BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Wireless Pressure Sensors in Endovascular Aneurysm Repair

Policy #: 488
Category: Surgery

Latest Review Date: December 2020
Policy Grade: **Effective July 14, 2016: Active policy but no longer scheduled for regular literature reviews and updates.**

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat the **use of wireless pressure sensors** as a **non-covered benefit** and as **investigational** in the management (intraoperative and/or postoperative) of patients having endovascular aneurysm repair.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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.

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 and 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.

KEY POINTS:

The most recent literature search was reviewed through November 7, 2019.

Summary of Evidence

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. 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 serious 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 is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

No guidelines or position statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable

KEY WORDS:

Abdominal Aortic Aneurysm, Pressure Sensor or Monitor, EndoSure Pressure Sensor, Abdominal Aortic Aneurysmal Sac, CardioMEMS, EndoSure, Impressure, AAA, Endovascular repair, wireless pressure sensor

APPROVED BY GOVERNING BODIES:

In October 2006, the EndoSure™ Wireless AAA Pressure Measurement System (CardioMEMS; now St. Jude Medical, Minneapolis, MN) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this 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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

As of 01/01/2018, there is no specific code for this procedure. Use unlisted code 93799.

PREVIOUS CODING:

CPT Codes:

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.) (Deleted 12/31/2017)
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. (Deleted 12/31/2017)

*CPT code 34806 is not to be reported in conjunction with 93982 as any study done at the time of insertion is included in 34806. Code 34806 includes deployment of the sensor, intraoperative calibration and any repositioning required.

REFERENCES:

1. 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.

2. 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.
3. Golzarian J, Valenti D. Endoleakage after endovascular treatment of abdominal aortic aneurysms: Diagnosis, significance and treatment. Eur Radiol 2006; 16(12):2849-57.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.

POLICY HISTORY:

Adopted for Blue Advantage, October 2011
Available for comment November 11 through December 27, 2011
Medical Policy Group, October 2012
Medical Policy Group, December 2013
Medical Policy Group, April 2015
Medical Policy Group, July 2016
Medical Policy Group, December 2017
Medical Policy Group, December 2020