Prior Authorization Review Panel  
MCO Policy Submission  

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
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<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 10/01/2019</th>
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<tbody>
<tr>
<td>Policy Number: 0572</td>
<td>Effective Date:</td>
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<tr>
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<td>Revision Date: 08/08/2017</td>
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<td>Policy Name: Home Ambulatory Spirometry</td>
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**Type of Submission – Check all that apply:**

- [ ] New Policy
- [ ] Revised Policy*
- [x] Annual Review – No Revisions
- [ ] Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document.*

Please provide any clarifying information for the policy below:

**CPB 0572 Home Ambulatory Spirometry**

Clinical content was last revised on 08/08/2017. No additional non-clinical updates were made by Corporate since the last PARP submission.

<table>
<thead>
<tr>
<th>Name of Authorized Individual (Please type or print):</th>
<th>Signature of Authorized Individual:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Bernard Lewin, M.D.</td>
<td>Bernard Lewin, M.D.</td>
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</table>
Aetna considers home spirometry and telespirometry medically necessary for lung transplant recipients.

Aetna considers home spirometry and telespirometry experimental and investigational for all other indications (asthma, cystic fibrosis, idiopathic pulmonary fibrosis, and persons with other chronic pulmonary diseases/disorders (e.g., emphysema)) because there is inadequate evidence that it will improve the care of persons with these disorders.

**Notes:** Home spirometry for monitoring lung function should not be confused with incentive spirometry. Use of an incentive spirometer may be medically necessary for preventing post-operative atelectasis.

Home spirometry should also not be confused with peak flow meters.

See also [CPB 0059 - Peak Flow Meters](https://www.aetna.com/cpb/medical/data/500_599/0059.html)
[CPB 0479 - Respiratory Devices: Incentive Spirometers and Intermittent Positive Pressure Breathing Machines](https://www.aetna.com/cpb/medical/data/400_499/0479.html)

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*
Background

Spirometry is a noninvasive pulmonary function test that measures the flow and volume of air entering and leaving the lungs. Home monitoring of pulmonary function by means of home spirometry (also known as ambulatory spirometry) has been primarily investigated among lung transplant recipients as a way to provide early diagnosis of infection and rejection. More recently, home spirometry has also been studied as a means of monitoring lung function in asthmatics.

Home spirometry monitoring should not be confused with incentive spirometry; the latter is a simple device that is used following thoracic surgery to mobilize secretions and increase lung volumes to reduce postoperative complications.

Home spirometry usually employs battery-operated spirometers, which allows daily measurement of respiratory function including forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC). Sometimes, a bronchodilator or a beta-2 agonist is given, and the spirometry is repeated. In general, home spirometry does not refer to the use of peak flow meters, which measure peak expiratory flow (PEF), an indicator of both the existence and the severity of airflow obstruction.

Telespirometry utilizes a small hand-held device that provides testing for both spirometry and oximetry. Oximetry measures oxygen saturation, a measurement of the percentage of red blood cells that are carrying oxygen to the body. The device records the results, which can then be sent via telephone in much the same way that a pacemaker transmits information to the healthcare provider. This has been proposed as a means to monitor lung function, sleep apnea or desaturation occurrences. An example of this device includes, but may not be limited to, the Spirotel.

There is inadequate evidence that home spirometry will improve the patient care of asthmatics, chronic obstructive pulmonary disease (COPD), and other pulmonary disorders. Wensley and Silverman (2001) concluded that even under ideal conditions, home spirometry provides an incomplete (and therefore potentially biased) picture of long-term changes in pulmonary function.

Tovar and Gums (2004) stated that despite recent advances in medical technology, monitoring of asthma and COPD has not changed significantly. Pulmonary function tests continue to be the gold standard for evaluating airway obstruction and/or restriction. Clinical trials that will evaluate outcomes such as decreased number of
hospitalizations, emergency department visits, unscheduled visits to physicians, and days absent from school or work are needed to determine the utility of new monitoring technologies such as portable spirometers that can be used at home without the need for supervision.

Brouwer and colleagues (2006) examined the relationship of PEF and FEV1 variation to other estimates of asthma severity in children, using an electronic home spirometer with automatic data storage. Over a 3-month period, 36 children with mild-to-moderate persistent asthma recorded PEF and FEV1 electronically twice daily and noted an asthma severity score in a written diary. Bronchial responsiveness was evaluated at the beginning and bronchodilator response and asthma-specific quality of life at the end of the study. Variations in PEF correlated significantly but weakly to bronchial responsiveness and bronchodilator response, but not to the asthma severity score or quality-of-life scores. Within-individual correlations between asthma severity scores and home spirometry indices and between PEF and FEV1 were highly variable. The authors concluded that variations in PEF and FEV1, obtained by home spirometry, show poor concordance with other indices of disease activity and with each other. This limits the usefulness of home spirometry in childhood asthma.

Brouwer et al (2007) assessed the agreement in vivo between measurements of lung function on an electronic spirometer and those obtained by the gold standard, a hospital lung function laboratory pneumotachograph. A total of 50 stable asthmatic children (33 boys), aged 6 to 17 years, performed PEF and FEV1 measurements according to international guidelines on a portable home spirometer and on the hospital pneumotachograph in random order. All measurements complied to standard quality criteria. The PEF and FEV1 values recorded with the home spirometer and on the hospital pneumotachograph were compared. All children performed reproducible high-quality measurements on both spirometers. Values for PEF on the home spirometer were considerably lower than on the laboratory pneumotachograph (95% confidence interval [CI] for difference in PEF: 14 to 30 L/min; p < 0.0001). Individual differences in PEF between the 2 devices could be greater than 100 L/min. The FEV1 values were slightly, but significantly, lower on the home spirometer (95% CI for difference in FEV1: 0.02 to 0.1 L; p = 0.0018). The authors concluded that a home spirometer provides reproducible and quality acceptable measures in children with asthma when performed under professional supervision and encouragement. Mean PEF and FEV1 values recorded on this home spirometer are significantly lower than those on a hospital
pneumotachograph, and individual differences may be large. Thus, home spirometry may not be interchanged with pneumotachography in a lung function laboratory.

Brouwer et al (2010) evaluated the usefulness of home spirometry in children with non-specific lower respiratory tract symptoms, to diagnose or exclude asthma. Subjects were school-aged children, referred by their general practitioner because of chronic respiratory symptoms of unknown origin, the diagnosis of asthma was made or excluded by a pediatric pulmonologist (gold standard), based on international guidelines and a standardized protocol. Additionally, children measured PEF and FEV1 twice-daily for 2 weeks on a home spirometer, from which diurnal variation was calculated. These results (index test) were not revealed to the pediatric pulmonologist. The value of home spirometry to diagnose asthma was calculated. A total of 61 children (27 boys) were included in this study (mean age of 10.4 years; range of 6 to 16 years). Between asthma and no asthma, the mean difference in PEF 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 PEF and FEV1 variation (12.3 % and 11.8 %, respectively) were 50 % and 72 % for PEF variation and 45 % and 92 % for FEV1 variation. The likelihood ratio was 1.8 for PEF and 5.6 for FEV1. The authors concluded that the contribution of home spirometry in the diagnosis of asthma in children with non-specific respiratory symptoms is limited.

Deschildre et al (2012) concluded that a treatment strategy based on daily FEV(1) monitoring via spirometry with medical feedback did not reduce severe asthma exacerbations. The investigators sought to assess the outcome (severe exacerbations and healthcare use, lung function, quality of life 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. A total of 50 children with severe uncontrolled asthma were enrolled in a 12-month prospective study and were randomized into 2 groups: (i) treatment managed with daily home spirometry and medical feedback (HM), and (ii) conventional treatment (CT). The children's mean age was 10.9 years (95 % CI: 10.2 to 11.6 years); 44 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 to 4.0) in the HM group and 3.0 (1.0 to 4.0) in the CT group (p = 0.38 with adjustment for age). The investigators reported that there were no significant differences between the 2 groups or unscheduled visits (HM 5.0 (3.0 to
Osthoff and Leuppi (2010) reviewed the literature regarding the management of patients with COPD after hospitalization for an acute exacerbation. Guidelines recommend a follow-up 4 to 6 weeks after hospitalization to assess coping strategies, inhaler technique, the need for long-term oxygen therapy and the measurement of FEV1. This review discussed the follow-up of patients with exacerbations of COPD, the use and value of spirometry in their further management, the potential benefit of home monitoring, the value of long-term oxygen therapy, the value of self-management programs including the use of action plans, the potential benefit of non-invasive ventilation as well as the value of early rehabilitation. There is insufficient literature to allow specific recommendations and to define components of a care plan following hospitalization for an acute exacerbation; however, early rehabilitation should be included.

A randomized study found no statistically significant differences in number of emergency room visits or hospital admissions in persons with COPD who were managed with home spirometry (Jodar-Sanchez et al, 2013). The study found a non-significant trend in improved quality of life in subjects managed with home spirometry. The investigators 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 on 2 days per week. The data were 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 by the case manager for a specialist consultation. There were clinically important differences in health-related quality of life in both groups. The mean score on the 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).
Kugler and colleagues (2009) stated that effects of non-adherence to home spirometry (HS) on detection of the bronchiolitis obliterans syndrome (BOS) and on graft survival are unknown. In a 7-year prospective, cohort study, these researchers assessed non-adherence longitudinally using electronic spirometry for 24 months. During follow-up, BOS, re-transplantation, and survival were stratified by adherence groups. Electronic monitoring of 226 patients confirmed that 123,487 measures were performed. Period prevalence was 0.76 measures per patient day and decreased significantly over time (p < 0.0001). During follow-up, BOS developed in 32 % of patients; 5 % received a second transplant, and mortality rate was 19 %. Kaplan-Meier event-free analysis showed decreased freedom from BOS time in non-adherers (30 %) compared with good (43 %) or moderate adherers (19 %) (log rank 6.008; p < 0.014) and a tendency toward lower re-transplantation rates (log rank 3.14; p < 0.07). Mantel Cox regression revealed no impact of adherence on patient survival. The authors concluded that this was the first study assessing non-adherence to HS based on electronic monitoring in relation to long-term outcome following lung transplantation. Non-adherers showed decreased freedom from BOS in the largest sample to date, but did not impact survival.

Wang et al (2013) conducted a study to develop, implement, and test an automated decision system to provide early detection of clinically important broncho-pulmonary events in a population of lung transplant recipients following a home spirometry 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. The investigators reported that, using FEV1 or symptoms, the detection captured the majority of events (sensitivity, 80 to 90 %) at an acceptable level of false alarms. On average, detections occurred 6.6 to 10.8 days earlier than the known event records. The investigators concluded that this approach 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 important events.

Finkelstein et al (2013) conducted a randomized controlled trial (RCT) to determine 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. This RCT had 65 lung transplant recipients assigned to either the Bayesian 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 (SF-36) survey at baseline and after 1 year. End-points were change from baseline after 1 year in FEV1 and quality of life (SF-36 scales) within and between each study arm. The authors found that 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 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 authors 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.

de Wall et al (2014) evaluated the utility of home spirometry (HS) versus office spirometry (OS) in assessing treatment response to azithromycin in BOS. In this study, 239 lung transplant recipients were retrospectively studied. Change in TEV1 (ΔFEV1 ± 10 %) from FEV1 at azithromycin initiation for greater than or equal to 7 consecutive days in HS or greater than or equal to 2 measures in OS were taken as cut-off for response or progression. Based upon HS, 161/239 (67 %) patients were progressive despite macrolide, 19 of who exhibited transient improvement in FEV1 (11 %). Time to progression was 29 (13 to 96) days earlier with HS than in OS. A total of 46 (19 %) recipients responded in HS after median 81 (22 to 343) days, while 22 % remained stable. Concordance in azithromycin treatment response between OS and HS 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). The investigators concluded that HS identified azithromycin refractory patients significantly earlier than OS, possibly facilitating aggressive treatment escalation that may improve long-term outcome. The investigators recommended 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.
An UpToDate review on “Evaluation and treatment of acute lung transplant rejection” (Pilewski, 2015) states that “Spirometry -- Many centers, including ours, utilize patient-administered, home spirometry several times a week to monitor lung function. All centers perform spirometry at the time of follow-up visits. Once postoperative function has stabilized, the variation in forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) is less than 5 %. Spirometry has been reported to have a sensitivity of 60 % in detecting rejection (grade greater than or equal to A2) or infection among bilateral lung transplant recipients. A decline of 10 % in spirometric values that persists for more than 2 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”.

Idiopathic Pulmonary Fibrosis

Russell et al (2016) stated that recent clinical trial successes have created an urgent need for earlier and more sensitive endpoints of disease progression in idiopathic pulmonary fibrosis (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 provided with instruction on how to self-administer spirometry. Subjects recorded daily FEV1 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 this study had several drawbacks. 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” FEV1 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 might have had an impact on accuracy, the authors’ anticipation was, as demonstrated by the data presented, 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 non-linear 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.
An UpToDate review on “Clinical manifestations and diagnosis of idiopathic pulmonary fibrosis” (King, 2016) states that “Complete pulmonary function testing (PFT; spirometry, lung volumes, diffusing capacity for carbon monoxide [DLCO]) and resting and ambulatory pulse oximetry are obtained in virtually all patients with suspected ILD. 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 IPF, PFTs typically demonstrate a restrictive pattern (e.g., reduced forced vital capacity [FVC], but normal ratio of forced expiratory volume in one second [FEV1]/FVC), a reduced DLCO, 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.

Johannson and colleagues (2017) examined the reliability, feasibility and analytical impact of home-based measurement of FVC and dyspnea as clinical end-points in IPF. 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 end-point would require 951 patients using weekly home spirometry compared with 3,840 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. The authors concluded that these findings demonstrated that weekly home assessment of FVC and dyspnea was reliable, feasible and informative over the course of 24 weeks in patients with IPF. Home measurement of clinical end-points in clinical trials has the potential to greatly improve analytical efficiency of clinical trials by reducing the sample size required, but this depends on the outcome-specific correlation structure of the repeated measurements -- something that warrants careful study in future clinical trials through the incorporation of home-assessment outcomes as exploratory endpoints.
These investigators stated that this study had several drawbacks. This was an exploratory study and the sample size was small (n = 25), although large enough to reveal nuanced statistical implications of repeated measures modeling. The study cohort was established from an academic referral center for ILD, thus, the findings may not be broadly generalizable. Larger and more diverse populations should be studied to further characterize the role of home monitoring in IPF. These researchers could not conclude whether one spirometry device performed better than another, or whether daily, weekly or some other frequency of home monitoring provided the optimal number of data. They arbitrarily selected weekly rather than daily spirometry with the goal of efficiently addressing the study hypothesis and achieving balance between data acquisition and patient burden.

Commenting on the afore-mentioned study by Johannson et al, Maher (2017) 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 … It should also be noted that a proportion of subjects examined by Johannson et al were either on anti-fibrotic medication at entry in to 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”.

Chronic Obstructive Pulmonary Disease

Rodriguez-Roisin and colleagues (2016) stated that the WISDOM study (NCT00975195) reported a change in lung function following withdrawal of fluticasone propionate in patients with severe-to-very severe COPD treated with tiotropium and salmeterol. However, little is known about the validity of home-based spirometry measurements of lung function in COPD. Therefore, as part of this study, following suitable training, patients recorded daily home-based spirometry measurements in addition to undergoing periodic in-clinic spirometric testing throughout the study duration. These researchers subsequently determined the validity of home-based spirometry for detecting changes in lung function by comparing in-clinic and home-based FEV1 in patients who underwent step-wise fluticasone propionate withdrawal over 12 weeks versus patients remaining on fluticasone propionate for 52 weeks. Bland-Altman analysis of these data confirmed good agreement between in-clinic and home-based measurements, both across all visits and at the individual visits at study weeks 6, 12, 18, and 52. There was a measurable difference between FEV1 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, these data demonstrated that home-based and in-clinic spirometric measurements were equally valid and reliable for assessing lung function in patients with COPD, and suggested that home-based spirometry may be a useful tool to facilitate analysis of changes in lung function on a day-to-day basis. The authors concluded that these findings suggested that home-based spirometry is a reliable tool and may prove useful in other proof-of-concept clinical studies. Daily spirometry performed at home could provide a powerful tool to characterize small changes in FEV1 in a large patient population. 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.

Cystic Fibrosis
Shakkottai and Nasr (2017) stated that medication adherence is poor among pediatric cystic fibrosis (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. They surveyed 40 adolescents with CF and asked about barriers to and motivators for their own adherence and to generate ideas for potential adherence interventions. Since most of the respondents chose frequent spirometry at home and medication reminders for interventions, these investigators selected 5 subjects, 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 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 spirometry at home on treatment adherence, health outcomes, and quality of life (QOL) over a longer period of time.

Choyce and colleagues (2017) noted that home monitoring has the potential to detect early pulmonary exacerbations in people with CF, with consequent improvements in health outcomes and healthcare associated costs. This study aims to evaluate the effects of home monitoring on hospital admissions, QOL, antibiotic requirements, exacerbation frequency, lung function, nutritional outcomes, anxiety, depression, costs and health outcomes, as well as the qualitative effects on the patient experience. This randomized controlled mixed-methods trial aims to recruit 100 adults with CF cared for in one large regional CF center. Participants will be randomly allocated 1:1 to the intervention group (twice-weekly home monitoring of symptoms measured by the Cystic Fibrosis Respiratory Symptom Diary - Chronic Respiratory Infection Symptom Score (CFRSD-CRISS) and Forced Expiratory Volume in 1 second (FEV1)) or a control group (routine clinical care) for the 12-month study period. Measurements are recorded at study visits at baseline, 3, 6, 9 and 12 months. Spirometry, body weight, co-morbidities, medications, hospital inpatient days, courses of antibiotics (oral and intravenous), pulmonary exacerbations (defined by the modified Fuchs criteria) are recorded at each study visit. Health status, capability and health economics are measured at each study visit by the Hospital Anxiety and Depression Scale (HADS), the ICEpop CAPability measure for Adults (ICECAP-A), EuroQol 5 dimensions (EQ-5D-5L) questionnaire and an adapted resource use questionnaire. The patient experience is assessed by semi-structured qualitative interviews at baseline and 12 months. Results from
this study will help to determine the effect of home monitoring on inpatient bed days and QOL in adults with CF, as well as other relevant health and health economic outcomes.

In a multi-center, randomized trial, Lechtzin and colleagues (2017) examined 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 with patients with CF (at least 14 years old). The early intervention arm subjects measured home spirometry and symptoms electronically twice-weekly. Sites were notified if a participant met criteria for an exacerbation and contacted participants to determine if treatment for acute exacerbation was needed. 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 was the 52-week change in FEV1; secondary outcomes included time to 1st exacerbation 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 FEV1 slope (mean slope difference, 0.00 L, 95 % CI: -0.07 to 0.07; p = 0.99). The early intervention arm subjects detected exacerbations more frequently than usual care arm subjects (time to 1st exacerbation HR, 1.45; 95 % CI: 1.09 to 1.93; p = 0.01); adverse events (AEs) were not significantly different between treatment arms. The authors concluded that an intervention of home monitoring among patients with CF was able to detect more exacerbations than usual care, but this did not result in slower decline in lung function.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tr>
<td>CPT codes covered if selection criteria are met:</td>
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<tr>
<td>94014</td>
<td>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 review and interpretation</td>
</tr>
<tr>
<td>94015</td>
<td>recording (includes hook-up, reinforced education, data transmission, data capture, trend analysis, and periodic recalibration)</td>
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<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>94016</td>
<td>physician review and interpretation only</td>
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**HCPCS codes covered if selection criteria are met:**

- **E0487** Spirometer, electronic, includes all accessories

**Other HCPCS codes related to the CPB:**

- **A9284** Spirometer, nonelectric, includes all accessories
- **S8096** Portable peak flow meter

**ICD-10 codes covered if selection criteria are met:**

- **T86.810 - T86.819** Complications of lung transplant [for monitoring of lung function at home]
- **Z94.2** Lung transplant status [for monitoring of lung function at home]

**ICD-10 codes not covered (not all inclusive):**

- **E84.0 - E84.9** Cystic fibrosis
- **J09.X1 - J18.9** Influenza and pneumonia [for monitoring of lung function at home]
- **J40 - J94.9** Chronic lower respiratory diseases, lung diseases due to external agents, other respiratory diseases principally affecting the interstitium, suppurative and necrotic conditions of the lower respiratory tract, other diseases of the pleura [for monitoring of lung function at home]
- **J95.4** Chemical pneumonitis due to anesthesia [for monitoring of lung function at home]
- **J95.5** Postprocedural subglottic stenosis [for monitoring of lung function at home]
- **J95.851 - J95.89** Complications of respirator (ventilator) [for monitoring of lung function at home]
- **J98.9** Respiratory disorder, unspecified [for monitoring of lung function at home]
- **R09.1** Pleurisy [for monitoring of lung function at home]
- **Z87.01 - Z87.09** Personal history of diseases of the respiratory system [for monitoring of lung function at home]

The above policy is based on the following references:

http://www.aetna.com/cpb/medical/data/500_599/0572.html

09/23/2019


There are no amendments for Medicaid.