Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/25**
(See policy history boxes for previous effective dates)

Title: Home Spirometry

Description/Background

Home spirometry devices allow monitoring of pulmonary function in the home. Home spirometry is a breathing test used to help diagnose and monitor lung conditions by measuring how much and how fast you can breathe out in one forced expiratory breath. Home spirometry usually employs battery-operated spirometers, which allows daily measurement of respiratory function including forced expiratory volume in one second and forced vital capacity
Home spirometry monitoring is not the same as incentive spirometry. An incentive spirometer is a simple device that is used following surgery or during and after hospitalization in order to mobilize secretions and increase lung volumes to reduce complications, such as pneumonia. A home spirometer is not a peak flow meter. A peak flow meter measures how quickly air is expelled from the lungs with a forceful exhale. It can help to identify early signs of worsening asthma.

The primary proposed use is to aid in the early diagnosis of infection and rejection by lung transplant recipients. The devices have also been suggested for use with other conditions that require pulmonary function monitoring. In the immediate postoperative period, lung transplant recipients must be carefully monitored for the development of either rejection episodes or infectious complications. Monitoring techniques include complete pulmonary function testing, serial chest x-rays, bronchioalveolar lavage, and transbronchial biopsy. Transbronchial biopsy is thought to be the only objective method of distinguishing between these common complications. Transbronchial biopsy is typically performed on a routine schedule, with additional biopsies performed if the patient becomes symptomatic. Home spirometry is proposed as a technique to identify presymptomatic patients who may benefit from a diagnostic transbronchial biopsy.

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Regulatory Status:

The U.S. Food and Drug Administration (FDA) has approved devices for home spirometry. In 2000, the SpiroPro® SpO2 (VIASYS Healthcare), a combination spirometer and pulse oximeter, was cleared for marketing by the FDA through the 510(k) process (K031515). The device is portable, battery operated and can be used by physicians in the office or hospital, in occupational medicine or by patients in the home.

In 2003, the IQTeQ Spirometer 2001 (IQTeQ Development) was cleared for marketing by the FDA through the 510(k) process (K020102). The FDA determined that this device was substantially equivalent to existing devices for use in pulmonary function evaluation in various settings, including homes, with a physician's prescription.

In 2013, Spirotel (Medical International Research), a pocket spirometer that has an optional pulse oximeter function, was cleared for marketing by the FDA through the 510(k) process (K130784). It is intended to be used as a single-patient device in any setting – home, factory, pharmacy, hospital or physician's office.

March 24, 2017, GoSpiro Home Spirometer (Monitored Therapeutics, a remote patient management company) received clearance from the FDA for the spirometer to be used in physician's offices, clinics and home settings to conduct basic lung function and spirometry testing. (K163249). It is the first wireless spirometer for home use.

Product code BZG.

Medical Policy Statement

Computerized capture of data and electronic transmission of home spirometry results is considered experimental/investigational. It has not been scientifically demonstrated to improve health outcomes over conventional testing for patients with pulmonary dysfunction.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

94014 94015 94016 A9284

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Lung Transplant Recipients

Otulana et al (1990) reported on the use of home spirometry in an initial case series of 15 heart-lung transplant recipients.[1] The authors hypothesized that the results of routine spirometry might better guide the use of transbronchial biopsy. They reported that episodes of rejection or infection were associated with a 10% decrease in FEV1 and recommended that this decrease should prompt a transbronchial biopsy. However, all patients also had symptoms at the same time, so it is unclear how the spirometry contributed to the decision to perform a transbronchial biopsy. On 9 occasions, the FEV1 was unchanged at the time of a routine scheduled transbronchial biopsy. Histologic results were normal in these patients.

Fracchia et al (1995) reported on a case series of 9 heart-lung transplant recipients who underwent monitoring of lung rejection with home spirometry.[2] Similar to the study of Otulana, patients underwent a "symptom" transbronchial biopsy if their FEV1 or FVC showed a decrease of 10%. Only 3 patients underwent a symptom biopsy, which revealed moderate rejection. It was not reported whether the patient was clinically symptomatic at that time. In addition, during routinely scheduled transbronchial biopsies, acute rejections were observed even in the face of normal FEV1 values.

A retrospective cost analysis published in 2007 evaluated home monitoring in 138 lung transplant recipients who were monitored for at least 1 year.[3] The analysis found that adherence to a program of home monitoring that included home spirometry was associated with lower overall costs (higher outpatient, lower inpatient). However, there was no comparison group of patients with lung transplant who did not have home monitoring and there are likely patient factors that impact adherence and preclude attributing the cost savings to the program.

A 2009 study conducted in Germany reported on results of a prospective study comparing outcomes 7 years post-transplant in lung transplant recipients who did and did not adhere to a 2-year program of home spirometry, beginning 6 months after the transplant.[4] A total of 271 patients met eligibility criteria and were invited to participate; of these, complete home spirometry data over 2 years was available for 226 (83%) participants. Follow-up data at 7 years were available for 183 of the 226 patients (81%) who completed home spirometry measurements; excluded were 36 patients who died and 7 who were lost to follow-up. Patients were placed in the following 3 categories according to their use of home spirometry: good adherers (performed at least 80% of expected home spirometry), moderate adherers (performed between 50% and 79% of expected home spirometry) or nonadherers (performed less than 50% of expected home spirometry). Adherence was rated separately for each of 4 6-month periods (months 6–12, months 13–18, months 19–24, and months 25–30). Adherence was highest during the first 6-month period; over 80% of participants were considered good adherers. The proportion of good adherers decreased to about 70% in the second period, and then to about 55% during both the third and fourth periods. Over the 7 years of follow-up, bronchiolitis obliterans syndrome developed in 72 out of 226 (31.9%) patients. According to Kaplan-Meier event-free analysis, there was a significantly lower freedom from bronchiolitis

obliterans syndrome time in nonadherers compared with good or moderate adherers ($p<0.014$). However, the retransplantation rate and mortality rate were not significantly associated with home spirometry adherence; 5% of patients received a second transplant and the mortality rate was 20%. While this study reported the association between spirometry and health outcomes, it was not randomized, and although the authors attempted to control for risk factors, there may be differences between groups that affected adherence and disease status.

Finkelstein et al (2013) reported on a randomized controlled study examining the relative performance of a computer based Bayesian algorithm versus a manual nurse decision process for triaging clinical intervention in lung transplant recipients in a home monitoring program. Sixty-five lung transplant recipients were assigned to either the Bayesian group or nurse triage group. Using an electronic spirometer/diary device, study participants monitored and transmitted spirometry and respiratory symptoms daily to the data center. Quality of life measures were taken using the Short Form-36 (SF-36) survey which study participants completed at baseline and after 1 year. Study end points were changed from baseline after 1 year in forced expiratory volume at 1 second (FEV1) and quality of life (SF-36 scales) within and between each study arm. There were no statistically significant differences between groups in FEV1 or SF-36 scales at baseline or after 1 year. Results were comparable between nurse and Bayesian system in detecting changes in spirometry and respiratory symptoms.[5]

Wang et al (2013) studied the development, implementation, and testing of an automated decision making system using a home monitoring program for early detection of clinically significant bronchopulmonary events in lung transplant population. Spirometry and symptoms were collected daily, at home, by lung transplant patients with weekly transmission to the study center. Decision making rules were developed using wavelet analysis of declines in spirometry and increases in respiratory symptoms from a learning set of patient home data and an independent validated patient set. The study results showed that, using FEV1 or reported symptoms, the detection method captured the majority of events with an acceptable level of false alarms. On average, detections occurred 6.6 to 10.8 days earlier than with known event records. Therefore, this approach may be useful for early detection of pulmonary events and may also decrease the time needed for clinicians to review large amounts of home monitoring data to uncover infrequent but clinically significant events.[6]

In a retrospective study by de Wall et al (2014) the utility of home spirometry versus office spirometry was assessed to determine treatment response to azithromycin in bronchiolitis obliterans syndrome in a population of 239 lung transplant recipients. The study results showed home spirometry was able to identify azithromycin refractory patients significantly earlier than office spirometry. Earlier identification could possibly facilitate more aggressive treatment that may improve long term outcomes.[7]

Other Pulmonary Conditions

Brouwer et al (2007) reported on a study that included 50 asthmatic children aged 6 to 17 years.[8] This was a sequence randomized study measuring peak expiratory flow and FEV1 using both a hospital-based pneumotachograph and a home spirometer (Koko Peak Pro). The study found both clinically and statistically significant differences between measures obtained using the two techniques in a controlled (professionally supervised) clinical setting. The results from each meter were reproducible but not interchangeable. The mean values for both measures were significantly lower when using the home spirometer compared to the hospital

spirometer. This study also had the limitation that it did not report on the impact of home spirometry on outcomes.

In 2010, Brouwer et al reported on a study examining the value of home spirometry in children with non-specific lower respiratory tract symptoms for the purpose of diagnosing or ruling out asthma. Participants were school-aged children (N=61) who were referred by their primary care physician due to chronic respiratory symptoms. Using international guidelines and a standardized protocol, a pediatric pulmonologist examined the participants and diagnosed or ruled out asthma. Additionally, using home spirometry equipment, peak expiratory flow and forced expiratory flow in 1 second (FEV1) were measured twice a day for 2 weeks from which diurnal variation was calculated. The results of the home spirometry tests were not given to the pediatric pulmonologist at any point during the study. Between asthma and no asthma, the mean difference in peak expiratory flow variation was 4.4 % (95% CI: 0.9 to 7.9; p=0.016) and in FEV1 variation 4.5% (95 % CI: 1.6 to 7.4; p=0.003). Sensitivity and specificity, based on the 95th-percentile of the reference values for peak expiratory volume and FEV1 variation (12.3% and 11.8%, respectively) were 50% and 72% for peak expiratory volume variation and 45% and 92% for FEV1 variation. The likelihood ratio was 1.8 for peak expiratory volume and 5.6 for FEV1. Based upon the study findings, the authors concluded that the home spirometry has limited utility for diagnosing asthma in children with nonspecific respiratory symptoms.[9]

Deschildre et al (2012) reported the results of a study examining whether daily home spirometry with teletransmission to an expert medical center improves outcomes (including severe exacerbations, healthcare use, lung function, quality of life and maintenance treatment) over conventional treatment using recommended guidelines. The study included 50 children with a mean age of 10.9 years who had severe uncontrolled asthma. The participants were randomized into 2 groups. In the first group, treatment was managed using daily home spirometry with medical feedback (HM). The second group received conventional treatment (CT). Forty-four children completed the study, 21 in the HM group and 23 in the CT group. The median number of severe exacerbations per patient was 2.0 (interquartile range 1.0–4.0) in the HM group and 3.0 (1.0–4.0) in the CT group (p= 0.38 with adjustment for age). There were no significant differences between the two groups for unscheduled visits (HM 5.0 (3.0–7.0), CT 3.0 (2.0–7.0); p=0.30), lung function (pre-β2-agonist forced expiratory volume in 1 s (FEV1) p=0.13), Paediatric Asthma Quality of Life Questionnaire scores (p=0.61) and median daily dose of inhaled corticosteroids (p=0.86). Based upon the study findings, the authors concluded that home spirometry with medical feedback did not reduce severe asthma exacerbations.[10]

Jódar-Sánchez et al (2013) reported on a randomized study in a population with chronic obstructive pulmonary disease (COPD). The aim of the study was to determine whether home spirometry management reduced the number of emergency room visits or hospital admissions in patients with COPD. The study found no statistically significant differences in the number of emergency room visits or hospital admissions. A nonsignificant trend was reported in improved quality of life in participants managed with home spirometry.[11]

Russell et al (2016) reported on a study assessing the feasibility and reliability of measuring daily FVC in individuals with idiopathic pulmonary fibrosis (IPF). Study participants were given hand-held spirometers and instructions on self-administered spirometry. Participants recorded daily FEV1 and FVC for up to 490 days. Clinical assessment and hospital based spirometry were performed at 6 and 12 months and outcome data was collected to 3 years. Daily spirometry was recorded by 50 participants for a median period of 279 days (range of 13 to 490). There were 18 deaths during the study period. Home spirometry showed excellent

correlation with hospital obtained readings. The rate of decline in FVC was highly predictive of outcome and subsequent mortality when measured at 3, 6, and 12 months.[12]

Lechtzin et al (2017) conducted a multicenter, randomized trial to determine if an intervention directed toward early detection of pulmonary exacerbations using home spirometry and symptom monitoring would result in slower decline in lung function than in control subjects.[13] The study was conducted at 14 cystic fibrosis centers with participants who were at least 14 years of age. In the early intervention arm, home spirometry and symptoms were measured by participants electronically twice per week. Sites were notified if a participant met criteria for an exacerbation and contacted participants to determine if treatment for acute exacerbation was required. Participants in the usual care arm were seen every 3 months and were asked to contact the site if they were concerned about worsening pulmonary symptoms. The primary outcome measure was 52-week change in FEV1. Secondary outcomes included time to first exacerbation and subsequent exacerbation, quality of life, and change in weight. A total of 267 patients were randomized, and the study arms were well matched at baseline. There was no significant difference between study arms in 52-week mean change in FEV1 slope (mean slope difference, 0.00 L, 95% confidence interval, -0.07 to 0.07; P = 0.99). The early intervention arm subjects detected exacerbations more frequently than usual care arm subjects (time to first exacerbation hazard ratio, 1.45; 95% confidence interval, 1.09 to 1.93; P=0.01). Adverse events were not significantly different between treatment arms. The authors concluded that home monitoring detected more exacerbations than usual care, but this intervention did not slow decline in lung function.

Noth et al (2020) reported on the feasibility and validity of home spirometry as a measure of lung function decline in patients with idiopathic pulmonary fibrosis. Subjects with IPF and preserved forced vital capacity (FVC) were randomised to receive nintedanib or placebo for 12 weeks followed by open-label nintedanib for 40 weeks. Clinic spirometry was conducted at baseline and weeks 4, 8, 12, 16, 20, 24, 36 and 52. Subjects were asked to perform home spirometry at least once a week and ideally daily. Correlations between home- and clinic-measured FVC and rates of change in FVC were assessed using Pearson correlation coefficients. A total of 346 subjects were treated. Mean adherence to weekly home spirometry decreased over time but remained above 75% in every 4-week period. Over 52 weeks, mean adherence was 86%. Variability in change from baseline in FVC was greater when measured by home rather than clinic spirometry. Strong correlations were observed between home- and clinic-measured FVC at all time-points (r=0.72-0.84), but correlations between home- and clinic-measured rates of change in FVC were weak (r=0.26 for rate of decline in FVC over 52 weeks). The authors concluded that although home spirometry was a feasible and valid measure of lung function in patients with IPF and preserved FVC, estimates of the rate of FVC decline obtained using home spirometry were poorly correlated with those based on clinic spirometry.[14]

Summary

There are limited studies on home spirometry use. Most of the available literature did not evaluate the impact of home spirometry use on health outcomes. The evidence is insufficient that home spirometry improves the net health outcome and, thus, the technology is considered experimental/investigational.

Technology Assessments, Guidelines and Position Statements

No national guidelines were identified that recommend using home spirometry.

SUPPLEMENTAL INFORMATION

American Academy of Allergy, Asthma & Immunology 2023[15]

Spirometry measures how much air you can inhale as well as how much and how fast you can exhale air. It is an important tool to diagnose and understand asthma severity and control. Home spirometry is not mentioned in their guidelines.

American Thoracic Society[16]

Many lung transplant recipients develop delayed allograft dysfunction that has been traditionally referred to as bronchiolitis obliterans syndrome (BOS), which is thought to be caused by inflammation, destruction and fibrosis of small airways in the lung allograft that leads to obliterative bronchiolitis (OB). (decline in FEV1 on home spirometry or at clinic visit follow-up evaluation) that may indicate allograft dysfunction, a comprehensive evaluation to determine the cause is typically initiated (fig. 2). This usually includes a routine evaluation in the clinic, followed by specific testing (imaging, confirmatory spirometry and bronchoscopy, as indicated) to identify a specific cause or causes of lung function decline. If BOS appears to be the cause of lung function decline, the treatment approaches discussed in the following section can be considered.

Government Regulations
National/Local:

There is no national or local coverage policy on this topic.

The 2024 CMS Physician Fee Scheduled has fees listed for procedure codes 94014-94016. An assigned fee is not a guarantee of coverage.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Acoustic Measurement of Wheeze Rate (Retired)
- Telemonitoring – Remote Patient Monitoring and Remote Therapeutic Monitoring
- Telemedicine Services

References

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3. Adam TJ, Finkelstein SM, Parente ST et al. Cost analysis of home monitoring in lung transplant recipients. Int J Technol Assess Health Care 2007; 23(2):216-22.
4. Kugler C, Fuehner T, Dierich M et al. Effect of adherence to home spirometry on bronchiolitis obliterans and graft survival after lung transplantation. Transplantation 2009; 88(1):129-34.

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8. Brouwer AF, Roorda RJ, Brand PL. Comparison between peak expiratory flow and FEV(1) measurements on a home spirometer and on a pneumotachograph in children with asthma. Pediatr Pulmonol 2007; 42(9):813-8.
9. Brouwer, AF, et al. Is home spirometry useful in diagnosing asthma in children with nonspecific respiratory symptoms? Pediatr Pulmonol 2010;45(4):326-32. doi: 10.1002/ppul.21183.
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13. Lechtzin, N et al. Home Monitoring of Patients with Cystic Fibrosis to Identify and Treat Acute Pulmonary Exacerbations. eICE Study Results. Am J Respir Crit Care Med. 2017 Nov 1;196(9):1144-1151. doi: 10.1164/rccm.201610-2172OC.
14. Noth I, Cottin V, Chaudhuri N, et al. Home spirometry in patients with idiopathic pulmonary fibrosis: data from the INMARK trial. Eur Respir J. 2021 Jul 5;58(1):2001518. PMID 33419890
15. American Academy of Allergy, Asthma & Immunology 2023 Spirometry Defined | AAAAI accessed 8/13/24
16. Meyer, Keith, Ranesh Raghu, Geert Verleden. An international ISHLT/ATS/ERS Clinical Practice Guideline: diagnosis and management of bronchiolitis obliterans syndrome. American Thoracic Society, August 24, 2014

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 8/13/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
2/8/02	2/8/02	5/6/03	Joint medical policy established
5/14/04	5/14/04	5/27/04	Routine maintenance
7/15/05	7/15/05	9/21/05	Routine maintenance
3/1/07	12/28/06	1/2/07	Routine maintenance
3/1/09	12/9/08	12/21/08	Routine maintenance
11/1/10	8/28/10	8/17/10	Routine maintenance
11/1/11	8/16/11	8/16/11	Routine maintenance
3/1/13	12/11/12	12/31/12	Routine maintenance
5/1/15	2/17/15	2/27/15	Routine maintenance Updated description, references and rationale Title changed from “Patient Initiated Spirometric Studies” to “Home Spirometry”
7/1/16	4/19/16	4/19/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance
1/1/22	10/19/21		Routine maintenance Ref 14 added
1/1/23	10/18/22		Routine maintenance (ls)
1/1/24	10/17/23		Routine maintenance (jf) Vendor Managed: Northwood (A9284) Ref added 15,16
1/1/25	10/15/24		Routine maintenance (jf) Vendor Managed: NA

Next Review Date: 4th Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: 10/11/99	Revised: 9/12/00

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: HOME SPIROMETRY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See Governmental Regulations Section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.