Shape Medical Systems, Inc.

2011 Coverage and Reimbursement Guide

(Effective January 1, 2011)

Medicare coverage, coding and payment guide for physicians

Shape Medical Systems provides this reference guide as part of our effort to consolidate publically available reimbursement information pertaining to the Shape-HF Cardiopulmonary Exercise Testing System (the "System"). Physicians and other care providers must confirm or clarify coverage from their respective local Medicare contractor, as each contractor may have differing coverage policies or decisions. Physicians and other care providers are responsible for accurate documentation of patient conditions, and for reporting procedures and products in accordance with Medicare requirements. Private payer and Medicare coding and coverage should be verified with the specific payer via information requested by the specific payer.

If you have any questions or are encountering difficulties, please contact Shape technical service at 651.621.2991.

I. General Coverage Guidelines

Exercise testing such as that provided by Shape-HF is indicated for helping to determine and evaluate:

- Dysfunction in the oxygen uptake, delivery, and utilization circuit (i.e., lung, heart, and circulatory systems);
- The contributing dysfunction to shortness of breath
- The cause of abnormalities contributing to shortness of breath within the disease process;
- The extent of patient disability associated with the disease or condition;
- The type and/or progression of disease; and
- Effective treatment for the particular condition.

The most common indication for using exercise testing is in patients with dyspnea and/or dyspnea on exertion to aid in deciding on a course of therapy and in monitoring patient response to therapy. Government and private health plans require documentation in the patient record that clearly states the reason why the test is medically indicated. Medicare, through its regional administrators, periodically issues clarifying statements about the indications and limitations on cardiopulmonary testing. One such statement outlined the conditions where testing similar to the Shape assessment is medically necessary:

- To determine whether shortness of breath and/or exercise intolerance is related to heart or lung disease or is due to lack of conditioning or poor patient exercise effort;
- To distinguish between cardiac and pulmonary causes for dyspnea;
- To detect exercise-induced bronchospasm, that is defined as the sudden onset of shortness of breath that is only manifested by exercise;
- To evaluate a newly established treatment regimen that is intended to impact cardiopulmonary function;
- To determine the need for and dose of ambulatory oxygen;
- To assist in developing a safe exercise prescription in patients with cardiovascular or pulmonary disease; and
- To titrate optimal settings in selected patients who have physiologic pacemakers.

The American Thoracic Society (ATS) has published the *ATS/ACCP Statement on Cardiopulmonary Exercise Testing* which is a Joint Statement of the American Thoracic Society (ATS) and the American College of Chest Physicians (ACCP).[1] The Statement provides additional information regarding the broad categories of diseases and/or disease processes for which cardiopulmonary exercise testing are indicated.

II. ICD-9-CM Diagnosis Codes

There are many ICD-9-CM diagnosis codes that are appropriate and indicate the need for either cardiopulmonary stress testing (simple or complex) or expired gas analysis. The following is a <u>sample</u> of some of the codes that may be considered. The clinical situation determines which code best matches the indications for the Shape-HF assessment.

Diagnosis	Code
• Cystic fibrosis	277.0
• Pulmonary heart disease/Chronic	416.1
• Heart failure	428.0
• Systolic heart failure	428.20
• Diastolic heart failure	428.30
• Heart failure unspecified	428.9
• Simple chronic bronchitis	491.0
• Unspecified chronic bronchitis	491.9
• Other Emphysema	492.8
• Asthma	493.02
• Exercise-induced bronchospasm	493.81
• Insomnia, unspecified with sleep apnea	780.51
• Apnea	786.03
• Shortness of breath	786.05
• Wheezing	786.07
• Respiratory Abnormality, other	786.09
• Respiratory/other chest symptoms	786.1
• Cough	786.2
• Late effect adverse event of drug/medicinal	909.5
• Long-term use of medications	V58.69
• Other, specified preoperative examination	V72.83

III. CPT Procedure Codes

CPT Procedure Codes do not list codes for specific proprietary testing systems like the Shape-HF assessment. There are four CPT codes, however, that describe the services performed using the Shape-HF system. Two are associated with exercise and two should be considered when the Shape-HF assessment is done with the patient at rest.

Cardiopulmonary exercise stress testing is either simple (94620) or complex (94621). If an EKG is done in association with the Shape-HF assessment, then the complex code (94621) may be considered. If no EKG is done while the patient is exercising, then the simple code (94620) may be more appropriate.

94690 is best used for oxygen update, expired gas analysis; rest, indirect. 94681 is appropriate when CO_2 output and percentage oxygen extracted at rest is measured."

Occasionally, a patient may have both a pulmonary and cardiac diagnosis that can be addressed in the interpretation of the

exercise test. In this circumstance, code 93018 (interpretation and report of cardiovascular stress test) can be reported in addition to code 94620 and 94621; however, a separate report interpreting the cardiac portion of the test must be generated (accompanied by the appropriate ICD-9-CM diagnosis code, showing medical necessity for the separately identifiable cardiac testing), in addition to the report of the pulmonary stress test. Append modifier 59 to 93018 to indicate a separate, distinct, and medically necessary service.

IV. ICD-9-CM Procedure Codes

ICD-9-CM Procedure Codes are used by hospitals to bill for inpatient services. The following codes should be considered for these services:

89.38 Other Non-operative Respiratory Measurements
89.51 Rhythm Electrocardiogram (rhythm EKG with 1-3 leads), or
89.52 Electrocardiogram: EKG NOS, or EKG (with 12 or more leads)

V. Coverage and Payment

Medicare and private insurance plans require accurate diagnosis and procedure coding for reimbursement. Each private insurance plan makes it own medical and benefit policy decisions, however, these decisions often mirror the regional Medicare administrators who develop coverage determination policies for Medicare beneficiaries. The regional Medicare administrators issue periodic LCDs (Local Coverage Determinations) that provide clarifications and changes in coverage determination decisions.

Shape Medical Systems has completed a review of LCDs in preparation of this document. The Shape-HF system has not been specifically mentioned in any LCD. Shape Medical Systems is not aware of any prior authorization requirements for cardiopulmonary exercise testing. Providers currently using the Shape-HF system report no difficulties in obtaining reimbursement. Any specific questions about service coverage or payment should be directed to your regional Medicare Administrative Contractor or specific health plan.

Payment rates from private insurers are not easily obtained, but Medicare publishes its payment rates. Medicare payment rates applicable to the Shape-HF system change from time to time and vary geographically. The national average for current Medicare reimbursement rates, unadjusted for geographic variances, can be found in a supplemental document provided by Shape Medical Systems, Inc.

VII. Questions

What is the level of physician supervision required during pulmonary stress testing?
Pulmonary stress tests should be conducted under general physician supervision, meaning the physician must be available in the clinic or healthcare facility while the test is in progress.

Is there a Medicare National Coverage Determination (NCD) specific to Pulmonary Function Testing?
There are no NCDs specific to Pulmonary Function Testing, however Trailblazer Health Enterprises, Medicare Part B carrier for Texas, Oklahoma, Colorado and New Mexico advises providers in its jurisdiction that the evaluation of lung function is indicated to determine:

- The presence of lung disease or abnormality of lung function.
- The extent of abnormalities and the potential causative disease process.
- The extent of disability due to abnormal lung function.
- The progression of the disease.
- The type of disease or lesion.
- The response to a course of therapy in the treatment of the particular condition.
- The presence of lung disease or abnormality of lung function secondary to toxicity of medication.

These Indications and Limitation of Coverage for Medical Necessity are cited in Trailblazers LCD L26829 updated effective Sept. 9, 2010 and are typical of LCDs in other jurisdictions. Providers must abide by the policies and guidelines of the contractor that processes their claims.

VIII. References

1. ATS/ACCP Statement on Cardiopulmonary Exercise Testing. *Am J Resp Crit Care Med*, 2003;167: 211-277.

2. Other references used in preparation of this document

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   - LCD for Pulmonary Diagnostic Services (L28974). First Coast Service Options, Inc., Part A Revision Effective Date October 1, 2010;
   - LCD for Pulmonary Function Testing (L28295), Palmetto GBA, Revision Effective Date October 1, 2010.

- LCD for Pulmonary Stress Testing Coverage Indications (L26497), Trailblazer Health Enterprises, Revision Effective Date October 18, 2010.
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