May 4, 2012

[redacted]
[redacted]vices, Inc.
[redacted]57

RE: Independent External Review – AMENDED

Covered Person: [redacted]
Health Carrier:
VA External Review#:
Date Assigned: 04/10/2012
Additional Files Received: 05/02/2012

ISSUE TO BE ADDRESSED:

Is the use of a wearable cardioverter defibrillator vest considered experimental/investigational and, therefore, not medically necessary for this patient?

APPEAL SUMMARY:

In its letter dated 02/06/2012, Anthem explains its determination as follows:

> "A board certified doctor of cardiovascular disease reviewed the entire record of the appeal, including any additional information you or your health care provider sent to us. Coverage for the device remains denied because it is considered investigational. The current medical studies do not show that this device is as good as, or better than, standard therapy for your heart condition. This decision is based on your health plan's coverage guideline for Wearable Cardioverter Defibrillators and the current medical literature."

PLAN LANGUAGE:

Anthem, *Coverage Guideline, Subject: Wearable Cardioverter Defibrillators, Document #: MED.00055,* at pages 1-2 holds:

> **"Position Statement**
>
> **Medically Necessary:**
>
> The wearable cardioverter defibrillator (WCD) is considered **medically necessary** for individuals at high-risk of sudden cardiac arrest, who meet the following criteria:
>
> 1. Individuals must meet the medical necessity criteria for an implantable cardioverter defibrillator* (ICD); **AND**
> 2. Individuals must have ONE of the following documented medical contraindications to ICD implantation;

a. Those awaiting a heart transplantation – on waiting list and meet medical necessity criteria for heart transplantation;** **or**
b. Those with a previously implanted ICD that requires explanation due to infection with waiting period before ICD reinsertion; **or**
c. Those with an infectious process or other temporary condition that precludes initial implantation of an ICD.

*Refer to SURG.00033 *Implantable Cardioverter-Defibrillator (ICD).*
**Refer to TRANS.00033 *Heart Transplantation.*

Investigational and Not Medically Necessary:

The wearable cardioverter defibrillator (WCD) is considered **investigational and not medically necessary** for all other indications, including but not limited to, the following:

- Individuals with a history of acute myocardial infarction (MI) within the last 40 days:
- Individuals with drug-refractory class IV congestive heart failure (CHF) who are not candidates for heart transplantation;
- Individuals with a history of psychiatric disorders that interfere with the necessary care and follow-up;
- Individuals in whom a reversible triggering factor for ventricular tachycardia/ventricular fibrillation (VT/VF) can be definitely identified, such as ventricular tachyarrhythmias in evolving acute myocardial infarction or electrolyte abnormalities;
- Individuals with terminal illnesses."

The rationale for this position is as follows:

"The U.S. Food and Drug Administration (FDA) approved the Lifecor Wearable Cardioverter Defibrillator (WCD®) 2000 system via premarket application approval in December 2001, based on clinical date submitted to the FDA by the manufacturer, which has subsequently been published in the peer-reviewed literature, and referred to as the BIROAD and WEARIT studies (Feldman, 2004). The trials consisted of prospective, non-randomized studies, which compared the outcomes of the WCD with historical controls of subjects suffering sudden cardiac arrest (SCD) who called 911 emergency services.

While this study demonstrated that the WCD could detect arrhythmias and appropriately deliver a counter shock its long-term efficacy will depend on user compliance, and from a practical perspective, the WCD cannot be continuously worn. For example, the BIROAD and WEARIT studies included 289 subjects; there were 12 deaths reported, and 50% occurred in those who were either not wearing the device or wearing it inappropriately. Additionally, 68 of the 289 subjects discontinued wearing the device due to comfort issues or adverse reactions. Therefore, an implantable cardiac defibrillator (ICD is considered the gold standard and, as such, a WCD would be considered an alternative to an ICD only in the small subset that have co-morbidities or other contraindications for an ICD." [Emphasis added.]

The document provided by Anthem, entitled *Form No. H-EXH.A (10/10), Exhibit A, Experimental/Investigative Criteria,* provides:

"**Experimental/Investigative Criteria**

Experimental/investigative means any service or supply that is judged to be experimental or investigative at the HMO's sole discretion. Nothing in this exclusion shall prevent a member from appealing the HMO's decision that a service is experimental/investigative. Services which to not meet each of the following criteria will be excluded from coverage as experimental/investigative:

1. Any supply or drug used must have received final approval to market by the U.S. Food and Drug Administration (FDA) for the particular indication or application in question.

2. There must be enough information in the peer-reviewed medical and scientific literature to let us judge the safety and efficacy.

3. The available scientific evidence must show a good effect on health outcomes outside a research setting.

4. The service or supply must be as safe and effective outside a research setting as current diagnostic or therapeutic options."

DETERMINATION and RATIONALE:

The previous denial is hereby **OVERTURNED.**

This is a repeat review following the receipt of new clinical data which were unavailable for the initial review. Records reviewed are enumerated below, but include a history and physical, dictated consult reports, cardiac catheterization, echocardiogram, assorted handwritten daily progress notes, and a discharge summary.

[redacted]s is a 71-year-old man admitted to hospital in on November 24, 2011. He presented to an outside hospital with chest pain and low blood pressure thought to represent an acute MI. He was transferred to CJW Medical Center in Richmond. On presentation he was unstable with hypotension, severe metabolic acidosis, new left bundle branch block, elevated troponin, and atrial fibrillation. He was cardioverted in the emergency department and brought for urgent catheterization. He was intubated and mechanically ventilated. He was found to have severe CAD with patent vein bypass grafts to the LAD and circumflex, and to have severe LV dysfunction with an ejection fraction of about 25% and LV dilation. During the hospital stay he received mechanical ventilation and hemodialysis (CVVH) and had shock liver. His multiple complications improved and he was discharged on 12/6/11 with a life vest wearable cardioverter defibrillatior (WCD). Mr. [redacted] has a past history of bypass surgery in 1986 and again in 2001, rheumatoid arthritis, diabetes, hypertension, lung surgery for a lung mass found to be bronchiectasis, and hypercholesterolemia. He is a former smoker.

The WCD is not considered investigational within the medical community. The AHA/ACC criteria (1) and literature documenting standard of care and best practice (2,3) provide recommended use for the WCD as a bridge to ICD in patients who may be at risk for sudden death but do not (yet) meet criteria for ICD. One common reason for not meeting criteria for ICD is in the 40 days after acute MI or 3 months after revascularization. This waiting period is recommended prior to ICD implant because some, but not all, patients recover ejection fraction and no longer require ICD. Another reason for the waiting period is because ICD implantation soon after CABG, for example (4), did not show reduced mortality. Nonetheless, the period immediately after an acute MI until 40 days when ICD is acceptable--according to clinical criteria (1) and Medicare guidelines--accounts for a substantial risk and burden of sudden death (5). This period of time is suitable, for patients in whom an ICD would be appropriate after an MI and who are at high risk of sudden death, to consider a WCD as medically appropriate and necessary. Mr. [redacted] is such a patient and for this reason the WCD is medically necessary, justified and noninvestigational.

Anthem's *Coverage Guideline* regarding wearable cardioverter defibrillators (i.e., *Document #MED.00055),* acknowledges the fact that the wearable cardioverter defibrillator (WCD) is not considered investigational in all situations. In fact, the policy provides that the WCD is considered **medically necessary** for individuals at high-risk of sudden cardiac arrest, who meet the following criteria:

1. Individuals must meet the medical necessity criteria for an implantable cardioverter defibrillator* (ICD); **AND**
2. Individuals must have ONE of the following documented medical contraindications to ICD implantation:
    a. Those awaiting a heart transplantation – on waiting list and meet medical necessity criteria for heart transplantation;** or
    b. Those with a previously implanted ICD that requires explanation due to infection with waiting period before ICD reinsertion; or
    c. Those with an infectious processor other temporary condition that precludes initial implantation of an ICD.

In this particular case, Mr. [redacted] is a suitable candidate for WCD for this indication, since he meets the medical necessity criteria for a defibrillator (ischemic cardiomyopathy with EF less than 35%), and a temporary condition that preculdes ICD implantation (in this case, within 40 days of an acute myocardial infarction).

REFERENCES:

1. Zipes DP, Camm AJ, Borggefe M, Buxton AE, Chaitman B, Fromer M, Gregoratos G, Klein G, Moss AJ, Myerburg RJ, Priori SG, Quinones MA, Roden DM, Silka MJ, Tracy C. ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology / American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). *J Am Coll Cardiol.* 2006 Sep;48(5): e247-346.

2. Chung MK, Szymkiewicz SJ, Shao M, Zishiri E, Niebauer MJ, Lindsay BD, Tchou PJ. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. *J Am Coll Cardiol.* 2010 Jul 13;56(3): 194-203.

3. Klein HU, Meltendorf U, Reek S, Smid J, Kuss S, Cygankiewicz I, Jons C, Szymkiewicz S, Buhtz F, Wollbrueck A, Zareba W, Moss AJ. Bridging a temporary high risk of sudden arrhythmic death. Experience with the wearable cardioverter defibrillator (WCD). *Pacing Clin Electrophysical.* 2010 mar; 33(3):353-367. Epub 2009 Nov 2.

4. Bigger JT Jr. Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. Coronary Artery Bypass Graft (CABG) Patch Trial Investigators. *N Engl J Med.* 1997 Nov 27;337(22):1569-75.

5. Solomon SD, Zelenkofske S, McMurray JJ, Finn PV, Velazquez E, Ertl G, Harsanyi A, Rouleau JL, Maggioni A, Kober L, White H, Van deWerf F, Pieper K, Califf RM, Pfeffer MA, Valsartan in Acute Myocardial Infarction Trial (VALIANT) Investigators. Sudden death in patients with myocardial infarction and left ventricular dysfunction, heart failure, or both. *N Engl J Med.* 2005 Jun 23;352(25):2581-8.

DOCUMENTS RECEIVED FOR REVIEW:

Medical Records:

1. Jiho Joseph Han, M.D., *Discharge Summary,* dated 12/06/2011 (4 pages).
2. LifeVest, *Medical Order,* dated 11/30/2011 (1 page).
3. Pulmonary Associates of Richmond, *Progress Notes,* dated 11/30/2011 and 11/26/2011 (2 pages).
4. Leanza H. Liu, M.D., *Consultation Report,* dated 11/26/2011 (3 pages).
5. Bradford J. Matthews, M.D., *Echocardiogram Report,* dated 11/25/2011 (2 pages).
6. Sarika S. Tripathi, M.D., *Consultation Report,* dated 11/25/2011 (3 pages).
7. Christopher G. Acker, M.D., *Consultation Report,* dated 11/24/2011 (2 pages).
8. James A. Apostle, M.D., *Consultation Report,* dated 11/24/2011 (3 pages).
9. Jiho J. Han, M.D., *Cardiac Cath Report,* dated 11/24/2011 (3 pages).
10. Jiho J. Han, M.D., *History and Physical,* dated 11/24/2011 (4 pages).
11. Chippenham Medical Center/Johnston-Willis Hospital, *Progress Notes,* dated 11/30/2011, 11/28/2011 and 11/26/2011 (4 pages).
12. Richmond Nephrology Associates, *Progress Note,* dated 12/05/2011, 12/02/2011, 11/30/2011, 11/29/2011, 11/28/2011, 11/27/2011, 11/26/2011 and 11/25/2011. (8 pages).
13. CJW Medical Center, *Progress Notes,* dated 12/06/2011, 12/05/2011, 12/02/2011, 12/04/2011, 12/01/2011 and 11/30/2011, 11/29/2011, 11/28/2011, 11/27/2011, 11/26/2011 and 11/20/2011 (35 pages).

Plan Language:

14. Anthem, *Coverage Guideline, Subject: Wearable Cardioverter Defibrillators, Document #: MED.00055,* last review date 11/18/2010 (8 pages).
15. Unidentified author, description of "What is not covered," alphabet letters "E" and "F," undated (1 page).
16. Unidentified author, *Form No. H-EXH.A (10/10), Exhibit A, Experimental/Investigative Criteria,* pages 70-71 (2 pages).

Appeal History:

17. Anthem UM Services, Inc., *Standard External Review: Gene Gaskins,* dated 04/09/2012 (?) (1 page).
18. Commonwealth of Virginia, *Request for External Review for Janna Altobeli on behalf of Gene Gaskins, for the Denial of the Zoll Life Vest,* addressed to IMX, dated 04/05/2012 (5 pages).
19. Commonwealth of Virginia, *Request for External Review for Janna Altobeli on behalf of Gene Gaskins, for the Denial of the Zoll Life Vest,* addressed to Anthem, dated 04/05/2012 (2 pages).
20. Anthem UM Services, Inc., external review eligibility letter, dated 03/28/2012 (2 pages).
21. State Corporation Commission, Bureau of Insurance – External Review, *External Review Request Form,* dated 03/23/2012 (3 pages).
22. State Corporation Commission, Bureau of Insurance – External Review, *Appointment of Authorized Representative,* dated 03/23/2012 (1 page).
23. State Corporation Commission, Bureau of Insurance – External Review, *Physician Certification Expedited External Review Request,* dated 03/20/2012 (1 page).
24. State Corporation Commission, Bureau of Insurance – External Review, *Physician Certification Experimental or Investigational Denials,* dated 03/20/2012 (2 pages).
25. Anthem UM Services, Inc., determination letter, dated 02/06/2012 (3 pages).
26. Advanced Medical Reviews, *Peer Reviewer Final Report,* dated 02/06/2012 (3 pages).
27. David Gundhart (illegible), letter, unable to determine date (2 pages).
28. Zoll, request for appeal, dated 01/09/2012 (2 pages).
29. Anthem UM Services, Inc., determination letter, dated 12/07/2011 (6 pages).

Miscellaneous Information:

30. Case notes/screen shots, for dates 12/01/2011 to 03/28/2012 (8 pages).
31. Screen shot, dated 03/28/2012 (1 page).

Sincerely,

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Steven Borzak, M.D.