

Name of Policy:

Cardiopulmonary Exercise Stress Test (CPET/CPX)

Policy #: 198 Latest Review Date: August 2010
Category: Medicine Policy Grade: Active Policy but no

longer scheduled for regular literature reviews and updates.

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
- 3. The technology must improve the net health outcome;
- 4. The technology must be as beneficial as any established alternatives;
- 5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and
- 4. 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.

Description of Procedure or Service:

Cardiopulmonary exercise testing (CPET) provides a global assessment of the integrative exercise responses involving the pulmonary, cardiovascular, hematopoietic, neurophysiological, and skeletal muscle systems.

Cardiopulmonary exercise testing involves measuring oxygen uptake (VO_2) , carbon dioxide output (VCO_2) , minute ventilation (V_E) and other variables in addition to a 12-lead EKG, blood pressure monitoring and pulse oximetry (SpO_2) . These measurements are obtained during a maximal symptom-limited incremental exercise test. In certain clinical situations, an additional measurement of arterial blood gases may be used to assess pulmonary gas exchange.

Two modes of exercise are commonly used in CPET: treadmill and cycle ergometer. The motor-driven treadmill increases exercise stress through a combination of speed and elevation or grade increases. There are several incremental protocols, i.e., Bruce, used for this testing. The protocol should be selected based on the objectives of the test and the patient's clinical condition. The treadmill test has several advantages over the cycle ergometry. Most individuals are more familiar with walking as an activity than cycling. In addition, maximal oxygen uptake is reported to be 5-10% higher on the treadmill than a cycle ergometer.

The cycle ergometer is less likely to introduce artifact into the measurements. The rate at which the external work is performed is also easily quantified. There are two types of cycle ergometers: mechanically braked and electrically braked. The mechanically braked ergometers generally do not offer precise work rate settings and require the individual to pedal at a fixed cadence to keep the work rate constant. The electrically braked ergometer provides direct quantification of the work performed and can be computer controlled to change work rate incrementally or continuously.

Both cycle and treadmill testing uses a progressive incremental exercise pattern which lasts for approximately 12 minutes or until symptoms occur. A constant work rate protocol is also gaining popularity for certain clinical applications such as evaluating the clinical response to cardiopulmonary rehab, lung volume reduction surgery, etc.

Policy:

Cardiopulmonary Exercise Testing (CPET) meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when basic clinical data such as a history and physical exam, CXR, pulmonary function studies and resting EKG have failed to provide sufficient diagnosis for the following indications:

- 1. Evaluation of exercise capacity and response to therapy in patients with heart failure who are being considered for heart transplantation.
- 2. 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.
- 3. Preoperative evaluation for lung cancer resection surgery or lung volume reduction surgery, 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, such as FEV1, diffusing capacity of the lung for CO).

CPET does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage when used to evaluate conditions not listed above. This would include but not be limited to the following:

- Chronic fatigue syndrome
- Fibromyalgia
- Exercise intolerance
- Pacemaker regulation
- Obesity
- Diabetes
- Hyperlipidemia
- Hypertension
- Routine pre-operative assessment
- Exercise prescription
- Asthma

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

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.

CPET is a safe procedure with the risk of death for the patients between 2-5 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. CPET 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 rulebook 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, oxygen uptake, or carbon dioxide output 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.

A number of variables are typically measured or derived during the CPET. The chart listed below shows the components and whether the components are invasive or non-invasive.

Measurements	Noninvasive	Invasive (ABGs)
External work	WR	
Metabolic gas exchange	VO ₂ , VCO ₂ , RER, AT	Lactate
Cardiovascular	HR, ECG, BP, O ₂ pulse	
Ventilatory	VE, VT, fR	
Pulmonary gas exchange	Sp_{O2} , VE/VCO_2 , VE/VO_2 , PET_{O2}	Pa _{O2} , Sa _{O2} , P(A-a)O ₂ , VD/VT
Acid-base		PH, Pa _{CO2} , standard HCO ₃ -
Symptoms	Dyspnea, fatigue, chest pain	

Definition of abbreviations: ABGs = Arterial blood gases; AT = anaerobic threshold; BP = blood pressure; ECG = electrocardiogram; fR = respiratory frequency; HR = heart rate; $P(A-a)O_2 = alveolar$ arterial difference for oxygen pressure; $Pa_{CO2} = arterial$ carbon dioxide pressure; $Pa_{O2} = arterial$ oxygen pressure $PET_{CO2} = end$ -tidal PCO_2 ; $PET_{O2} = end$ -tidal PCO_2 ; $PCO_2 = end$ -tidal PCO_2

In clinical practice, CPET may be considered when specific questions persist after consideration of basic clinical data such as a history and physical exam, chest x-ray, pulmonary function studies, and resting EKG have failed to provide sufficient answers. For individuals with unexplained dyspnea and for when initial test results are non-diagnostic, CPET may be a useful tool in identifying the true underlying cause of the dyspnea. CPET may efficiently direct further diagnostic testing to target the suspected organ involved or may limit subsequent testing depending upon results of the CPET. In patients with heart failure who are being considered for heart transplantation, there is strong evidence to support the value of CPET in the assessment of exercise capacity and the response efficacy of current therapy of patients with heart failure who are being considered for heart transplantation.

In the study by Stelken et al, there was confirmation of prognostic value of CPET for patients with the ischemic and dilated cardiomyopathies. In this study, the VO₂ max less than 50% predicted was the most significant predictor of cardiac death in multivariant analysis. In the study by Meyers, et al, which was a large prospective study, peak VO₂ outperformed all other clinical, exercise and hemodynamic data in determining the risk of death among patients with severe heart failure. These authors suggested that all patients being evaluated for heart failure should undergo CPET. However, routine use of CPET for monitoring physiological

improvement in patients with heart failure who are undergoing exercise training as part of cardiac rehabilitation requires additional study to be considered for coverage. Although CPET has been used to demonstrate the value of early exercise training after heart transplantation on quality of life and increased capacity for workflow its routine use in this setting also remains uncertain and requires additional investigation.

CPET is frequently used as a preoperative evaluation prior to lung cancer resection surgery. Routine pulmonary function tests such as a FEV₁ or diffusion capacity of the lung for CO₂ is usually adequate in documenting physiological operability in low-risk patients. But for individuals who are at moderate to high risk, additional diagnostic modalities including CPET are split function assessment by quantitative lung scintigraphy may often be necessary. These tests may be particularly useful in predicting postoperative pulmonary complications. CPET is also emerging as an important tool in the evaluation of emphysema patients who are being considered for lung volume reduction surgery. In this application, the CPET includes the determination of cardiopulmonary function status and assessment of potential operative risk prior to surgery. The use of CPET for individuals undergoing lung volume reduction surgery (LVRS) continues to be investigated as a possible tool for determining exercise training prescription before and after LVRS and also the quantification and monitoring of the clinical response to surgery; however, this use of CPET requires additional study to be considered for coverage.

A comprehensive CPET is also being used for individuals who are considered for lung and heart/or lung transplantation for patients with end stage pulmonary vascular and parenchymal lung disease. CPET is useful in assessing disease progression before transplantation and assessing functional capacity for these individuals. However, there is presently no consensus on how indices of exercise performance may impact the clinical decision making process for lung transplantation selection. Selection guidelines for cardiac transplantation based on exercise performance (VO₂ max) have been previously established.

In summary, the technique of ambulatory gas measurement has a number of potential limitations that hinder its broad applicability. Gas exchange measurement systems are costly and require precise maintenance and calibration for optimal use. The American Thoracic Society states that personnel who administer the test and interpret results need to be trained and proficient in this technique. The clinically exercise laboratory should be under <u>direct supervision</u> of a pulmonologist or cardiologist certified in advanced cardiovascular life support with knowledge of exercise physiology and is trained 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.

August 2008 Update

There is no new published peer-reviewed literature identified that would alter the coverage statement of this policy.

August 2010 Update

In a July 2010 publication from the American Heart Association, a "Clinician's Guide to Cardiopulmonary Exercise Testing in Adults…" was published. The American Heart Association (AHA) states the following in their summary of Key Points of this guide:

- These guides are based primarily on expert consensus interpretation of published data as available as there are no randomized trials to address diagnostic and prognostic applications of CPX.
- CPX systems must be properly maintained and calibrated to ensure that high-quality data are provided.
- CPX test supervision, monitoring, and interpretation should be performed by competent personnel as recommended in established exercise testing guidelines.
- Integration of CPX test data with exercise-ECG test data provides optimal comprehensive use of CPX.
- CPX in clinical populations has been well studied and appears most useful in the evaluation of patients with heart failure and those with unexplained dyspnea. Other uses include the assessment of patients with mitochondrial myopathies, development of the exercise prescription in patients with cardiovascular disease or stroke, and the assessment of disability in patients with cardiac or pulmonary disease.
- Emerging and less well studied applications of CPX include the evaluation of patients with adult congenital heart disease, pulmonary hypertension, cardiac arrhythmias and pacemakers, and ischemic heart disease and the pre-operative assessment of patients undergoing pulmonary resection or bariatric surgery.
- Assessment of CPX data should be done to ensure its validity before a final report is generated.
- Future studies are needed to rigorously evaluate whether CPX provides additional discriminatory diagnostic and prognostic value over and above that provided by standard exercise tests and other clinical variables.

Key Words:

Metabolic GXT, Met-Test, exercise testing with ventilatory gas analysis, cardiopulmonary exercise testing, CPX, CPET

Approved by Governing Bodies:

Not applicable

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

Pre-certification/Pre-determination requirements: Not applicable

Coding:

CPT coding: 93015 Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with physician supervision, with

interpretation and report

In addition, several of the following codes may be used to report the pulmonary variables of this test.

94010	Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation
94070	Prolonged postexposure evaluation of bronchospasm with multiple spirometric determinations after antigen, cold air, methacholine or other chemical agent, with subsequent spirometrics
94150	Vital capacity, total (separate procedure)
94200	Maximum breathing capacity, maximal voluntary ventilation
94240	Functional residual capacity or residual volume: helium method, nitrogen open circuit method, or other method (Effective 01/01/2012)
94370	Determination of airway closing volume, single breath tests
94375	Respiratory flow volume loop
94621	Pulmonary stress testing; complex (including measurements of co2 production, o2 uptake, and electrocardiographic recordings)
94681	Oxygen uptake, expired gas analysis; including co2 output, percentage oxygen extracted
94720	Carbon monoxide diffusing capacity (e.g., single breath, steady state) (Effective 01/01/2012)

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Policy History:

Medical Review Committee, July 2004

Medical Policy Group, August 2004 (3)

Medical Review Committee, August 2004

Medical Policy Administration Committee, September 2004

Available for comment September 8-October 22, 2004

Medical Policy Group, August 2006 (1)

Medical Policy Group, August 2008 (1)

Medical Policy Group, August 2010 (1) Key Points updated, no coverage change

Medical Policy Group, August 2011 (1): Active policy but no longer scheduled for literature updates.

Medical Policy Group, December 2011(3); 2012 Coding Update – Code 94240 & 94720 delete 1/1/12

<u>Medical Policy Group, December 2012(3); 2013 Coding Update – Verbiage update to Code</u> <u>93015 – removed "physician"...</u>

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review)in Blue Cross and Blue Shield's administration of plan contracts.