COALITION OF

Wound Care Manufacturers

November 7, 2013

Novitas Solutions
Medical Policy Department
Union Trust Building
Suite 600
501 Grant Street
Pittsburgh, PA 15219

Submitted electronically to donna.mandella@Novitas-solutions.com

RE: Draft LCD – Wound Care and Bioengineered Skin Substitutes

Dear Ms. Mandella:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition") I am pleased to submit the following comments in response to Novitas Solutions ("Novitas") draft LCDs (DL32687 and DL27547), "Wound Care and Bioengineered Skin Substitutes". The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to this draft policy. Since our members have a vested interest in the coverage of these products, this draft policy is of concern to us. The Coalition appreciates the opportunity to offer our comments.

GENERAL COMMENTS

The Coalition has the following three general concerns on this draft LCD:

1. Novitas has created a draft LCD which encompasses too many wound care related services and technologies into one policy. This will create issues for providers. Therefore, we suggest that Novitas separates out the technologies and corresponding treatments into more specific policies. In the event that Novitas decides not to do this, the Coalition recommends that at the very least Novitas separate out the products identified in your policy as Bioengineered Skin Substitutes (which we now refer to in this document as Cellular and/or Tissue-based Products for Wounds [CTPs]) in a separate LCD policy.

2. Novitas has not included the diagnosis codes related to each technology or procedure in this LCD, creating confusion for providers. As such, the Coalition recommends that prior to finalizing this policy, Novitas provide the specific diagnosis codes related to each advanced therapy to assist providers in their selection of an appropriate treatment for the appropriate patient. These codes should be itemized per technology and not simply listed in the overall

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policy since products differ in their approved indications and ICD-9s that will relate to these indications for use.

3. The term "Bioengineered Skin Substitutes" that Novitas uses in this draft LCD is not a technically accurate term and does not describe the technology that is either currently or will be in the marketplace. Instead, the Coalition recommends that Novitas adopt the term "Cellular and/or Tissue-based Products for Wounds (CTPs)" which is accurate, broad, and inclusive of both current and future technology.

SPECIFIC COMMENTS

The following are our specific comments which are presented in the order of the draft LCD rather than in order of importance. Our format for addressing them is to state the language in the draft LCD, address our concerns and offer our recommendations. The issues are as follows:

Negative Pressure Wound Therapy (NPWT)

The Coalition is pleased that Novitas has recognized that technologies have advanced and has decided to cover disposable NPWT. However, we still have some concerns with language contained in the policy that we request to be resolved prior to this policy becoming finalized.

1. The Coalition has noticed that Novitas has not included any utilization parameters within this policy. We believe that there should be coverage limitations based on the different devices. We would like to work with you to establish these parameters as we are concerned that without them there is a possibility of misuse/overutilization in comparison to traditional NPWT.

   Below, we have provided a chart of the disposable NPWT devices that are currently in the market place which reflects the frequency of change and exudate collection capabilities.

Device	Device Life (all single patient use)	Dressing Change Frequency	Exudate Collection / Management Volume
Spiracur SNaP	When pressure is lost or canister is full…generally 2 times per week	At least 2 times per week	~60 ml
Smith and Nephew Pico	7 days	Twice weekly	Max 50 ml/day for most dressing sizes
KCI VAC Via	7 days	48-72 hours	250 ml
Medela Invia Motion	60 days	48-72 hours – foam Two-three times weekly - gauze	150 ml

2. It appears that the disposable NPWT covered under this policy are included in the G codes issued by CMS under the OPPS. The current descriptor for the G codes is for mechanical NPWT. However, since the development of the new G codes, CMS has already acknowledged that all types of disposable NPWT will be included and covered under these G codes. As stated below in our recommendations, we ask that Novitas add a clarifying statement in the policy that coverage for the G codes apply to both mechanical and electric disposable NPWT. This point should be clarified as many of our members manufacture not only mechanical but also electrical disposable NPWT and would like to ensure that these products will be covered under this policy as well.

Recommendations: The Coalition would like to recommend that Novitas:

1. Work with the Coalition to establish coverage parameters.
2. Add a clarifying statement in the policy that coverage for the G Codes apply to both mechanical and electric disposable NPWT.

BIOENGINEERED SKIN SUBSTITUTES

The Term "Bioengineered Skin Substitute" is Clinically Inaccurate and Should be Replaced with the More Inclusive Descriptor "Cellular and/or Tissue-based Products for Wounds (CTPs)".

The Coalition is concerned with Novitas using the term "Bioengineered Skin Substitutes" since it is not a technically accurate term and does not describe the technology that is either currently or will be in the marketplace. Instead, the Coalition recommends that Novitas adopt the term "Cellular and/or Tissue based Products for Wounds (CTPs)" which does accurately describe and is broad and inclusive of both current and future technology. A clinical, non-profit, multidisciplinary association, the Alliance of Wound Care Stakeholders (see www.woundcarestakeholders.org for more information) recently voted positively on the adoption of this term – and we agree with the new term as it describes these products more accurately. As a result, as mentioned above, we will be using the acronym "CTPs" when referring to Cellular and/or Tissue-based Products for Wounds in this document.

Specifically, we believe that the term "skin substitute" is misleading and inaccurate to describe the products that are the subject of this LCD for the following reasons:

1. This term is not used by either regulatory agency--FDA in its classification of these products nor by CMS in its coding descriptors.
2. The CMS division that addresses HCPCS coding for these biologic products abandoned the term "skin substitute" effective in 2010 when a manufacturer requested that CMS delete this term since it was an incorrect descriptor. The manufacturer stated at the 2010 CMS HCPCS Public Meeting that that this language was wrong since allografts are mislabeled as "skin substitutes." Allografts differ in structure, tissue origin, and in some cases differ from biologic products in terms of how they are

approved by the FDA (human cells and/or tissue for homologous use versus medical devices). CMS thus changed the descriptors and eliminated the term "bioengineered skin substitutes and the shortened version "skin substitutes" from all of its Q codes for these items.

3. In addition, the Agency for Healthcare Research and Quality (AHRQ), in its 2012 final draft technology assessment on skin substitutes inferred that these products were not "skin substitutes," when the Agency stated:

   "A true "skin substitute" would act like an autologous skin graft in adhering to the wound bed while providing the physiological and mechanical functions of normal skin. The skin substitutes included in this report contain various combinations of cellular and acellular components intended to stimulate the host to regenerate lost tissue and to replace the wound with functional skin. Presumably, successful healing during management with these products would also require maintenance of a moist wound environment and other procedures thought to promote healing."

4. As we understand it, the following were criteria used by the Alliance of Wound Care be based on science
   - be inclusive of all products in marketplace today with eye towards what is in the "pipeline"
   - be neutral in regards to FDA--- nothing that would be offensive and not allow manufacturers to get their products approved in the future if needed
   - ensure that all products are eligible for Medicare coverage as drugs and biologicals consistent with their USP monographs
   - easily understood by clinicians
   - easily linked to the existing CPT codes for the application of the products

Recommendation: Based on the information provided above, the Coalition recommends that Novitas adopt and use the more inclusive term "cellular and/or tissue-based wound care products for wounds" (CTPs) instead of "bioengineered skin substitutes" in this LCD.

INDICATIONS

Language in the policy: any bioengineered skin substitute may be considered reasonable and necessary if it is provided in accordance with the material's Food and Drug Administration (FDA) approved package label with respect to application requirements, frequency, etc.

Concerns: The Coalition is concerned that Novitas is requiring information that does not exist for some of these products in order for the coverage criteria to be met and we did not want that to be a barrier for coverage for these products which are used in the same way as those who received 510k or PMA designation. In addition, the information that Novitas is interested in would either be provided in the PDA approved package label (if it is PMA or 510k cleared) or packaged instructions for use (if a HCT/P)

CTPs have several FDA pathways to enter the market:

- PMA and 510K products are approved with specific indications for use and have FDA approved package labels.
- Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) have another FDA pathway and have packaged instructions for use.

The authority for the framework for HCT/Ps is the Federal Food Drug & Cosmetic Act, which requires premarket clearance or approval for certain products, Sections 351 and 361 of the Public Health Service Act (PHS Act), and 21 CFR 1271, which FDA promulgated to effectuate the requirements for tissue products. The FDA regulatory framework for HCT/Ps has been in place and routinely enforced for 14 years.

A product eligible for regulation as a 361 HCT/P solely under Part 1271 is not subject to premarket clearance or approval. To be a 361 HCT/P, the product must meet all four of the following criteria:

1. It is minimally manipulated.
2. It is intended for homologous use as determined by labeling and advertising.
3. Its manufacture does not involve combination with another article, except for water, crystalloids, or a sterilizing, reserving, or storage agent.
4. It does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function.

Therefore, as stated previously, HCT/Ps do not have any FDA approved package instructions. If the product is more than minimally manipulated there is a higher risk, they are required to seek FDA PMA or 510K approval. These products do have FDA approved package instructions. HCT/P products have instructions for use.

Recommendation: The Coalition recommends that Novitas edit the draft policy language which reads, “any bioengineered skin substitute may be considered reasonable and necessary if it is provided in accordance with the material's Food and Drug Administration (FDA) approved package label with respect to application requirements, frequency, etc” and instead utilize the following language, “any CTP may be considered reasonable and necessary if it is provided in accordance with the materials packaging instructions with respect to application requirements, frequency, etc.”

OTHER INFORMATION – DOCUMENTATION REQUIREMENTS

Language in the Policy: The record must document that wound treatments with bioengineered skin substitutes are accompanied by appropriate adjunctive wound care measures such as dressing changes during the healing period, appropriate compressive dressings, appropriate off-loading, etc.

Recommendation: The Coalition would like to recommend that instead of using the language “appropriate off-loading" in this policy, Novitas use the language "proven off-loading" in its place.

HCPCS CODES

Finally, The Coalition noticed two errors with the HCPCS codes listed in this draft policy:

1. Novitas incorrectly included Endoform Dermal Template in this policy. The "C" code referred to in the policy (C9367) was terminated effective 12/31/2012 per the 2013 HCPCS corrections at and Endoform Dermal Template is now coded with A codes. The Coalition recommends removing Endoform from the list of HCPCS codes covered under this policy.

2. The description for Q4123 is not complete. The descriptor should read as follows: Q4123 Alloskin RT. Q4115 is for standard Alloskin. **The Coalition therefore recommends changing the descriptor for Q4123 to Alloskin RT.**

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On behalf of the Coalition of Wound Care Manufacturers, we appreciate the opportunity to submit these comments. If you have any questions of would like further information, please do not hesitate to contact me.

Sincerely,

Karen S. Ravitz, JD
Senior Policy Advisor
Coalition of Wound Care Manufacturers