

Alliance of Wound Care Stakeholder Comments on Novitas Draft LCD on Wound Care (DL35125) at Novitas January 26, 2017 Public Meeting

My name is Marcia Nusgart and I serve as the executive director of the Alliance of Wound Care Stakeholders. ("Alliance"). 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. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

The Alliance can serve as a resource for the Novitas medical directors in that we:

- Serve as unbiased multidisciplinary knowledgeable clinical resource for information and as a collaborator
- Can address any wound care related subject matters
- Consist of physicians, surgeons (general, vascular and foot/ankle), podiatrists, physical therapists, nurses, dieticians
- Can help Novitas with:
 - Technical questions
 - Organizing educational seminars
 - Educating staff
- Can convene an educational seminar on wound care technologies which we have done with CMS staff in the past

The foundation of the Alliance's workplan focuses on wound care research, wound care quality measures (and educating our members on MACRA) and reimbursement issues regarding coverage, coding and payment.

In that light, today, I am presenting some general issues the Alliance has with the draft policy. We will be providing more details in our written comments since these issues are of great importance to our members. The overarching issue that I will express today is that many of the statements and limitations in the policy do not seem to have the scientific evidence to support them. We have great concerns that a thorough evaluation has not been done since Novitas has also omitted known published evidence. The issues we have the most concerns about are the following:

- For Negative Pressure Wound Therapy, we have three initial concerns:
 - Under the limitations section: Disposable non-powered mechanical or single use non-electrically powered NPWT (CPT codes 97607, 97608) for any indication is considered not medically reasonable and necessary.

We were very surprised at this statement, since in our 2013 comments on your LCD for wound care and bioengineered skin substitutes, we complimented Novitas recognizing and deciding to cover disposable NPWT. We are interested in the basis for Novitas making this decision and would like to have a discussion with the medical directors regarding the rationale. Our members have been using disposable NPWT in their practices since Novitas first allowed coverage. In fact, our members have seen success in treating wounds with this therapy, so we are puzzled by this change.

- In the coding descriptor for CPT 97607 for disposable NPWT, there is no mention of power—unlike in the Novitas policy where it described the technology as non-powered or single use non-electrically powered. Instead the correct language should be: NPWT (e.g. vacuum assisted drainage collection) utilizing disposable, non-durable medical equipment Similarly, in #5 under "Covered indications", Novitas uses the terms "electrically powered" to describe Negative Pressure Wound Therapy which is not accurate. The CPT code descriptor 97605 does not mention anything about Negative Pressure Wound Therapy being electrically powered. As such, we would recommend that Novitas is consistent with the CPT coding language when referring to these technologies to ensure accuracy.
- We also question the utilization parameters in this draft policy for Negative Pressure Wound Therapy which states that no more than 6 NPWT services in a four month period will be considered reasonable and necessary. We would like to request that Novitas provide the evidence for which this number is based on for establishing these utilization parameters. We will be providing additional details on this issue and add recommendations for Novitas to consider.
- Under utilization guidelines, we have concerns regarding the statement: "Debridements will be limited to eight total services per year for any of the debridement codes listed in this LCD." Again, we question the reference source for which this number is based on. We will be providing additional details on this issue and add recommendations for Novitas to consider.
- Under covered indications, we have concerns with #7 regarding the application of the Unna's Boot or application of a multi-layer compression system. We have concerns with the inability in this draft for our members to get reimbursed when providing an Unna's Boot on the same day as a debridement. The NCCI edits allow the use of both procedure codes with a modifier, during a patient visit. Again, we will provide additional information in our written comments.

The Alliance appreciates the opportunity to provide our comments in this public meeting and as mentioned will provide more detailed written comments for your review and consideration by the March 9 submission deadline.

Sincerely,

Marcia Murgart R. PL.

Marcia Nusgart R.Ph. Executive Director