
We have been following and reporting in Ventilator-Assisted Living the unending battle with the Centers for Medicare and Medicaid Services (CMS) to assure that they pay for the correct breathing devices needed in the home by people who are beneficiaries of Medicare and Medicaid. In the case of polio survivors, it is the correct device needed to support their breathing due to respiratory muscle weakness. Historically, polio survivors used negative pressure ventilators (e.g., iron lungs and chest cuirasses) powered by electric motors. Next came the basic volume ventilators (e.g., PLV-100, 102), which replaced the older machines and were used noninvasively by polio survivors experiencing new breathing muscle weakness. With the development of bi-level devices such as the “BiPAP,” offering an inspiratory assist (breath) and a lower pressure assist while breathing out, it was prescribed to many for night-time use. It has not been approved by the FDA for life support or for use with a tracheostomy. Consequently, the machine is less expensive. When deciding payment to home healthcare companies, the CMS logically decided on a lower rate and to not confuse them with a “true vent” that was for life support and more costly, they called them respiratory assist devices (RADs). RADs is a term that is not used by the FDA when approving devices nor a term used by researchers when studying the benefits of the devices. Simply, respiratory assist devices is a term used by CMS and not recognized in the clinical literature.

What happened next: Manufacturers continued to develop more complex machines that could “do everything.” Health professionals in Europe wanted one machine that could be used during the duration of a person’s illness. When the multi-mode devices (e.g. Trilogy, LTV Series, Newport) were approved for payment, the payment code assigned was the one that paid the most because the machine could be used as life support. What happened in reality is that many of the machines were prescribed for conditions that used the CPAP or bi-level mode, which the machine could provide. (The CPAP mode is approved for treatment of obstructive sleep apnea while the bi-level modes are for distinctly different, more problematic scenarios.) Even set at the other modes, the home healthcare companies received the higher payment as if it were for life support.

Another factor in the increase in the use of the code was that it was much easier to medically qualify for the “Cadillac” device than the more appropriate “Chevy/bi-level device.” Additionally, many receiving the devices were diagnosed with COPD, shifting from

**In the case of polio survivors, it is the correct device needed to support their breathing due to respiratory muscle weakness.**
used mostly by individuals with neuromuscular conditions to those with respiratory conditions.

The payment for the E0464 code and combined expenditures skyrocketed 89-fold from 2009-2015 ($3.8 million to $340 million).

CMS noticed.

Their first act, starting January 1, 2016, was to simplify the codes from five to just two. They are E0465 – home ventilator, any type, used with invasive interface, (e.g., tracheostomy tube) and E0466 – home ventilator, any type, used with non-invasive interface, (e.g., mask, chest shell). They lowered the monthly payment to home healthcare companies by about 33%. (A side benefit for ventilator users is that their 20% co-pay is also lowered.) I have not seen data as to the results of this move.

Meanwhile, Phil Porte, Executive Director of National Association for Medical Direction of Respiratory Care (NAMDRC) reported in the March 2016 CHEST Physician that it continues to work with Centers of Medicare and Medicaid (CMS) and interested parties to address issues related to home mechanical ventilation (HMV) and bilevel/RADs (respiratory assist devices).

As NAMDRC explains, Medicare home mechanical ventilation policies are outdated and do not reflect the state-of-the-art standard of care. For example, the Medicare policies have not incorporated the latest thinking (backed by research) on the use of a ventilator using noninvasive ventilation rather than always requiring ventilator use with a tracheostomy.

Additionally, many times they incorrectly interpret the guidelines to mean that a ventilator is only for those in danger of death, aka as the “imminent death requirement.”

For more than two years NAMDRC, with additional help from the American Association of Respiratory Care and the American College of Chest Physicians, has attempted to work with CMS and submitted a reconsideration of the current Medicare National Coverage Determination for home ventilators, including bi-level devices, to CMS. The group presented rationale and documentation and waited and waited.

Just this month, CMS responded saying it will not move forward on the request saying, “As stated in the FR Notice, in the event that we have a large volume of NCD requests for simultaneous review, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources.”

The only recourse is to go to Congress and change the law. That will be a difficult task but necessary. Work has begun. Grassroots assistance will be needed.

To be involved, connect with IVUN at info@ventusers.org and www.ventusers.org or www.ventnews.org.