I. Aetna considers cardiac monitoring using electrical bioimpedance devices medically necessary for any of the following uses, when medical history, physical examination, and standard assessment tools provide insufficient information and the treating physician has determined that thoracic electrical bioimpedance hemodynamic data are necessary for appropriate management of the member:

A. Differentiation of cardiogenic from pulmonary causes of acute dyspnea; or

B. Evaluation for rejection in persons with a heart transplant as a pre-determined alternative to a myocardial biopsy. Medical necessity would need to be documented should a biopsy be performed after thoracic electrical bioimpedance; or

C. Monitoring of response to medication changes in treatment of drug-resistant hypertension; or

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.
D. Optimization of atrio-ventricular (AV) interval for member with AV sequential cardiac pacemakers; or
E. Optimization of fluid management in persons with congestive heart failure (CHF); or
F. Outpatient monitoring of continuous inotropic therapy for persons with terminal CHF.

II. Aetna considers cardiac monitoring using electrical bioimpedance devices experimental and investigational for any other indications because of insufficient evidence of safety and effectiveness, including the following uses:

A. Monitoring in congenital heart disease surgery; or
B. Monitoring of persons on a cardiopulmonary bypass machine as these devices do not render accurate measurements in this situation; or
C. Monitoring of persons who have ischemic heart disease, but without overt cardiac failure, edema or arrhythmias; or
D. Monitoring of persons with minute ventilation sensor function pacemakers as the device may adversely affect the functioning of this type of pacemaker; or
E. Monitoring of persons with proven or suspected disease involving severe regurgitation of the aorta as these devices have not been proven to provide reliable measurements in this situation.

Background

This policy is consistent with the Centers for Medicare & Medicaid Services (CMS), coverage guidelines on measurement of cardiac output (CO) with electrical bioimpedance.
Hemodynamic measurements of CO using thoracic electrical bioimpedance (TEB) devices, a form of plethysmography, relate change in thoracic electrical conductivity to changes in thoracic aortic blood volume and blood flow. This form of impedance cardiography has been proposed as a simple and readily reproducible non-invasive technique for the determination of CO, specifically, stroke volume, contractility, systemic vascular resistance and thoracic fluid content. Proponents claim that TEB can measure CO with the same clinical accuracy as either the Fick or thermodilution (TD) technique and that it offers the potential for sequential measurements of CO in patients for whom invasive measurements are impractical or contraindicated. In addition, TEB can determine CO on a beat-to-beat basis or a predetermined intermittent frequency, which may, if required, permit a more rapid intervention than techniques using time-averaged data. Its modest gain in popularity as a clinical technique appears to be related to its suggested usefulness as a monitor to detect changes in CO within individual subjects as an alternative to invasive techniques, especially when serial measurements are required.

Gujjar and colleagues (2010) compared CO measured by TEB with that measured by multi-gated radionuclide equilibrium cardiography (RNEC). Studies on CO were carried out sequentially at a single sitting by TEB and RNEC methods among patients with cardiac symptoms referred for radionuclide study as part of their evaluation. Thoracic electrical bioimpedance-CO was measured by placing 2 pairs of electrodes on either side of neck and 2 other pairs on either side of the lower chest. Stroke volume was estimated from the sequential changes in TEB induced by rhythmic aortic blood flow, using Kubicek equation; RNEC-CO was measured by intravenous injection of radio-active technium-tagged red blood cells followed by electrocardiography-gated blood pool imaging over the chest (multiple-gated acquisition study). Bland-Altman analysis was used to compare the measurements. A total of 32 subjects with proven or
suspected ischemic heart disease, but without overt cardiac failure, edema or arrhythmias were studied (male:female ratio was 26:6; mean age of 48 +/- 12 years). The mean TEB-CO was 3.54 +/- 1.052 L/min and mean RNEC-CO was 3.907 +/- 0.952 L/min. Correlation coefficient (r) for these measurements was 0.67 (p < 0.01), with bias: -0.421 L/min; precision: 1.557 L/min; and percentage error of measurement: 42.35 %. The authors concluded that this study found a moderate correlation between TEB and RNEC methods of CO measurement. They stated that further studies are needed to examine the relative utility of TEB in comparison with RNEC as well as other methods of CO measurement before considering its use in patients with ischemic heart disease.

Taylor et al (2011) evaluated the measurement of CO using continuous electrical bioimpedance cardiography (Physioflow; Neumedx, Philadelphia, PA) (CO(PF)) with a simultaneous direct Fick measurement (CO(FICK)) in children with congenital heart disease. The Physioflow measured continuous real time CO in 15-second epochs and simultaneous measurement of CO by direct Fick (with mass spectrometry to assess VO(2)) were acquired. A total of 65 patients were recruited, and data from 56 (25 males) were adequate for analysis. The median age at study was 3.5 years (range of 0.4 to 16.6 years), and the median body surface area was 0.62 m(2) (range of 0.31 to 1.71). There were 25 of 56 (45 %) with uni-ventricular physiology. A total of 19,228 Physioflow data points were available for the analysis of which 14,569 (76 %) were valid; 96 % of the invalid measurements were identified as artifacts by the device. The average cardiac index of valid measurements was 3.09 +/- 0.72 L/min/m(2). Compared with the Fick CO, the mean bias was -0.09 L/min, but the 95 % limits of agreement were -3.20 to +3.01 L/min/m(2). Consequently, only 20 of 56 (36 %) of measurements were within 20 %, and 31 of 56 (55 %) of measurements were within 30 % of each other. The authors concluded that
compared with measurements made by direct Fick, CO measured using the Physioflow device was unreliable in anesthetized children with congenital heart disease.

Currently, there are 2 Food and Drug Administration-approved electrical bioimpedance devices in the marketplace: Bio Z® (Cardiodynamics, Inc.), and TEBCO (Thoracic Electrical Bioimpedance Cardiac Output, Hemo Sapiens, Inc.).

### CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>93701</td>
<td>Bioimpedance, thoracic, electrical</td>
</tr>
<tr>
<td>I09.81</td>
<td>Rheumatic heart failure</td>
</tr>
<tr>
<td>I10 - I16.2</td>
<td>Hypertensive diseases</td>
</tr>
<tr>
<td>I50.1 - I50.9</td>
<td>Heart failure</td>
</tr>
<tr>
<td>R06.00-R06.09</td>
<td>Dyspnea [acute]</td>
</tr>
<tr>
<td>T86.20 - T86.39</td>
<td>Complications of heart transplant</td>
</tr>
<tr>
<td>Z45.010</td>
<td>Encounter for checking and testing of cardiac pacemaker pulse generator [battery]</td>
</tr>
<tr>
<td>Z45.018</td>
<td>Encounter for adjustment and management of other part of cardiac pacemaker</td>
</tr>
<tr>
<td>Z48.21</td>
<td>Encounter for aftercare following heart transplant</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Z48.280</td>
<td>Encounter for aftercare following heart-lung transplant</td>
</tr>
<tr>
<td>Z94.1</td>
<td>Heart transplant status</td>
</tr>
<tr>
<td>Z94.3</td>
<td>Heart and lungs transplant status</td>
</tr>
<tr>
<td>Z95.0</td>
<td>Presence of cardiac pacemaker</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I20.0 - I25.9</td>
<td>Ischemic heart disease [without overt cardiac failure, edema, or arrhythmias]</td>
</tr>
<tr>
<td>I35.0 - I35.9</td>
<td>Nonrheumatic aortic valve disorders</td>
</tr>
<tr>
<td>Q20.0 - Q26.9</td>
<td>Bulbus cordis anomalies and anomalies of cardiac septal closure, other congenital anomalies of heart, other congenital anomalies of circulatory system, and anomalies of great veins [monitoring congenital heart disease surgery]</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


12. Weiss S, Calloway E, Cairo J, et al. Comparison of cardiac output measurements by thermodilution and


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0472 Thoracic Electrical Bioimpedance for Cardiac Output Monitoring

There are no amendments for Medicaid.