



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject Home Spirometry

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Hyperlink to Related Coverage Policies

Lung and Heart-Lung Transplantation
Peak Flow Meters

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Coverage for a spirometry device is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for a spirometry device is available, the following conditions of coverage apply.

CIGNA covers a handheld, portable, battery-operated home spirometry device as medically necessary for home monitoring of pulmonary function following lung or heart-lung transplantation.

CIGNA does not cover any of the following because each is considered not medically necessary:

- home spirometry for the monitoring of other medical conditions
- home spirometry device enhancements
- services associated with the use of a home spirometry device including but not limited to:
 - recording of data
 - transmission of data
 - data analysis

General Background

Spirometry is a noninvasive pulmonary function test. Pulmonary function tests are used to detect lung disease or to monitor the progression of a particular disease. Spirometry is performed with the patient breathing into a tube that is attached to the spirometer. Spirometry is frequently used in physician offices and other outpatient settings. Indications for performing spirometry in these settings may include the following (American Association for Respiratory Care [AARC], 1996):

- to detect the presence of lung dysfunction suggested by history or physical signs and symptoms and/or the presence of other abnormal diagnostic tests
- to quantify the severity of known lung disease
- to assess the change in lung function following administration or a change of therapy
- to assess the potential effects or response to environmental exposure
- to assess the risk for surgical procedures known to affect lung function

Spirometry measures the flow and volume of air entering and leaving the lungs. The measurements obtained by spirometry may include:

- forced expiratory volume in one second (FEV₁): the volume of air exhaled in one second
- forced vital capacity (FVC): maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration

Home Spirometry Use Post Lung Transplantation

Lung transplantation is the surgical replacement of the lung(s) of a patient with end-stage pulmonary disease with the lung(s) of a living or deceased donor (Orens, 2006). Heart-lung transplantation is the surgical replacement of the heart and lungs of a patient who has end-stage cardiopulmonary disease. Combined heart-lung transplantation is reserved for candidates in whom either a heart transplant or lung transplant alone would not improve the recipient's condition. These transplantation procedures are the accepted therapy for patients whose disease is refractory to standard optimal medical or surgical treatment when no contraindications are present.

Rejection is a major common occurrence after lung transplantation (Whelan and Hertz, 2005). This includes acute rejection and chronic lung allograft rejection, which is also referred to as bronchiolitis obliterans syndrome. Allograft surveillance for signs of rejection includes monitoring of symptoms, chest radiography, and spirometry (Warrell, et al., 2003). Home spirometry has been a standard of care for monitoring after lung transplantation. It is used to detect early signs of rejection and/or infection. Measurements obtained include FEV₁ and FVC. A 10% or greater fall in FEV₁ will prompt review and investigation of the cause (Warrell, et al., 2003; Dabbs, et al., 2003; Huddleston, et al., 2002). Earlier detection of rejection may allow for earlier interventions and may improve the prognosis associated with rejection.

Home spirometry after lung transplantation is performed with a small, portable, handheld, battery-operated spirometer. An example of this type of spirometer includes the Micro Spirometer (Micro Direct, Inc., Lewistown, ME). This device measures and displays on a screen the FEV₁ and FVC.

While the medical literature is not robust, the use of a hand held spirometer at home after lung transplantation is considered a well-accepted and established practice. A study conducted was conducted by Otulana et al. (1990) of 15 heart-lung transplant recipients over six months to determine the value of home spirometry to detect acute lung rejection and opportunistic infections. After the results of the home spirometry were compared to results of transbronchial biopsy, it was noted that FEV and FVC fell by a mean of 6.9% and 9.3%, respectively, during 20 episodes of lung rejection leading to the study's conclusion that regular home spirometry offered early detection of complications as well as assessing efficacy of therapy.

Other Types of Home Spirometers

There are spirometers that have been developed and proposed for use that also include enhanced features, such as additional respiratory measurements, oximetry readings, telemetric monitoring, and telephonic transmission of the results, attached computers or internet connections to transmit results. There is insufficient

evidence found in the medical literature that demonstrates that these additional features are medically necessary or more effective in detecting early signs of infection or rejection, or in the home monitoring of respiratory conditions.

Examples of these devices include, but are not limited to:

- Micro/MicroPlus Spirometer (Micro Direct, Inc., Lewistown, ME)
- Flowmate III, Flowmate V plus, PC Classic (Spirometrics, Gray, ME)
- SpiroPhone AG-SP (Card Guard, Rheinfal, Switzerland)
- VM Plus (Clement Clarke, Essex, UK)

Literature Review—Other Types of Home Spirometers: Morlion et al. (2002) conducted a prospective study of 22 bilateral lung and heart-lung transplant recipients to assess all of the following: patient adherence with the monitoring; agreement between home and hospital spirometry; intra-subject variation with spirometry readings; and sensitivity of these variables for the detection of acute complications. As noted by the authors, it is a widely-accepted recommendation that the follow-up of lung transplant recipients should include daily measurements of FEV₁ at home with a portable spirometer. The authors report that using transbronchial lung biopsy and/or bronchoalveolar lavage as gold standards, the sensitivity of home spirometry was 63%, and 23% of true positives were detected by changes in mid-expiratory flow rate (forced expiratory flow [FEF]). It was concluded that “home monitoring for pulmonary function in lung transplant recipients via the Internet is feasible and provides very reproducible data, yet it has only a mild sensitivity for the detection of acute allograft dysfunction.” There was no comparison to handheld portable spirometers.

Wagner et al. (1999) conducted a case report of seven lung transplant recipients to test a system that allows daily monitoring of expiratory volumes along with daily transmission of the value via telemetry. The authors reported that telemetric monitoring of pulmonary function in lung transplant recipients is a reliable and useful tool for early diagnosis and treatment of acute graft dysfunction regardless of etiology. It was also noted that “any further impact on long-term outcomes after lung transplantation requires further studies with a longer follow-up.”

U.S. Food and Drug Administration (FDA)

Spirometers are classified by the FDA as class II devices. They are identified as devices used in pulmonary function testing to measure the volume of gas moving in or out of a patient’s lungs.

Other Devices

Home spirometry should not be confused with incentive spirometers. Incentive spirometers are devices used postoperatively to assist with deep breathing exercises for the purpose of preventing complications such as atelectasis.

Home spirometers should not be confused with peak flow meters. Peak flow meters are simple, portable devices that measure air flow, or peak expiratory flow rate (PEFR). They are used in the management of asthma to assist in determining airway status.

Summary

Home spirometry is a noninvasive method of measuring pulmonary function. Home spirometry provided with a handheld, portable, battery-operated device is considered a standard of care in the postoperative treatment of lung and heart-lung recipients. There is insufficient evidence that additional enhanced features are necessary or more effective in detecting early signs of infection or rejection. The medical literature does not demonstrate that home spirometry is effective in the management of other medical conditions.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

HCPCS	Description
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Codes	
A9284	Spirometer, non-electric, includes all accessories
E0487	Spirometer, electronic, includes all accessories

ICD-9-CM Diagnosis Codes	Description
996.84	Complications of transplanted organ lung
V42.6	Lung replaced by transplant

Not Medically Necessary/Not Covered:

CPT* Codes	Description
94014	Patient-initiated spirometric recording per 30-day period of time; includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and physician reviews and interpretation
94015	Patient-initiated spirometric recording per 30-day period of time; recording (includes hook-up, reinforced education, data transmission, data capture, trend analysis and periodic recalibration)
94016	Patient-initiated spirometric recording per 30-day period of time; physician review and interpretation only

ICD-9-CM Diagnosis Codes	Description
	All codes

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	7/15/2007	0387	Home Spirometry

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