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Home Spirometry

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Home monitoring of pulmonary function utilizing a spirometer or telespirometer **is considered experimental, investigational and/or unproven** for all indications.

NOTE: Home spirometry for monitoring pulmonary function should not be confused with incentive spirometry. Incentive spirometry is commonly utilized to mobilize secretions and increase lung volumes following thoracic surgery.

Policy Guidelines

None.

Description

Home spirometry (also known as ambulatory spirometry) devices allow for the monitoring of pulmonary function in the home environment. These noninvasive devices measure the vital capacity, forced expired volume and airflow rates at various lung volumes. The primary proposed use is by lung transplant recipients to aid in the early diagnosis of infection and rejection. They can potentially be used to detect the presence of lung disease and to monitor changes in severity and response to treatment. (1)

In the immediate post-operative 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 2 common complications. Schedules for surveillance bronchoscopies vary, but generally involve monthly biopsies in the immediate post-transplant period (when the incidence of acute cellular rejection is the highest) and continue at less regular intervals for the period from 3 to 12 months after transplant. (2) Home spirometry is proposed as a technique to provide daily monitoring to promptly identify presymptomatic patients who may benefit from a diagnostic transbronchial biopsy.

Home spirometry uses battery operated spirometers that permit daily measurement of pulmonary function in the home, typically forced expiratory volume in 1 second (FEV-1) and forced vital capacity (FVC). (1, 2)

Telespirometry is performed using a hand-held device (telespirometer) that provides testing for both spirometry and oximetry. The device records the results, which can then be sent via telephone to a designated healthcare provider. This has been proposed to monitor lung function, sleep apnea or desaturation occurrences. (3)

Regulatory Status

In 2002, the IQTeQ Spirometer 2001 (IQTeQ Development) was cleared for marketing by the United States (U.S.) Food and Drug Administration (FDA) through the 510(k) process. (4) 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 2003 the SpiroPro SpO2 (VIASYS Healthcare) was cleared for marketing by the U.S. FDA through the 510(k) process. (5) The indications for use include use in the home.

In 2013, the Spirotel (MIR Medical International Research) was cleared for marketing by the U.S. FDA through the 510(k) process. Spirotel is a pocket spirometer that can also feature a pulse oximeter function (optional). It measures a range of functional respiratory parameters, and the oxygen saturation and pulse rate. The FDA determined that this device was substantially equivalent to existing devices. (6)

In 2023, the FDA provided 510(k) clearance for marketing of the SpiroHome Ultrasonic Spirometer, also called SpiroHome Clinic or SpiroHome Personal (Inofab Health). It is intended to be used by adults and children over 5 years old in physician offices, clinics, and home settings to conduct basic lung function and spirometry testing. (7)

The Air Next device (NuvoAir) received 510(k) clearance for marketing from the FDA in 2024. It is intended to perform basic lung function and spirometry testing in adults and children 5 years of age and older. It can be used in hospitals, clinical settings, and at home. (8)

Refer to <https://www.fda.gov> for the most comprehensive list of FDA spirometry and telespirometry approved devices. FDA product codes BZG and/or DQA.

Rationale

This policy was originally created in January 2000 and has been updated regularly with searches of the PubMed database. The most recent literature review was performed through April 9, 2024. Following is a summary of the key literature to date.

Use of Home Spirometry in Lung Transplant Recipients
Otulana and colleagues (9) reported on the use of home spirometry in an initial case series of 15 heart-lung transplant recipients. The authors hypothesized that the results of routine spirometry might better guide the use of transbronchial biopsy. The authors reported that episodes of rejection or infection were associated with a 10% decrease in forced expiratory volume in 1 second (FEV-1) 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 nine occasions, the FEV-1 was unchanged at the time of a routine scheduled transbronchial biopsy. Histologic results were normal in these patients.

Fracchia and colleagues (10) reported on a case series of nine heart-lung transplant recipients who underwent monitoring of lung rejection with home spirometry. Similar to the study of Otulana, patients underwent a “symptom” transbronchial biopsy if their FEV-1 or forced vital capacity (FVC) showed a decrease of 10%. Only three 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 FEV-1 values.

A retrospective cost analysis published in 2007 evaluated home monitoring in 138 lung transplant recipients who were monitored for at least 1 year. (11) 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. (12) 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 was 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 non-adherers (performed less than 50% of expected home spirometry). Adherence was rated separately for each of four 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 (BOS) developed in 72 out of 226 (31.9%) patients. According to Kaplan-Meier event-free analysis, there was a significantly lower freedom from time in non-adherers compared with good or moderate adherers ($p<0.014$). However, the re-transplantation 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 impacted disease status.

In 2013, Finkelstein et al. (13) studied the relative performance of a computer-based Bayesian algorithm compared with a manual nurse decision process for triaging clinical intervention in lung transplant recipients participating in a home monitoring program. The randomized controlled study had 65 lung transplant recipients assigned to either the Bayesian probability or nurse triage study arm. Subjects monitored and transmitted spirometry and respiratory symptoms daily to the data center using an electronic spirometer/diary device. Subjects completed the Short Form-36 survey at baseline and after 1 year. End points were change from baseline after 1 year in FEV-1 and quality of life (QOL) (SF-36 scales) within and between each study arm. There were no statistically significant differences between groups in FEV-1 or SF-36 scales at baseline or after 1 year. Results were comparable between nurse and Bayesian system for detecting changes in spirometry and symptoms, providing support for using computer-based triage support systems as remote monitoring triage programs become more widely available. The study concluded that the feasibility of monitoring critical patient data with a computer-based decision system is especially important given the likely economic constraints on the growth in the nurse workforce capable of providing these early detection triage services. The study is limited by its sample size, which may introduce potential bias, as well as adherence issues that impact data collection. Validation of these results with larger numbers of subjects

and multisite collaboration would provide further evidence of the feasibility and clinical appropriateness of instituting such programs.

In 2014, Fadaizadeh et al. (14) conducted a pilot study to evaluate the role of home spirometry in the follow-up of lung transplant recipients and early detection of complications in these patients. PC-based portable spirometry set was used to evaluate the well-being of two lung transplant recipients on a regular daily basis for a 6-month period. Patient satisfaction and compliance, and device sensitivity in detecting complications were evaluated. Results of follow-up were compared with 2 matched control patients. Patient adherence to home spirometry was 80% in one and 61% in the other patient and both patients were satisfied with the method, although this satisfaction declined towards the end of the study period. The main reason for low adherence was insufficient internet access. This method succeeded in early detection of infectious complications. The study concluded that home spirometry seems to be a reliable method for follow-up of lung transplant recipients, but further studies in a larger group of patients is recommended.

In 2013, Wang et al. (15) studied the use of automatic event detection in lung transplant recipients based on home monitoring of spirometry and symptoms. The goal of this study was to develop, implement, and test an automated decision system to provide early detection of clinically important bronchopulmonary events in a population of lung transplant recipients following a home monitoring protocol. Spirometry and other clinical data were collected daily at home by lung transplant recipients and transmitted weekly to the study data center. Decision rules were developed using wavelet analysis of declines in spirometry and increases in respiratory symptoms from a learning set of patient home data and validated with an independent patient set. Using FEV-1 or symptoms, the detection captured the majority of events (sensitivity, 80–90%) at an acceptable level of false alarms. On average, detections occurred 6.6–10.8 days earlier than the known event records. The authors determined that spirometry is useful for early discovery of pulmonary events and has the potential to decrease the time required for humans to review large amount of home monitoring data to discover relatively infrequent but clinically notable events. Non-pulmonary events that affect pulmonary functions may not be distinguishable from pulmonary events on the basis of spirometry and symptom surveillance alone.

In 2014, de Wall et al. (16) researched home spirometry as an early detector of azithromycin refractory BOS in lung transplant recipients which evaluated the utility of home spirometry versus office spirometry in assessing treatment response to azithromycin in BOS. Two hundred thirty-nine (n=239) lung transplant recipients were retrospectively studied. Change in TEV1 (ΔFEV-1 ± 10 %) from FEV-1 at azithromycin initiation for greater than or equal to 7 consecutive days in home spirometry or greater than or equal to 2 measures in office spirometry were taken as cut-off for response or progression. Based upon home spirometry, 161/239 (67 %) patients were progressive despite macrolide, 19 of whom exhibited transient improvement in FEV-1 (11 %). Time to progression was 29 (13 to 96) days earlier with home spirometry than in office spirometry. A total of 46 (19 %) recipients responded in home spirometry after median 81 (22 to 343) days, while 22 % remained stable. Concordance in azithromycin treatment

response between office spirometry and home spirometry was observed in 210 of 239 patients (88 %). Response or stabilization conferred significant improvement in survival (p = 0.005). Transient azithromycin responders demonstrated improved survival when compared to azithromycin refractory patients (p = 0.034). Home spirometry identified azithromycin refractory patients significantly earlier than office spirometry, possibly facilitating aggressive treatment escalation that may improve long-term outcome. The investigators recommend that treatment response to azithromycin be assessed 4 weeks after initiation. Responders demonstrated best survival, with even transient response conferring benefit. Macrolide-refractory BOS carried the worst prognosis. The authors noted that the retrospective single-center nature of the study potentially impacted the analysis, and that bias may have occurred in patient adherence due to selection criteria (patients without home spirometry and non-adherent patients were not evaluated).

In 2014, Robson and West (17) performed a systematic review to determine the impact of daily home spirometry as a BOS detection tool in lung transplant patients and the impact on survival. Eight RCTs met inclusion criteria and were included in the study. Two studies compared the use of traditionally scheduled pulmonary function testing (PFT) with daily home spirometry and found BOS stage 1 to appear 341 days earlier with home spirometry (P<0.001). Other studies that investigated the impact early detection had on office spirometry showed a positive trend toward freedom from BOS and reduced rates of retransplantation, although these results did not reach statistical significance (P<0.07). The authors concluded that daily home spirometry has been shown to lead to earlier detection and staging of BOS when compared with standard PFT. Although FEV-1 has been shown to be the most sensitive and reliable marker of BOS onset, the impact of earlier staging via home spirometry on survival has not been reliably determined.

UpToDate (18) evaluated the treatment of acute lung transplant rejection and offered the following observations on the use of spirometry:

- Office-administered spirometry has been reported to have a sensitivity of 60 percent in detecting rejection (grade ≥A2) or infection among bilateral lung transplant recipients. A decline of 10 percent in spirometric values that persists for more than two days has been reported to indicate either rejection or infection. In single lung transplant recipients, spirometry is less helpful as changes may reflect progression of the underlying disease in the native lung.
- Performance of patient-administered home spirometry several times a week may lead to earlier detection of BOS, but the effect on long-term outcomes is less clear. The potential benefit of frequent spirometry remains an area of active research.

Use of Home Spirometry Excluding Lung Transplant Recipients

Several studies have addressed home spirometry for patients other than lung transplant recipients. A 2007 publication reported results on using home spirometry to detect pulmonary complications in recipients of allogeneic stem cell transplants. (19) While the authors concluded it was a useful procedure, further investigation is needed to determine potential impact on outcomes.

Asthma

Brouwer et al. completed a study included 50 asthmatic children aged 6 to 17 years. (20) This was a sequence randomized study measuring peak expiratory flow and FEV-1 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 2012, Deschildre et al. (21) focused a study on pediatric patients with severe asthma that develop frequent exacerbations despite intensive treatment. The study aimed to assess the outcome (severe exacerbations and healthcare use, lung function, QOL and maintenance treatment) of a strategy based on daily home spirometry with teletransmission to an expert medical center and whether it differs from that of a conventional strategy. Fifty children with severe uncontrolled asthma were enrolled in a 12-month prospective study and were randomized into two groups: treatment managed with daily home spirometry and medical feedback (HM) and conventional treatment. The children's mean age was 10.9 years (95% confidence interval [CI] 10.2-11.6). Forty-four children completed the study (21 in the HM group and 23 in the conventional treatment 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), Conventional treatment 3.0 (2.0-7.0); p=0.30), lung function (pre-β (2)-agonist FEV-1, p=0.13), Pediatric Asthma Quality of Life Questionnaire scores (p=0.61) and median daily dose of inhaled corticosteroids (p=0.86). The authors determined that a treatment strategy based on daily FEV-1 monitoring with medical feedback did not reduce severe asthma exacerbations.

Kupczyk et al. (2021) evaluated the feasibility and safety of a portable spirometer for unsupervised home spirometry measurements among patients with asthma. (22) A multi-center, prospective, single-arm, open study recruited 86 patients with controlled or partly controlled asthma (41 women, 38.6 ± 10.4 y/o and 45 men, 36.2 ± 12.1 y/o). After a training session, patients performed daily spirometry at home with the AioCare® mobile spirometry system. Each spirometry examination was recorded and evaluated according to the ATS/ERS acceptability and repeatability criteria. The primary endpoint was defined as three or more acceptable examinations in any given seven-day period (+/- 1 day) during any of the three weeks of the study. The system allowed for online review of measurements by physicians/nurses to provide feedback to patients. Of 78 patients with complete data, 67 (86%) achieved the primary endpoint. Seventy-five (96%) participants used the device correctly once or more, and 10 (13%) patients succeeded every single day over the three-week follow-up. The rate of acceptable spirometry examinations differed between the sites (p = 0.013). Retraining was required in 20 of 62 (32%) eligible patients, and successful in 8 individuals (40%). Satisfaction with the AioCare® system was high, 90% of respondents perceived it as useful and

user-friendly. Investigators concluded that self-monitoring of asthma with a connected mobile spirometer is feasible, safe and satisfactory for patients with asthma. However, it remains to be established whether unsupervised home spirometry measurements may improve early diagnosis and outcomes of self-management in cases of exacerbation or loss of asthma control.

Cystic Fibrosis (CF)

Individuals with CF typically experience frequent acute pulmonary exacerbations, which lead to decreased lung function and reduced QOL.

In 2017, Lechtzin et al. (23) sought to test the hypothesis that earlier treatment of CF exacerbations would result in better clinical outcomes and result in a slower decline in lung function than in control participants. This multicenter, randomized trial was performed at 14 CF centers and enrolled patients that were at least 14 old. The early intervention arm participants measured home spirometry and symptoms electronically twice per week. Participants in the usual care arm were seen every 3 months and were notified to contact the CF center if they were concerned about worsening pulmonary symptoms. The primary outcome was the 52-week change in FEV-1. Secondary outcomes included time to first and subsequent exacerbation, QOL 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 FEV-1 slope (mean slope difference, 0.00 L, 95% CI, −0.07 to 0.07; P = 0.99). The early intervention arm participants detected exacerbations more frequently than the usual care arm participants (time to first exacerbation hazard ratio, 1.45; 95% CI, 1.09 to 1.93; P = 0.01). Adverse events were not significantly different between treatment arms. This study concluded that intervention of home monitoring among participants with CF was able to detect more exacerbations than usual care, but this did not result in slower decline in lung function.

In 2017, Shakkottai and Nasr (24) noted that medication adherence is poor among pediatric CF patients, with adolescents having one of the lowest adherence rates. These researchers identified an adherence intervention that would be acceptable to CF adolescents and evaluated its feasibility. Forty adolescents with CF were surveyed regarding adherence barriers and motivators. Most of the respondents chose frequent home spirometry and medication reminders for interventions. The investigators selected 5 patients, 10 to 14 years of age, with CF to test the feasibility of home spirometry and medication reminders in pediatric CF patients. The authors concluded that the findings of this small pilot study showed that adolescents with CF valued the feedback from frequent pulmonary function studies monitoring and that home spirometry could be successfully used in pediatric CF patients. Moreover, they stated that a larger study is currently underway to evaluate the impact of performing frequent home spirometry on treatment adherence, health outcomes, and QOL over a longer period of time.

Bell et al. (2022) sought to evaluate the quality of spirometry performance by adult CF patients with and without observation by a trained respiratory scientist in an observational single center study conducted between February to December 2020. (25) Seventy-four adults were recruited and instructed to perform spirometry without supervision within 24 hours of their remote CF

clinic consultation. Spirometry was repeated at their consultation, supervised by a respiratory scientist using video conferencing. The majority of patients achieved grade A (excellent) or B (very good) spirometry quality with (95%) and without supervision (93%) independent of lung function severity. Similarly, FEV-1 demonstrated no significant differences with paired spirometry performed within a 24-hour period. For a large proportion of adult CF patients, unsupervised portable spirometry produces acceptable and repeatable results.

Paynter et al. (2022) evaluated the accuracy and precision of longitudinal home spirometry. (26) Participants aged ≥14 years with percent predicted forced expiratory volume in 1 second ($ppFEV_1$) >25 were recruited from 2011-2015, issued a home spirometer, and asked to complete spirometry efforts twice per week for one year. Clinic spirometry was collected at baseline and every three months. Cross-sectional differences between clinic spirometry and the closest home spirometry measurement were analyzed. Home spirometry is estimated to be 2.0 (95% CI: 0.3, 3.5) percentage points lower than clinic spirometry cross-sectionally. Longitudinally, the estimates of 12-month change in home spirometry varied by analysis method from -2.6 to -1.0 $ppFEV_1$/ year, with precision markedly different. However, home spirometry change estimates were qualitatively similar to the clinic results: -3.0 $ppFEV_1$/year (95% CI: -4.1, -1.9). Researchers concluded that significantly lower $ppFEV_1$ in home devices shows that direct comparison to clinic spirometers may induce a spurious change from baseline, and additional variability in home devices impacts statistical power. The effect of coaching, setting, and equipment must be understood to use and improve home spirometry in CF.

A real-life observational study by Beaufils et al. (2023) included patients with CF (PwCF), followed for 6 months, in whom lung function (i.e., FEV_1, FVC, FEF, and FEV_1/FVC ratio) was monitored by both conventional and home spirometry between July 2015 and December 2021. (27) The adherence, reliability and variability of home spirometry was assessed in 174 patients with CF and compared between 74 children (<12 years old), 43 teenagers (12-18 years old), and 57 adults. Home spirometry was used at least once per week by 64.1 ±4.9% of PwCF and was used more frequently in children and teenagers than in adults (79.4 ± 2.9%, 69.2 ± 5.5% and 40.4 ± 11.5% respectively). The reliability to conventional lung function testing was good for all assessed parameters (e.g., FEV_1: $r=0.91$, $p<0.01$), and the variability over the 6 months of observation was low (FEV_1 coefficient of variation = 11.5%). For each parameter, reliability was better, and the variability was lower in adults than in teenagers than in children. Several factors may have influenced the difference in patients' adherence between groups. First, recommendations were different for the two groups, since at least 3 weekly measurements were required for children compared to only one in adults leading to an increased number of tests performed in children and teenagers compared to adults. Secondly, the difference in adherence between groups might be due to the encouragement of physiotherapists who were seeing patients for regular treatment more frequently in children and teenagers than in adults. Indeed, the presence of a caregiver is known to promote compliance in chronic respiratory diseases, and this can explain the difference in adherence and early stops between adults and children/teenagers. In addition, children probably have more parental support than teenagers who are more independent. Thirdly, the disease severity, greater in adults, may impact adherence due to increased daily medication and reduced quality of life. The addition of an

extra device may have made daily life more difficult, discouraging them from using this new device. The results of this study indicate that home spirometry can be useful and could be used to detect exacerbations at an early stage, changing the management of the disease by decreasing clinic visits. However, further studies are needed to confirm this.

Chronic Obstructive Pulmonary Disease (COPD)

In 2013, Jódar-Sánchez et al. (28) conducted a pilot study of the effectiveness of home telehealth for patients with advanced COPD treated with long-term oxygen therapy. Patients were randomized into a telehealth group (n = 24) and a control group (n = 21) who received usual care. Patients in the telehealth group measured their vital signs on weekdays and performed spirometry two days per week. The data was transmitted automatically to a clinical call center. After 4 months of monitoring the mean number of accident and emergency department visits in the telehealth group was slightly lower than in the control group (0.29 versus 0.43, P = 0.25). The mean number of hospital admissions was 0.38 in the telehealth group and 0.14 in the control group (P = 0.47). During the study a total of 40 alerts were detected. The clinical triage process detected 8 clinical exacerbations which were escalated for a specialist consultation. There were clinically significant differences in health-related QOL in both groups. The mean score on the *St. George's Respiratory Questionnaire* (SGRQ) was 10.9 versus 4.5 in the control group (P = 0.53). The EuroQol-5D score improved by 0.036 in the telehealth group and by 0.003 in the control group (P = 0.68). The study found no statistically significant differences in the number of emergency room visits or hospital admissions in persons with COPD who were managed with home spirometry.

In 2016, Rodriguez-Roisin et al. (29) completed the WISDOM study which evaluated lung function following withdrawal of fluticasone propionate in patients with severe to very severe COPD treated with tiotropium and salmeterol. Patients recorded daily home spirometry measurements and periodic in-clinic spirometry testing throughout the study duration. The researchers determined the validity of home spirometry for detecting changes in lung function by comparing in-clinic and home-based FEV-1 in patients who underwent step fluticasone propionate withdrawal over 12 weeks versus patients remaining on fluticasone propionate for 52 weeks. Bland-Altman analysis of data was performed between in-clinic and home-based measurements, across all visits and at the individual visits at 6, 12, 18, and 52 weeks. There was a measurable difference between the FEV-1 values recorded at home and in the clinic (mean difference of -0.05 L), which may be due to suboptimal patient effort in performing unsupervised recordings. However, this difference remained consistent over time. Overall, data demonstrates that home spirometry and in-clinic spirometry measurements were equally valid and reliable for assessing lung function in patients with COPD which suggest that home spirometry potentially could be a powerful tool for detecting slight changes in lung function in large populations. However, the value of home-based spirometry for detecting changes of this magnitude in individual patients is more questionable, as such changes might fall within the range of day-to-day variability of lung-function assessment.

Baroi et al. (2018) (30) conducted a systematic review on the use of remote respiratory assessment in people with COPD, which included the following questions: What devices have

been used? Can acute exacerbations of chronic obstructive pulmonary disease (AECOPD) be predicted by using remote devices? Do remote respiratory assessments improve health-related outcomes? Fifteen studies met the inclusion criteria. Forced expiratory volume assessed daily by using a spirometer was the most common modality. Other measurements included resting respiratory rate, respiratory sounds, and end-tidal carbon dioxide level. Remote assessments had high user satisfaction. Benefits included early detection of AECOPD, improved health-related outcomes, and the ability to replace hospital care with a virtual ward. Reviewers concluded that remote respiratory assessments are feasible and when combined with sufficient organizational backup can improve health-related outcomes in some but not all cohorts. Future research should focus on the early detection, intervention, and rehabilitation for AECOPD in high-risk people who have limited access to best care and investigate continuous as well as intermittent monitoring.

Idiopathic Pulmonary Fibrosis (IPF)

In 2016, Russell et al. (31) stated that recent clinical trial successes have created an urgent need for earlier and more sensitive endpoints of disease progression in IPF. Domiciliary spirometry permits more frequent measurement of FVC than does hospital-based assessment and therefore affords the opportunity for a more granular insight into changes in IPF progression. These researchers determined the feasibility and reliability of measuring daily FVC in individuals with IPF. Subjects with IPF were given hand-held spirometers (Carefusion, UK) and were instructed on use. Subjects recorded daily FEV-1 and FVC for up to 490 days. Clinical assessment and hospital-based spirometry was undertaken at 6 and 12 months and outcome data was collected to 3 years. Daily spirometry was recorded by 50 subjects for a median period of 279 days (range of 13 to 490). There were 18 deaths during the active 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-months (hazard ratio [HR] 1.040, CI: 1.021 to 1.062, p = <0.001), 6-months (HR 1.024, CI: 1.014 to 1.033, p <0.001) and 12-months (HR 1.012, CI: 1.007 to 1.016, p = 0.001). The authors concluded that measurement of daily home spirometry in patients with IPF is highly clinically informative and, for the majority, is feasible to perform. The relationship between mortality and rate of change of FVC at 3 months suggested that daily FVC may be of value as a primary end-point in short, proof-of-concept IPF studies.

However, the authors noted that the study had several limitations. All subjects were recruited from a single center; therefore, these observations merit repeating across other centers to ensure generalizability. Subjects underwent limited training on performing spirometry. Variability in readings might have been reduced by more intensive and repeated training before initiation of home measurements. However, this did not prevent home FVC from being predictive of outcome. The current international guidelines on spirometry recommend that subjects perform 3 good-quality maneuvers and that the best readings be used to determine subjects' "true" FEV-1 and FVC. To try and minimize intrusiveness and to limit intolerable effects (e.g., cough), these researchers simply asked subjects to perform a single daily reading. Although this potentially had an impact on accuracy, the authors' anticipation was that this would be compensated for by the number of readings undertaken over time. An alternative

approach to the one that the authors took would be to undertake weekly spirometry, but when doing so, to mandate 3 high quality spirometry maneuvers. This could potentially reduce the intrusiveness of measurements while at the same time retaining the benefit gained through increased frequency of readings. The spirometer used for this study did not record flow-volume loops and nor did it store data; therefore, all daily readings had to be transcribed into a paper diary by subjects. The lack of flow-volume loops meant that it was not possible to validate the quality of individual daily readings. The use of paper diaries might have introduced error, which could not be corrected for by data cleaning, because there were no electronic records of results. Newer, internet connected spirometers should enable these limitations to be overcome in the future and may also provide a way of permitting real-time identification of patients who are poorly compliant or misperforming spirometry, and those patients who are experiencing an acute exacerbation or with rapidly worsening disease. Finally, in analyzing individual disease behavior, these investigators used a regression model that assumed linearity of disease decline. This approach is in keeping with that used in recent registration clinical trials in IPF. A small number of subjects, particularly those who had exacerbations, violated the assumptions of linearity. It could be that using nonlinear models of disease progression over time might provide additional insights into IPF disease behavior. The authors hope to explore this possibility with larger cohorts in the future. They stated that the use of home spirometry offers the potential to transform early phase clinical trials by providing an efficacy readout in a time scale better suited to drug discovery than that provided by current hospital-based approaches. (31)

Johannson et al. (2017) investigated the reliability, feasibility and analytical impact of home-based measurement of FVC and dyspnea as clinical endpoints in IPF. (32) Patients with IPF performed weekly home-based assessment of FVC and dyspnea using a mobile hand-held spirometer and self-administered dyspnea questionnaires. Weekly variability in FVC and dyspnea was estimated, and sample sizes were simulated for a hypothetical 24-week clinical trial using either traditional office-based interval measurement or mobile weekly assessment. In total, 25 patients were enrolled. Mean adherence to weekly assessments over 24 weeks was greater than 90%. Compared with change assessment using baseline and 24-week measurements only, weekly assessment of FVC resulted in enhanced precision and power. For example, a hypothetical 24-week clinical trial with FVC as the primary endpoint would require 951 patients using weekly home spirometry compared with 3840 patients using office spirometry measures at weeks 1 and 24 only. The ability of repeated measures to reduce clinical trial sample size was influenced by the correlation structure of the data. Researchers concluded that home monitoring can improve the precision of endpoint assessments, allowing for greater efficiency in clinical trials of therapeutics for IPF.

Commenting on the Johannson et al. study, Maher (2017) (33) noted that “The improvements in precision seen with weekly spirometry were not observed when it came to the weekly measurement of breathlessness by either VAS score or UCSD-SOBQ. The authors attribute this to the underlying structure of the data generated and the fact that FVC decline is essentially linear whilst the week-by-week change in breathlessness score is less predictable, especially when readings are compared many weeks apart. This observation highlights the importance of

prospective observational studies when it comes to validating or refuting observations derived from historical retrospective studies." Furthermore, "…It should also be noted that a proportion of subjects examined by Johannsson et al. were either on anti-fibrotic medication at entry into the study or else commenced treatment at some point during their participation in the home monitoring program. The authors did not examine the effect background treatment had on their assumptions regarding temporal change in FVC during the 24-week observation period. Home spirometry is already being introduced into clinical trials for individuals with fibrotic lung disease and is even being used as a primary end-point in a recently initiated trial of pirfenidone in individuals with unclassifiable interstitial lung disease (NCT 03099187). The next step for home monitoring is for studies to examine the value of such an approach for improving outcomes in clinical practice. This will require the development and testing of algorithms for detecting individuals with rapidly progressive disease and those experiencing acute deterioration. It also remains to be examined whether home monitoring can be used to determine response to anti-fibrotic therapy and therefore be used as a tool to decide when to switch therapies. A further area for research is to determine whether integration of other monitoring modalities (oximetry, pulse and blood pressure measurements, actigraphy, etc.) better identifies change in health status in individuals with IPF. The work by Johannson et al. provides an important foundation for changing the delivery of care for individuals with IPF and hopefully represents a stepping stone towards empowering disease sufferers to better participate in the management of their condition".

Noth et al. (2021) investigated the feasibility and validity of home spirometry as a measure of lung function decline in patients with IPF. (34) Subjects with IPF and preserved FVC were randomized 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. In total, 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). Researchers concluded that home spirometry was a feasible and valid measure of lung function in patients with IPF and preserved FVC but estimates of the rate of FVC decline obtained using home spirometry were poorly correlated with those based on clinic spirometry.

UpToDate (35) published a review on clinical manifestations and diagnosis of IPF which states "Complete pulmonary function testing (PFT; spirometry, lung volumes, diffusing capacity for carbon monoxide and resting and ambulatory pulse oximetry are obtained in virtually all patients with suspected interstitial lung disease. These tests are helpful in establishing the pattern of lung involvement (e.g., restrictive, obstructive, or mixed) and assessing the severity of impairment. In patients with interstitial pulmonary fibrosis, PFTs typically demonstrate a restrictive pattern (e.g., reduced FVC, but normal ratio of FEV-1), a reduced diffusing capacity

for carbon monoxide, and, as the disease progresses, a decrease in the six-minute walk distance". The review does not mention ambulatory/home spirometry as a management tool.

Interstitial Lung Disease (ILD)

In a 2021 systematic review, Althobiani et al. evaluated the evidence for use of home monitoring for early detection of exacerbations and/or progression of ILD. (36) Thirteen studies involving 968 patients have demonstrated that home monitoring is feasible and of potential benefit in patients with ILD. Nine studies reported that mean adherence to home monitoring was >75%, and where spirometry was performed there was a significant correlation (r=0.72-0.98, p<0.001) between home and hospital-based readings. Two studies suggested that home monitoring of forced vital capacity might facilitate detection of progression in idiopathic pulmonary fibrosis. Despite the fact that individual studies in this systematic review provide supportive evidence suggesting the feasibility and utility of home monitoring in ILD, further studies are necessary to quantify the potential of home monitoring to detect disease progression and/or AEs.

Bronchiolitis Obliterans Syndrome (BOS)

Turner et al. (2021) evaluated the feasibility of home monitoring of weekly spirometry via a wireless handheld device and a web monitoring portal in a cohort of high-risk patients for the detection of lung function changes preceding BOS diagnosis. (37) In this observational study, 46 patients with chronic graft-versus-host disease or a decline in FEV_1 of unclear etiology after allogeneic hematopoietic cell transplantation (HCT) were enrolled to perform weekly home spirometry with a wireless portable spirometer for a period of 1 year. Measurements were transmitted wirelessly to a Cloud-based monitoring portal. Feasibility evaluation included adherence with study procedures and an assessment of the home spirometry measurements compared with laboratory pulmonary function tests. Thirty-six patients (78%) completed 1 year of weekly monitoring. Overall adherence with weekly home spirometry measurements was 72% (interquartile range, 47% to 90%), which did not meet the predetermined threshold of 75% for high adherence. Correlation of home FEV_1 with laboratory FEV_1 was high, with a bias of 0.123 L (lower limit, -0.294 L; upper limit, 0.541 L), which is within acceptable limits for reliability. Of the 12 patients who were diagnosed with BOS or suspected BOS during the study period, 9 had an antecedent FEV_1 decline detected by home spirometry. The data indicated that wireless handheld spirometry performed at home in a high-risk HCT cohort is feasible for close monitoring of pulmonary function and appears to facilitate early detection of BOS.

The study was limited by the small sample size, and it was not designed or powered to test the efficacy of an early detection strategy. Nonetheless, home spirometry monitoring is likely to be of benefit in high-risk patients with further refinements in implementation that encourages adherence to monitoring and efficient clinical evaluation. The optimal threshold and duration of FEV_1 decline that should trigger clinical action needs to be determined. This depends on a better understanding of the progression and etiology of lung function changes after HCT, which requires additional investigation.

Practice Guidelines and Position Statements

No guidelines were identified that mention the use of home spirometry as a treatment modality. (38-41)

Summary of Evidence

There is inadequate evidence that home monitoring of pulmonary function utilizing a spirometer or telespirometer will improve health outcomes for lung transplant recipients or patients with other pulmonary disorders such as asthma, cystic fibrosis, chronic obstructive pulmonary disease, or idiopathic pulmonary fibrosis, etc. Consequently, home spirometry is considered experimental, investigational, and/or unproven.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	94014, 94015, 94016
HCPCS Codes	E0487

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
06/15/2024	Document updated with literature review. Coverage unchanged. References 7, 8, 27 were added; others updated.
05/01/2023	Reviewed. No changes.
10/15/2022	Document updated with literature review. Coverage unchanged. Added/updated the following references: 16, 20, 23, 24, 31-35, and 38.
09/15/2021	Reviewed. No changes.
09/01/2020	Document updated with literature review. Coverage unchanged. Added/updated the following references: 1, 3, 7, 24-26, 27-28, and 31.
10/15/2019	Reviewed. No changes.
04/15/2019	Document updated with literature review. Added “telespirometer” and “for all indications” to the following Coverage statement “Home monitoring of pulmonary function utilizing a spirometer or telespirometer is considered experimental, investigational and/or unproven for all indications.” Added references 1-6, 15, 19, 20, 22, 27 and 28.
10/15/2017	Reviewed. No changes.
11/15/2016	Document updated with literature review. Coverage unchanged.
11/15/2015	Document updated with literature review. Coverage unchanged.
10/15/2014	Reviewed. No changes.

10/01/2013	Document updated with literature review. The following change was made to coverage: Addition of note on incentive spirometry. CPT/HCPCS code(s) updated.
04/15/2008	Policy reviewed.
11/15/2006	Revised/updated entire document
02/01/2002	Revised/updated entire document
11/01/2000	Revised/updated entire document
01/01/2000	New medical document