Policy Replaced with LCDs L33444 & L34430 Effective February 26, 2018

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Cardiopulmonary Exercise Stress Test (CPET/CPX)

Policy #: 198
Category: Medicine

Latest Review Date: August 2010
Policy Grade: **Effective 01/01/2012 Active Policy but no longer scheduled for regular literature reviews and updates.**

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

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:

Effective for dates of service on or after July 1, 2005 and prior to February 26, 2018:
Blue Advantage will treat **Cardiopulmonary Exercise Testing (CPET)** as a **covered** benefit 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).

Blue Advantage will treat **CPET** as a **non-covered** benefit 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 Advantage 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 Advantage administers benefits based on the members' contract and 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	$\dot{V}O_2$, $\dot{V}CO_2$, RER, AT	Lactate
Cardiovascular	HR, ECG, BP, O_2 pulse	
Ventilatory	$\dot{V}E$, VT, fR	
Pulmonary gas exchange	Sp_{O2}, $\dot{V}E/\dot{V}CO_2$, $\dot{V}E/\dot{V}O_2$, PET_{O2}	Pa_{O2}, Sa_{O2}, $P(A\text{-}a)O_2$, 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; $P(A\text{-}a)O_2$ = 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 PO_2; RER = respiratory exchange ratio; Sa_{O2} = arterial oxygen saturation; Sp_{O2} = arterial oxygen saturation as indicated by pulse oximetry; $\dot{V}CO_2$ = carbon dioxide output; VE = minute ventilation; VD/VT = ratio of physiologic dead space to tidal volume; $\dot{V}O_2$ = oxygen uptake; VT = tidal volume; WR = work rate.

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 VO_2 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 VO_2 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 FEV_1 or diffusion capacity of the lung for CO_2 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 (VO_2 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 direct supervision 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.

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 post-exposure 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	Cardiopulmonary exercise stress testing; ~~complex~~ including measurements of minute ventilation, 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)**

References:

1. American Thoracic Society. ATS/ACCP statement on cardiopulmonary exercise testing, American Journal of Respiratory and Critical Care Medicine 2003, Vol. 167, pp. 211-277.
2. American Thoracic Society. Erratum: ATS/ACCP statement on cardiopulmonary exercise testing, American Journal of Respiratory and Critical Care Medicine 2003, Vol. 167, pp. 1451-1452.
3. Balady GJ, Arena R, Sietsema, et al. Clinician's guide to cardiopulmonary exercise testing in adults: A scientific statement from the American Heart Association. Circulation 2010; 122: 191-225.
4. Belardinelli Romualdo, Lacalaprice Francesca, Carle Flavia, et al. Exercise-induced myocardial ischaemia detected by cardiopulmonary exercise testing, European Heart Journal 2003; 24: 1304-1313.
5. Chaitman Bernard R. Exercise stress testing, Braunwald: Heart Disease: A Textbook of Cardiovascular Medicine, 6th edition, Chapter 6, pp. 129-131.
6. Fleg Jerome L, Pina Ileana L, Balady Gary J, et al. Assessment of functional capacity in clinical and research applications: An advisory from the Committee on Exercise, Rehabilitation, and Prevention, Council on Clinical Cardiology, American Heart Association, Circulation 2000; 102(13): 1591

7. Fletcher Gerald F, Balady Gary, Froelicher Victor F, et al. Exercise standards: A statement for healthcare professionals from the American Heart Association, Circulation 1995; 91(2): 580.
8. Gibbons Raymond J, Balady Gary J, Bricker J Timothy, et al. ACC/AHA 2002 guideline update for exercise testing: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines (Committee on Exercise Testing), American College of Cardiology Foundation and the American Heart Association, Inc. 2002, www.acc.org or www.americanheart.org.
9. Hone Rodney. Perioperative evaluation of cardiac failure and ischemia in elderly patients by cardiopulmonary exercise testing, Chest September 1993.
10. Myers J, Gullestad L, Vagelos R, Do D, Bellin D, et al. Clinical, hemodynamic, and cardiopulmonary exercise test determinants of survival in patients referred for evaluation of heart failure, Ann Intern Med 1998; 129: 286-293.
11. Older P, Smith R, Courtney P, and Hone R. Preoperative evaluation of cardiac failure and ischemia in elderly patients by cardiopulmonary exercise testing, Chest, September 1993; 104(3): 701-4 (Abstract).
12. Pina Ileana L, Balady Gary J, et al. Guidelines for clinical exercise testing laboratories: A statement for healthcare professionals from the Committee on Exercise and Cardiac Rehabilitation, American Heart Association, Circulation 1995; 91(3): 912-921.
13. Singh Vibhuti. The role of gas analysis with exercise testing, Primary Care, March 2001, Vol. 28, No. 1, pp. 159-178.
14. Stelken AM, Younis LT, Jennison SH, Miller DD, et al. Prognostic value of cardiopulmonary exercise testing using percent achieved of predicted peak oxygen uptake for patients with ischemic and dilated cardiomyopathy, J Am College of Cardiology 1996; 27: 345-352.
15. Sun Xing-Guo, Hansen James E, Garatachea Nuria, et al. Ventilatory efficiency during exercise in healthy subjects, American Journal of Respiratory and Critical Care Medicine 2002, Vol. 166, pp. 1443-1448.
16. United States Preventive Services Task Force (USPSTF). Recommendation statement: Screening for coronary heart disease, www.ahrq.gov/clinic/3rduspstf/chd/chdrs.htm.
17. Wasserman Karlman. Impact of integrative cardiopulmonary exercise testing on clinical decision making, Chest; April 1991.
18. Wasserman Karlman. Preoperative evaluation of cardiovascular reserve in the elderly (Editorial), Chest, September 1993.
19. Weisman IM. Cardiopulmonary exercise testing in the preoperative assessment for lung resection surgery, Semin thorac Cardiovasc Surg, April 2001; 13(2): 116-25.
20. Weisman Idelle M and Zeballos R Jorge. Clinical exercise testing, Clinics in Chest Medicine December 2001, Vol. 22, No. 4, pp. 679-701, viii.

Policy History:

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Medical Policy Group, August 2006
Medical Policy Group, August 2008
Medical Policy Group, August 2010

Medical Policy Group, December 2011
Medical Policy Group, December 2012
Medical Policy Group, December 2017
Medical Policy Group, January 2018

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.