COALITION OF

Wound
Care
Manufacturers

Coalition of Wound Care Manufacturers Comments related to Suction Pump draft LCD for Aug 30, 2011 DMEMAC meeting

My name is Marcia Nusgart and I serve as the executive director of the Coalition of Wound Care Manufacturers. The Coalition represents leading manufacturers of surgical dressings, negative pressure wound therapy and other medical devices and supplies used by Medicare beneficiaries for the treatment of wounds. I am here today to address our concerns on the suction pump LCD.. We will be submitting more specific written comments, but we wanted you to be aware of our major concerns.

I. One area that the Coalition is always concerned about is the process of how CMS and it contractors develop coding, coverage and payment policies. In this case, we have concerns that to our knowledge the process in developing this LCD and policy article have been lacking in any appropriate stakeholder involvement.

   While we recognize that the DMEMACs have great discretion and latitude when developing coverage policies, there would not have been as many concerns or areas of confusion had appropriate stakeholders been included prior to the development of the draft policy. As new and innovative technology is being developed, we believe it is imperative for CMS and its contractors to meet with medical device manufacturers and the physicians and clinicians who use this technology in order to work together to ensure appropriate coverage policies for products which are clinically and cost effective.

   Innovation in medical device technology – including wound care – is incremental. Just like cell phones evolved in being smaller, more portable and less expensive –wound care technology is also evolving in the same direction.

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The device included in the K0743 code is an example of the evolution of technology in wound care and we would ask that the DME MACs cover this under the Medicare program.

- The product has been covered and reimbursed under the Medicare program **for over two** years. As Dr. Serena has indicated in his comments this morning, the product treats and heals chronic wounds effectively and efficiently and maintains the same pressure as other NPWT devices. The length of treatment and number of dressings used are consistent or less than current Medicare allowables. Therefore it has proven to be reasonable and necessary in the treatment of chronic wounds.

- In addition, the functions of the products as defined in the current NPWT policy and the draft wound suction pump are the same. The device provides continuous and intermittent function, and provides subatmospheric pressure within the ranges of the current NPWT policy. The definition of a wound suction pump as defined in the draft LCD is, "provides controlled subatmospheric pressure that is designed for use with dressings without a canister". The definition of NPWT as defined in its current LCD is: "provides controlled subatmospheric pressure that is designed for use with NPWT dressings to promote wound healing". In both cases, the products achieve results though subatmospheric pressure which lead to wound healing. The only difference between the two types of products is the availability of a canister, or as stated in the new NPWT draft LCD, an exudate collection device.

- Similarly, we note that the draft suction pump LCD does not contain any clinical indications for K0743. We would submit that if this product functions the same as NPWT and, as Dr. Serena says, has treated pressure, venous insufficiency and neuropathic ulcers then the clinical indications for the wound suction pump should be the same as the clinical indications for NPWT.

- Therefore, we would suggest, there should be coverage for KO743 since it is used to treat the same patient population, functions the same and has the same clinical results as those products in the NPWT LCD.

II. We also ask for clarification on two issues regarding the following sentences contained in the draft suction pump LCD. The sentences states, "Wound suction to remove exudate can be accomplished with the use of non-covered disposable suction devices such as a Jackson – Pratt drain or via straight drainage. When a non-covered alternative exists, it is not reasonable and necessary to use a covered DME item."

    The issues are:

    - What is the criteria for disposable suction devices such that both the Jackson Pratt drain and straight drainage would be included in this category?
    - The second sentence is confusing since the items of covered DME are not clearly identified. If the covered DME item is K0743 then this example is inappropriate since it is our understanding that the Jackson Pratt and straight drainage are both used for acute surgical wounds and the K0743 is used for chronic wounds.

Over the years, in working with the DME MACs, we have had discussions regarding the levels and types of clinical evidence for wound care studies. The Alliance of Wound Care Stakeholders will be requesting a meeting with you to discuss "Principles of Wound care Research" a Delphi study that included over 115 wound care experts that will soon be published in a peer reviewed medical journal. We believe this information will be helpful to you in the future as you write coverage policies for future wound care products and therapies.