HERC Coverage Guidance: High-Frequency Chest Wall Oscillation Devices
Disposition of Public Comments

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A3, A4, A6, B2–B8, C3–C6, C8	Evidence not included in this review shows effectiveness of HFCWO for COPD, bronchiectasis, neuromuscular disease, and cystic fibrosis.	Most of the data submitted from commenters were not published in peer-reviewed journals (e.g., posters and conference abstracts) or used noncomparative before-after designs. Others did not appropriately include the relevant populations or appropriate outcomes to address the Key Questions. One study did meet inclusion criteria and has since been added to the coverage guidance, but it did not change conclusions.
B1, B2, B9, C3	The state of the evidence for HFCWO therapy is sparse given the rare diseases it treats, lack of consensus on study endpoints, and inability to use blinding. Lower-quality evidence obtained from real-world data (claims databases) shows this therapy is effective and cost-effective. This lower-quality evidence should be considered, and coverage should be recommended for other conditions.	Although observational before-and-after studies (like those submitted by commenters), do appear to show benefit, the study designs do not permit us to determine whether the effect was caused by HFCWO devices; these study designs cannot control for confounding factors. More robust study designs exist, such as the randomized trial, or if that is not feasible, a matched-cohort or interrupted-time-series study. Though a randomized trial would be very challenging for the heterogenous population with neuromuscular disease, it would be feasible for COPD and bronchiectasis, as they are relatively common conditions. Initially, evidence related to non-CF bronchiectasis and neuromuscular conditions supported non-coverage. However, we have revised our recommendation to allow limited coverage based on the potential benefit and expert recommendation to extrapolate evidence from CF to other non-CF bronchiectasis and on pathophysiological reasoning. For neuromuscular conditions, the variety of disease manifestations makes

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		the development of a strong evidence base for each condition unlikely. Thus, we have based our recommendation on expert input and the potential to reduce costs associated with hospitalization and chronic airway infection.
A9, C2, D1, D4	Patients prefer the convenience and independence afforded by HFCWO. The availability of HFCWO devices respects patient preferences and offers several practical advantages. Some patients with varying conditions cannot use chest physiotherapy for practical reasons or because of contraindications related to their conditions.	We note patient preferences for convenience and independence in our GRADE tables and the Values and Preferences section in the report. Patient values and preferences are an important part of the rationale for coverage of HFCWO for patients with cystic fibrosis, for which evidence indicates HFCWO is comparably safe and effective to chest physiotherapy.
A5, C3, C7	Medicare, most state Medicaid programs, and most commercial payers provide coverage for cystic fibrosis, neuromuscular disease, and bronchiectasis. HERC should recommend coverage for patients with these conditions for whom other therapies are ineffective or contraindicated.	The report describes coverage for Medicare, Washington's Medicaid program, and selected payers active in Oregon (e.g., Aetna, Moda, Cigna, and BlueCross BlueShield of Oregon). These payers do cover HFCWO device therapy for cystic fibrosis and bronchiectasis, as well as for certain neuromuscular disorders. However, the subcommittee views other payer policies as contextual information rather than evidence of effectiveness. Step therapy is an appropriate utilization management tool for facilitating limited access to higher-cost services. However, even second-line covered services need to have sufficient evidence of effectiveness for improving critical or important outcomes.
D1–D5	Description of personal experience with a child with Rett's Syndrome and knowledge of other families whose children use the devices and are part of the Children's In-Home Intensive Waiver program.	Personal experiences, including reports of variation in provider and health plan decisions and processes, provide important context for the subcommittee's decisions. HERC's coverage decisions are made at the population level based on available evidence, informed by testimony and expert opinion. These decisions are intended primarily for health plans, including the Oregon Health Plan. The Children's In-Home Intensive Waiver program is not a health plan, and recommendations for that program are outside the scope of this report and outside the purview of the HERC.

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Commenters

Identification	Stakeholder
A	David Chandler, Senior Director of Payer Relations at American Association for Homecare *[Submitted July 2, 2021]*
B	Gary Hansen, Director of Scientific Affairs at RespirTech *[Submitted June 29, 2021]*
C	Kari Roehrich, Executive Director Managed Care Market Access at Hillrom Respiratory Health *[Submitted July 1, 2021]*
D	Joey Razzano, Oregon Representative for the International Rett Syndrome Foundation, NW Rett Syndrome Association Board member, and mother to child with Rett Syndrome *[Submitted July 5, 2021]*

Public Comments

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A1	Dear Committee Members, The American Association for Homecare ("AAHomecare") includes a cross section of durable medical equipment ("DME") suppliers, manufacturers, and other stakeholders that furnish DME to acute patients and chronically ill individuals. AAHomecare's members are proud to be part of the continuum of care that assures that individuals receive cost-effective medical equipment and supplies, and related services, in their homes. AAHomecare supports high frequency chest wall oscillation (HFCWO) coverage for patients with airway clearance needs and appreciates the opportunity to comment on the Evidence-based Guidance Subcommittee coverage recommendations for HFCWO. HFCWO is an airway clearance therapy that healthcare professionals have long-used to treat patients with impaired mucociliary clearance and mucus hypersecretion – specifically for the clinical management of cystic fibrosis, neuromuscular disease (NMD), bronchiectasis, and chronic obstructive pulmonary disease (COPD). Due to the lack of coverage criteria and fee schedule for HFCWO in Oregon Medicaid's Durable Medical Equipment (DME), Prosthetics, Orthotics and Supplies	*Thank you for your comments. We have written specific responses to individual sections of your letter in the rows that follow.*

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	Administrative Rulebook and corresponding fee schedule, there may be access issues for patients with airway clearance concerns. AAHomecare strongly supports the subcommittee's guidance to recommend HFCWO coverage for patients with cystic fibrosis (CF) and urges the committee to consider HFCWO coverage for patients with NMD, bronchiectasis and COPD for the following reasons:	
A2	1) HFCWO therapy is an established technology that has served chronic respiratory patients for decades and is considered the standard of care for cystic fibrosis patients with an estimated 76% of the US CF population using the therapy for airway clearance, according to the 2019 CF Foundation Patient Registry Annual Data Report.	*Our background section acknowledges HFCWO device therapy is a commonly used treatment option for cystic fibrosis.*
A3	2) Respiratory complications are the leading cause of morbidity and mortality for patients with NMD, and HFCWO has been shown to reduce these complications. Some NMD patients are not able to tolerate manual CPT or be put in all of the required positions to receive the treatment.	*Our review found insufficient evidence that HFCWO device therapy reduces exacerbations and hospitalizations for conditions other than cystic fibrosis.*
A4	3) For patients with non-cystic fibrosis bronchiectasis, HFCWO therapy reduces the frequency of acute exacerbations, hospitalizations, antibiotic use and costs.	*For bronchiectasis, our review found very-low-confidence evidence that HFCWO device therapy improves key outcomes.*
A5	4) Medicare, most state Medicaid programs, and nearly all commercial payers, provide HFCWO coverage for CF, NMD and bronchiectasis patients.	*Our policy is to report coverage for Medicare, Washington's Medicaid program, and selected payers active in Oregon (e.g., Aetna, Moda, Cigna, and BlueCross BlueShield of Oregon). These payers do cover HFCWO device therapy for cystic fibrosis and bronchiectasis as well as for certain neuromuscular disorders.*
A6	5) For COPD, airway clearance devices reduce exacerbations and hospitalizations. According to a recent meta-analysis across 18 studies of airway clearance devices, future exacerbations were reduced by 50%. In addition, analysis of real-world data	*We identified the meta-analysis that you refer to (Daynes et al., 2021). The single included study of HFCWO devices that reported exacerbations for patients with COPD in this*

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	from the Optum claims database found that respiratory-related hospitalizations were reduced by 17% with the application of vest therapy. All-cause hospitalizations were reduced by 40%, ER visits by 27%, and office visits by 12% during the same time in a 2017 study using the Truven MarketScan database.	*meta-analysis was included and summarized in the coverage guidance. The other 17 studies included in this meta-analysis did not report exacerbations for patients with COPD in studies testing the effectiveness of HFCWO devices.* *The 2 other studies that you refer to (Berry et al., 2019; McEvoy et al., 2020) do not meet the study design requirement of the scope of this coverage guidance, as they were retrospective registry studies which additional devices and a broader set of disease entities than was included in this review. The analysis of claims from the Optum database was published as a poster (McEvoy et al., 2020), and is ineligible for inclusion.*
A7	6) Coverage criteria can ensure appropriate utilization by requiring patients to either try and fail other airway clearance therapies or have the therapy be contra-indicated by the patient's prescriber.	*Step therapy is an appropriate coverage tool for enabling access to higher-cost services. However, even second-line covered services need to have sufficient evidence of effectiveness for improving critical or important outcomes.*
A8	7) It is in the best interest of the patient to give physicians access to all therapies and devices to address specific patient needs.	*Thank you for your comment.*
A9	8) Coverage for HFCWO would respect patient preference, increase adherence to therapy, and provide assurance of reliable and consistent treatment, which would ultimately offset costs through reduced exacerbations and hospitalizations. 9) HFCWO offers practical advantages over other airway clearance approaches. For example, unlike chest physical therapy (e.g. chest physiotherapy, which is when a respiratory therapist claps on the chest to loosen mucus from the lungs), HFCWO	*Our review did not look at evidence regarding adherence to therapy and found insufficient evidence that HFCWO device therapy reduces exacerbations and hospitalizations for conditions other than cystic fibrosis. We have noted patient preference for convenience and efficiency in our GRADE table.*

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	devices make it easier and more efficient to perform chest physical therapy at home without the need for care delivery by a respiratory therapist or caregiver.	*The Values and Preferences section of the coverage guidance details how the lack of trained or willing caregivers can be a barrier to care, as well as how the use of HFCWO device therapy provides independence from caregivers.*
A10	HFCWO reduces respiratory complications for patients with CF, NMD, bronchiectasis and COPD. AAHomecare believes every effort should be made to facilitate access to effective therapies that can improve patient outcomes, reduce hospitalizations, and reduce further burdens to the healthcare system. For these reasons, AAHomecare encourages the committee to provide HFCWO coverage for CF, NMD, bronchiectasis and COPD patient populations. AAHomecare appreciates the opportunity to provide these comments.	*Thank you for your comments.*
B1	To Whom It May Concern: We reviewed the draft guidance for coverage of high-frequency chest wall oscillation (HFCWO) and are pleased with the recommendation for coverage of cystic fibrosis (CF). Thank you for this change and for hearing my testimony at the HERC meeting on June 3. We ask that you reconsider the recommendation for denial of coverage to patients with bronchiectasis (BE), neuromuscular conditions, and COPD in light of real-world evidence that was possibly not considered in the analysis presented. We would first like to comment on the state of evidence for HFCWO therapy. Despite being used for over 20 years, there is a paucity of comparative evidence for any airway clearance technique and a particular paucity of randomized control trials (RCT). There are good reasons for this.	*Thank you for your comments. We have written responses to specific individual sections of your letter in the rows that follow.*

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	1. HFCWO often treats rare diseases which makes it difficult to recruit cohorts of adequate size. There is little agreement on study endpoints. Prior studies did not identify or control for machine power settings or adherence. 2. Airway clearance studies cannot be blinded, making it impossible to do a double-blind study. HFCWO patients tend to be considerably sicker because of current prescribing habits, making post hoc comparisons between different types of devices difficult to interpret. 3. Lastly, there seems to be little interest among independent researchers on this topic, perhaps because the therapy has been around for so long. These difficulties should be considered when setting expectations for the evidence.	
B2	Here we provide additional evidence about the impact of HFCWO for bronchiectasis, neuromuscular disorders, and COPD that may have been overlooked in the systematic review. This evidence is derived from several objective sources (principally healthcare claims databases) and is complemented by patient-reported outcomes collected in a clinical registry of users of the Philips InCourage System. Collectively, real-world data supports the effectiveness of HFCWO for outcomes such as hospitalization, quality of life, and antibiotic use. We respectfully ask that this evidence be taken into account as you work to finalize the guidance. In 2016, your group expressed enthusiasm about our HFCWO outcomes in bronchiectasis patients and recommended that we publish the results - advice that we followed. We and others have made efforts to address evidence gaps by reporting patient outcomes as well as leveraging external databases of cleared healthcare claims. Collectively, these complementary sources have been published and/or presented at national and international conferences. Based on the data overview provided at the recent HERC meeting, much of this evidence was not considered or shared with the members of the committee.	*Although observational before-and-after studies, such as the real-world studies you refer to, do appear to show benefit, this study design does not permit causal inference, and cannot control for confounding factors. More robust study designs exist, such as the randomized trial or, if that is not feasible, a matched-cohort or interrupted-time-series study.*

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B3	The RespirTech bronchiectasis registry has been a source of outcomes for our product, the methodology and results appearing in a recent peer-reviewed publication.[4] The results show a reduction in hospitalizations for bronchiectasis patients after the initiation of HFCWO (Figure 1).[4] The authors took specific measures to reduce the risk of bias: (1) registry findings were validated against objective patient chart data, (2) all data were housed and managed by an independent actuarial firm, and (3) all statistics were conducted by a 3d-party biostatistician. While pre-post studies are subject to regression to the mean, these concerns are mitigated by the large sample and the persistent character of the improvement. The data show the response to HFCWO is sustained for up to two years; regression to the mean, if present, would become evident by this point.	*See response to B2 regarding study designs.* *Fundamentally, a before-and-after study may have other limitations in addition to regression toward the mean. In the example of a registry, confounders can include, but are not limited to, the patient characteristics and family context of individuals who have access to HFCWO device therapy, and changes in clinical care aside from the HFCWO device therapy.*
B4	With a larger data set of over 12,000 patients, we extended the results to two years of follow-up, revealing a 72% reduction in hospitalization rate in the two years after initiating vest therapy (Figure 2).[5] Regarding potential cost savings, this works out to be a bit less than one-half of an avoided hospitalization per patient per year. The avoided cost of an expensive inpatient admission compares favorably with the purchase price of the device.	*See response to B2 regarding study designs.*
B5	Real-world evidence from two separate databases of cleared healthcare claims also demonstrates reductions in hospitalization in bronchiectasis patients following initiation of vest therapy. As an example, Weycker showed all-cause hospitalizations were reduced by 33% (n=865 patients).[6] A new study by Basavaraj presented at the 2021 ATS meeting reports that hospitalizations reduced by 73% in year one and by 64% in year two.[7]	*See response to B2 regarding study designs.*
B6	Claims data support the benefits of HFCWO therapy for neuromuscular patients. Analysis of claims data showed a 25% reduction in respiratory-related hospitalizations.[8] In addition, a peer-reviewed publication found a corresponding 20% reduction in inpatient admissions and a 44% reduction in inpatient days.[9]	*Although Lechtzin et al., 2016 is a peer-reviewed publication, the study design was before-after, and the McEvoy et al., 2020 reference cited in this row was presented at a conference and not published in a peer-*

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		reviewed journal. See response to B2 regarding study design.
B7	Concerning COPD, we bring to your attention a new systematic review and meta-analysis which found that the use of airway clearance devices can improve exacerbation frequency.[10] 18 randomized controlled trials of airway clearance devices for patients with stable COPD were evaluated and reported that using devices to support everyday management reduced future exacerbations by 50%.	*The single included study of HFCWO devices that reported exacerbations for patients with COPD in this meta-analysis was included and summarized in the coverage guidance. The other 17 studies included in this meta-analysis did not report exacerbations for patients with COPD in studies testing the effectiveness of HFCWO devices.*
B8	In terms of hospitalization outcomes from patients with COPD (n=219) within our registry, we found a 54.4% reduction in annualized hospitalization rate for respiratory causes.[11] In addition, a study of Optum claims data found that respiratory-related hospitalization was reduced by 17% in the year after receiving vest therapy.[12] Similarly, a 2017 study using MarketScan data showed that all-cause hospitalization was reduced by 40%.[6]	*All 3 references cited in this row were presented as conference submissions and not published in peer-reviewed journals.*
B9	In summary, this beneficial therapy should be available in the toolkit for physicians in the treatment of patients with bronchiectasis, COPD, and neuromuscular disorders. The difficulties of designing and performing true comparative studies in this area are considerable and the likelihood of new large-scale RCTs being conducted for these disease states is low. However, recent real-world evidence directly addresses critical outcomes identified by this committee. The outcomes for HFCWO have been demonstrated using multiple independent sources. The convergent findings from these studies, specifically as it relates to reducing hospitalizations and improving patient quality of life, should be considered so that this life-altering treatment is available to those who need it.	*Thank you for your comments.* *We reviewed the references that you provided and considered each for inclusion in the coverage guidance. Two references were excluded for not meeting the scope of the coverage guidance (Mikesell et al., 2017; Rubin, 2007). Six references were excluded because they were conference presentations (Barto et al., 2019a; Barto et al., 2019b; Weycker et al., 2017; Basavaraj et al., 2021; McEvoy et al., 2020a; McEvoy et al., 2020b). Three references were excluded due to ineligible study designs (noncomparative observational: Basavaraj et al., 2020; Barto et al., 2020; observational before-after: Lechtzin et al., 2016).*

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		Your work to address the evidence gaps is helpful and may motivate others to perform more rigorous research on these conditions. However, the subcommittee uses only peer-reviewed studies and generally requires between-group comparison for evidence of treatment effectiveness.
C1	Dear EbGS Committee Members, Hillrom appreciates the opportunity to provide comment on the coverage recommendation for high frequency chest wall oscillation (HFCWO). HFCWO therapy is an established technology that has served chronic respiratory patients for over 30 years. Hillrom strongly supports the EbGS Committee's guidance to recommend HFCWO coverage for patients with cystic fibrosis (CF). Hillrom also requests the committee consider HCFWO coverage for patients with neuromuscular disease (NMD) and bronchiectasis.	*Thank you for your comments. We have written responses to specific individual sections of your comment in the rows that follow.*
C2	HFCWO coverage for patients with CF has expanded across the payer continuum such that at least 45 of the Medicaid fee-for-service plans cover HFCWO for CF beneficiaries. HFCWO is considered standard of care for CF as evidenced by the CF foundation's estimate that 76% of the US CF population uses HFCWO for airway clearance.[1] This is largely attributable to assurance or reliable and consistent treatment, adherence to therapy, and patient preference. Accordingly, providing HFCWO coverage for the CF population would ultimately offset costs through reduced exacerbations and hospitalizations.	*We recognize that HFCWO device therapy is a commonly used treatment option for cystic fibrosis. Though the available evidence shows no difference in hospitalizations compared to chest physiotherapy, we are recommending coverage because of patient preferences and because chest physiotherapy may not be available or feasible for all patients.*
C3	Hillrom strongly encourages the committee also consider coverage for patients with NMD. Respiratory complications are the leading cause of morbidity and mortality for patients with NMD and HFCWO has been shown to reduce these complications. The rationale for the recommendation for coverage for patients with NMD starts that there is no evidence that HFCWO devices improve key outcomes compared to	*No economic studies met our inclusion criteria for this coverage guidance.* *See response to comment A5 regarding other payer coverage.*

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	standard treatments. Hillrom asserts that sufficient comparative clinical evidence is available that supports the HFCWO therapy on improved key outcomes over standard treatments. Multiple economic outcome studies from highly reputable sources support HFCWO as a cost-saving strategy. Further, including HFCWO coverage for patients with NMD is consistent with Medicare, many Medicaid departments, and an increasing number of commercial payers.	
C4	The Yuan and Landon clinical studies compared the efficacy of HFCWO to chest physiotherapy (CPT). Both studies demonstrated significantly decreased rates of hospitalization for intravenous antibiotics and superior oxygenation for patients using HFCWO as well as superior adherence to the therapy. The investigator-initiated Fitzgerald study demonstrated a 32% reduction in hospitalizations (P<.01) in neurologically impaired children with respiratory symptoms. These studies provide sufficient comparative evidence of the superior benefits of HFCWO over standard treatment for this population.	*The Yuan et al., 2010 reference has been added to the coverage guidance since the submission of this comment. The Landon et al., 2022 reference was excluded because it was a conference abstract. The Fitzgerald et al., 2014 reference reported a before-after study. Although observational before-and-after studies, such as the real-world studies you refer to, do appear to show benefit, this study design does not permit causal inference, and more robust study designs exist, such as the randomized trial or, if that is not feasible, a matched-cohort study.*
C5	In addition, multiple economic outcomes data studies confirm the positive impact of HFCWO therapy on healthcare costs for neuromuscular disorders, which supports the efficacy of HFCWO when compared to standard treatment. Most notable is the 2019 research article published by the National Institute for Health Care Excellence (NICE) which analysed the cost-effectiveness of HFCWO compared to CPT in patients with complex neurological disorders, including neuromuscular disease and cerebral palsy.[5] This analysis revealed that per 1000 patients, the Vest System results in 2,422 less hospitalizations, and 49,868 less bed days compared to CPT, resulting in $8 M in cost savings over a five-year time frame.[5]	*This reference was excluded because the cost effectiveness estimates produced for the health system in the UK are not directly related to cost effectiveness estimates for the health system in the US (Javanbakht et al., 2019). Additionally, this study included information from a before-after study and from the Yuan et al., 2010 study that we have incorporated into the coverage guidance.*

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C6	Another important economic data study, 2020 Pandya,[6] analysed the claimed of 1008 patients from the Optum healthcare claims repository. The study demonstrated a reduction of respiratory-related hospitalizations by 24.7% ($p<0.005$) in patients receiving HFCWO therapy. Similarly, Lechtzin demonstrated a 41.7% decrease in inpatients costs post intitation of HFCWO.[7] These studies are based on thousands of patient records and clearly show the benefit of HFCWO compared to standard treatment.	*The Pandya et al., 2020 reference was a conference presentation of a before-after study; the other 2 references also utilized a before-after design.*
C7	Additionally, Medicare, most Medicaid departments, and nearly all commercial payers include HFCWO coverage for NMD patients. As of October 1, 2008, all CMS jurisdictions revised the HFCWO Local Coverage Determination to include NMD while over 40 Medicaid departments cover NMD disease state. Consistent with the criteria considerations included in the guidance, payer coverage policies ensure appropriate utilization by requiring patients must either try and fail other airway clearance therapies or have the therapy by contra-indicated by the patient's prescriber.	*See response to comment A5 regarding other payer coverage.*
C8	Hillrom also strongly encourages the committee to approve coverage for patients with non-cystic fibrosis bronchiectasis. In a comparative study, bronchiectasis patients on HFCWO demonstrated superior improvement in dyspnea, pulmonary function tests, and quality of life compared to patients on PEP or CPT.[8] Additional analyses suggest that HFCWO therapy reduces the frequency of acute exacerbations, hospitalizations, antibiotic use and costs in patients with bronchiectasis.[9,10,11,12,13]	*The first reference (Nicolini et al., 2013) is already included in the coverage guidance. The Weycker et al., 2017 and Basavaraj et al., 2021 references are conference abstracts. The remaining 3 references (Barto et al., 2020; Seivert et al., 2018; Sievert et al., 2017) references report studies with noncomparative observational designs. The remaining references are addressed in the previous rows.*
D1	I personally know hundreds of families in the Northwest that have benefited from the use of the HFCWO device aka "The Shaker Vest" when experiencing respiratory distress. The scope of the current coverage guidance is limited to CF and bronchiecstasis. While it refers to other neuromuscular disease resulting in chronic lung disease, Rett Syndrome does not really fall into any of those categories.	*Thank you for your comments and for sharing the story of a patient's care. While individual stories provide context for the Subcommittee's decisions, the Subcommittee makes coverage decisions on a population-level basis and*

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	Rett Syndrome is like having a child with autism, cerebral palsy, Parkinson's epilepsy and an anxiety disorder all in one. Our daughter also experiences osteoporosis, scoliosis and uses a wheelchair. She is at constant risk for aspiration which can lead to pneumonia literally in a matter of hours. The majority (>80%) of people with Rett Syndrome experience a neurological scoliosis which can require titanium rods to assist with opening the chest cavity. Otherwise, the lung is crushed and tends to fester a chronic infection in one lobe that quickly turns acute. When O2 sats drop, the shaker vest is the first step to increase O2 saturation. In the year before her spinal surgery, [Redacted name] was hospitalized 6 times for pneumonia and this was always the protocol. O2 sats drop, use shaker vest, then on to cough assist, bi-pap, cpap and then trach in that order. If a family has a shaker vest at home, this can often be avoided and it also helps with home care after a hospital stay. During each of these stays the therapists made sure we had this device at home despite having both primary and secondary insurance denying it. We appealed the denial over the course of a year, eventually losing all appeals because this committee has determined that CPT is cost effective and only bronchiecstasis and CF are coverable conditions. We were also at Randall Children's Hospital. My personal experience is that these devices get covered if you go to OHSU but not if you go to Randall. Why the inconsistency? As a parent, the unequal coverage and prescription among hospital systems suggests to me there are magic buzzwords being used that I am not privy to. As a family we were repeatedly assured that we had to go through the appeal and denial process – but that we would be denied eventually due to the current HERC guidance – and that Hill-Rom would gift it to us after that process. That is how I learned that Oregon is the ONLY state that doesn't cover these devices. What is it that 49 other states saw that Oregon does not? At the end of the long and complicated process of applications, appeals and denials, we had to send the device back to the company or pay them	*must base these decisions on evidence and other factors with respect to the population in general.* *Health plans can and sometimes do make individual coverage exceptions for patient circumstances. Appeal and hearing processes are required by law, but outside the Subcommittee's purview.* *The draft coverage guidance recommends coverage for certain patients with cystic fibrosis.* *HERC's coverage decisions are intended primarily for health plans, including the Oregon Health Plan. The Children's In-Home Intensive Waiver program is a separate program, and decisions on which services that program provides are outside the scope of this report.*

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	$16,000 for the privilege of having it on hand. We made the decision as a family that if her sats drop, we will take her straight to the emergency room because we don't have a shaker vest at home, even though it's the first thing the ER will do after the X-ray confirms diminished breathing in the lower lobes – every single winter….we are just one family on the hundreds of families on the CIIS waivers. Reading this guidance the short version is that: It ONLY covers CF and bronchiectasis and other neuromuscular disease resulting in chronic lung disease. What if you had a MEDICALLY INVOLVED person (as defined by the Children's In Home Intensive Waiver) that resulted in multiple chronic and acute lung and respiratory-related incidents that were not considered 'disease'?	
D2	The current recommendation is "weak" but I find this term vague for a variety of reasons – is it weak because there no empirical evidence or independent analysis on the cost-benefit ratio on the reduction or avoidance of hospitalization? Or is it weak due to the small sample size? IS it weak because the population is limited in scope? Any of those reasons would keep the financial liability limited as well	*According to the subcommittee's methodology (Appendix A), a weak recommendation indicates that "The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors, but further research or additional information could lead to a different conclusion."* *The factors leading to the recommendation are described in the GRADE table.*
D3	CPT is as cost effective as the shaker vest with similar results and can be done by paid or unpaid caregivers for 20-40 minutes per day multiple times a day – try to do that for even 10 minutes on a girl with a T2-Pelvis titanium rod in her back and see how effective that is! It is exhausting and the CPT provider is in constant fear of injuring the patient.	*We did not identify any cost-effectiveness studies that met our inclusion criteria and also addressed the scope of this coverage guidance with information that is relevant to the US health system.* *See response to comment D1 regarding individual patient circumstances.*

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	There is not enough evidence because the sample size is too small - but it always will be due to the population making it too small to fall under normal distribution confidence intervals – chicken and egg.	*Evidence is often insufficient, especially for rare conditions, which is why the subcommittee considers public comments and expert testimony, among other factors.*
D4	Evidence showing cost effectiveness has been presented as reduction or avoidance of hospital visits– this committee has disregarded such evidence because it was produced from the manufacturer. Has any analysis been done on any of the population covered by the CIIS waiver? This is the target population that would benefit from this device (even after they turn 18), allowing them to be treated in their home, saving the state money. You could extrapolate what 6 hospitalizations in one year cost the Oregon Health Plan even as secondary provider to determine the cost effectiveness of the shaker vest. I am not including the multiple times that we provided acute care at home during the same time period although there are many. While it would be a sound decision to expand the coverage guidance to people who meet the "medically involved" definition, it would also be financially prudent to cover the shaker vest if the initial expenditure of approximately $16k is less than the cost of even one nights hospitalization which is what the unintended consequence of the current guidance has been. Thank you for your consideration.	*The subcommittee bases decisions regarding effectiveness on peer-reviewed evidence. The Subcommittee does not disregard evidence produced from the manufacturer merely because it was produced by the manufacturer. Registry information from the manufacturers was excluded from the coverage guidance because the way that the information was gathered (a before-after study design) cannot account for competing hypotheses for why individuals using HFCWO device therapy improved or stabilized in terms of symptoms or health care utilization.* *Thank you for your comments.*

References Provided by Commenters

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A	Excluded from the coverage guidance Berry JG, Goodman DM, Coller RJ, et al. Association of home respiratory equipment and supply use with health care resource utilization in children. *J Pediat*. 2019;207:169-175.e162. doi: 10.1016/j.jpeds.2018.11.046. Daynes E, Jones AW, Greening NJ, Singh SJ. The use of airway clearance devices in the management of chronic obstructive pulmonary disease. A systematic review and meta-analysis of randomized controlled trials. *Ann Am Thorac Soc*. 2021;18(2):308-320. doi: 10.1513/AnnalsATS.202005-482OC McEvoy C, Pandya P, Weycker D, Hanson GL. Outcomes with high-frequency chest wall oscillation among patients with COPD using a large claims database. Presented at: CHEST 2020 Annual Meeting; October 18-21, 2020; Online. P1468.
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