Submitted via Electronic Mail

November 25, 2016

Ricky Harrison, Jr.
U.S. Government Accountability Office
441 G St., N.W.
Washington, DC 20548

Dear Mr. Harrison;

AAHomecare would like to reiterate our appreciation for allowing us to participate in an interview on disposable medical devices. As the national association representing the durable medical equipment (DME) industry, including all leading manufacturers, we are uniquely capable to provide feedback.

After our discussion, I wanted to provide a summary of our responses to the questions posed as well as attachments on the disposable nebulizer and CPAP replacement device and the CMS regulation from 2011 in which CMS defines durable as meeting a 3-year minimum useful life.

Disposable Products we are aware of:

Provent is used for patients who required CPAP therapy. Initially this was used when patients were traveling and did not want to take along heavy CPAP devices. Over the years the CPAP device has become much more portable and patients tend to travel with these devices.

Aero Go Nebulizer is manufactured by Philips and is currently coded by CMS as A9270, a disposable, non–covered device.

There are many challenges for the Medicare program to set payment rates for disposable devices. Current legislative language indicates setting the rate for disposable devices at 95% of the durable device allowable. AAHomecare recommends that the GAO and CMS step back and relook at how the entire payment rate setting is established.

Current payment rates are set via gap filling methodology. Per our discussion, I have attached an article on how the process works. As one of our members indicated on the call, the concept of pricing new innovative technology by deflating to 1986 pricing and then inflating to get to present day does not work. There is no way to take new and developing technology and equate it to any of the current

Medicare allowables that was developed for predecessor products that are substantively different than the new technology. AAHomecare recommends that the CMS works with industry stakeholders to establish a methodology for pricing of new disposable technology.

One of the challenges under the DMEPOS benefit is the requirements to meet several thresholds established in Medicare Local Coverage Determinations (LCDs) and policy articles. As disposable technology is created, it will need to be considered in the LCDs and articles as well.

In addition to being added to LCDs and articles, there may also need to be factors determined for when to provide a durable versus a disposable product. If disposable products are provided to a patient, are there limitations to the quantity of these products versus a durable product that provides the same clinical benefits?

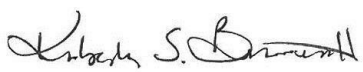
The currently covered disposable Negative Pressure Wound Therapy (NPWT) device is only available via a home health agency. As NPWT requires skilled care, it makes sense to marry the device with the home health agency benefit. For other currently available and innovative products that can replace DME, the benefit needs to be established under the DMEPOS benefit. Skilled service and homebound status requirements under the home health benefit do not lend well to requirements for coverage of other disposable medical devices.

One of the limitations of coverage for disposable products is the establishment of new HCPCS codes to allow for coverage. In recent practice, CMS has been disinclined to create any additional codes. In fact, in recent years CMS has established very few new DMEPOS codes. In addition, the existence of competitive bidding in 130 competitive bid areas throughout the country has added complexity to the creation of additional codes. As an example, a nebulizer, HCPCS code E0570, the most common HCPCS for nebulizers, is included in competitive bidding. If a disposable nebulizer receives a HCPCS code, it would not necessarily be included in competitive bidding. Considerations would have to be made on the impact to access to care given these constraints.

One of the items we discussed on our call was what incentives exist for manufacturers to spend time and money to develop innovative/disposable technologies. Due to the current nature of the benefit and the requirement for a 3-year minimum useful life, manufacturers have not developed disposable technologies. Once a change is made to the benefit to allow for coverage, manufacturers can then take into consideration new disposable technologies.

If durable and disposable devices can be interchanged, they both need to be considered under the DME benefit. AAHomecare looks forward to continued discussions as the study moves forward. Please feel free to reach out to me at (202) 372-0750 or Kimb@aahomecare.org for additional information or discussions.

Sincerely,



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