Medical Policy

Subject:	Intrapulmonary Percussive Ventilation Devices		
Document #:	DME.00012	**Publish Date:**	10/01/2024
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Description/Scope

This document addresses the use of intrapulmonary percussive ventilation devices (IPV) (such as the Percussionaire® family of devices and the Volara™ System) as an alternative to conventional chest physical therapy to promote the clearance of respiratory secretions in individuals with impaired ability to cough or otherwise expel them on their own.

Note: Other types of mucous clearance systems are not addressed within this document (for example, the Flutter® Mucous Clearance System, the Acapella® Vibratory PEP Therapy System, etc.).

Note: For information regarding high frequency chest compression devices, please refer to:

- CG-DME-43 High Frequency Chest Compression Devices for Airway Clearance

Position Statement

Investigational and Not Medically Necessary:

Intrapulmonary percussive ventilation devices are considered **investigational and not medically necessary** for all indications, including but not limited to the following:

- Cystic fibrosis; **or**
- Bronchiectasis; **or**
- Chronic obstructive pulmonary disease; **or**
- Neuromuscular conditions associated with retained airway secretions or atelectasis.

Rationale

Chest physiotherapy (CPT), which is also known as percussion and postural drainage (P/PD), is traditionally seen as the standard of care of secretion clearance methods for individuals with excessive or retained lung secretions.

IPV devices have been investigated as an alternative to standard CPT and P/PD with or without manual vibration, with most studies having been in individuals with a diagnosis of cystic fibrosis (CF). Multiple IPV devices have been cleared by the FDA for similar indications, including the mobilization of endobronchial secretions. However, there is limited published data by which to establish the effectiveness of IPV as a beneficial modality for airway clearance. In the available studies, the numbers of participants have been small, the study populations different, and the treatment settings different (in-hospital versus outpatient). Also, outcome measurements differed among the studies, including factors such as sputum volume, sputum viscosity, pulmonary function data or radiographic changes, depending on the study design and study population. The studies that compare IPV to different alternative

airway clearance modalities, (for example, Flutter valve, and/or high frequency chest compression [HFCC] device, and/or standard CPT and P/PD), are inconclusive.

Lauwers and colleagues (2018) conducted a systematic review on the effect of IPV in pediatric individuals. The researchers included trials through January 2018 in which individuals who were younger than18 years old and had a respiratory disease requiring airway clearance. A total of nine articles (n=277) met the inclusion criteria (four randomized controlled trials, two randomized crossover trials, one prospective cohort study, and three retrospective studies; one article contained both a randomized controlled trial and a retrospective study). Due to the heterogeneity of the studies, the researchers were not able to conduct a meta-analysis. After a qualitative synthesis, the researchers concluded that IPV appears to be a safe and effective technique for airway clearance in pediatric individuals, with the most promising results found in those with atelectasis, neurological/neuromuscular diseases, and acute bronchiolitis. For clinically stable cystic fibrosis, the researchers did not find enough evidence to support IPV over conventional CPT. Because the available research is limited and the sample sizes are small, the researchers noted that the conclusions should be interpreted with caution. They recommended further research.

In 2018, Nicolini and others reported the results of a single-blind randomized clinical trial involving 60 participants with severe chronic obstructive pulmonary disease (COPD). Participants were assigned to one of three groups: 1) IPV with P/PD, 2) high-frequency chest wall oscillation (HFCWO) with P/PD, and 3) P/PD alone. Participants were treated for a period of 2 weeks and evaluated 1 week after completion. Compared to the control group, both IPV and HFCWO significantly improved scores on the Breathlessness, Cough and Sputum scale (BCSS), modified Medical Research Council (mMRC) scale and COPD Assessment Test (CAT) (no p-values provided). When compared to HFCWO, IPV resulted in significantly better scores on the BCSS and CAT scales ($p<0.001$ and $p<0.02$, respectively). Additionally, IPV improved total lung capacity (TLC, $p<0.03$) and TLC% ($p<0.04$), residual volume (RV) and RV% ($p<0.04$ for both), and diffusing lung capacity monoxide (DLCO), maximal inspiratory pressure (MIP), and maximal expiratory pressure (MEP; $p<0.01$ for all). No COPD exacerbations were reported during the study period. While the results of the study are promising, data from larger trials of longer duration are warranted to better understand the durability of the findings, including evaluation of net health outcomes. Use of a sham control group is important to assess the impact of participant measures such as dyspnea.

In 2019 Huynh and colleagues described the results of a non-randomized trial. The study reported the results of IPV therapy for individuals at high risk of pulmonary complications after thoracic, upper abdominal, or open aortic surgery. Participants needed to have no history of major pulmonary disease . A total of 210 historical controls who were treated postoperatively with standard care were compared to 209 participants who were treated with IPV therapy postoperatively using the Hill-Rom MetaNeb® System. All participants were followed for a total of 7 days postoperatively. Participants in the IPV arm were significantly older and had higher risk of complications than controls based on American Society of Anesthesiologists (ASA) risk scores ($p<0.05$ for both). The rate of postoperative pulmonary complications was not significantly different between groups in unadjusted analysis ($p=0.06$), however, after adjusting for age, risk, and operative procedure duration a significant difference was reported (n=48 vs. 33, $p=0.007$). The number of participants requiring high level respiratory support decreased from 12.9% to 11.5% between groups, but this difference was not statistically significant. Similarly, no significant differences were reported with regard to the number of participants with ≥ 2 postoperative pulmonary complications, rates of pneumonia, or ICU admissions. The authors reported that a significant reduction in ICU

admissions or transfers to higher levels of care were noted between groups in participants with ASA risk scores of 4 and 5 (p=0.02). Additionally, mean reduction in time to initial extubation and total time on mechanical ventilation were both significantly decreased in the IPV group compared to controls (p<0.02 for both). The results of this trial indicate some promise for the postoperative use of IPV in individuals with high risk of pulmonary complications. However, additional data is needed to further evaluate the potential benefits and to identify the appropriate populations who might benefit from this treatment..

Hassan and colleagues (2021b) conducted a retrospective pilot study to investigate the safety and effectiveness of IPV in non-ventilated individuals in critical care. A total of 22 participants who received IPV intervention were compared with 13 participants who received chest physiotherapy (CPT). The 2 cohorts were matched for age, sex and primary diagnosis. IPV intervention was delivered using the Hill-Rom MetaNeb System. Medical records were evaluated for the feasibility of IPV application, safety, changes in oxygen saturation, chest X-ray changes, and intensive care unit length of stay. There were no differences in intensive care unit length of stay or peripheral oxygen saturation between the IPV and CPT groups. A higher percentage of individuals the IPV group had lower radiological atelectasis scores post-intervention compared to those the CPT group. Individuals receiving IPV had no adverse events. The authors concluded that IPV was feasible and safe to administer. They also concluded that an adequately powered randomized control trial will be needed to properly assess effectiveness outcomes. The study did not show that use of IPV is associated with improvement of patient-centered health outcomes.

Hassan and colleagues (2021a) also reported on a systematic review of the effect of IPV on ICU length of stay (ICU-LOS), the incidence of pneumonia, and gas exchange in critically ill patients. Studies were included in the review if they examined the effectiveness of IPV in individuals greater than16 years old who received invasive or non-invasive ventilation or were breathing spontaneously while being treated in critical care for acute or acute-on-chronic respiratory dysfunction. Seven studies involving a total of 630 participants met the eligibility criteria. Of these studies, four were randomized controlled trials (RCT), one used a historical control group, and two were prospective observational studies. IPV was delivered by Percussionaire device or Hill-Rom MetaNeb System. The reported outcomes were ICU-LOS, incidence of pneumonia, changes in PaO_2, ratio of the partial pressure of arterial oxygen and fraction of inspired oxygen (PaO_2/FiO_2), $PaCO_2$, and respiratory rate. The Physiotherapy Evidence Database (PEDro) scale was used to measure the quality of all the included studies, allowing assessment of 10 different domains that affect study quality. Using the PEDro scale, the quality of the studies ranged from "poor" to "good." Overall, the authors concluded that "the evidence to support the role of IPV in reducing ICU-LOS, improving gas exchange, and reducing respiratory rate is weak. The therapeutic value of IPV in airway clearance, preventing pneumonia, and treating pulmonary atelectasis requires further investigation."

In the American College of Chest Physicians (ACCP) Evidence-Based Clinical Practice Guidelines on Nonpharmacologic Airway Clearance Therapies (McCool, 2006), the ACCP determined that the evidence supporting the use of oscillatory devices, including IPV, in the treatment of individuals with CF was low, and the reported benefits were conflicting.

The Cystic Fibrosis Foundation commissioned a systematic review to examine the evidence surrounding the use of airway clearance therapies (ACTs) for treating CF. Seven unique reviews and 13 additional controlled trials were deemed eligible for inclusion. Recommendations for use of the ACTs were made, balancing the quality of evidence and the potential harms and benefits. The committee determined that:

> Although there is a paucity of controlled trials that assess the long-term effects of ACTs, the evidence quality overall for their use in CF is fair and the benefit is moderate… There are no ACTs demonstrated to be superior to others, so the prescription of ACTs should be individualized (Flume, 2009).

In a clinical practice guideline from the American Association for Respiratory Care (AARC) on the effectiveness of nonpharmacologic airway clearance therapies (Strickland, 2013), the investigators state that IPV cannot be recommended due to insufficient evidence.

The limited data that is available suggests that IPV does not produce a superior outcome compared to standard CPT and P/PD, an HFCC device, or a Flutter valve device. Based on the lack of scientific data demonstrating its effectiveness and equivalence or superiority to established treatments, IPV is considered investigational and not medically necessary as an airway clearance modality.

Finally, the use of IPV devices for indications not related to airway clearance has not been adequately described in any well-designed trials the published peer-reviewed literature. Thus, such use is also considered investigational and not medically necessary.

Background/Overview

Intrapulmonary Percussive Ventilation (IPV) devices are a type of pneumatic, oscillating pressure breathing device that is designed to loosen mucus by internally percussing the airways using high frequency, high flow, and low pressure bursts of gas delivered via a mouthpiece, mask or endotracheal tube. The user actuates a thumb control to trigger 15 to 25 high frequency pulses of air during inspiration and releases the control to allow for passive exhalation. Airway pressures oscillate between 5 and 35 cm H_2O, and the walls of the airways vibrate synchronously with these oscillations. A Venturi type system, powered by compressed gas, generates the oscillations at a rate of 100 to 300 cycles per minute. Pressures, inspiratory time, and delivery rates are adjustable. Additionally, some devices are designed to deliver aerosolized medications, such as bronchodilators and mucolytics, as well as other pulmonary therapies such as bi-level positive airway pressure (BiPAP) and continuous positive expiratory pressure (CPEP). The clinical utility of the device is purportedly to loosen retained secretions by means of these airway oscillations, and it has been investigated in the treatment of individuals suffering from secretion retention (particularly that associated with CF), as well as atelectasis.

There are several devices with IPV capability currently available on the market, including the Volara™ System (Hill-Rom Services, Inc., Chicago, IL), and multiple Sentec, Inc. products (Lincoln, RI) including the Bronchotron® Transport, Impulsator®, IPV®-1C, IPV®-2C, Phasitron®, Travel Air®, TXP®5, and the VDR®-4.

Definitions

Bronchiectasis: A disorder of major bronchi and bronchioles characterized by abnormal airway dilatation and destruction of walls with resulting inflammation, edema, ulceration, and distortion. When large, unusual spaces are formed inside the airways of the lungs, mucus secretions can collect in these spaces and be difficult to clear. This can often lead to more infections and further lung damage, most commonly from infection or recurrent inflammation. Bronchiectasis can also be acquired from a tumor, inhaling a foreign object, or from a congenital condition.

Bronchitis: An inflammation of the upper airways associated with cough and mucus. It can be caused by infections (infectious bronchitis) or inflammation (smoker's cough). Chronic bronchitis means that over the last 2 or more years, a person has been coughing up some mucus every day for at least 3 months out of the year.

Chest physiotherapy (CPT) (also known as chest physical therapy): The use of postural drainage, percussion, and vibration (PDPV) for airway clearance, which may also be referred to as percussion and postural drainage (P/PD). CPT is considered the standard of care of secretion clearance methods. This technique is time consuming, requires a skilled care provider and may be associated with discomfort, gastroesophageal reflux, and hypoxemia. The purpose of CPT is to improve mucociliary clearance and pulmonary function in order to reduce the risk of infection and lung damage.

Cystic fibrosis (CF): An autosomal recessive condition, the pulmonary manifestations of which include the production of excessive tenacious tracheobronchial mucus, leading to airway obstruction and secondary infection. This is the principal cause of morbidity and mortality associated with CF.

Intrapulmonary Percussive Ventilation (IPV): A treatment designed to promote mobilization of retained endobronchial secretions and resolution of diffuse patchy atelectasis (areas of partial lung collapse/dysfunction). IPV delivers a series of pressurized mini-bursts of inhaled air and continuous therapeutic aerosol through a nebulizer. IPV users breathe through a mouthpiece and then cough to clear the loosened secretions.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time for service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

HCPCS	
A7021	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)
E0469	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device
E0481	Intrapulmonary percussive ventilation system and related accessories

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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13. Nicolini A, Grecchi B, Ferrari-Bravo M, Barlascini C. Safety and effectiveness of the high-frequency chest wall oscillation vs intrapulmonary percussive ventilation in patients with severe COPD. Int J Chron Obstruct Pulmon Dis. 2018; 13:617-625.
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15. Toussaint M, De Win H, Steens M, Soudon P. Effect of intrapulmonary percussive ventilation on mucus clearance in Duchene muscular dystrophy patients: a preliminary report. Respir Care. 2003; 48(10):940-947.

16. Varekojis SM, Douce FH, Flucke RL, et al. A comparison of the therapeutic effectiveness of and preference for postural drainage and percussion, intrapulmonary percussive ventilation, and high-frequency chest wall compression in hospitalized cystic fibrosis patients. Respir Care. 2003; 48(1):24-28.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Centers for Medicare and Medicaid Services. National Coverage Determination for Intrapulmonary Percussive Ventilator. NCD #240.5. Effective date: July 14, 1997. Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=229&ncdver=1&bc=AAAAgAAAAAAA&. Accessed on March 12, 2024.
2. Finder JD, Birnkrant D, Carl J, et al.; American Thoracic Society. Respiratory care of the patient with Duchenne muscular dystrophy: ATS consensus statement. Am J Respir Crit Care Med. 2004; 170(4):456-465.
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Websites for Additional Information

1. Cystic Fibrosis Foundation. Available at: www.cff.org. Accessed on March 12, 2024.

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Bronchotron Transport
Impulsator
Intrapulmonary Percussive Ventilation (IPV)
IPV-1C
IPV®-2C,
Percussionaire Device

Travel Air
TXP5
VDR-4
Volara System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
	10/01/2024	Updated Coding section with 10/01/2024 HCPCS changes, added A7021 and E0469 replacing NOC code.
Reviewed	05/09/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Rationale, Background/Overview, References and Websites for Additional Information sections.
Reviewed	05/11/2023	MPTAC review. Updated References and Websites for Additional Information sections.
Reviewed	05/12/2022	MPTAC review. Updated Rationale and References sections.
Revised	05/13/2021	MPTAC review. Revised Title to remove "for airway clearance". Clarified Position Statement. Updated Description/Scope, Background, Coding, References, and Index sections.
Reviewed	08/13/2020	MPTAC review. Rationale, References and Websites sections updated.
Reviewed	08/22/2019	MPTAC review. References and Websites sections updated.
Reviewed	11/08/2018	MPTAC review. Rationale, Background/Overview, References, and Websites sections updated.
Revised	01/25/2018	MPTAC review. Moved content related to HFCC Devices to new document CG-DME-43 "High Frequency Chest Compression Devices for Airway Clearance." The document header wording updated from "Current Effective Date" to "Publish Date." Description/Scope, Definitions, Coding, References, and Websites sections updated.
Revised	02/02/2017	MPTAC review. Updated formatting in Position Statement section. Updated References section.
Reviewed	02/04/2016	MPTAC review. References were updated. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Reference and Index sections.
Reviewed	02/13/2014	MPTAC review. Updated Reference and Index sections.
Reviewed	02/14/2013	MPTAC review. The Rationale, Background, and References were updated.
Reviewed	02/16/2012	MPTAC review. References were updated.
Revised	02/17/2011	MPTAC review. Age criteria of 2 years and older was removed for HFCC devices. A not medically necessary statement was added regarding device

		replacement/upgrade. The title was revised to remove brand names. The Rationale and References were updated.
Reviewed	02/25/2010	MPTAC review. The Rationale, Background, Definitions and References were updated.
Revised	02/26/2009	MPTAC review. No change to the actual medical necessity criteria but the language of the reporting requirement to demonstrate compliance with device use was clarified. The Coding section was updated. Definitions and References were also updated.
Reviewed	02/21/2008	MPTAC review. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting. References were updated.
Reviewed	03/08/2007	MPTAC review. The Rationale and References sections were updated.
Reviewed	03/23/2006	MPTAC review. References were updated to include the AARC Clinical Practice Guideline: Postural Drainage Therapy.
Revised	04/28/2005	MPTAC review. Revised document: High Frequency Chest Compression Devices revised based on Pre-merger Anthem and Pre-merger WellPoint Harmonization. Position statement revised to include Intrapulmonary Percussive Ventilation (IPV); removed HCPCS codes S8200 and S8205 (deleted 01/01/2003) Updated coding: Added ICD-9 codes 335.10-335.19, 335.20-335.29, 358.0-359.9, 359.0-359.9, 494.0-494.1

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	03/20/2003	DME.00012	High Frequency Chest Compression Devices
WellPoint Health Networks, Inc	12/02/2004	2.05.02	High-Frequency Chest Wall Compression