ALLIANCE OF

Wound Care Stakeholders

April 7, 2010

Dr. Craig Haug
NHIC, Corp.
75 Sargeant William Terry Drive
Hingham , MA 02043

Sent electronically to craig.haug@hp.com

RE: Draft Local Coverage Determination (LCD) for Biologic Products for Wound Treatment and Surgical Interventions (DL 29867)

Dear Dr Haug,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am submitting the following comments in response to the NHIC draft Local Coverage Determination (LCD) on Biologic Products for Wound Treatment and Surgical Interventions. I serve as the Executive Director of the Alliance of Wound Care Stakeholders ("Alliance"), a multidisciplinary consortium of over 15 physician, clinical, provider, manufacturer and patient organizations whose mission is to promote quality care and patient access to wound care products and services. These comments were written with the advice of Alliance organizations. This LCD will have a major impact on our Alliance organizations and as such appreciate NHIC has issued its LCD with the ability to offer our comments. Our specific comments follow.

Specific Comments

The Alliance would like to commend NHIC in the drafting of the LCD. It appears to be well thought out. We especially appreciate that NHIC has recognized that the design, conduct and analysis of trials are important factors as well as the rankings of research. The Alliance agrees that a well designed conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. Please recognize however, that in wound care, it is difficult to have large sample sizes as patient comorbidities often vary making large sample sizes difficult to achieve. We also appreciate the language provided in the draft LCD regarding product wastage.

Having said that, the Alliance has a couple of areas of concern which I have outlined below.

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INDICATIONS

In the indications section of the draft policy, NHIC states, "*the application of these products is defined by the procedure and the specific applicable scope of practice.*" We agree with this sentence, but, for clarity sake would like to recommend that NHIC acknowledge that the scope of practice is based on state law. As such, the Alliance would like to recommend that NHIC state the following, "the application of these products is defined by the procedure and the specific applicable scope of practice outlined in State Practice Acts".

Additionally, NHIC states, "*managed wounds should be clean and free of infection and are of a reasonable size (at least 1.0 cm2 and with adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (presence of acceptable peripheral pulses and/or Doppler toe signals and/or ABI of no less than 0.65).*" The Alliance does not agree with this statement since it is not evidence based. As larger chronic wounds progress towards closure, they may become smaller but could still require support with skin substitutes to support healing towards final closure.

As such, the Alliance recommends that in order to continue coverage of skin substitutes, there should be evidence of visible clinical improvement towards closure. This would support continued use of skin substitutes. If there is failure of visible clinical improvement towards closure after 30 days of application then the skin substitute would no longer be covered.

The Alliance believes that NHIC is only taking into consideration the size of the wound when determining coverage. However, wound size should not be the sole determinant. Wound edge physiology – irrespective of size – has similar requirements throughout the healing process.

DOCUMENTATION

In the documentation section of the draft LCD, NHIC states, "*Documentation of response or lack thereof, requires measurement of the ulcer at baseline and following cessation of conservative or conventional management and must be included in the medical record. Documentation should also include measurement of the ulcer immediately prior to the placement of skin substitutes/replacements. A "failed response" is defined as an ulcer that has increased in size or depth, or for which there has been no change in baseline size or depth and no sign of improvement or indication that improvement is likely, such as granulation, epithelialization or progress toward closing.*"

It is recognized that slow healing (e.g. less than 30% area in four weeks) is a strong indicator of ultimate healing failure or of a very prolonged healing trajectory. Biologic skin substitutes may significantly alter this poor prognosis, and result in both improvement in patient's wound conditions AND in overall reduction of medical costs due to expedited wound healing. The Alliance is concerned that the listed indications excludes such "slowly healing" wounds from such optimal treatment – which is

detrimental to the patient. Moreover, "failed response" is not addressed anywhere in the indications for use or medical necessity portion of this policy. It is therefore unclear to the Alliance what time period is being covered to determine the "failed response".

Moreover, "failed response" is not addressed anywhere in the Indications for Use or Medical Necessity portion of this policy. It is therefore unclear to the Alliance what time period is being covered to determine the "failed response".

As such, the Alliance would like to recommend that under the Indications for Use section, NHIC add the following language, **"Applied to wounds that have demonstrated a failed or insufficient response to no fewer than four weeks of conservative wound care measures. For initial applications of skin substitutes/replacements, a failed response to conservative measures is defined as an ulcer that has increased in size or depth or for which there has been less than 30% closure from baseline. For purposes of this LCD conservative treatment includes, but is not limited to: reduction or elimination of underlying cellulitis or other infection; reduction of edema; appropriate debridement of necrotic tissue; appropriate non-weight bearing and/or other means of off-loading pressure; and optimization of wound environment to promote healing."**

POLICY ARTICLES

In each of the product specific policy articles, it appears that NHIC provides instruction on when to utilize the JC or JD modifier. However, the language is not provided in the policy article for Oasis – it is merely contained in the section that identifies the revisions to the article. It is the opinion of the Alliance that NHIC should be consistent and place the JC/JD modifier information in the actual policy article as was done for Apligraf, Dermagraft, etc. and not simply in the revisions section.

Moreover, the Alliance would like to point out that in the final Outpatient Prospective Payment System regulation (OPPS) issued on November 20, 2009, the Center for Medicare and Medicaid Services (CMS) defined implantable biologics as, "products that are surgically inserted or implanted through a surgical incision or a natural orifice". The Alliance believes that the definition provided by NHIC directly conflicts with that provided in the OPPS final rule issued by CMS. It is the opinion of the Alliance that NHIC follow the definition provided by CMS.

Based on our concerns above regarding the OPPS definition, we believe that providers will be confused regarding when to utilize the modifier and for which products – since the definitions are not consistent. As a result, for clarity sake, the Alliance recommends utilizing the definition provided in the OPPS final rule and also suggests using some examples which would assist providers on when to use the appropriate modifier. We would like to recommend modifying the language on the use of the JC and JD modifiers to add the following language:

The JC and JD modifiers should be used when billing for skin substitutes. The difference between them is whether the skin substitute is used as a graft or as a skin covering. The definition of a skin graft for this purpose is whether the skin substitute is implanted into the wound to be incorporated in the healing of the wound. If the skin substitute is used to cover a wound, to protect it from contamination or fluid loss, then it is not a graft, but a dressing. The JC and JD modifiers should be used when billing for applications of products used as grafts and should not be used for products when used as implants or dressings. Implantable biologics are products that are surgically inserted or implanted through a surgical incision or a natural orifice" Those products covered by the NHIC LCD which are surgically inserted or implanted through a surgical incision or a natural orifice, should require the JD modifier to the HCPCS code and to the CPT® codes for that product and procedure.

Skin substitute products, HCPCS codes Q4102-Q4116, are examples of products that may be covered as biologics. The JC modifier should be attached to the products currently covered by the policy Articles and all subsequent Articles affiliated with LCD 29867.

The JC modifier should not be utilized when utilizing products that may be covered as wound dressings (HCPCS codes A6000-A6549).

The Alliance appreciates the opportunity to provide our comments on the draft LCD for Biologics for Wound Treatment and Surgical Interventions. I look forward to working with you as you finalize this policy. If you have any questions or would like more information, please feel free to contact me.

Sincerely,

Marcia Nusgart
Executive Director