Prior Authorization Review Panel
MCO Policy Submission

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Plan: Keystone First Community Health Choices	**Submission Date**: 08/22/2022
Policy Number: CCP.1494	**Effective Date:** 9/2021 **Revision Date:** August 1, 2022
Policy Name: Home spirometry	
Type of Submission – Check all that apply: ☐ **New Policy** **X Revised Policy*** ☐ **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:** Please see the tracked changes below for updates.	
Name of Authorized Individual (Please type or print): Akintayo Akinlawon, MD	**Signature of Authorized Individual:** 

Home spirometry

Clinical Policy ID: CCP.1494

Recent review date: 8/2021

Next review date: 12/2022

Policy contains: home; portable; spirometry.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

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 tests can be performed in inpatient facilities, along with ambulatory settings such as physician offices, emergency rooms, and specialty labs. Home (ambulatory) spirometry offers the potential to record measures of lung function such as forced expiratory volume in one second and forced vital capacity more

frequently than in regularly scheduled visits. The procedure uses battery-operated spirometers. Depending on the condition and its severity, patients can be advised to take spirometry measurements as often as one to two times daily. Subsequent technological improvements have allowed results to be transmitted to caregivers electronically (Robson, 2014).

The U.S. Food and Drug Administration has approved several spirometers for home use (U.S. Food and Drug Administration, 2022). In April 2017, the GoSpiro® Home Spirometer (Monitored Therapeutics Inc., Dublin, Ohio) was approved for full home use to collect spirometry data, and provide patients with feedback on the quality of the test's performance. Data from the device are transmitted to physicians, and instructions from physicians are returned to the patient (Jessup, 2017).

In January 2020, the U.S. Food and Drug Administration granted 510(k) clearance for the Air Next wireless spirometer (NuvoAir®, Stockholm, Sweden), which uses a single-use turbine to transmit data via a Bluetooth smartphone app after home use (U.S. Food and Drug Administration, 2020).

Findings

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). A 2017 summary report by the members of 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 (Vogelmeier, 2017). A 2013 guideline by the Canadian Thoracic Society on spirometry in primary care also makes no mention of home use (Coates, 2013).

A systematic review of 15 studies showed daily forced expiratory volume using spirometry to be the most commonly used modality in remote monitoring of chronic obstructive pulmonary disease. Benefits of remote monitoring included early detection of the disorder, improved health-related outcomes, and the ability to replace hospital care with a virtual ward. Patient satisfaction was also high (Baroi, 2018).

A review of 16 commercially available portable electronic spirometers included just four approved for use by the U.S. Food and Drug Administration. The study 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", thus restricting provider ability to make informed decisions on improving outcomes in asthma patients (Carpenter, 2018).

A review of 10 remote patient monitoring tools that forecast exacerbations of chronic obstructive pulmonary disease rated each tool on forecasting ability, cost, ease of use, and appearance. Home spirometry was one of four tools with a 1/5 (lowest) rating for forecasting ability, while five others received 5/5. Tools with higher ratings tended to have high or unlisted prices (Fan, 2020).

An evaluation of 17 spirometers used in primary care offices revealed only one met accuracy criteria, with mean errors for forced vital capacity, forced expiratory volume at one minute, and the ratio between the two ranging from 1.7% to 3.1%. These results led to the estimate of 28% of tests recategorized from obstructed to nonobstructed. Just 60% were considered acceptable for clinical use. Authors found no association between the number of tests performed by a clinic and spirometry quality. These quality issues in spirometry in primary care offices raise similar questions about home spirometry (Hegewald, 2016).

A trial included 281 patients with severe chronic obstructive pulmonary disease with high risk of exacerbation; subjects were randomized to those treated by telemonitoring or treated with usual care. Telemonitoring included recording of symptoms, oxygen saturation, spirometry, and weekly video consultations. After six months, authors observed no difference in dropout rate and mortality between groups. A significant improvement from baseline

in quality of life score (*P* = .03) compared with baseline occurred in only in the tele-monitoring group, but no significant changes were found in chronic obstructive pulmonary disease assessment test score (Tupper, 2018).

This same study had earlier shown no significant differences in rates of hospital admissions between the two groups, for either all causes combined or chronic obstructive pulmonary disease. No differences existed in average time to first admission (Ringbaek, 2015).

The medical literature contains numerous studies in the past several decades assessing the accuracy of home spirometers for monitoring pulmonary disease. However, no systematic review or meta-analysis of results from these studies exist. Many individual studies have small sample sizes, and/or make no comparison of results using home spirometers with results of the gold standard of facility-based spirometers. Finally, none address any effects on patient outcomes.

A study of 200 patients at two hospital centers evaluated the ability of the Air Smart Spirometer (Stockholm Healthcare Innovation), the first portable device accepted by the European community to display results on a smartphone or a tablet, to detect pulmonary obstructions. Conventional spirometry detected obstruction in 40% (73) of patients. The Air Smart Spirometer resulted in 90.4% sensitivity, 97.2% specificity, 95.7% positive predictive value, and 93.7% negative predictive value (Hernandez, 2018).

A randomized controlled trial including 14 cystic fibrosis centers (n = 267 patients older than age 14) measured home spirometry and symptoms twice weekly. In the treatment arm, centers received notification if a subject met criteria for pulmonary exacerbation, and contacted participants to determine if treatment was required. Patients in the usual care arm were seen every three months and asked to contact the site about any worsening pulmonary symptoms. No significant difference occurred between groups in 52-week mean change in forced expiratory volume at one-minute slope (*P* = .99). The early intervention group had more frequently detected exacerbations (*P* = .01). Adverse events were not significantly different (Lechtzin, 2017; Early Intervention in Cystic Fibrosis Exacerbation trial; Clinicaltrials.gov identifier NCT01104402).

After the start of the COVID-19 pandemic, a tertiary care center in London set up a system of 400 home spirometers within nine months for children with chronic lung diseases. While authors state that overall initiation of the program was successful, they listed a number of problems, including:

- The process of setting up home spirometers was time-consuming.
- Many initial tests had poor technical quality.
- Numerous software issues proved to be an obstacle to rollout.
- Adherence to one to three spirometer tests is poor, in adults as well as in children.
- Many socially disadvantaged families could not afford up-to-date smartphones.
- Non-English speakers present with difficulties in preparing for and using the test (Richardson, 2021).

In 2022, differences between clinic and unattended home spirometry measurement and the lack of testing standards continue to hamper the utility of home spirometry. Education and training increase the feasibility of unattended home monitoring, but the underlying etiologies, patient characteristics, and spirometry equipment appear to influence testing quality (Bell, 2022; Fettes, 2022; Paynter, 2022).

Results from the Early Intervention in Cystic Fibrosis Exacerbation trial suggest, compared to clinic spirometry, home spirometry lacks the precision of forced expired volume in one second measurement and the ability to detect subtle changes that may occur, particularly in patients with cystic fibrosis who are on modulator therapy; there were no significant differences in outpatient utilization or overall health care costs (Curley, 2022; Franz, 2022; Paynter, 2022). 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 reasons for the differences in diagnostic efficacy are not clear and require further research. No policy changes are warranted.

References

On June 6, 2022, 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.

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Policy updates

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

8/2022: Policy references updated.