ALLIANCE OF
Wound
Care
Stakeholders

October 15, 2010

Dr. Sidney Hayes
Pinnacle Business Solutions, Inc
515 West Pershing Blvd
North Little Rock, AR 72114

SUBMTTED ELECTRONICALLY

RE: Draft Local Coverage Determination (LCD) for Skin Substitute Use in Lower Extremities Chronic Ulcers (DL31385)

Dear Dr. Hayes:

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.

On behalf of the Alliance, I am submitting the following comments and references in response to the Pinnacle draft Local Coverage Determination (LCD) on Skin Substitutes. These comments were written with the advice of Alliance organizations whose members possess expert knowledge in complex acute and chronic wounds. This LCD will have a major impact on our Alliance organizations and the thousands of providers they represent and as such we appreciate the opportunity to offer our comments.

As Medicare continues to transition to the Medicare Administrative Contractors (MACs), the MACs are reissuing LCDs. While we understand, for consistency sake, the MACs are required to reissue LCDs that are coming under their jurisdiction many MACs are substantively changing existing LCDs. Some of these changes are significant and are impacting coverage – without the ability of the provider community to offer their comments. We appreciate that Pinnacle has issued its LCD with the ability to provide our comments.

General Comments

Recommendations Regarding Description of Products Covered

The Alliance recommends that Pinnacle utilize the same structure as some of the other LCDs on this topic and provide the guidelines for each covered brand separately. Because the covered products differ in their source of origin and their cellularity, they have different FDA indications. Therefore, the Alliance believes that the final LCD should list the indications and

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guidelines for each covered brand separately. A great example is the NHIC Corp Articles (A48910, A48911, A49162) attached to the NHIC LCD L29867. The brand specific guidelines are for the covered indications, limitations, documentation requirements, utilization guidelines, and coding guidelines. The Alliance believes this information will help to explain the coverage and limitations and allow clinicians to better understand your policy and the parameters surrounding the products contained within.

Recommendations Regarding Terminology within the LCD

The Alliance has concerns regarding the following terms that are included within the LCD:

1. ***The term "skin substitute" should be eliminated both in the definitions of the products and in the title of the LCD.***

We recommend that Pinnacle eliminate the term "skin substitute" when listing the various products in the "Limitations" section so as to reflect the current recommendations by Centers for Medicare & Medicaid Services (CMS). The CMS HCPCS Workgroup has recommended deletion of the term " skin substitute" from the definition of the product specific HCPCS codes and only use the product name and the size.

In addition, the Alliance recommends using the term **"bioengineered products"** in the title of the LCD and throughout the LCD itself. The Alliance recommends that the title of the LCD be changed to: *DRAFT LCD for Bioengineered Product Use in Lower Extremities Chronic Wounds (DL31385)*

For clarification purposes, the Alliance recommends that Pinnacle add an introductory paragraph under **Indications and Limitations of Coverage and/or Medical Necessity.** This paragraph is similar to what is contained in the First Coast Policy and defines the types of products covered under this draft LCD. The Alliance recommends the language should read as follows:

> *This LCD applies to payment for bioengineered products and physician/non-physician services associated with the application of such products to lower extremity wounds. Bioengineered products (i.e., human skin equivalents, dermal substitute tissues) are human cellular and tissue based products that use living cells (e.g., fibroblasts or keratinocytes)* ***or*** *other collagen-derived or biologically-derived extracellular matrix in a scaffold of natural, biodegradable or synthetic matrices to support wound healing. The scaffold provides a stable framework that guides tissue integration and development. The scaffold is also able to bind autologous proteins which influence cell migration and adherence. Bioengineered products are indicated in the management of wounds that have not responded to aggressive conventional wound therapy or as outlined in the indications given below.*

In the rest of our comments, we will be using the term "bioengineered products" instead of skin substitutes when applicable.

2. In addition, the LCD uses the words "ulcer" and "wound" interchangeably. To be consistent, the Alliance recommends the use of the word "wound" throughout the LCD.

3. To further clarify the products that are/are not covered by this LCD, the Alliance recommends Pinnacle add the following to the Limitations section of the LCD:

> *Products that have been assigned HCPCS codes (A6000-A6549) are covered as surgical dressings, not as bioengineered products. Application of a "surgical dressing" is included in the payment for the e/m service and should not be billed separately, even when the service is on the same or previous day.*

This information should also be used in the Definition section to define a "surgical dressing".

Additional Recommendations

- The Alliance recommends that the LCD specify the providers who are covered to apply the products. Specifically, the Alliance recommends using the following language – as has been used in many other LCDs:

  The application of all covered products is limited to physicians and non-physician practitioners and is defined by the procedure and the specific applicable scope of practice outlined in State Practice Acts.
- The Alliance requests that Pinnacle specify the payable places of service. One of the most comprehensive lists of payable places of service can be found in the NHIC Corp. A4916 Article for OASIS® Wound Matrix and OASIS® Burn Matrix that is related to LCD L29867.
- The Alliance requests that Pinnacle make a slight modification to the section entitled "ICD-9 Codes That DO NOT Support Medical Necessity". It is more appropriate to state "untreated diabetes" rather than "uncontrolled diabetes" and therefore, the Alliance recommends that Pinnacle change the language prior to the final policy being released.

Specific Comments

In addition to the general comments regarding the description of the products covered, the Alliance has some specific comments and recommendations pertaining to clinical issues. While the Alliance believes that some of the draft policy is well written, it is overshadowed by the significant clinical errors that will greatly impact the delivery of bioengineered products. The areas of concern addressed in our comments include the following:

1. Skin Substitutes that act as matrix or scaffolding viewed as wound dressings
2. Definition of "Failed Response"
3. Non-coverage of skin substitute application to a wound smaller than 1.0 sq cm
4. Skin substitute application limitations
5. The parameters for adequate circulation/oxygenation

Skin substitutes acting as a matrix or scaffold

The Alliance has significant concerns with the following provisions in the LCD that are italicized:

1. *"Providers should note that the use of "graft" in the product description does not automatically qualify for coverage. If the product acts as a matrix or scaffolding that encourages and/or otherwise supports the ingrowth of the patients own tissues in order to achieve permanent wound closure, the product will not be seen as a true graft. At best these products will be viewed as a wound dressing".*

   COMMENT: The Alliance believes that the statement above is erroneous and recommends that Pinnacle eliminate it from their coverage determination. .

   If a product is classified by the FDA as a skin substitute, then it should be covered as a skin substitute regardless if the product description indicates that it acts as a matrix. FDA approved skin substitutes are not wound dressings, which have a different FDA categorization process. The wording in the draft Pinnacle policy suggests that the "skin substitute" – if it acts as a matrix is really a "wound dressing". Skin substitutes do not 'dress' a wound they "substitute" for the patient's own skin in order to promote wound healing.

   Furthermore, the definition of a skin graft is determined by whether the skin substitute is implanted into the wound to be incorporated in the healing of the wound. If the skin substitute is implanted into the wound to be incorporated into the healing of the wound – whether or not the product acts as a scaffold or matrix that encourages and/or otherwise supports the ingrowth of the patient's own tissue to achieve wound closure - it is a skin substitute and, by definition, also a graft since it was implanted. To state otherwise is erroneous.

   Finally, 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. There are modifiers in place that are already being utilized to make this determination. 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 an implant or dressings. An implantable skin substitute is a product that is surgically inserted or implanted through a surgical incision or a natural orifice" As such, skin substitutes 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.

   RECOMMENDATION: Based on the Alliance comments provided above, the Alliance strongly recommends that this language be eliminated from the policy prior to it becoming final.

2. All *products, unless they are FDA labeled for use in the types of ulcers considered in this LCD, will be considered to be, at most, 'biologic wound dressings' and part of the relevant evaluation and management service provided and not separately payable. Furthermore, even in those instances when the labeled indications include venous stasis or neuropathic diabetic ulcers, if the product is not biologically active, they will be considered as not covered under the terms of this LCD.*

COMMENT: The Alliance believes that the Pinnacle draft LCD is somewhat contradictory and as such, we would like to seek the following clarification: If the skin substitute is a biologically active skin substitute (living cells and growth factors/cytokines) – that has a collagen component and also provides a matrix or scaffolding to promote wound healing would it be covered under your policy as a bioengineered product as defined on page 2 of our comments?

Failed Response Definition

In essence, the Pinnacle policy states that "all covered bioengineered skin substitutes must be applied to wounds that have demonstrated a failed or insufficient response to no fewer than four weeks of conservative wound care measures when applied to chronic wounds. Pinnacle defines a failed response to conservative measures 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 the Pinnacle LCD conservative measures include, but are not limited to: elimination of underlying cellulitis, osteomyelitis or other infection; elimination of edema; appropriate debridement of necrotic tissue; appropriate non-weight bearing and/or other means for off loading pressure; provision of appropriate wound environment to promote healing."

COMMENTS: The Alliance generally agrees with the statement provided above, however, we question the evidence supporting 30% closure from baseline in 4 weeks as the basis for a failed response. We are unable to locate any research that identifies 30% closure as a valid clinical marker for the types of chronic wounds that are reflected in this coverage policy.

RECOMMENDATION: The Alliance would like to request that Pinnacle provide the Alliance with a citation for this policy.

Non-coverage of skin substitute application to a wound smaller than 1.0 sq cm

The Pinnacle draft policy states, "All covered bioengineered skin substitutes must be …..applied to wounds of reasonable size given the clinical circumstances. For instance, Medicare would not expect routine use of graft material in treating small wounds (smaller than 1.0 cm2 or 1 cm in smallest diameter) unless documentation demonstrated the wound to be refractory to conservative treatment but otherwise healable. Use on small wounds that have demonstrated adequate healing by conservative means is not covered."

COMMENTS: The Alliance does not agree with this statement since it is not evidence based and cautions against specifying a physical size to define "small wound" with the presumption that a "small wound" has some inherent improved potential to heal.

Evidence shows that for some wounds, characteristics other than physical size (area, volume), may be more influential in determining healing outcomes: anatomical characteristics (depth, type, and location), inciting cause of tissue injury (burn, pressure, ischemia/reperfusion, infection, inflammation) and underlying co-morbidities (diabetes, inadequate nutrition, connective tissue disease, hematological disorders, depression). Pressure ulcers with larger physical sized measured as area or volumes heal faster than pressure ulcers of smaller initial size. Wounds involving exposed prominent bony projections or cartilaginous tissues, such as malleolar, pretibial, ischial tuberosity or auricular cartilage are usually small in physical size but notably difficult to heal since these locations have relatively little overlying cutaneous skin, poor local perfusion and/or lack adequate dermal support to facilitate healing without application of natural or biological tissue. For these locations with only millimeters of cutaneous tissue coverage, a superficial 1 cm^2 injury with enough depth to expose underlying fascia, bone or cartilage may prove exceptionally difficult to heal without the use of a dermal substrate or skin graft.

The Alliance agrees the initial and subsequent changes in wound size are important parameters to document and monitor. Area and volume changes are easily described and reliably demonstrate response to therapy. However, a specific physical wound measurement (1.0 cm^2 or 1.0 cm diameter) may not impact wound healing as much as other inherent wound characteristics and should not be the sole determinant for approving or denying coverage. Historically, overreliance on wound size for claim determination has resulted in nonpayment for advanced therapy claims even though the therapy may have demonstrated positive healing outcomes in previously recalcitrant wounds, avoided a more costly skin graft/flap, or provided a viable alternative when more conventional options could not be performed.

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. The Alliance believes that Pinnacle 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.

RECOMMENDATION: The Alliance recommends that in order to continue coverage of bioengineered products, there should be evidence of visible clinical improvement towards closure. This would support continued use of these products. 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 also recommends Pinnacle avoid depending upon a specified wound size to approve or deny a given claim.

Applications of bioengineered products

Within the LCD, Pinnacle provides application and diagnosis of specific application parameters for bioengineered products.

> **COMMENTS**: While these parameters may be appropriate, rather than setting limitations on the applications for these products, Pinnacle should recognizes that in order to continue coverage of bioengineered products there should be evidence of visible clinical improvement towards closure to support continued use of them.
>
> **RECOMMENDATION:** The policy should instead state if there is failure of visible clinical improvement towards closure after 30 days of application then the bioengineered products would no longer be covered.

Adequate circulation/oxygenation

The Pinnacle policy states the following, *"Skin substitutes must be applied only to wound with adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination with presence of acceptable peripheral pulses and or Doppler toe signals and/or ankle-brachial index (ABI) of no less than 0.65."*

> **COMMENTS**: The Alliance believes, as is noted in many research citations, ankle-brachial indexes (ABIs) are unreliable particular in patients with diabetes. Therefore, a patient could have an abnormally high ABI and yet have local tissue ischemia. As such, ABIs are not reflective of the microvascular perfusion, particularly in the distal portion of the foot. Furthermore, many patients have significant edema or pain where a good pulse, waveform or oxygen measurement cannot be determined. In such patients, clinical documentation of capillary refill, skin temperature / color and quality can be provided as a clinical documentation to support adequate circulation for bioengineered products. In other cases, blood flow may be poor but the patient may not be an operative candidate due to morbid risk factors. In such cases, wounds may fail conservative healing methods and bioengineered products can be considered.
>
> Currently, there is no single stand alone assessment that can be used and those recommended as part of an algorithm are noted- palpable pulses, ABI and toe Doppler perfusion pressures. The Alliance would like to point out however, that most wound care studies use TcPO2 values of 20 mmHg or greater for enrollment. Therefore, the Alliance believes this measurement should also be listed in the Pinnacle policy. Similarly, distal perfusion assessments such as PPG and PVR are far more indicative than perhaps even digital doppler. The Alliance believes that these should also be included in the types of assessments accepted by Pinnacle in their policy.
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> **RECOMMENDATION:** The Alliance recommends that Pinnacle modify the language for this provision as follows: "Applied only to wound with adequate perfusion to support tissue growth/wound healing as evidenced by physical examination with presence of

palpable peripheral pulses, Doppler toe signals, ankle–brachial index (ABI) of no less than 0.65, PPG, PVR or TcPO2 values of 20 mmHg or greater".

Furthermore, while the Alliance believes the value of the ABI of "no less than 0.65" is reasonable but we are requesting information why this value was chosen over some other value.

Finally, the Alliance would like to recommend that Pinnacle add PPG, PVR and TcPO2 values of 20 mmHg or greater as alternative measurements.

Conclusion

The Alliance appreciates the opportunity to provide Pinnacle with our comments on the draft LCD for skin substitutes. The Alliance has attached to this document a list of references that support our comments and believe that Pinnacle would find helpful. We look forward to working with you as you finalize this policy. If you have any questions or would like additional information, please feel free to contact me.

Sincerely,

Marcia Nusgart
Executive Director
Alliance of Wound Care Stakeholders

Alliance of Wound Care Stakeholders
Suggested References

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