Cardiopulmonary Exercise Stress Test (CPET)

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00161
Original Effective Date: 03/07/2005
Archived Date: 08/21/2013

 Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider cardiopulmonary exercise stress test to be eligible for coverage.

Patient Selection Criteria
Coverage eligibility will be considered for any of the following indications, when basic clinical data such as a history and physical examination, chest radiographs, pulmonary function studies and resting electrocardiogram have failed to provide sufficient diagnosis:

- Differentiation of cardiac versus pulmonary limitations as a cause of exercise-induced dyspnea or impaired exercise capacity when traditional testing is inconclusive or non-diagnostic; or
- Evaluation of exercise capacity and response to therapy in patients with heart failure who are being considered for heart transplantation; or
- Preoperative evaluation for lung resection surgery (cancer or lung volume reduction) when pulmonary function studies alone are unable to accurately assess moderate to high-risk patients. (Low-risk patients can be evaluated accurately with routine pulmonary function test.)

Note: Test must be administered under direct supervision of a physician with documented evidence of certification in advanced cardiovascular life support, knowledge of exercise physiology and training in calibration, quality control, performance and interpretation of cardiopulmonary exercise testing.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers use of cardiopulmonary exercise stress test for all other indications, including but not limited to the following, to be investigational*: 

- Chronic fatigue syndrome
- Fibromyalgia
- Exercise intolerance

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- Pacemaker regulation
- Obesity
- Diabetes
- Hyperlipidemia
- Hypertension
- Routine pre-operative assessment
- Exercise prescription
- Asthma

Background/Overview

Cardiopulmonary exercise stress test (CPET) is a well established technique that provides a more objective assessment of exercise performance and has been widely used in further evaluating and distinguishing cardiac and pulmonary pathology. It is a safe procedure with the risk of death for the patients between two to five per 100,000 exercise tests performed. For all tests, attention to patient safety is of the utmost importance. Only qualified personnel should supervise testing. These trained individuals should be knowledgeable about the test, the risk of testing, contraindications to testing and the criteria for terminating the exercise test. Appropriate patient and equipment preparation must also be undertaken along with measures to ensure the factors affecting the validity and reproducibility of measured exercise responses are controlled.

Cardiopulmonary exercise stress test is the combination of exercise stress testing with the concurrent measurement of respiratory gas exchange. Cardiopulmonary exercise stress test provides a global assessment of responses involving the pulmonary, cardiovascular, hematopoietic, neuropsychological and skeletal muscle systems. Cardiopulmonary exercise stress test has been generally performed in specialized cardiology or pulmonary laboratories.

Exercise stress testing involves the continuous monitoring of a three- or 12-lead EKG during exercise of progressively increasing intensity. Heart rate and blood pressure are monitored at specified intervals during the test. The exercise can be performed using a treadmill or cycle ergometer. The measurement of respiratory gas exchange includes the breath-by-breath measurement of oxygen uptake, carbon dioxide production and ventilatory parameters including respiratory rate, tidal volume and minute ventilation. Cardiopulmonary exercise stress test permits the calculation of a wide variety of other parameters, including maximal oxygen uptake (VO\textsubscript{2} max), carbon dioxide output (VCO\textsubscript{2}), minute ventilation (V\textsubscript{E}) and pulse oximetry (SpO\textsubscript{2}), to assess pulmonary gas exchange. VO\textsubscript{2} max is defined as the point at which no further increase in measured VO\textsubscript{2} occurs despite an increase in work rate during graded exercise testing. VO\textsubscript{2} max is commonly performed in the evaluation of patients for heart transplant.
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Cardiopulmonary exercise stress test exercise testing, especially when it features breath-by-breath gas exchanged analysis, requires meticulous attention to calibration procedures to assure accurate and reproducible measurements. This system should be calibrated daily with a calibration logbook maintained so that long-term trends can be monitored. In addition, a physiological calibration, which is usually performed on a health laboratory staff member, should be undertaken to record constant work rate at several workloads at regular intervals for comparison. Subsequent steady state variations from minute ventilation (VE), oxygen uptake (VO\textsubscript{2}) or carbon dioxide output (VCO\textsubscript{2}) are then compared with the database and values outside of the established 95% confidence interval for that individual should prompt a thorough system-wide reassessment. If within tolerance, they are then added to the quality of control database to ensure proper calibration of the equipment.

Note: Recent technological advances have made it easier to perform gas exchange analysis during exercise. Gas exchange analysis techniques are now being used in an increasing number of clinical research trials. However, the additional accuracy and information provided by this technology is dependent on some basic skills required of both the technician, who must properly calibrate the system and perform the test, and the physician, who must interpret the results and communicate them to the patient.

The American Thoracic Society states that personnel who administer the test and interpret results need to be trained and proficient in this technique. The clinical exercise laboratory should be under the direction of a physician, preferably a pulmonologist or cardiologist certified in advanced cardiovascular life support, with knowledge of exercise physiology and with training in calibration, quality control, performance and interpretation of cardiopulmonary exercise testing. The physician is responsible for the clinical decisions, including clinical evaluation, determination of the type of test to be performed, monitoring of the patient during the test, interpretation of the results and provision of appropriate recommendations following the test.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The Epic HF V-338 and Atlas + HF V-340 were originally approved on June 30, 2004 under PMA PO30054.
The Epic HF V-337 and Atlas + FH V-343 were approved on November 17, 2004 under PMA PO30054/S 1.
The sponsor has submitted the current supplement to further expand the indications for use statement.

The clinical data to support the expanded indication, i.e., to maintain synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure, are provided in this summary and were the basis for the approval of the Frontier TM Biventricular Pacing System reviewed under PO30035.

The pre-clinical test results were presented in the original PMA application and subsequent supplement as mentioned above. The summary of PO30054 can also be found on the FDA CDRH Internet Home Page located at http://www.fda.gov/cdrh/nmapage.html.
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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies and accredited national guidelines.

References


Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2012 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<th>Code Type</th>
<th>Code</th>
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<td>CPT</td>
<td>No unique code identified cardiopulmonary exercise stress testing. Combinations of the following codes may identify components procedure, 93000, 93015, 93016, 93017, 93018, 94010, 94060, 94070, 94150, 94200, 94240, 94360, 94370, 94375, 94621, 94681, 94720, 94761</td>
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<td>ICD-9 Diagnosis</td>
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Policy History

Original Effective Date: 03/07/2005
02/01/2005 Medical Director review
02/15/2005 Medical Policy Committee review
03/07/2005 Managed Care Advisory Council approval
03/09/2006 Medical Director review
03/15/2006 Medical Policy Committee review. Format revision. FDA information added. No change to policy guidelines.
03/14/2007 Medical Director review
03/21/2007 Medical Policy Committee approval. Additional references added. No change to policy guidelines.
03/12/2008 Medical Director review
03/19/2008 Medical Policy Committee approval. No change to policy guidelines
03/04/2009 Medical Director review
03/18/2009 Medical Policy Committee approval. No change to coverage.
09/03/2009 Medical Policy Committee approval.
09/16/2009 Medical Policy Implementation Committee approval. Changed note after Patient Selection Criteria to read "Note: Test must be administered under direct supervision of a physician with documented evidence of certification in advanced cardiovascular life support, knowledge of exercise physiology and training in calibration, quality control, performance and interpretation of cardiopulmonary exercise testing." No change to coverage eligibility.
07/01/2010 Medical Policy Committee approval
07/21/2010 Medical Policy Implementation Committee approval. No change to coverage.
07/07/2011 Medical Policy Committee approval
07/20/2011 Medical Policy Implementation Committee approval. No change to coverage.
06/28/2012 Medical Policy Committee approval
07/27/2012 Medical Policy Implementation Committee approval. No change to coverage.
08/01/2013 Medical Policy Committee approval. Recommend archiving
08/21/2013 Medical Policy Implementation Committee approval. Archived.

Next Scheduled Review Date: Archived medical policy.

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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