ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY
★ CELEBRATING 15 YEARS ★

November 21, 2017

Honorable Marsha Blackburn
2266 Rayburn Building
Washington, D.C. 2051

Dear Representative Blackburn:

On behalf of the Alliance of Wound Care Stakeholders (Alliance), I am sending a letter in support of H.R. 2445, the DMEPOS Access and Transparency Act of 2017, also known as the DATA Act of 2017. However, we have a concern regarding the inclusion of Negative Pressure Wound Therapy (NPWT) as part of any prior authorization program and request that your office provide a carve out for NPWT from any prior authorization requirements.

The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Alliance members actively engage in clinical practice and possess expert knowledge in complex chronic wounds. Most of our members have utilized NPWT for their patients that require it. As such, we are very concerned about the impact that prior authorization will have in a clinician's ability to continue treatment protocols for patients while awaiting a prior authorization approval.

NPWT is used as an advanced therapy for acute wounds and burns and as a treatment for chronic wounds such as severe pressure ulcers and diabetic foot ulcers, particularly when the wound is very deep or when there are several wounds. Most NPWT is initiated in the hospital where prior authorization is not required. However when a patient is discharged from the inpatient setting their NPWT therapy will likely be continued. If prior authorization is required in the outpatient setting, a significant interruption in care for the beneficiary will occur while waiting for the prior approval request to be processed. This interruption in care is concerning as it could cause complications for the patients – who already have multiple comorbid conditions.

The Alliance recommends 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. While there are other items of DMEPOS that are prescribed prior to treatment, NPWT is only used after treatment has begun. As such, prior authorization would unintentionally undermine the treatment protocol and quality of care for those patients who require Negative Pressure Wound Therapy.

The Alliance respectfully requests that NPWT technology be carved out from the DATA Act's prior authorization requirements in order to ensure that patients have uninterrupted access to NPWT for severe and chronic wounds and burns when Medicare local coverage criteria are met. As you are aware, there is a Local Coverage Determination ("LCD") governing NPWT that has been adopted by all four of the Durable Medical

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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 requirements 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.

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 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. The Alliance is aware that there is a draft circulating which carves out NPWT from the DATA Act. We support the NPWT carve out language - which we have attached.

Furthermore, we would request, that any legislation that is passed contains provisions which would ensure that there is a transparent process in place for any prior authorization program. It is important that there is transparency in the actions of CMS and its contractors in administering this program and the prior authorization requirements are clearly established. This has not been the case with the current demonstration project for Hyperbaric Oxygen Therapy (HBOT). Prior authorization has negatively impacted access to HBOT to Medicare beneficiaries. Since the demonstration project began, quality of care and access issues have been reported and the prior authorization determinations appear to be arbitrary.

We recognize that CMS would like to ensure that the use of NPWT meets appropriate utilization criteria as detailed in LCDs. However, we believe there are better mechanisms than prior authorization to achieve this. We support the voluntary reporting of "Appropriate Use" quality measures as a way to monitor compliance with Medicare utilization policies. This mechanism harnesses work the clinicians are already doing under the Merit Based Incentive Payment System (MIPS) and leverages the capabilities inherent in the electronic medical record. Alliance member organizations have already developed Appropriate Use quality measures for other advanced therapeutics through the Qualified Clinical Data Registry (QCDR) with which we are affiliated. We would be happy to discuss this option in more detail.

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

Sincerely,

Marcia Nusgart R.Ph

Marcia Nusgart, R.Ph
Executive Director

cc: Meghan Stringer

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