, and it can also cause patient morbidity due to the dye load from repeated injections of contrast material. Direct measurement of sac pressure provides a physiologic assessment of success. Studies have used direct sac pressure measurements with a catheter; the drawback of this approach is the interference by the catheter during endovascular repair and the inability to leave it in

place. Because endoleaks may also develop subsequent to the time of surgery, magnetic resonance imaging and ultrasound are used in monitoring the aneurysmal sac. Percutaneous catheter-based approaches can also be used to measure intrasac pressures postoperatively.

Several factors determine aneurysm sac pressure after EVAR. These include graft-related factors, such as endoleak, graft porosity, and graft compliance and anatomic factors, such as patency of aneurysm side branches, aneurysm morphology, and the characteristics of aneurysm thrombus.

Given this situation, wireless implantable pressure-sensing devices are being evaluated to monitor pressure in the aneurysm sac. These implanted devices use various mechanisms to wirelessly transmit pressure readings to devices for measuring and recording pressure. These devices have the potential to improve outcomes for patients who have had endovascular repair. They may change the need for or the frequency of monitoring of the aneurysm sac using contrast-enhanced computed tomography scans. They may improve postoperative monitoring. However, the accuracy of these devices must be determined, and potential benefits and risks must be considered and evaluated. At present, 2 types of systems are being evaluated: radiofrequency and ultrasound-based systems.

For individuals who have received endovascular aneurysm repair who are monitored with wireless pressure sensors, the evidence consists of case series. Relevant outcomes are test accuracy and validity, resource utilization, and treatment-related morbidity. Evidence from small case series is insufficient to indicate whether use of this device improves clinical outcomes. Device performance over time, including the accuracy of the device in patients with various types of endoleaks, needs to be assessed. Work is also needed to determine the type and number of devices that might best for monitoring because sac compartmentalization might lead to a pressure-sensing device missing an endoleak. It also is not known whether there are serious long-term complications from this implanted device. Furthermore, the extent to which the device can reduce imaging requirements following endovascular aneurysm repair (which can be established using direct comparison to computed tomography) is undetermined. The evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

BlueCHiP for Medicare and Commercial Products

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:

- 34806** Transcatheter placement of wireless physiologic sensor in aneurysmal sac during endovascular repair, including radiological supervision and interpretation, instrument calibration, and collection of pressure data (List separately in addition to code for primary procedure)
- 93982** Noninvasive physiologic study of implanted wireless pressure sensor in aneurysmal sac following endovascular repair, complete study including recording, analysis of pressure and waveform tracings, interpretation and report

RELATED POLICIES

None

PUBLISHED

Provider Update, February 2019
Provider Update, May 2017
Provider Update, September 2016

Provider Update, August 2015
Provider Update, November 2013

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2. Sonesson B, Dias N, Malina M et al. Intra-aneurysm pressure measurements in successfully excluded abdominal aortic aneurysm after endovascular repair. *J Vasc Surg* 2003; 37(4):733-8.
3. Dias NV, Ivancev K, Malina M et al. Intra-aneurysm sac pressure measurements after endovascular aneurysm repair: differences between shrinking, unchanged, and expanding aneurysms with and without endoleaks. *J Vasc Surg* 2004; 39 (6):1229-35.
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5. Ellozy SH, Carroccio A, Lookstein RA et al. Abdominal aortic aneurysm sac shrinkage after endovascular aneurysm repair: correlation with chronic sac pressure measurement. *J Vasc Surg* 2006; 43(1):2-7.
6. Silveira PG, Miller CW, Mendes RF et al. Correlation between intrasac pressure measurements of a pressure sensor and an angiographic catheter during endovascular repair of abdominal aortic aneurysm. *Clinics (Sao Paulo)* 2008; 63(1):59-66.
7. Hoppe H, Segall JA, Liem TK et al. Aortic aneurysm sac pressure measurements after endovascular repair using an implantable remote sensor: initial experience and short-term follow-up. *Eur Radiol* 2008; 18(5):957-65.
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