**Medical Coverage Policy** | Wireless Pressure Sensors in Endovascular Aneurysm Repair



**EFFECTIVE DATE:** 9/03/2013 **POLICY LAST UPDATED:** 08/15/13

## **OVERVIEW**

This policy documents the coverage determination for Wireless Pressure Sensors in Endovascular Aneurysm Repair. These implanted devices use various mechanisms to wirelessly transmit pressure readings to devices for measuring and recording pressure. The evidence to date, which consists of small case series, is insufficient to permit conclusions concerning the effect of this device on health outcomes.

# **PRIOR AUTHORIZATION**

Not applicable.

# **POLICY STATEMENT**

BlueCHiP for Medicare and 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 due to lack of medical literature to support its use.

# **MEDICAL CRITERIA**

None

# BACKGROUND

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.

The goal of abdominal aortic aneurysm repair is to reduce pressure in the aneurysm sac and thus prevent rupture. Failure to completely exclude the aneurysm 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 lead to continued sac pressurization and therefore may be considered technical failures of endovascular aneurysm repair (EVAR).

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 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 (CardioMEMS EndoSure<sup>TM</sup>) and ultrasound-based (ImPressure<sup>TM</sup>) systems.

Data is 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. That is, because of sac compartmentalization a pressure-sensing device might not detect an endoleak. It also is not known if there might be important long-term complications from this implanted device. 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 not medically necessary.

# COVERAGE

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

# CODING

# BlueCHiP for Medicare and Commercial products:

The following codes are not medically necessary:

- 34806 Transcatheter placement of wireless physiologic sensor in aneurysmal sac during endovascular repair, including radiological supervision and interpretation, instrument calibration, and collection of pressure date (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	Nov 2013
Provider Update	June 2011
Provider Update	Aug 2010
Provider Update	April 2009

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