COALITION OF

Wound
Care
Manufacturers

Coalition of Wound Care Manufacturers Comments on FCSO Draft LCD on Wound Care (DL37166)
February 16, 2016 Public Meeting – Oral Testimony

Good Afternoon. My name is Karen Ravitz and I am the Policy Advisor for the Coalition of Wound Care Manufacturers. Thank you for the opportunity to provide the Coalitions comments on the draft wound care LCD. Founded in 2000, the Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. Our members manufacture products that have been identified in this draft policy – including but not limited to wound dressings, negative pressure wound therapy and disposable negative pressure wound therapy.

While the Coalition has many concerns with the most recent draft LCD, for the purposes of this public meeting I have narrowed our concerns down to three. First with respect to disposable negative pressure wound therapy the current draft LCD states that this service is not medically reasonable or necessary. We disagree with this statement. 2. Utilization parameters that have been provided in this draft LCD seem arbitrary and are not supported in the evidence provided by FCSO in the bibliography at the end of this draft LCD and finally, there is conflicting,

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confusing and/or incorrect information contained in the draft LCD that needs to be corrected prior to the policy being finalized.

So if I may take a couple of minutes to elaborate briefly on each of these points. FCSO has stated that dNPWT is not medically necessary or reasonable yet in reviewing the bibliography the evidence that has been provided does not capture the evidence that exists for the use of disposable negative pressure wound therapy. As Congress and CMS are moving forward in recognizing disposable NPWT as a valuable device to treat patients with wounds, FCSO believes that it is not reasonable and necessary and thus will not cover it as a tool for clinicians to use when treating patients.

Legislation was passed by Congress in late 2015 to allow for payment of disposable negative pressure wound therapy devices in the home health setting. Congress defined a "disposable device" as: a disposable negative pressure wound therapy device that is an integrated system comprised of a receptacle for collecting exudate, and dressings for the purposes of wound therapy; They further stated that disposable negative pressure wound therapy is a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy. This is an important point. Disposable negative pressure

wound therapy is a substitute for traditional negative pressure wound therapy – in which FCSO IS providing coverage. The pressure that is utilized in both a disposable device as well as traditional negative pressure wound therapy meet the same criteria in order to provide negative pressure yet the device is smaller and portable enabling the care of wounds on an outpatient basis at home or in a skilled nursing facility. Furthermore it allows greater utilization of a therapy that was once bulky, cumbersome, and expensive to use. Portability, discreetness, and simplicity of use usually lead to greater patient compliance.

While FCSO does reference older coverage policies with outdated information (such as CGS), FCSO policy does not include any published studies on DNWPT that provide evidence of efficacy. While we will be providing studies as part of our written comment, we urge you to review the Hurd, Marston and Armstrong studies in particular. In these published clinical studies they have either demonstrated that wound healing rates using dnpwt are comparable to similar wounds treated with traditional NPWT or that there was a greater likely hood of complete closure when using dnpwt.

We request that FCSO provide analysis and evidence of their review of disposable utilization since 2013 and reconsider reinstating coverage of disposable negative pressure wound therapy. It is a valuable effective tool for clinicians to use and helps to increase the quality of life for the patients that receive it.

In addition to the lack of evidence provided in the bibliography for disposable negative pressure wound therapy, Coalition members are also very concerned that

the bibliography published in this draft policy does not substantiate the utilization parameters that are identified in this draft policy. We are concerned that FCSO has created arbitrary parameters without clinical or scientific basis. We would like to request that FCSO provide the evidence for the utilization parameters identified with respect to debridement as well as Negative Pressure Wound Therapy. Clinicians have performed debridement of wounds for years. Clinical practice guidelines do exist and they should be utilized. We recommend that FCSO work with clinical organizations in order to establish utilization parameters that conform to standards of clinical practice with respect to debridement. Furthermore, NPWT has been utilized as a treatment modality for years. Clinical practice guidelines also exist for NPWT. We recommend that FCSO work with not only the clinicians but also the manufacturers to establish correct utilization parameters for Negative Pressure Wound Therapy.

The market place changes rapidly and studies are published often. It is important to review the most recent information especially if coverage policies are based on whether a particular product has a study. Similarly, it is important to review clinical practice guidelines or other clinical evidence to support utilization parameters being established. The Coalition is very concerned that FCSO has not done a thorough review of the literature that exists.

Finally, the Coalition has concerns with some of the language contained in the policy, which we believe is incorrect or misleading. We will provide you with all of these issues in our formal comments but I did want to highlight a couple of examples:

- First FCSO lists Negative Pressure Wound Therapy in the policy as Negative Pressure Wound Therapy electrically powered. However, electrically powered is not contained in the CPT descriptor. So we question why FCSO would add the electrically powered language to the existing CPT descriptor for Negative Pressure Wound Therapy when Negative Pressure Wound Therapy is being identified in this policy. The power source should and does not matter. Congress, the AMA and CMS have all recognized that. As such, we request that FCSO utilize what was included in the official CPT code descriptor and not add additional language.
- Similarly FCSO incorrectly uses language not in the CPT code descriptor when describing DNPWT. the CPT codes identified for this procedure/device does not mention the power source and therefore the added language "*non-powered mechanical or single use non-electrically powered" should be removed from this draft policy.*
- FCSO states, "Dressing changes (removal and subsequent reapplication) alone do not require the skills of physicians, podiatrists, physical therapists, occupational therapists or wound care nurses and in fact are usually performed by non-physician providers. First this statement implies that PTs, OTs and

wound care nurses are not non-physician providers. Second, dressing changes often are preformed by wound care nurses and other non-physician providers. Finally, does this sentence mean that if any of the providers that are listed will not be reimbursed for their services should they remove and perform a subsequent reapplication of a dressing?

The Coalition has many other concerns in this policy but we wanted to highlight just a few of our major concerns during the open meeting. The Coalition will continue to work with our members in order to identify our many concerns and recommendations as well as the evidence to support our recommendations in our formal written comments. I appreciate the opportunity to provide our comments. Thank you.