



VIA Electronic Submission to <http://www.regulations.gov>

September 8, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Room 445-G
Washington, DC 20201

RE: CMS-1631-P, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

Dear Acting Administrator Slavitt:

The American Association for Homecare (AAHomecare) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on the Physician Fee Schedule (PFS) for calendar year (CY) 2016 (the "Proposed Rule").¹ These comments address our concerns with the lack of transparency in pricing for new CPT codes 97607 and 97608 that replaced Healthcare Common Procedure Coding System (HCPCS) codes G0456 and G0457. Physicians use these codes to bill Medicare for therapy rendered using single use, disposable negative pressure wound therapy devices (NPWT). AAHomecare requests that payment rate information for these new CPT codes be made available as it was for their predecessor HCPCS codes, ideally on the MAC websites.

AAHomecare represents durable medical equipment (DME) suppliers, manufacturers, and others in the homecare community that serve the medical needs of millions of Americans

¹ CMS, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, Proposed Rule, CMS-1631-P, 80 Fed. Reg. 41686 (July 15, 2015), available at: <http://www.gpo.gov/fdsys/pkg/FR-2015-07-15/pdf/2015-16875.pdf>.

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who require oxygen systems, wound therapy, medical supplies, inhalation drug therapy, and other medical equipment and services in their homes. In light of our members' expertise and experience, AAHomecare is uniquely qualified to comment on the proposed rule.

We discuss our comments in detail below.

Background

By way of background NPWT is a cutting edge therapy that has revolutionized the way clinicians manage wounds and improved clinical outcomes for Medicare beneficiaries. NPWT devices apply negative pressure suction to complex wounds through a foam or gauze dressing beneath a sealed adhesive film. This technology promotes wound healing through the application of physical force to cells, stimulation of blood flow and removal of exudate. There are over 2,000 published articles describing the clinical effectiveness of NPWT. Wound therapy with NPWT devices is also widely accepted by clinicians as an effective way to reduce complications, promote the development of granulation tissue and simplify the management of complex wounds.

The effectiveness and widespread use of NPWT therapy, has resulted in even greater innovation in this technology leading to the introduction of single-use NPWT devices. One such device is the Smith & Nephew PICO single use NPWT system. Single use NPWT devices are simple to use, portable, and much more affordable than traditional NPWT systems and they have FDA labels that are identical to the labels on NPWT devices. Patient outcomes with single use NPWT compare favorably with those of traditional NPWT. Recent, reproducible clinical observations and a published study show that using the single use wound healing rates are comparable to similar wounds treated with traditional NPWT.² Single use NPWT has proven effective and less costly than therapy with traditional NPWT devices.

Therapy with single use NPWT devices, however, was not designed to replace traditional NPWT in all cases. Single use NPWT devices are appropriate for wounds that are less complex with a wound volume < 300cc, wound depth < 2cm (without a filler) and wound exudate in the low to moderate range. Notwithstanding this more limited clinical criteria, a large number of wound therapy patients qualify for treatment with single use NPWT. In a recent review of a large wound registry database, one manufacturer estimates that as many as 80% of all patients treated with traditional NPWT could have been appropriately treated with single use devices.³ AAHomecare believes that therapy with single use NPWT devices has the potential to lower Medicare program expenditures for care of patients with certain wounds, like diabetic foot ulcers that are common among Medicare patients.

² In a March 2014 study published in *Ostomy Wound Management*, Hurd et. al. found that PICO was well received by patients and healthcare providers, and the majority of wounds healed over the course of the eight-week evaluation. Very few complications were observed, and 97% of patients reported that they were pleased or satisfied with PICO.

³ Smith & Nephew applied the criteria for use of single use NPWT devices to a large wound registry database (approximately 92,000 patients, reporting 545,000 wounds, and 1,200,000 visits). When this set of criteria was applied to wounds treated with NPWT for conditions more commonly seen in the Medicare patient population (diabetic foot ulcers, venous leg ulcers, pressure ulcers and surgical/traumatic wounds), a large percentage of wounds meet these criteria and could be appropriately treated with single use NPWT devices.

Lack of Transparency and Predictability Regarding Negative Pressure Wound Therapy Payment Rates

On January 1, 2015 CMS established new CPT codes for therapy with single use NPWT. Since then we have been made aware of confusion among physicians about payment rates under the new codes. In the past, many of the MACs had published payment rates for the predecessors to the new CPT codes, HCPCS codes G0456 and G0457. When CMS implemented G0456 and G0457, the Agency clarified that these codes were not limited to any one-particular NPWT technology, but that the code could be used by providers for all NPWT product types.

Single use NPWT codes have been carrier priced from their inception. MACs published payment rates for these codes on their websites, creating transparency and predictability for physicians providing these services.

However, as we noted above, for CY 2015, CMS replaced G0456 and G0457 with permanent, Category I CPT codes for disposable NPWT. The new codes and descriptors are:

CPT Codes implemented January 1, 2015 to describe NPWT and replacing previously implemented HCPCS codes

CPT Codes	Descriptor
97607	Negative pressure wound therapy less than or equal to 50 square cm
97608	Negative pressure wound therapy greater than 50 square cm

The new CPT codes are also carrier priced based on the status indicator of “C” that CMS has assigned to them and on the code descriptors which are very similar to the descriptors for the predecessor G codes. These similarities created an expectation among physicians that the transition from the G-codes to the new CPT codes would be uneventful. But MACs stopped publishing the payment rates for therapy with single use NPWT when CMS adopted the new HCPCS codes. Now there is significant confusion among physicians about how MACs will treat services they render using the single use NPWT device. In contrast to the payment transparency surrounding the old G codes, the lack of transparency on payment rates for therapy rendered single use NPWT has created confusion and unpredictability for doctors.

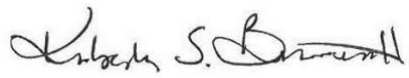
To preserve appropriate access to cost effective and clinically proven therapy with single use NPWT devices, AAHomecare asks CMS to urge the MACs to publically post payment rates for CPT codes that are contractor priced under the PFS, specifically the new codes for single-use NPWT. This will restore the previous transparency and predictability with respect to claims adjudications for these therapies.

CONCLUSION

To increase transparency, AAHomecare requests that payment rate information for the new CPT codes, 97607 and 97608, be made publicly available, as it was for their predecessor HCPCS codes. We ask CMS to urge the MACs to publically post payment rate information, preferably on the MAC websites.

We look forward to reviewing the final rule and working with CMS staff on the issues we have raised. If you have any questions concerning our recommendations, please contact me at the number below.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberley S. Brummett". The signature is fluid and cursive, with the first name being the most prominent.

Kimberley S. Brummett, MBA
Vice President Regulatory Affairs