HERC Coverage Guidance: High-Frequency Chest Wall Oscillation Devices
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A3, A4	Bronchiectasis is a rare disease, resulting in low impact of adding coverage.	Bronchiectasis is not a rare disease, although it is a heterogenous condition. Data for Oregon Health Plan (OHP) claims from 2018-2020 showed claims for nearly 1,500 members which included a diagnosis of bronchiectasis. This number is likely an underestimate to the true bronchiectasis population in Oregon.
A1, A4-A9, B1, C2	The nature of the very low quality evidence for bronchiectasis stems from lack of consensus on study endpoints and other factors, as well as lack of interest among independent researchers, making it difficult to conduct novel research for this population. This lower-quality evidence should be included in this review.	Although observational noncomparative 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 and more robust study designs exist. Further, the size of the bronchiectasis population is large enough to feasibly conduct studies.
A2, A10, A11, B8, C3	There is an equity consideration in noncoverage of HFCWO devices, as patients may be located in more rural or economically disadvantaged areas, are from developing countries, have comorbidities, and/or have language or cultural barriers to care.	The subcommittee acknowledges that patients in these groups/areas may have more limited access to care options. These contextual factors will inform subcommittee deliberation. *For EbGS discussion.*

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B2, C1	Expert opinion supports the use of HFCWO in selected patients with bronchiectasis	*For EbGS consideration:* Previous expert opinion-generated "blue box" language is shown below and can be included again if EbGS considers the expert recommendations to be strong enough to justify inclusion. High-frequency chest wall oscillation devices are recommended for coverage for patients with non–cystic fibrosis bronchiectasis (*weak recommendation*) when the 4 criteria below are met: A. The bronchiectasis is confirmed by computed tomography (CT) scan, *AND* B. There is evidence of chronic lung infection, *AND* C. The patient has experienced either: 1. Daily productive cough for at least 6 continuous months, *OR* 2. Frequent (> 2 times a year) exacerbations requiring antibiotic therapy, *AND* D. The patient has received chest physiotherapy and positive expiratory pressure therapy OR chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy).

Commenters

Identification	Stakeholder
A	Gary Hansen, PhD, Director of Scientific Affairs, RespirTech [April 29, 2022]
B	Alan Barker, MD, Professor of Medicine, Pulmonary and Critical Care, Oregon Health & Science University [May 4, 2022]
C	Aaron Trimble, MD, Assistant Professor of Medicine, Pulmonary and Critical Care, Oregon Health & Science University [May 10, 2022]

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Public Comments

ID/#	Comment	Disposition
A1	We reviewed the revised draft guidance for coverage of high-frequency chest wall oscillation (HFCWO) and are pleased with the recommendation for coverage of cystic fibrosis (CF) and neuromuscular disorders. However, we strongly urge the EbGS and HERC committee to reconsider the recommendation for denial of coverage to the vulnerable and at-risk Oregonian patients with bronchiectasis (BE). Despite the lack of high-quality evidence, HFCWO has become well-established as an important means of airway clearance therapy for this population.	*Thank you for your comments. We have written responses to specific individual sections of your letter in the rows that follow.*
A2	Vest therapy has been clinically shown to be just as effective as other methods of airway clearance and does not depend on the user's skill or effort.[1] This makes the device an important alternative for persons in disadvantaged socio-economic circumstances, or for persons who have not been successful with other methods.	*The publication referenced here presents narrative summaries of published studies but does not include meta-analyses or present any original research findings.*

<table>
<tr><th>ID/#</th><th>Comment</th><th>Disposition</th></tr>
<tr><td>A3</td><td>Accordingly, allow me to address several points raised in the most recent meeting.
There seemed to be some uncertainty about the number of BE patients in the state who are potential users of HFCWO, and a few members suspected that the number was large. We have found it to be otherwise. A recent study reports the prevalence of diagnosed BE in the general population; this may be extrapolated to the Oregonian under-65 population as follows:

<table>
<tr><th>Age Range</th><th>Oregon Population[2]</th><th>BE Prevalence Cases/100,000[3]</th><th>Estimated BE Cases</th></tr>
<tr><td>35 to 44 years</td><td>568,712</td><td>18</td><td>102</td></tr>
<tr><td>45 to 54 years</td><td>510,127</td><td>43</td><td>219</td></tr>
<tr><td>55 to 64 years</td><td>538,950</td><td>122</td><td>658</td></tr>
<tr><td>Total</td><td>1,617,789</td><td>183</td><td>979</td></tr>
</table>

The roughly one-thousand BE cases in Oregon can be further reduced because not all cases require airway clearance and most patients below age 65 have coverage other than Medicaid.[4] A few members suggested that studies for BE are easier to conduct than for CF or neuromuscular conditions. As noted in previous meetings, conducting a randomized controlled trial (RCT) for BE has proven challenging and is unlikely to occur despite considerable and well-intentioned efforts. We provided considerable rationale in prior communications to this committee (Submissions dated 12/1/2020 and 6/25/2021). There are good reasons for this.[5]</td><td>The Weycker et al., 2017 publication cited here used health-care claims data from 2009 to 2013 to estimate the prevalence and incidence of bronchiectasis in adults enrolled in multiple private health plans. Between 2018-2020, claims were submitted for nearly 1,500 OHP members showing a diagnosis of bronchiectasis, and this number is likely an underestimate of the true size of this population in Oregon.

Furthermore, the Weycker et al., 2017 publication estimates that there has been an annual growth rate of 8% per year since 2001 of patients with newly diagnosed bronchiectasis, and further suggests that cases that were identified represented only a small part of the true population with bronchiectasis. This suggests that even their proposed method of estimating prevalence and incidence may provide underestimates.

Responses to prior comments can be viewed here and here.</td></tr>
<tr><td>A4</td><td>First, HFCWO often treats rare diseases which makes it difficult to recruit cohorts of adequate size.</td><td>We understand that cystic fibrosis and many of the neuromuscular diseases in scope for this topic are rare, but chronic obstructive pulmonary disorder and non–cystic fibrosis bronchiectasis are not rare diseases. See response A3 regarding the population estimate for bronchiectasis in Oregon.</td></tr>
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A5	Second, there is little agreement on study endpoints, and many older studies rely on problematical proxy measures such as sputum volume or changes in forced expiratory volume (FEV1).	*Outcomes such as sputum volume or changes in volume were not selected as critical or important outcomes for this report.*
A6	Third, past studies did not identify or control for machine power settings or adherence.[6]	*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.*
A7	Fourth, airway clearance studies cannot be blinded, making it impossible to do a truly double-blind study.	*The subcommittee does not require studies to have a double-blind design for inclusion in coverage guidance reports.*
A8	Lastly, there has been little interest among independent researchers on this topic, perhaps because the therapy has been around for so long. We ask that you take these well-known difficulties into account.	*Thank you for your comment. The EbGS does take these contextual factors into account in its decision-making.*
A9	The Barto et al (2020) peer-reviewed publication[7] was unfortunately not among those included in the overall evidence evaluation by all members of the committee, yet it is among the most substantial pieces of contemporary evidence that supports the use of vest therapy in the BE patient population. This peer-reviewed outcomes publication has already been cited by several key thought leaders in the field of bronchiectasis as a positive contribution to the BE airway clearance literature – so we were naturally disappointed that the broader committee elected to not consider this data in their assessment.	*The Barto et al., 2020 publication did not meet inclusion criteria for this coverage guidance because it used noncomparative observational data from a registry using patient-reported outcomes that they were asked to retrospectively recall.*
A10	From a health equity perspective, the collective needs of these patients need to be considered. Patients with pulmonary diseases requiring airway clearance are likely to be located in areas where access to health care services may be limited. This situation is clear from the following map, which shows the high prevalence of COPD in rural and/or economically disadvantaged areas in Oregon.[8]	*Though we acknowledge that access to treatments may be more difficult to obtain in rural areas, any available treatment must still be evidence-based and be sufficiently effective at improving critical or important outcomes. Our review found insufficient evidence that HFCWO devices improve key outcomes for patients with chronic obstructive pulmonary disease compared to*

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	[Image of CDC model of COPD prevalence by census tract, 2018, retrieved from: https://www.cdc.gov/copd/data.html]	*alternatives. Expert opinion does not recommend use in this population.*
A11	Dr. Trimble stated, and medical literature concurs, that patients respond differently to different forms of airway clearance and a personalized approach to airway clearance is key to positive patient outcomes.[9] For various reasons, patients frequently fail their initial attempts at an airway clearance modality; this may be due to motivational issues, lack of social support, physical limitations, or improper use of devices. There is a high treatment burden for traditional chest physiotherapy and the number of personnel with appropriate training is limited. In addition, there is a tremendous amount of variability in the delivery of many of the manual airway clearance techniques that are offset/addressed by the standardization offered by HFCWO. Therefore, Medicare and most insurance payors in the US include HFCWO as an option for BE patients and specifically took into account a 'tried and failed criterion'. We respectfully request that the draft coverage be amended to include coverage for BE on a tried-and-failed basis. This would minimize confusion among patients and health care providers in Oregon and better align with Medicare, other state Medicaid programs, and most private insurance payors. By doing so, it would help Oregonians avoid having to pursue an arduous and time-consuming appeals process and would likely proactively reduce healthcare resource utilization from a population health perspective. We hope these comments are constructive to the committee as they make their final recommendations for coverage criteria to the HERC committee. Thank you for considering our request to include BE for the aforementioned reasons. Please let us know if we can answer any questions, and do not hesitate to contact me directly.	*The Sontag et al., 2010 publication referenced here reports on lessons learned after a randomized trial of airway clearance techniques for patients with cystic fibrosis. This draft of the coverage guidance has a weak recommendation for covering HFCWO devices for patients with cystic fibrosis who have frequent exacerbations and for whom chest physiotherapy and positive expiratory pressure are not available, effective, or tolerated.* *The coverage criteria from Medicare, Aetna, Cigna, Moda, Regence BlueCross BlueShield, and the Washington Medicaid program are summarized in the coverage guidance.* *Thank you for your detailed comments and your interest in ensuring that Oregon Medicaid members have access to the best available treatment options.*

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B1	I would like to address and encourage consideration of coverage for HFCWO devices for (non-CF) bronchiectasis. The draft document on HFCWO is well studied and researched. Part of the problem acquiring evidence for HFCWO is the lack of endpoints for studies in bronchiectasis. Mortality over a few months is not an appropriate endpoint. Bronchiectasis patients have permanent structural airway damage that does not show improvement in pulmonary function after antibiotics or other therapies. In uncontrolled studies exacerbations are reduced and quality of life improved after airway clearance therapies (ACT). I would suggest several considerations for provision of HFCWO devices based on authoritative opinion:	*Thank you for your comments. We have written responses to specific individual sections of your letter in the rows that follow.*
B2	Bronchiectasis is the prototypical condition for which ACT including HFCWO is therapeutic. The pathophysiology includes airway inflammation and infection leading to exceptional and tenacious mucus for which enhancing secretion removal is salutary (1).	*The publication referenced here is for a nearly 200-page issue of the publication* Clinics in Chest Medicine*. This issue presented articles that summarize the current state of research related to bronchiectasis and future directions in research.*
B3	International Guidelines for the diagnosis of bronchiectasis and for exacerbations can be utilized for clinical consideration and management as well as research studies (2,3).	*The Aliberti et al., 2022 publication summarized consensus recommendations for establishing criteria and definitions for radiological and clinical diagnosis of bronchiectasis to improve patient recruitment for future clinical trials of treatments for bronchiectasis. Similarly, the Hill et al., 2017 publication summarized a consensus definition for pulmonary exacerbations in adults with bronchiectasis.*
B4	Airway Clearance Therapies (ACT) are a well accepted part of the management of bronchiectasis, promoted strongly by Guidelines from Great Britain, Europe, Spain, Australia, and New Zealand. There are no US Guidelines, but the Bronchiectasis Research Registry (of which I am a board member and includes experts throughout the US) actively promotes ACT and further study of ACT.	*For bronchiectasis, our review included evidence-based guidelines and recommendations from the European Respiratory Society and the American College of Chest Physicians.*

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B5	In US bronchiectasis centers, HFCWO is the 2nd most utilized ACT modality. Chest physical therapy (CPT) is rarely practiced (4). The Guidelines from abroad do not focus on HFCWO because they have a long tradition of encouraging traditional CPT (patient positioning and chest percussion) through specialized physiatry services. CPT is labor intensive and the positioning can be uncomfortable for some patients. HFCWO mimics percussion in a more gentle and concerted fashion. Some types of HFCWO (battery generated) allow movement away from a fixed source and patients do not need a companion or professional assistant (Respiratory or Physical Therapist).	*The Basavaraj et al., 2020 publication cited here was not eligible for inclusion in the coverage guidance due to the study's noncomparative observational retrospective design. Additionally, very few of the participants in this study (N = 51) used HFCWO devices and only two-thirds of those participants were included in the follow-up (N = 34).* *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.*
B6	HFCWO is approved for cystic fibrosis (CF). The airway condition in CF IS bronchiectasis. CF is now an adult disease and has many similarities to (non-CF) bronchiectasis	*Our review found insufficient evidence that HFCWO device therapy reduces exacerbations and hospitalizations for conditions other than cystic fibrosis.*
B7	The FDA now promotes patient centered outcomes in diseases. There are well-studied and established HRQL instruments in bronchiectasis including SGRQ, QOL-B, LQ, and CAT. They have been used and can be followed during management including ACT in bronchiectasis (5).	*The De la Rosa Carrillo et al., 2020 publication cited here did not meet inclusion criteria for the coverage guidance due to its noncomparative observational design. The primary purpose of the publication was to validate the COPD assessment tool (CAT) for use in patients with bronchiectasis, and this publication may be helpful for researchers planning clinical trials.*

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B8	Most importantly each patient adapts, finds efficacy, and tolerates various forms of ACT. Although many can utilize directed coughing, or positive expiratory pressure (PEP) devices, elderly patients (average age bronchiectasis patients-63) with substantial co-morbidities may not tolerate or even perform directed coughing or PEP. HFCWO may be more effective, comfortable, and tolerable. Use of HFCWO fits into the principle of personal and collaborative management and furthering education that include regular exercise, pulmonary rehabilitation, maintaining a healthy diet, and on-going learning that are key to chronic disease management including bronchiectasis (6).	*Thank you for providing important context for the subcommittee's deliberation.*
C1	I am a clinician with experience and expertise in the area of Cystic Fibrosis (CF) as well as non-CF bronchiectasis. I am concerned that Health Evidence Review Commission is proposing a guideline for patients with non-CF bronchiectasis involving High Frequency Chest Wall Oscillating Vests (HFCWO vests) for airway clearance therapy (ACT) which burdens patients with an appeals process to secure coverage for this therapy. While data supporting the use of ACT techniques and devices is better in CF than in non-CF bronchiectasis, even in CF, the data supporting its use is weak and of low quality. However, the use of ACT remains central to the treatment of both CF and non-CF bronchiectasis, and effective adherence to ACT is widely considered to be among the most important factors in patient outcomes, including exacerbation/hospitalization frequency and even mortality.	*Thank you for providing your expertise for this coverage guidance report. The health equity concerns you outline will be important considerations for subcommittee discussion.*
C2	The reasons for the low quality and quantity of data for ACT likely stem, at least in part, from need for personalization of ACT technique to the individual patient, as different methods of ACT may have variable efficacy for each patient. HFCWO vests are important tools as they do not require the use of a caregiver (manual chest PT requires 40-60 minutes a day of high-intensity manual therapy from a caregiver) and produce more force transmitted through the airway than active-ACT devices such as positive expiratory pressure devices and autogenic drainage.	*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.*

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C3	I am particularly concerned that the current planned recommendation of the HERC places the burden of appeal on the individual patient, which will lead to disparities of care. The most common cause of clinically significant bronchiectasis is prior severe infection with organisms such as TB, which disproportionally affects vulnerable individuals, such as those with low socioeconomic status and/or those who have immigrated from developing countries. These individuals are more likely to have language and cultural barriers making it unacceptably difficult to obtain an exception to allow coverage for HFCWO devices. These individuals are also more likely to need access to effective independent ACT therapy options.	*The health equity concerns you outline will be important considerations for subcommittee discussion.*
C4	I urge the HERC to recommend that individuals with non-CF bronchiectasis with clinically active/severe disease (as defined by the HERC; i.e. frequent exacerbations, declining lung function, etc.) be allowed access to HFCWO devices. Note, the vast minority of individuals with the diagnosis of bronchiectasis have clinically active/severe disease. The diagnosis is frequently given to individuals based on imaging, but these clinical criteria are rarely met.	*Thank you for providing important context for the subcommittee's deliberation.*

References Provided by Commenters

ID	References
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