



Wireless Pressure Sensors in Endovascular Aneurysm Repair

Policy Number: 7.01.111
Origination: 9/2007

Last Review: 9/2014
Next Review: 3/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for wireless pressure sensors in endovascular aneurysm repair. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Use of wireless pressure sensors is considered **investigational** in the management (intra-operative and/or post-operative) of patients having endovascular aneurysm repair.

Considerations

For these FEP reviews of the CardioMEMS Endosure system, it is important to note that the FDA language comments only on intraoperative use of the device.

Description of Procedure or Service

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

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 10–50% 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. Since endoleaks may also develop subsequent to the time of

surgery, magnetic resonance imaging (MRI), 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 (CT) 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.

Regulatory Status

In October 2006, the U.S. Food and Drug Administration (FDA) cleared the CardioMEMS EndoSure™ (radiofrequency-based) system through the 510(k) process. (2) The favorable FDA review indicated only that the device was substantially equivalent to legally marketed predicate devices. The FDA labeling indications noted that the device is intended for measuring intrasac pressure during endovascular AAA repair. It also noted that it may be used as an adjunctive tool in the detection of intraoperative endoleaks. In March 2007, additional language was added stating that the CardioMEMS device may be used to measure intrasac pressure during thoracic aortic aneurysm repair.

The ImPressure™ system (ultrasound-based) is used in Europe and is being used as part of an investigation device exemption (IDE) trial of stent grafts (see Rationale).

Rationale

This policy was originally created in 2007 and was regularly updated with searches of the MEDLINE database. The most recent literature search was performed for the period August 28, 2012 through November 7, 2013. The following is a summary of the key findings to date.

While multiple factors (see above) influence aneurysm sac pressure after endovascular aneurysm repair (EVAR), models have demonstrated that with exclusion of the sac after EVAR, sac pressures diminish significantly. Using direct translumbar puncture in 10 patients after EVAR with sac shrinkage and no evidence of endoleak, Sonesson et al demonstrated that mean intrasac pressure diminishes to 20% of mean arterial pressure.(2) Dias et al reported on 46 percutaneous intrasac pressure readings in 37 patients following EVAR.(3) In these patients, they calculated the mean pressure index (MPI)—the percentage of mean intra-aneurysm pressure relative to the simultaneous mean intra-aortic pressure. Median MPI was 19% in 11 patients with shrinking sacs, 30% in 10 patients with unchanged sacs, and 59% in 9 expanding aneurysms. Type II endoleaks (6 patients) were associated with a wide range of MPI (22%-92%). The authors comment that the findings from this small series do not imply that imaging follow-up can be replaced by pressure measurements. They also note that a definitive pressure threshold using direct measurement for subsequent intervention needs to be defined by further studies.

For the wireless devices, Ohki et al reported initial results from the APEX study—acute pressure measurement to confirm aneurysm sac exclusion.(4) They reported 30-day results on 76 of 90 enrolled patients at 12 sites worldwide who received the CardioMEMS wireless pressure sensor during EVAR. Of the patients enrolled, results were not reported on 14 patients due to “protocol deviations, typically a missed measurement.” In 1 patient, the device could not be deployed because space was inadequate (<10 mm) within the aneurysm sac after graft deployment. In all 76 patients, there was close agreement between the wireless sensor and angiographic catheter for a type I endoleak equivalent. As defined in the study, a reduction in pulse pressure of 30% or more from the initial pressure measurement would

be associated with a sealed sac, and a less than 30% reduction in pulse pressure would indicate a type I or III endoleak. With angiography as the standard, for detection of type I or III endoleak at the completion of the procedure, the sensor detected 4 of 5 (80%) of the leaks. The authors comment that the case that was not detected was not clinically significant, ie, no intervention was required. The wireless sensor indicated no endoleak in 66 of 71 (93%) cases without an angiographic endoleak. Deployment of the device was noted to add 10 minutes to the EVAR procedure; the average operative time for those in the study was 205 (87) minutes. No complications were felt due to the wireless sensor, although the authors did comment that there was a learning curve associated with deployment and using the device. This report also notes that these patients will be followed up for 5 years and that long-term data will provide information to evaluate the value of the sensor for postoperative follow-up surveillance. The value of the device will need to include not only benefit but also any potential complications due to the implanted device.

Ellozy et al reported results with a mean follow-up of 11 months of 21 patients using the Impressure™ AAA (abdominal aortic aneurysm) Sac Pressure Transducer.(5) This device was studied as part of an investigational device exemption examining use of an endovascular stent-graft in the repair of infrarenal AAAs in high-risk patients. This transducer is hand-sewn into the outside of the stent-graft and then packaged as part of the delivery sheath. During follow-up, pressures could be obtained at all visits in 15 of the 21 patients. There were problems with readings from 4 of the devices thought to be due to placement of the devices between the iliac limbs of the stent graft. For the 14 patients with follow-up of at least 6 months, aneurysm sac shrinkage of more than 5 mm was seen in 7 patients, and the MPI was significantly lower in those with sac shrinkage at 6 months. Two patients with shrinking aneurysms had type II endoleaks.

In 2008, 2 case series were published, both using the Endosure™ radiofrequency device, one of intraoperative use and one of postoperative follow-up for 30 days. The intraoperative series reported the correlation of measurements made during the procedure using the pressure sensor and a catheter inserted into the aneurysm sac among 19 patients.(6) Although the authors reported that all correlation coefficients were statistically significant, they ranged from 0.50 to 0.96. Data presented in the paper show marked differences in measurement, suggesting that the accuracy of the measures requires further study. Of 8 sets of measurements, 4 had more than 50% of patients with at least 10% variation between methods. A second series was a U.S.-based study of postoperative monitoring for endoleaks using the EndoSure™ sensor in 12 patients with 30-day follow-up.(7) At 30 days, 2 type II endoleaks were noted on computed tomography (CT). Sac pressures were unchanged in 1 patient and had decreased in the other. One patient with a type III endoleak on CT had increasing sac pressure. Delivery of the sensor was complicated in 2 of 12 patients (17%). Additional data are needed for these devices with larger patient series and longer duration of follow-up.

In 2010, Parsa et al reported on a single-center case series of 43 patients undergoing thoracic endovascular aneurysm repair (TEVAR). (8) Each patient's aneurysm was implanted with the EndoSure™ device. Aneurysm sac pressures were taken predischarge and at follow-up visits. In 3 patients, pressure measurements prompted imaging that confirmed leakage, which was corrected with further procedures. However, the study was not designed to evaluate how the device contributes to clinical utility.

Ongoing Clinical Trials

A clinical trial began in 2008 to assess the safety and efficacy of the EndoSure™ device in comparison to CT angiography for long-term follow-up after EVAR (NCT00831870). This trial, sponsored by CardioMEMS, is officially titled: Pressure and Imaging—Using the CardioMEMS EndoSure Sensor for Long-term follow-up after EVAR with Standard Surveillance (PRICELESS). As of November 2013, the study is continuing to enroll participants.

Summary

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

Data are currently insufficient to indicate if use of this device improves clinical outcomes. The accuracy of the device in those with various types of endoleaks needs to be determined with larger numbers of patients. Also, the performance over time needs to be addressed. Work is also needed to determine the type and number of devices that might best be used in monitoring given that sac compartmentalization might lead to a pressure-sensing device missing an endoleak. It also is not known whether there might be important long-term complications from this implanted device. Furthermore, the extent to which the device can reduce imaging requirements following endovascular aneurysm repair (via direct comparison with computed tomography) is undetermined. The evidence to date, which consists of small case series, is insufficient to permit conclusions concerning the effect of this device on health outcomes. Therefore, the use of wireless pressure sensors in detecting endoleaks in aneurysm repair is considered investigational.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References

1. Golzarian J, Valenti D. Endoleakage after endovascular treatment of abdominal aortic aneurysms: Diagnosis, significance and treatment. *Eur Radiol* 2006; 16(12):2849-57.
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.
4. Ohki T, Ouriel K, Silveira PG et al. Initial results of wireless pressure sensing for endovascular aneurysm repair: the APEX Trial--Acute Pressure Measurement to Confirm Aneurysm Sac EXclusion. *J Vasc Surg* 2007; 45(2):236-42.
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.
8. Parsa CJ, Daneshmand MA, Lima B et al. Utility of remote wireless pressure sensing for endovascular leak detection after endovascular thoracic aneurysm repair. *Ann Thorac Surg* 2010; 89(2):446-52.

Billing Coding/Physician Documentation Information

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

Additional Policy Key Words

N/A

Policy Implementation/Update Information

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| 9/1/07 | New policy; considered investigational. |
| 3/1/08 | No policy statement changes. |
| 9/1/08 | No policy statement changes. |
| 3/1/09 | No policy statement changes. |
| 9/1/09 | No policy statement changes. |
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| 9/1/10 | No policy statement changes. |
| 3/1/11 | No policy statement changes. |
| 9/1/11 | No policy statement changes. |
| 3/1/12 | No policy statement changes. |
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| 3/1/14 | No policy statement changes. |
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