Protocol

Wireless Pressure Sensors in Endovascular Aneurysm Repair

(701111)

Medical Benefit		Effective Date: 01/01/14	Next Review Date: 09/14
Preauthorization	No	Review Dates: 09/08, 09/09, 09/10, 09/11, 09/12, 09/13	

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 but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.*** *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

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 five 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, two 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. 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 investigational device exemption (IDE) trial of stent grafts.

Related Protocol:

Endovascular Grafts for Abdominal Aortic Aneurysms

Corporate Medical Guideline

Use of wireless pressure sensors is considered **investigational** in the management (intraoperative and/or postoperative) of patients having endovascular aneurysm repair.

Benefit Application

Because the value of providing this service in addition to the endovascular repair has not been established, we will not reimburse a separate payment when wireless pressure sensor has been implanted.

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.

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.