COALITION OF

Wound Care Manufacturers

November13, 2017

Honorable Marsha Blackburn
2266 Rayburn Building
Washington, D.C. 20515

Dear Representative Blackburn:

On behalf of the Coalition of Wound Care Manufacturers, I would like to thank you for your leadership to alleviate regulatory burdens that preclude patient access to life-saving and life-extending medical technologies by introducing H.R. 2445, the DMEPOS Access and Transparency Act of 2017, also known as the DATA Act of 2017. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including, but not limited to, Negative Pressure Wound Therapy (NPWT).

While we generally support the DATA Act and its provisions to protect suppliers of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") from burdensome and potentially duplicative pre- and post-payment audits when they participate in a prior authorization program, the approach would unintentionally undermine the treatment protocol and quality of care for those patients who require Negative Pressure Wound Therapy.

NPWT is used as an advanced therapy for acute wounds and burns and as a treatment of last resort for chronic wounds such as severe pressure ulcers and diabetic foot ulcers, where other options have been tried and ruled out. The therapy functions by applying continuous vacuum pressure to a sealed wound. The vacuum pressure increases blood circulation to the wound and draws out fluid residing in the wound to facilitate the healing process and stimulate granulation tissue formation. There is vast evidence to show its benefit in improved healing.

While prior authorization could protect suppliers of DMEPOS from burdensome and potentially duplicative pre and post payment audits – we need to evaluate this policy from the patient perspective. The Coalition believes that prior authorization should only be used when patients are not already undergoing treatment for a condition. Once treatment begins, any prior authorization requirement will impact their care.

As such, we respectfully request that NPWT technology be exempted from the DATA Act's requirements to ensure that patients have uninterrupted access to NPWT for severe and chronic wounds and burns when Medicare coverage criteria are met.

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It is important to note that there is a Local Coverage Determination ("LCD") governing NPWT that has been adopted by each of the four Durable Medical Equipment Medicare Administrative Contractors ("MACs").[1] This LCD establishes a set of specific clinical criteria that must be met before Medicare will cover NPWT. These protections extend to extensive, hard-to-heal wounds, regardless of where they are first treated. The vast majority of patients requiring NPWT require continuous use of the vacuum pump as they transition from the inpatient hospital to the home care setting. Any interruption or delay in treatment imposed by a prior authorization process, further compromises the patient's health and unnecessarily exposes the wound to contamination.

The LCD has stringent coverage requirements which enable continuous coverage of NPWT following discharge from the hospital to another setting, as well as when there is appropriate documentation that other treatment options have been tried and have failed.

Thus, the decision to provide NPWT is time sensitive. Any duplicative prior authorization requirements for NPWT would cause treatment delays and lead to avoidable and costly complications.

We urge you to amend the DATA Act to exempt NPWT from prior authorization requirements. We have support the amendment – which is attached. This amendment would promote patient access to continuous NPWT across all settings of care – which is consistent with Medicare policy.

Should you have any questions or would like further information, please do not hesitate to contact me.

Thank you for your consideration,

Sincerely,

Karen S. Ravitz, JD
Senior Policy Advisor
Coalition of Wound Care Manufacturers
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cc: Meghan Stringer

[1] Local Coverage Determination (LCD): Negative Pressure Wound Therapy Pumps (L33821).