Prior Authorization Review Panel  
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 11/01/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number: 0692</td>
<td>Effective Date:</td>
</tr>
<tr>
<td></td>
<td>Revision Date:</td>
</tr>
<tr>
<td>Policy Name: Acoustic Heart Sound Recording and Computer Analysis</td>
<td></td>
</tr>
</tbody>
</table>

**Type of Submission – Check all that apply:**
- [x] New Policy*
- [ ] Revised Policy
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0692 Acoustic Heart Sound Recording and Computer Analysis**

Policy is new to Aetna Better Health of Pennsylvania.

<table>
<thead>
<tr>
<th>Name of Authorized Individual (Please type or print):</th>
<th>Signature of Authorized Individual:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Bernard Lewin, M.D.</td>
<td>[Signature]</td>
</tr>
</tbody>
</table>
Acoustic Heart Sound Recording and Computer Analysis

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

Aetna considers acoustic heart sound recording, computer analysis and interpretation experimental and investigational because of a lack of clinical studies demonstrating that this technology improves clinical outcomes.

Aetna considers auscultation jacket, ballistocardiography, optical vibrocardiography, phonocardiography, and vectorcardiography experimental and investigational because their clinical value has not been established.

Background

Computer-aided electronic auscultatory devices have been developed that acquire, record, and analyze the acoustic signals of the heart. Using acoustic signal processing algorithms, a computer analyzes the recording to identify specific heart sounds that may be present, including S1, S2 and suspected murmurs. A graphic user interface displays the results. These computer-aided electronic auscultatory
devices are intended to provide support to the physician in the evaluation of heart sounds for the identification of suspected murmurs, a potential sign of heart disease.

Zargis Medical Corporation (Princeton, NJ) has received U.S. Food and Drug Administration (FDA) clearance to market Zargis Acoustic Cardioscan, a computer-aided electronic auscultatory device intended to support physicians in analyzing heart sounds in patients. As this clearance was based on a 510(k) premarket notification, the manufacturer was not required to provide the evidence of efficacy that is necessary to support a premarket approval application (PMA). The FDA indications for use states that the device is not intended as a sole means of diagnosis and that interpretation of heart sounds with the Zargis Acoustic Cardioscan are only significant when used in conjunction with physician over-read as well as consideration of all other patient data.

There is inadequate evidence of the validity of computer-aided electronic auscultatory devices, or their impact on clinical outcomes in the peer-reviewed published medical literature. Clinical studies are necessary to determine the performance characteristics (sensitivity, specificity, and predictive values) of computer-aided electronic auscultatory devices and their impact on clinical management and patient outcomes.

Another brand of computer-aided electronic auscultatory device (correlated audioelectric cardiography device) is the Audicor System (Inovise Medical, Inc., Portland, OR). It received marketing clearance from the FDA through the 510(k) process in 2003. According to the product labeling, the Audicor Upgrade System, when used with Audicor Sensors in the V3 and V4 positions on the chest wall, is for use in attaining, analyzing and reporting electrocardiographic and phonocardiographic data, and to provide interpretation of the data for consideration by physicians.
Mansy et al (2005) found that computerized analysis of vascular sounds may be useful in vessel patency surveillance. Moreover, they stated that further testing using longitudinal studies may be warranted.

Watrous and colleagues (2008) noted that as many as 50 % to 70 % of asymptomatic children referred for specialist evaluation or echocardiography because of a murmur have no heart disease. These researchers hypothesized that computer-assisted auscultation (CAA) can improve the sensitivity and specificity of referrals for evaluation of heart murmurs. In this study, 7 board-certified primary care physicians were evaluated both with and without the use of a computer-based decision-support system using 100 pre-recorded patient heart sounds (55 innocent murmurs, 30 pathological murmurs, and 15 without murmur). The sensitivity and specificity of their murmur referral decisions relative to American College of Cardiology/American Heart Association guidelines, and sensitivity and specificity of murmur detection and characterization (innocent versus pathological) were measured. Sensitivity for detection of murmurs significantly increased with use of CAA from 76.6 % to 89.1% (p < 0.001), while specificity remained unaffected (80.0 % versus 81.0%). Computer-assisted auscultation improved sensitivity of correctly identifying pathological murmur cases from 82.4 % to 90.0 %, and specificity of correctly identifying benign cases (with innocent or no murmurs) from 74.9 % to 88.8 %. (p < 0.001). Referral sensitivity increased from 86.7 % to 92.9 %, while specificity increased from 63.5 % to 78.6 % using CAA (p < 0.001). The authors concluded that CAA appears to be a promising new technology for informing the referral decisions of primary care physicians.

Computer-aided electronic auscultatory devices differ from phonocardiograms in that only the former incorporate computer analysis of the heart sounds. The Center for
Medicare and Medicare Services (CMS, 1997) has determined that phonocardiography and vectorcardiography diagnostic tests are “outmoded and of little clinical value.”

Ballistocardiography refers to the recording of movements of the body caused by cardiac contractions and associated blood flow. It had been investigated for potential use in measuring cardiac output (CO) and other aspects of cardiac function. Taylor and Sheffer (1990) stated, however, that thermodilution is the preferred method of measuring CO, and has achieved universal appeal in the clinical setting. The ballistocardiogram and other means of detecting CO, such as the impedance-cardiogram, have been developed and are being used clinically, but the development of the flow-directed thermodilution catheter has profoundly affected the universal acceptance of the thermodilution method (Taylor and Sheffer, 1990). Thermodilution techniques, when performed properly, are capable of obtaining accurate and reproducible results.

McKay et al (1999) described a CO measurement using a new method to derive and analyze the long-axis ballistocardiogram that is less invasive than pulmonary artery thermodilution. A total of 39 patients in sinus rhythm with pulmonary artery thermodilution catheters or radial artery catheters in place were studied. The first 30 subjects were the "learning set" and the next 9 were the "test set". A small (54-g) accelerometer was taped on the patient's chest. Outcome measures were time and amplitude coordinates of the acceleration and radial artery pressure wave-peaks, as well as anthropometric information. A stroke volume prediction equation was generated (R² = 0.76) from the learning set. This equation was applied to the test set and correlated with the pulmonary artery thermodilution-derived stroke volumes (R = 0.79). Stroke volumes were compared using a previously described statistical method: (i) bias (predicted greater than thermodilution) = 0.03 ml (95 % confidence interval [CI]: -4.2 to 4.8 ml); (ii) lower limit of agreement = -21 ml (95 % CI: -29 to -13 ml); and (iii) upper limit of agreement = 22 ml (95 % CI: 14
to 29 ml). Of derived stroke volumes, 82 % were within 15 ml of pulmonary artery thermodilution-derived values. The authors concluded that sternal acceleration ballistocardiogram combined with hemodynamic and demographic data in a probabilistic model shows promise of providing a less invasive measure of CO than thermodilution.

Optical vibrocardiography (VCG) is a novel, non-contact, tool for monitoring cardiac activity. Morbiducci et al (2007) described the use of VCG for heart rate (HR) monitoring, based on the measurement of chest wall movements induced by the pumping action of the heart, which is eligible as a surrogate of electrocardiogram (ECG) in assessing both cardiac rate and HR variability (HRV). The method is based on the optical recording of the movements of the chest wall by means of laser Doppler interferometry. To this aim, the ECG signal and the velocity of vibration of the chest wall, named VCG, were simultaneously recorded on 10 subjects. The time series built from the sequences of consecutive R waves (on ECG) and vibrocardiographic (VV) intervals were compared in terms of HR. To evaluate the ability of VCG signals as quantitative marker of the autonomic activity, HRV descriptors were also calculated on both ECG and VCG time series. Heart rate and HRV indices obtained from the proposed method agreed with the rate derived from ECG recordings (mean percent difference less than 3.1 %). The authors concluded that optical VCG provides a reliable assessment of HR and HRV analysis, with no statistical differences in term of gender are present. They noted that optical VCG appears promising as non-contact method to monitor the cardiac activity under specific conditions (e.g., in magnetic resonance environment, or to reduce exposure risks to workers subjected to hazardous conditions). The technique may be used also to monitor subjects (e.g., severely burned, for which contact with the skin needs to be minimized).
Mahnke (2009) noted that heart disease is a major cause of worldwide morbidity and mortality. Properly performed, the cardiac auscultatory examination is an inexpensive, widely available tool in the detection and management of heart disease. Unfortunately, accurate interpretation of heart sounds by primary care providers is fraught with error, leading to missed diagnosis of disease and/or excessive costs associated with evaluation of normal variants. Thus, automated heart sound analysis, also known as CAA, has the potential to become a cost-effective screening and diagnostic tool in the primary care setting.

Visagie and colleagues (2009) presented the findings of a study using an auscultation jacket with embedded electronic stethoscopes, and a software classification system capable of differentiating between normal and certain auscultatory abnormalities. The aim of the study is to demonstrate the potential of such a system for semi-automated diagnosis for under-served locations, for instance in rural areas or in developing countries where patients far out-number the available medical personnel. Using an "auscultation jacket", synchronous data was recorded at multiple chest locations on 31 healthy volunteers and 21 patients with heart pathologies. Electrocardiograms were also recorded simultaneously with phonocardiographic data. Features related to heart pathologies were extracted from the signals and used as input to a feed-forward artificial neural network. The system is able to classify between normal and certain abnormal heart sounds with a sensitivity of 84 % and a specificity of 86 %. Although the number of training and testing samples presented were limited, the system performed well in differentiating between normal and abnormal heart sounds in the given database of available recordings. The results of this study showed the potential of such a system to be used as a fast and cost-effective screening tool for heart pathologies.
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>S3902</td>
<td>Ballistocardiogram</td>
</tr>
</tbody>
</table>

HCPCS codes not covered for indications listed in the CPB:

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>I00 - I99.9</td>
<td>Diseases of the circulatory system</td>
</tr>
<tr>
<td>R00.8 - R00.9</td>
<td>Other and unspecified abnormalities of heart beat</td>
</tr>
<tr>
<td>R01.0 - R01.2</td>
<td>Cardiac murmurs and other cardiac sounds</td>
</tr>
<tr>
<td>R09.89</td>
<td>Other specified symptoms and signs involving the circulatory and respiratory systems</td>
</tr>
<tr>
<td>R93.1</td>
<td>Abnormal findings on diagnostic imaging of heart and coronary circulation</td>
</tr>
<tr>
<td>R93.8</td>
<td>Abnormal findings on diagnostic imaging of other specified body structures</td>
</tr>
<tr>
<td>R94.30 - R94.39</td>
<td>Abnormal results of cardiovascular function studies</td>
</tr>
<tr>
<td>Z13.6</td>
<td>Encounter for screening for cardiovascular disorders</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


5. Becker C. Still hard to beat. Doctors don't have the heart--or a clinical reason--to part with their old-fashioned stethoscopes. Mod Healthc. 2003;33(19):30, 32.


11. Mansy HA, Hoxie SJ, Patel NH, Sandler RH. Computerised analysis of auscultatory sounds


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0692 Acoustic Heart Sound Recording and Computer Analysis

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania

new 11/01/2018