Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona, Inc.

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Implantable Wireless Abdominal Aortic Aneurysm Pressure Management System (EndoSure®)

Policy Number: HS-175

Original Effective Date: 6/17/2010

Revised Date(s): 8/2/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

IMPLANTABLE WIRELESS ABDOMINAL AORTIC ANEURYSM PRESSURE MANAGEMENT SYSTEM (ENDOSURE®) HS-175

BACKGROUND

The goal of abdominal aortic aneurysm (AAA) 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 are reported to vary from 10%–50% of cases, and there are 5 types of endoleaks. (2) 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, computed tomography (CT), 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 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.

POSITION STATEMENT

The use of the EndoSure® implantable wireless pressure management system following abdominal aortic aneurysm repair **is considered experimental and investigational and NOT a covered benefit.**

CODING

Non-covered CPT© Code

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.
+ Add on code, this is listed separately in addition to code for primary procedure.

93982 Non-invasive 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.

Non-Covered ICD-9-CM Procedure Code
39.71 Endovascular implantation of graft in abdominal aorta

HCPCS Code - Not applicable

Non-Covered ICD-9-CM Diagnosis Code
441.4 Abdominal aneurysm without mention of rupture

REFERENCES

Peer Reviewed

1. Hayes, Inc. Search and Summary. Endosure® Wireless Abdominal Aortic Aneuysm (AAA) Pressure Measurement System (CardioMEMS Inc.). Lansdale, PA: Hayes, Inc. February, 19, 2008.
2. Hirsch AT, Haskal ZJ, Hertzer NR, Bakal CW, Creager MA, Halperin JL, et al. American Association for Vascular Surgery; Society for Vascular Surgery; Society for Cardiovascular Angiography and Interventions; Society for Vascular Medicine and Biology; Society of Interventional Radiology; ACC/AHA Task Force on Practice Guidelines; American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; Vascular Disease Foundation. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): executive summary a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease) endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. J Am Coll Cardiol. 2006 Mar 21;47(6):1239-312.
3. Hoppe H, Segall JA, Liem TK, Landry GJ, Kaufman JA. Aortic aneurysm sac pressure measurements after endovascular repair using an implantable remote sensor: initial experience and short-term follow-up. Eur Radiol. 2007 Dec 20.
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):236-242.
5. Silveira PG. Miller CW. Mendes RF. Galego GN. Correlation between intrasac pressure measurements of a pressure sensor and an angiographic catheter during endovascular repair of abdominal aortic aneurysm. Clinics (Sao Paulo, Brazil). 63(1):59-66, 2008 Feb.
6. Wilt TJ, Lederle FA, MacDonald R, Jonk YC, Rector TS, Kane RL. Comparison of Endovascular and Open Surgical Repairs for Abdominal Aortic Aneurysm. Evidence Report/Technology Assessment No. 144. (Prepared by the University of Minnesota Evidence Based Practice Center under Contract No. 290-02-0009.) AHRQ Publication No. 06-E017. Rockville, MD. Agency for Healthcare Research and Quality. August 2006.

Government Agencies, Professional and Medical Organizations - N/A

Other

1. BlueCross BlueShield Association Medical Policy Reference Manual, Policy No. 7.01.111

HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC. No changes.