COALITION OF

Wound
Care
Manufacturers

Coalition of Wound Care Manufacturers Comments on Novitas Draft LCD on Wound Care (DL35125) for January 26, 2017 Public Meeting

My name is Karen Ravitz and I am the Policy Advisor for the Coalition of Wound Care Manufacturers. 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 are included/identified in this draft policy – including but not limited to wound dressings, Negative Pressure Wound Therapy and disposable Negative Pressure Wound Therapy. Thus the Coalition is very interested in this policy.

While we have several concerns with the most recent draft LCD, for the purposes of this public meeting I have narrowed our concerns down to three. First the current draft LCD is drastically different from the previous draft LCD without any explanation as to why this change occurred with respect to disposable Negative Pressure Wound Therapy. 2. Utilization parameters that have been provided in this draft LCD seem arbitrary and are not supported in any of the evidence provided by Novitas in the draft LCD bibliography and 3. There is conflicting, confusing and/or incorrect information contained in the draft LCD that needs to be corrected prior to the policy being finalized.

Disposable NPWT

In 2013, the Coalition submitted comments to Novitas praising it for recognizing that technologies had advanced and as a result decided to cover disposable Negative Pressure Wound Therapy. Yet, as Congress and CMS are moving forward in recognizing disposable NPWT as a valuable device to treat patients with wounds, Novitas believes that it is not reasonable and necessary and thus will no longer 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 (DNPWT) 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), a receptacle for collecting exudate, and dressings for the purposes of wound therapy; and (b) 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. 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 Novitas does reference older coverage policies with outdated information (such as CGS), its draft LCD does not include any published studies on DNWPT that provide evidence of efficacy. These studies do exist.

We request that Novitas provide analysis and evidence of its 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 decrease cost and increase in the quality of life for the patients that receive it.

Utilization Parameters

Coalition members are very concerned that the bibliography published with this draft policy is not only outdated, it is also limited. There are 14 studies cited regarding maggot therapy yet the studies that exist for DNPWT are not cited at all. Furthermore, the literature cited in this draft policy does not substantiate the utilization parameters identified in this draft policy. We are concerned that Novitas has created arbitrary parameters without clinical or scientific basis. We would like to request that Novitas 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 and not arbitrary numbers.

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We recommend that Novitas 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 Novitas 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 you are basing your coverage 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.

Language in the Draft LCD

Finally, the Coalition has concerns with some of the language contained in the policy, which is incorrect or misleading. A couple of examples include:

- Novitas lists Negative Pressure Wound Therapy in the policy as Negative Pressure Wound Therapy electrically powered. However, that is not what is contained in the CPT descriptor. So we question why Novitas would add language to the existing CPT descriptor for Negative Pressure Wound Therapy when identifying it in this policy. We request that Novitas utilize what was included in the CPT code descriptor.
- Similarly, Novitas incorrectly uses language not in the CPT code descriptor when describing DNPWT
- Novitas 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 other concerns with language contained in this policy that we will address in our written comments.

CONCLUSION

The Coalition appreciates the opportunity to provide our comments. Due to the short time frame between the release of this draft policy and this public 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.

Sincerely,

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Senior Policy Advisor