

February 2021

INSIDE THIS ISSUE

CHEST-Hosted TEP Meeting to Yield Consensus Paper on Noninvasive Ventilation

TEP Overview

Perspectives From TEP Participants

Webinar discusses recent changes in Physician Fee Schedule Final Rule

Conference Tackles Current Issues in Health Policy and Advocacy

CHEST Collaborations Address Clinician Issues in Multiple Areas

CHEST Analytics Offers Clinical Trials Matching Service

HPAC Continues Planning for Future of Advocacy at CHEST

Staffing Support Available Through CHEST Program

Be sure to check [chestnet.org](https://www.chestnet.org) and *CHEST Today* for COVID-19 related education, practice, and regulatory updates.

CHEST-HOSTED TEP MEETING TO YIELD CONSENSUS PAPER ON NONINVASIVE VENTILATION

As described in the August and October issues of *Washington Watchline*, a virtual meeting of a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) panel led to a CHEST-hosted Technical Expert Panel (TEP) on home use of noninvasive positive pressure ventilation in early October.

Central to the message of the MEDCAC meeting was that any comprehensive policy addressing home mechanical ventilation requires additional review to address all the relevant disease states, as well as the appropriate devices to support the affected patients and their caregivers. Encouraged by the proceedings of the MEDCAC, CHEST formed a coalition with the American Academy of Sleep Medicine (AASM), the American Association for Respiratory Care (AARC), and the American Thoracic Society (ATS) to create an external TEP.

Under the leadership of Peter Gay, MD, FCCP, and Robert Owens, MD, the expert panel is now in the process of developing a clinically relevant consensus paper for submission to a peer-reviewed journal, along with an executive summary and an outline of clinical pathways related to this issue. The group's hope is that through communication of clear, objective clinical practice guidance and participation with CMS in outlining goals of improved patient care, an updated and relevant coverage document can be created in this most important area of patient and clinical need.

Perspectives from TEP participants shared inside this issue of Washington Watchline.

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Consultant

TEP OVERVIEW

Drs. Gay and Owens led a group of thought leaders in this space during a two-day session in October. The participants were organized and convened to discuss the following five clinical areas:

- **Bilevel transition from CPAP**—When therapeutic benefit was not achieved
Chair/Co-chair: Nancy Collop and Susheel Patil
Committee: Eric Olson, Praveen Vohra, and Alex Chediak
- **Hypoventilation syndrome**
Chair/Co-chair: Babak Mokhlesi and Christine Won
Committee: Bernardo Selim, Barry Make, and Bernie Sunwoo
- **Restrictive thoracic disorders**
Chair/Co-chair: Lisa Wolfe and Josh Benditt
Committee: Loutfi Aboussouan, John Coleman, and Dean Hess
- **Central/complex sleep apnea**
Chair/Co-chair: Tim Morgenthaler and Atul Malhotra
Committee: Karin Johnson and Marc Raphaelson
- **Severe COPD**
Chair/Co-chair: Nick Hill and Jerry Criner
Committee: Neil MacIntyre, Richard Branson, Bart Celli, and Amen Sergrew

On the first day, the individual panel members presented their initial comments for discussion by the panel as a whole in each of the clinical areas. Edited comments were presented the following day for additional discussion in an attempt to reach a clinical consensus.

External presenters were also allowed to make a formal presentation to the TEP on the first day followed by questions and discussion. Presentations were given by John Cronin, MD, for Philips Healthcare; Louis Libby, MD, for ALS Association; Carlos Urrea, MD, MPH, for Hillrom; Carlos Nunez, MD, for ResMed; Kathy Lester for Council for Quality Respiratory Care, and Thomas Ryan for American Association for Homecare.

In addition to the panel and external presenters, 35 observers joined the virtual meeting. The group included representatives from CMS, the device manufacturing industry, and home medical equipment providers, among others. Several participants were invited by *Washington Watchline* to share their perspectives about the unique event. Their comments appear in the accompanying callout box.

PERSPECTIVES FROM TEP PARTICIPANTS

From Robert Owens, MD, and Peter Gay, MD, FCCP:

Patients who require noninvasive ventilation are medically complex and struggle with severe nocturnal sleep-disordered breathing disorders. Unfortunately, clinicians who care for such patients often face additional hurdles when trying to get patients the ventilator devices they need and regulations have not been updated to reflect new science and technologic advances.

In addition to noninvasive ventilation for COPD and neuromuscular disease, the panel also addressed patients with obesity-related hypoventilation, CPAP-intolerant obstructive sleep apnea, and central sleep apnea. While the TEP members were the expert clinicians, the summit also included viewpoints from representatives of industry and durable medical equipment companies who provided valuable input, and it was attended by members from CMS.

The overarching goal is to formulate recommendations that will allow the “right device to the right patient at the right time.” The TEP has met regularly to continue to refine its ideas and policies, which we hope will ultimately influence payors via updated national coverage determinations. Our executive summary and constituent documents are being drafted and will be reviewed for publication shortly. While focused on ventilation for a variety of disorders, the structure and purpose of the TEP may be a model for future advocacy and change.

From the American Association for Homecare: AAHomecare appreciates CHEST’s leadership in bringing together clinician and respiratory therapy stakeholders to develop policy recommendations for home-based noninvasive ventilators (NIV). The presentations and discussion at the October 2020 Technical Expert Panel on NIV demonstrated the high degree of clinical knowledge and commitment to improving standards of patient care of the groups involved in the process. AAHomecare supports efforts to reach a durable consensus on policies to ensure the best outcomes for patients utilizing NIV or other respiratory therapies. We believe that such policies should: 1) be driven by patients’ needs over cost considerations; 2) maintain a single NCD for NIVs; 3) include clear and objective clinical criteria for using NIV, including specific testing criteria for beneficiaries to qualify for NIV therapy and separate criteria for utilizing other treatments; and 4) employ a uniform Clinical Data Elements (CDE) format to capture objective criteria for treatment. AAHomecare looks forward to continuing to work with CHEST and the organizations sharing their expertise to the benefit of individuals who require respiratory support.

From the Council for Quality Respiratory Care: CQRC appreciates CHEST’s efforts to provide clinical guidance to physicians prescribing access to noninvasive ventilators (NIV) to patients. As the pandemic has demonstrated, patient access to NIV is essential to protect patients and address public health infrastructure challenges. This clinical clarity

should support individualized shared decision-making between physicians and patients and avoid cost considerations. Any coverage decision should be developed in partnership with patients, suppliers, caregivers, and manufacturers, as well, to ensure that documentation requirements do not create barriers to patient access. CQRC believes coverage criteria should be:

- Clearly defined and based on objective, clinically appropriate tests.
- Avoiding “tried and failed” language, so patients do not endure ineffective treatments.
- Practical to obtain and not limited to a single care setting.
- Avoiding requiring physicians sharing patient medical records with the government.
- Not including “usage” requirements but permitting flexibility to meet individual patient needs.
- Addressing noninvasive ventilators and respiratory assist devices separately.

From ResMed: ResMed sincerely appreciates CHEST’s convening of this Technical Expert Panel to develop clinical consensus recommendations on noninvasive ventilation outside of the hospital. CHEST’s willingness to lead this discussion and gather a distinguished group of physicians, stakeholders, and industry leaders to tackle these issues is vital to protect patient access and drive improved quality of care in the home. We relay our utmost thanks to the panel and co-chairs, Drs. Peter Gay and Robert Owens, for the invitation to participate in this robust discussion, and reiterate our support for policies that are not administratively burdensome, maintain objective criteria, and enable physician flexibility and clinical decision making. ResMed looks forward to the continued partnership between patients, suppliers, clinicians, and manufacturers as we work to ensure patients have access to the right device at the right time, as determined clinically appropriate by their physician.

From Hillrom: Hillrom appreciates the opportunity to provide feedback on this important coverage development process. We value the transparency, inclusion of diverse perspectives, and the careful consideration of critical factors impacting patients and relevant stakeholders. We acknowledge the important role we play in the revision process of current CMS regulations for home mechanical ventilation. As both a medical device manufacturer and a direct patient provider, Hillrom’s input throughout this process was intended to provide technical and regulatory considerations, as well as real-world experience in the utilization of noninvasive ventilation at home. Our recommendations were rooted in evidenced-based clinical practice, clinical studies, and patient experiences. With the overarching goal of improving patient care for all, our hope is that consideration is also given to those patients with specific clinical and lifestyle needs where specific therapy modalities, such as mobile noninvasive ventilation, are also included.

WEBINAR DISCUSSES RECENT CHANGES IN PHYSICIAN FEE SCHEDULE FINAL RULE

CHEST and ATS offered a joint [webinar](#) that explained key policies finalized in the [CMS 2021 Medicare Physician Fee Schedule](#).

The final rule incorporates many important coding, billing, and documentation changes that will affect pulmonary, critical care, and sleep medicine providers.

In response to targeted communication from specialty societies, including CHEST, whose members’ reimbursement levels were proposed to be cut despite increased demands due to the COVID-19 pandemic, lawmakers ultimately gave providers an across-the-board 3.75% increase for 2021. The webinar covered topics such as payment increases for outpatient E/M services, how to use new E/M documentation guidelines, COVID public health emergency considerations, provision of virtual medical services, and more.

Additional information on coding changes will be presented at the [CHEST Health Policy and Advocacy Conference](#) on March 23 and 25.

HPAC CONTINUES PLANNING FOR FUTURE OF ADVOCACY AT CHEST

The Health Policy and Advocacy Committee (HPAC), Executive Leadership team, and the Presidents of CHEST met in November in a strategic planning session to collectively discuss the group’s recent and future activities.

There was strong agreement that the efforts since the completion of the NAMDRC acquisition have outpaced the initial expectations. The group described themselves as being on an incredibly vertical trajectory in the advocacy space. Several factors have led to this:

1. CMS prioritization of the issues of noninvasive ventilation and “home” oxygen access, both of which are among HPAC policy priorities.
2. COVID-19 and the national health emergency thrusting pulmonary medicine and critical care into the public’s awareness.
3. The recognition and progress in development of meaningful and effective partnerships with other organizations and stakeholders with common concerns.

As a result of this strategic planning session, in addition to continued efforts in the five priority areas the group has identified, HPAC will address the broader issues of:

- Best governance structure to support this function within CHEST.
- Best staffing model.
- Effective communication of HPAC’s efforts.

CHEST COLLABORATIONS ADDRESS CLINICIAN ISSUES IN MULTIPLE AREAS

CHEST's commitment to collaborate with many different organizations on multiple issues of importance to pulmonary, critical care, and sleep medicine has resulted in a number of joint activities and statements recently. Of special interest are the following:

Joint Statement of the Critical Care Societies Collaborative to the Trump Administration, President-elect Biden's COVID-19 Taskforce, Congressional Leadership, & State Governors on Distribution of Personal Protective Equipment (PPE) and Allocation of Other Resources: On November 16, 2020, CHEST joined the American Association of Critical-Care Nurses (AACN), American Thoracic Society (ATS), and the Society of Critical Care Medicine (SCCM), collectively the CCSC, to urge for a national plan addressing three aspects of patient care and public health to ensure an effective response to curb COVID-19 transmission: 1) provision of appropriate personal protective equipment; 2) equitable allocation of other resources, including ventilators, medication, vaccines, and staff; and 3) a commitment to basic health measures that disrupt the transmission of the virus. Read the entire statement [here](#).

Campaign for Tobacco-Free Kids Call for Prohibition of Menthol Flavoring: In a [letter](#) to FDA Commissioner Stephen Hahn, CHEST voiced support for the Campaign for Tobacco-Free Kids' call to prohibit menthol as a characterizing flavor in cigarettes and endorses the need for action on the related citizen petition (FDA-2013-P-0435-0001). The letter continues, "As stated in the FDA's own scientific analysis and the Tobacco Products Scientific Advisory Committee (TPSAC) report, menthol cigarettes pose a public health risk even greater than that seen with nonmenthol cigarettes. Studies on menthol cigarettes have repeatedly shown that flavoring increases the initiation of smoking among young people. This preference increases with Black youth smokers, an ongoing disparity, with menthol cigarettes taking a disproportionately high toll of disease and death in the African American community."

National Lung Health Organizations' Joint Public Statement Regarding COVID-19 Vaccine: The American Lung Association, American Thoracic Society, and CHEST issued a joint [statement](#) to the public on December 4 in advance of the holiday season calling for widespread adoption of the COVID-19 vaccine to ensure the public health protections needed to end the pandemic. They emphasized that even after a safe and effective vaccine is available, it is critical for all Americans to protect their health and that of their community by continuing to follow public health guidance. This

includes wearing a mask, physically distancing, and washing hands thoroughly until enough of the US population is vaccinated to stop the spread of the virus.

AMA House of Delegates' Special Meeting: N. R. Desai, MD, MBA, FCCP, CHEST's delegate to the American Medical Association House of Delegates (HOD), provided a [report](#) on their virtual special meeting of November 20 at which more than 170 societies were represented. As the principal policy-making body of the AMA, the House has guided AMA's efforts during the COVID-19 epidemic as the leading physician and patient ally—voicing recommendations to key Congressional leaders and agency staff, state policymakers, and private sector stakeholders. Acting on both federal and state levels, examples of AMA's recent efforts include actions in financial relief, telehealth, testing and vaccine development, health equity, and more.

Due to the virtual nature of the meeting, resolutions coming forth from reference committees were prioritized for discussion. The Constitution & Bylaws, Medical Service, Legislation, Medical Education, Public Health, Science and Technology, Finance, and Medical Practice committees met. Some of the issues addressed by the complete House of Delegates related to continuing board certification; graduate medical education; bullying in the practice of medicine; availability of personal protective equipment; establishment of a private practice physicians' section; merit-based incentive pay systems; and establishing professional services claims-based payment enhancement for activities associated with the COVID-19 pandemic.

CHEST members who are interested in observing or participating in AMA HOD activities are encouraged to contact Jenny Nemkovich jnemkovich@chestnet.org for information.



CONFERENCE TACKLES CURRENT ISSUES IN HEALTH POLICY AND ADVOCACY

Join CHEST for a two-session Health Policy and Advocacy Conference chaired by Neil S. Freedman, MD, FCCP and Kathleen F. Sarmiento, MD. The free conference will provide an outstanding overview of current issues related to pulmonary, critical care, and sleep medicine.

Presentation topics include:

- perspectives on how health policy will likely change with the new administration; and
- an overview of health care disparities in the management of sleep disorders and approaches to improve outcomes for at-risk groups.

Updates to relevant topics that affect our patients and practices will be covered, including:

- coding and reimbursement;
- changes in oxygen access, delivery, technology, and patient education;
- multisociety efforts to improve access to home mechanical ventilation, noninvasive ventilation, and other PAP therapies for OSA and complex patients; and
- the current and future roles of telemedicine in the management of pulmonary, critical care, and sleep medicine.

Mark your calendar now:

Health Policy and Advocacy Conference

Tuesday, March 23 and Thursday, March 25, 2021 | 5 pm - 7 pm CT

Presentations will be interactive and delivered in several formats, including expert panel discussions, multidisciplinary roundtable discussions, and interactive didactic lectures.

Both live sessions will be recorded, so if you are unable to attend either of them, the recordings will be made available in the CHEST learning management system for all registered learners for 3 months. CME/CE credits are available. Register [here](#).

CHEST ANALYTICS OFFERS CLINICAL TRIALS MATCHING SERVICE

CHEST Analytics has announced its new resource for members interested in serving as investigators in industry-sponsored clinical trials. The new program, tentatively entitled CHEST Clinical Trials Solutions, will pair members who have indicated their interest in specific research topics with companies seeking investigators. According to CHEST President Steven Q. Simpson, MD, FCCP, "For members who would like to be involved in research and for companies that have defined distinct criteria for their studies, CHEST Analytics can pair qualifying parties to facilitate communication between researcher and sponsor. It's a great way for young investigators to get started or accomplished members to share their experience while helping industry expedite introducing new products that improve patient care." More information regarding enrollment will be available at info.chestnet.org/clinical-trials.

STAFFING SUPPORT AVAILABLE THROUGH CHEST PROGRAM

In support of hospital systems and clinicians who need physician resources as a result of ongoing COVID-19 pressures, CHEST continues to offer the Clinician Matching Network. Hospital systems that have high demand can apply for assistance using the [clinician request form](#). The Clinician Matching Network pairs volunteer physicians with hospitals based on need. This program combines the resources of the American College of Chest Physicians (CHEST), American Association for Respiratory Care (AARC), and American Thoracic Society (ATS), and partners with PA Consulting.