

MEDICAL POLICY

POLICY TITLE	WIRELESS PRESSURE SENSORS IN ENDOVASCULAR ANEURYSM REPAIR
POLICY NUMBER	MP-1.133

Original Issue Date (Created):	February 28, 2012
Most Recent Review Date (Revised):	September 24, 2013
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I. POLICY

Use of wireless pressure sensors is considered **investigational** in the management (intraoperative and/or postoperative) of patients having endovascular aneurysm repair, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP-1.090 Endovascular Grafts for Abdominal Aortic Aneurysms

MP-1.132 Endovascular Stent Grafts for Thoracic Aortic Aneurysms or Dissections

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids

[N] PPO

[N] HMO

[N] SeniorBlue HMO

[N] SeniorBlue PPO

[N] Indemnity

[N] SpecialCare

[N] POS

[Y] FEP PPO*

* Refer to FEP Medical Policy Manual MP-7.01.111 Wireless Pressure Sensors in Endovascular Aneurysm Repair. The FEP Medical Policy manual can be found at:

<http://bluewebportal.bcbs.com/landingpagelevel3/504100?docId=23980>

III. DESCRIPTION/BACKGROUND

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.

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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. 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.

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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. 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.

IV. RATIONALE

This policy is regularly updated with searches of the MEDLINE database. The most recent literature search was performed for the period of August 2011 through August 28, 2012. 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 and colleagues 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 and colleagues 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

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14 patients due to “protocol deviations, typically a missed measurement.” In 1 patient, the device could not be deployed because space was inadequate (less than 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, i.e., 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 (IDE) 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 mean pressure index (MPI) was significantly lower in those with sac shrinkage at 6 months. Two of the patients with shrinking aneurysms had type II endoleaks.

In 2008, two 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

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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 and colleagues 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 pre-discharge 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). This trial is scheduled for completion in October 2012.

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 EVAR (via direct comparison with CT) 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.

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V. DEFINITIONS

STENT refers to any material or device used to hold tissue in place, to maintain open blood vessels, or to provide support for a graft or anastomoses while healing is taking place.

THORACIC refers to the chest or thorax.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. 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.*

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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.
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.

IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

CPT Codes®							
34806	93982						

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X. Policy History

MP 1.133	CAC 2/28/12 Adopt BCBSA. Information related to wireless pressure sensors in endovascular repair was extracted from MP 1.090, Endovascular Repair of Aortic Aneurysms, and this separate policy created. No change to policy statement. Remains investigational.
	7/29/13 Admin coding review complete--rsb
	CAC 9/24/13 Consensus. No change to policy statements. References updated. Changed FEP variation to reference the FEP manual. Added Rationale section.

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