

Home spirometry

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Next review date: 12/2025

Policy contains: Home; portable; spirometry.

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Coverage policy

Home spirometry for monitoring of pulmonary disease is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Facility-based spirometry.

Background

Spirometry is a test that measures air volume during complete exhalation by force over time, following maximal inhalation. It is a key diagnostic test for many obstructive and restrictive pulmonary diseases. Spirometry can evaluate and monitor patient condition; assess disease severity, effects, and prognosis; and screen for pulmonary diseases (Lamb, 2021).

During the procedure, a mouthpiece is placed between the patient's teeth, after deep inhalation. Exhalation usually lasts at least six seconds, or as long as possible. The procedure is repeated in one-minute intervals until similar results are obtained. Spirometry can measure different variables, most often forced vital capacity and forced expiratory volume in one second (de Jong, 2020).

Spirometry can be performed in inpatient facilities, physician offices, emergency rooms, and specialty labs. Regular access to accurate, reliable pulmonary function data is essential to managing many chronic lung conditions. During the pandemic, alternatives to comprehensive pulmonary function testing, such as home-based electronic spirometry, became available to continue to diagnose and manage patients with lung conditions while minimizing infectious disease transmission. Technological advances allow for electronic data transmission to caregivers (Kouri, 2020).

The U.S. Food and Drug Administration (2024) has approved or cleared several spirometers for home use, including the GoSpiro® Home Spirometer (Monitored Therapeutics Inc., Dublin, Ohio) and the Air Next wireless spirometer (NuvoAir®, Stockholm, Sweden).

Findings

Guidelines

A technical statement from the American Thoracic Society and European Respiratory Society on spirometry notes that updated standards are required for unattended home spirometry (Graham, 2019). The Global Initiative for Chronic Obstructive Lung Disease notes that “good quality spirometry is possible in any healthcare setting,” with no mention of home use of the technology (Global Initiative for Chronic Obstructive Lung Disease, 2024).

Evidence reviews

There is increasing interest in home spirometry for its convenience and potential for early detection of exacerbations and improved self-management, infection control, and outcomes in patients with chronic lung conditions. However, the published evidence raises concerns about quality control, clinical effectiveness, and clinical utility. Education and training may increase the feasibility of unattended home monitoring, but underlying etiologies, patient compliance, and differences in spirometry equipment appear to influence testing quality (Bell, 2022; Bindler, 2023; Fettes, 2022; Paynter, 2022; Wang, 2023; Williams, 2023).

A review of 16 commercially available portable electronic spirometers, including four approved for use by the U.S. Food and Drug Administration, found 63% provided graphical representations of lung function results; 44% gave immediate feedback on the quality of the breathing maneuver. Authors describe the proportion of devices that provided information on data security (63%), measurement accuracy (50%), and association with patient outcomes (0%) to be “commonly limited” (Carpenter, 2018).

Many individual studies have small sample sizes or do not compare home spirometry to clinic spirometry, which is considered the standard of care. Where a comparison was conducted, the best available evidence suggests poor agreement between clinic and unattended home spirometry measurement, indicating that clinic and home spirometry results are not interchangeable (Anand, 2023; Oppenheimer, 2023). Lower-quality cohort studies reported mixed results for correlating home spirometry with clinic spirometry and detecting differences in health care utilization (Nichols, 2022; Noth, 2021).

The Early Intervention in Cystic Fibrosis Exacerbation trial (ClinicalTrials.gov identifier NCT01104402), a randomized controlled trial of 267 participants older than age 14 with cystic fibrosis, compared pulmonary function outcomes using home spirometry to usual care. Home spirometry was measured twice weekly with automated notification if pulmonary exacerbation criteria were met. Participants in the usual care arm were seen every three months and asked to contact the site about any worsening pulmonary symptoms. No significant difference between groups occurred in the 52-week mean change in forced expiratory volume in one minute slope ($P = .99$). The early intervention group had more frequently detected exacerbations ($P = .01$). Adverse events were not significantly different (Lechtzin, 2017). Home spirometry lacked the precision of forced expired volume in one second measurement and the ability to detect subtle changes, particularly in patients who were

on modulator therapy. There were no significant differences in outpatient utilization or overall health care costs (Franz, 2022; Paynter, 2022).

A prospective study randomized 60 Turkish children with cystic fibrosis between six and 18 years of age to receive four quarterly visits with or without twice-weekly home spirometry measurement using the SpiroHome device with mobile application. Participants were followed for one year. From baseline to the 12th month, there were no statistically significant differences between groups in the absolute (primary outcome) or relative (secondary outcome) change in forced expired volume in one second as percentage of predicted value, or in the number of pulmonary exacerbations detected or change in lung clearance index. Among 22 children who completed 70% of the measurements over 12 months, there was a significant difference in the primary outcome, favoring the home spirometry group (mean 5.56%, interquartile range – 3.33 to 13.50 versus mean 2.46%, – 7.57 to 4.24; $P = .01$). The authors suggest high adherence with home spirometry use may improve lung function. Among participants younger than 14 years of age, there was a significant increase in the social domain of the health-related quality of life questionnaire for patients with cystic fibrosis (from 59.1 to 76.2, $P = .01$) (Yanaz, 2024).

In 2023, we updated the Global Initiative for Chronic Obstructive Lung Disease 2023 annual report with no policy changes warranted.

In 2024, we updated the references and added several new studies with no policy changes warranted.

References

On July 1, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “spirometry (MeSH),” “vital capacity (MeSH),” “telemedicine (MeSH),” and “home spirometry.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Anand R, McLeese R, Busby J, et al. Unsupervised home spirometry versus supervised clinic spirometry for respiratory disease: A systematic methodology review and meta-analysis. *Eur Respir Rev*. 2023;32(169):220248. Doi: 10.1183/16000617.0248-2022.

Bell JM, Sivam S, Dentice RL, et al. Quality of home spirometry performance amongst adults with cystic fibrosis. *J Cyst Fibros*. 2022;21(1):84-87. Doi: 10.1016/j.jcf.2021.10.012.

Bindler R, Haverkamp HC, O'Flanagan H, et al. Feasibility and acceptability of home monitoring with portable spirometry in young adults with asthma. *J Asthma*. 2023;60(7):1474-1479. Doi: 10.1080/02770903.2022.2160345.

Carpenter DM, Jurdi R, Roberts CA, Hernandez M, Horne R, Chan A. A review of portable electronic spirometers: Implications for asthma self-management. *Curr Allergy Asthma Rep*. 2018;18(10):53. Doi: 10.1007/s11882-018-0809-3.

de Jong CCM, Pedersen ESL, Mozun R, et al. Diagnosis of asthma in children: Findings from the Swiss Paediatric Airway Cohort. *Eur Respir J*. 2020;56(5):2000132. Doi: 10.1183/13993003.00132-2020.

Fettes E, Riley M, Brotherston S, et al. “You're on mute!” Does pediatric CF home spirometry require physiologist supervision? *Pediatr Pulmonol*. 2022;57(1):278-284. Doi: 10.1002/ppul.25708.

Franz N, Rapp H, Hansen RN, et al. Health care costs related to home spirometry in the eICE randomized trial. *J Cyst Fibros*. 2022;21(1):61-69. Doi: 10.1016/j.jcf.2021.02.014.

Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2024 report). <https://goldcopd.org/2024-gold-report/>. Published 2024.

Graham BL, Steenbruggen I, Miller MR, et al. Standardization of spirometry 2019 update. An Official American Thoracic Society and European Respiratory Society Technical Statement. *Am J Resp Crit Care Med*. 2019;200(8):e70-e88. Doi: 10.1164/rccm.201908-1590ST.

Lamb K, Theodore B, Bhutta BS. Spirometry. [Updated 2023 Aug 17]. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. <https://www.ncbi.nlm.nih.gov/books/NBK560526/>. Last updated August 17, 2023.

Lechtzin N, Mayer-Hamblett N, West NE, 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;196(9):1144-1151. Doi: 10.1164/rccm.201610-2172OC.

Nichols AL, Sonnappa-Naik M, Gardner L, et al. COVID-19 and delivery of difficult asthma services. *Arch Dis Child*. 2022;107(3):e15. Doi: 10.1136/archdischild-2021-322335.

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;58(1). Doi: 10.1183/13993003.01518-2020.

Oppenheimer J, Hanania NA, Chaudhuri R, et al. Clinic vs home spirometry for monitoring lung function in patients with asthma. *Chest*. 2023;164(5):1087-1096. Doi: 10.1016/j.chest.2023.06.029.

Paynter A, Khan U, Heltshe SL, et al. A comparison of clinic and home spirometry as longitudinal outcomes in cystic fibrosis. *J Cyst Fibros*. 2022;21(1):78-83. Doi: 10.1016/j.jcf.2021.08.013.

U.S. Food and Drug Administration. 510(k) premarket notification database searched July 1, 2024 using product code BZG. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>.

Wang R, Usmani OS, Chung KF, et al. Domiciliary fractional exhaled nitric oxide and spirometry in monitoring asthma control and exacerbations. *J Allergy Clin Immunol Pract*. 2023;11(6):1787-1795.e5. Doi: 10.1016/j.jaip.2023.02.009.

Williams Z, Hull JH, Ge Y, et al. Feasibility and value of a domiciliary spirometry programme in the assessment of severe asthma: A real-world evaluation. *ERJ Open Res*. 2023;9(6): 00635-2023. Doi: 10.1183/23120541.00635-2023.

Yanaz M, Yilmaz Yegit C, Gulieva A, et al. Electronic home monitoring of children with cystic fibrosis to detect and treat acute pulmonary exacerbations and its effect on 1-year FEV(1). *J Cyst Fibros*. 2024;23(2):329-333. Doi: 10.1016/j.jcf.2023.09.007.

Policy updates

8/2021: initial review date and clinical policy effective date: 9/2021

8/2022: Policy references updated.

8/2023: Policy references updated.

8/2024: Policy references updated.