ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

February 3, 2020

Texas Health and Human Services Commission
Brown-Heatly Building
4900 N. Lamar Blvd.
Austin, Texas 78751-2316

RE: Texas Medicaid DRAFT Coverage Policy for Wound Care Management Services

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the Texas Medicaid draft policy on Wound Care Management Services. The Alliance is a nonprofit multidisciplinary trade association of health care professional societies and organizations 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.

General Comments

The Alliance appreciates that Texas Medicaid decided to update its wound care policy since it takes a great effort to do so. However, we would expect that if a policy is being updated, it would reflect current clinical terminology and include best practices in chronic wound care. We have concerns that are many provisions within this policy which the Alliance believes are antiquated and do not represent current standards of good wound care practice.

The Alliance has served as a resource to CMS and its contractors to educate their staff on wound care. These issues are very important to our members and it is critical that Texas Medicaid have a wound care policy that is clinically correct and that patients have access to wound care products and services that are medically necessary to treat their wounds. We appreciate your reviewing our comments and implementing the recommendations in them. We also would be pleased to provide an educational inservice to you and your staff on these very important issues to clarify the important points we made about the use of these products and procedures in wound care.

We will address below many specific comments and give recommendations that we suggest that Texas Medicaid adopt in its final version. One important term that Texas Medicaid uses throughout this policy is "skin substitutes" which is clinically inaccurate since this technology is not a substitute for skin and should be replaced with more inclusive descriptor "Cellular and/or tissue based products for skin wounds" (CTPs).

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Instead, the Alliance respectfully recommends that Texas Medicaid use the term "Cellular and/or tissue based products for skin wounds" which does accurately describe all technologies in this category and inclusive of both current and future technology.

The Alliance adopted this term in 2013 after a year long effort - working with leading wound care scientists, clinical organizations, and business entities - to develop a more appropriate term to represent this product sector. Thus, we will be using the acronym "CTPs" when referring to "Cellular and/or tissue based products for wounds" in this document.

The Alliance believes that the term "skin substitute" is misleading and inaccurate to describe the products that are the subject of this LCD for the following reasons:

- The FDA does not allow these products to be called ''skin substitutes'' because they do not actually substitute for skin.
- Both CMS and AHRQ have concerns with the terms and did the following:
    1. AHRQ in its draft technology assessment on skin substitutes stated that these products were not "skin substitutes"
    2. CMS abandoned the term in the code descriptors for these products in 2010 when the Agency agreed that these products are not skin substitutes and instead issued Q codes for each individual product by its brand name.
- ASTM, the international standard setting organization, thought so highly of this new unique terminology that in February 2016 it published a new standard devoted to the nomenclature for these products. The workgroup that created this standard included FDA (who agreed with the term!), scientists, engineers and clinicians who worked collaboratively to ensure that the standard is inclusive of all the products in this space. It is now used by not only them but also by those who do wound care research. This ASTM standard (F3163-16) is titled, "Standard Guide for Classification of Cellular and/or Tissue-Based Products for Skin Wounds."
- Government payers in their LCDs are using this term. Several Medicare Administrative Contractors (MACs) refer to CTPs in their LCDs. The rest of the MACs describe CTPs in a variety of ways.
- This term has been adopted by the wound care community and is currently used by physicians when speaking at national wound care conferences and in clinical studies in scientific journals.

As stated above, the ASTM adopted the CTP nomenclature and we believe that it is only a matter of time before the AMA CPT panel makes an editorial change to reflect this terminology. **As such, the Alliance recommends that Texas Medicaid replace the term "skin substitute" in its policy with the more clinically correct term "cellular and/or tissue based products for wounds (CTPs)".**

Specific Comments

The Alliance has provided specific comments below. We have presented them not necessarily in order of importance but in the order that they appear in the draft policy. The issues are as follows:

Definition of Venous Ulcers 5.1 – The policy states that venous ulcers are also known as venous insufficiency ulcers, stasis ulcers, or varicose veins. This statement is not clinically correct as venous ulcers are not also known as varicose veins. They have different clinical etiology. Varicose veins are enlarged, swollen, and twisting **veins**, often appearing blue or dark purple. They happen when faulty valves in the veins allow blood to flow in the wrong direction or to pool. Varicose veins are not ulcers. Perhaps what was intended to be stated is varicose ulcers. This would be more clinically accurate.
Recommendation: As such, the Alliance recommends that the policy should read *venous ulcers are also known as venous insufficiency ulcers, stasis ulcers, or varicose ulcers*.

Additionally, we encourage that venous disease be carefully considered in the clinical pathway, as leg ulcer patients in wound care centers are often not properly screened for venous disease even though venous disease is statistically the leading cause of leg ulcers. We request the following to be added to the policy:

- We recommend a lower extremity venous duplex study for all patients with skin changes of venous insufficiency such as hyperpigmentation or stasis dermatitis; current or previous venous leg ulcers; or lower extremity edema.
- Rather than waiting for a conservative management period, early intervention for treatment of venous ulcers and venous insufficiency is indicated. A landmark New England Journal of Medicine study entitled "*A Randomized Trial of Early Endovenous Ablation in Venous Ulceration*", published May 2018, concluded what every experienced vein care physician has understood for more than a decade. Direct from the study is the following text:

  > "Venous disease is the most common cause of leg ulceration. Although compression therapy improves venous ulcer healing, it does not treat the underlying causes of venous hypertension. Pathways of care for leg ulcers, in general, do not include a provision for early assessment and treatment of superficial venous reflux. The lack of standardized models of care for leg ulcers and the involvement of a range of specialists may contribute to the inconsistent care delivered."

  The one-line conclusion from the study reads:

  > "Early endovenous ablation of superficial venous reflux resulted in faster healing of venous leg ulcers and more time free from ulcers than deferred endovenous ablation."

Recommendation: We would encourage Texas Medicaid to add these important clinical distinctions to the final policy

First Line Wound Care Therapy 17: It is unclear from the policy whether debridement as well as compression is only considered a first line of therapy - defined as an acute wound - and therefore if a patient does not improve and the wound becomes chronic – those treatment modalities are no longer covered under this policy. All of the first line wound care therapies should be able to be used in the treatment arsenal for a patient that has a chronic wound. Limiting coverage of these treatment modalities to patients with an acute wound only

would be detrimental to patient care. Additionally, it is not clear what other treatments may be performed as a first line wound therapy to treat a patient with a wound. The policy as written is not clear.

Recommendation: **The policy should be modified to read, "Wound care management includes first line and second line therapies. First line wound care is used for acute wounds. If the wound does not improve with first line treatment, adjunctive second line therapy may be used alone or in combination with first line wound care therapy.**

Debridement 23 - Furthermore, when discussing debridement in section 23, the policy appears to mis-state the CPT code descriptor, limiting the description of selective debridement to: concervative sharp debridement. Technically, this is not correct as selective debridement consists of surgical and conservative sharp debridement.
Recommendation: The policy would be more clear if the language was modified to read as follows: ***selective debridement includes the removal of specific, targeted areas of devitalized or necrotic tissue from a wound along the margin of viable tissue by sharp dissection utilizing scissors, scalpel, curettes, and/or tweezers/forceps.*** **This language is consistent with most policies referencing selective debridement.**

Surgical Dressings 28 - The policy states that the only way a patient can be treated with a surgical dressing is if the clinician performs a debridement.
Recommendation: The policy should state that accepted methods of debridement which justify the use of surgical dressings include autolytic, enzymatic and mechanical non-selective debridement.

Procedure code for compression 31– It appears that Texas Medicaid may have inadvertently left out HCPCS code 29581.
Recommendation: This code should be added in for compression. In addition, these compression codes need to be linked to edema and not to debridement.

Recommendation: In addition to the compression codes, the Alliance believes that Texas Medicaid also inadvertently left out total contact casting from this policy. We recommend that Texas Medicaid should include those HCPCS codes in this policy as it is important for diabetic foot patients to take weight off of the foot (off-loading). Reducing pressure on the wound by taking weight off the foot is a very effective diabetic foot ulcer treatment. Therefore, the Alliance recommends that Texas Medicaid include the following CPT codes 29445 and HCPCS code Q4038.

24.5 - Hydrotherapy and Wound Immersion *are listed as non selective debridment.*

Recommendation: The Alliance would like to point out that this type of therapy is no longer considered standard of care for wounds and should be deleted from the policy.

Second Line Wound Care Therapy: The first concern that the Alliance has with this section is that it does not include Negative Pressure Wound Therapy as a treatment option. The Alliance assumes that this is just an oversight and this type of therapy was intended to be included. There are a significant number of studies

showing the efficacy/effectiveness of NPWT as well as disposable NPWT being used to treat patients with wounds.

<u>Recommendation</u>: The Alliance recommends that Texas Medicaid include NPWT as well as disposable NPWT as an advanced therapy in first line and second line wound care therapy.

CTPs: starting at 39 This policy spends a significant amount of time discussing the application of CTPs - when they will be covered and under what circumstances. The Alliance has significant concerns with the language in this portion of the policy which includes the following:

1. Under the contraindications section, the policy states that CTPs are contraindicated in clients with inadequate control of underlying conditions or exacerbating factors and therefore CTPs are not considered reasonable and necessary if the patient has uncontrolled diabetes, active infection, vasculitis, or in patients who continue to smoke tobacco. It is not possible to implement such a policy at a practical level if the policy does not provide a specific definition of "uncontrolled diabetes" or the specific way in which tobacco cessation is to be defined. CTPs can be provided to patients with vasculitis and autoimmune disorders when the underlying conditions are treated. In fact, complex patients such as these are the patients most likely to require and benefit from CTPs.

2. We have a few significant concerns regarding the Limitations Section including, but not limited to the following:.
    - Texas Medicaid will have a 10 CTP application per episode limitation in a 12 week period of time. First, it is unclear what scientific evidence was used to establish this limitation in utilization. Second, it is unclear what is defined as "per episode" and whether it is intended to mean "per episode per wound".
    - We are concerned that if more than one specific product is used or there is a product change that occurs during the 12-week period of care that the cumulative number of applications will not be permitted to exceed 10 applications.

The Alliance has concerns about the timeframe of "only 12-week treatment," which may be in conflict with the FDA labeling and clinical practice for many of the CTPs that are only applied every 2-3 weeks to allow incorporation and to see results.

Moreover, if the policy limits treatment to 12 weeks, some of these products will not be able to be used as some of the products, per their FDA labeling, require multiple treatments in a span of time that would exceed 12 weeks. The Alliance is concerned that clinicians would see an increased administrative burden in justifying utilization of the product chosen to treat their patients – even though they are following the FDA labeling.

The Alliance appreciates that Texas Medicaid has contained language in this draft policy that allows clinicians to utilize more than one CTP in the course of a patients' treatment. However, we do not believe that the number of applications is satisfactory when a clinician needs to change treatment options. If a physician begins to utilize one CTP product – with the expectation that the product chosen will work for their patient – yet finds it is unsuccessful – OR if the patients health status changes and/or the presentation of the wound changes – a clinician should be able to change the course of treatment and be able to utilize the product chosen in the most optimal manner. However, based on the limitation to the number of applications – and treatment time - the

clinician will not only be ignoring the labeling requirements for the new product chosen, the patient will not be able to get the full benefit of the new treatment option. Realistically, while Texas Medicaid is permitting a clinician to change treatment options, this policy is still limiting a physician's ability to change course in treating their patients upon the realization that the product chosen is not successfully working in their patient, or when the health status or wound changes. As such, this policy is not only limiting treatment options for the clinician, it is inhibiting a patient from receiving the best optimal treatment.

Furthermore, our clinicians often use one CTP to achieve a certain goal, such as to initiate granulation. Depending on the presentation of the wound and the patient's current health status, they may change to another product to close the wound, which may require more than the number of applications left in the total number of applications permitted under this draft policy.

Recommendations: In order to afford our clinicians the type of autonomy to customize their treatment plan to individual patients that this policy seems to suggest, we recommend allowing treatment according to the product usage and placing the burden on the physicians to document the need for multiple products.

The Alliance also recommends that Texas Medicaid utilize a simple statement that the CTPs should be applied in accordance with their product labeling. This places the responsibility on the physician to apply the product correctly. In addition, their documentation should be sufficient to show that the physician followed labeling instructions for the product being utilized.

Retreatment 50-51

The Alliance is concerned that retreatment of a successfully healed ulcer is not covered nor is retreatment of an ulcer following an unsuccessful course of treatment. This is hugely problematic as patients can down the road, due to mechanical issues often not resolvable, develop another ulcer in the same location or can have further breakdown OR can be placed on another type of product after an unsuccessful course of treatment with one type of product. The Alliance does not agree with the language as drafted in this policy as it is not appropriate to eliminate coverage for Medicare beneficiaries if they have further breakdown after a successful treatment of a wound or if a particular product was tried unsuccessfully on a patient and the clinician determines that another product may be used to help heal the wound.

Recommendation: We recommend that this language be eliminated from the policy as it is not clinically sound.

Prior Authorization

Non-operative debridement is considered the standard of care for chronic wounds. It is not an advanced treatment modality and should not be delayed for a prior authorization process, particularly when infected tissue is present. Delay in performing appropriate debridement of necrotic and/or heavily infected or colonized

wounds may lead to hospitalization and sepsis which could otherwise have been avoided by providing the standard of care in a timely fashion.

Documentation

Smoking 101.2 – The Alliance is concerned about language in this draft policy which seems to discriminate against patients who smoke. Specially, we have concerns that if a patient continues to use tobacco products on a regular basis after a 4 week period of conservative wound care, Texas Medicaid will then deny coverage of treatments that could close a patient's wound. This seems to be a bit extreme and without merit. We respectfully request that Texas cite the studies/evidence used to make this decision.

Recommendation: We understand and support the efforts to provide counseling that other policies have proposed but believe that to deprive patients of these products to help treat their wounds if they are not able to stop smoking will impact patient care. While lab testing is available to validate nicotine levels, it can be costly and could delay care.It is interesting to note that when other draft wound care policies contained this language, it was NOT included in the final published medical policy. The Alliance urges Texas to do the same.

ABI 101.3 – ABIs are not reliable in diabetic patients as a result of calcified vessels. In general, ABIs are a less accurate method to assess healing potential and perfusion than transcutaneous oximetry and skin perfusion pressure which also indicate adequate perfusion when the values are at least 30 mmHg.

Recommendation: All 3 methods of assessing perfusion are accepted by CMS as part of a CMS approved quality measure for the assessment of healing potential in patients with lower extremity wounds and ulcers and **we recommend that Texas Medicaid also accept all three methods.** https://uswoundregistry.com/wp-content/uploads/2020/01/2020QCDRMeasureSpecification-USWR23_US-Wound-Registry-01.13.2020.pdf

FDA requirement 106 – Wound care services that include the use of a CTP must be provided in accordance with the FDA approved package label and applied according to the manufacturers' instructions for use. CPT products not used within the scope of the FDA's intended use and indications are considered experimental and/or investigational. The Alliance is concerned that Texas is requiring information that does not exist for some of these products in order for the coverage criteria to be met. CTPs have several FDA pathways to enter the market and not all of them require FDA "approval."

PMA and 510K products are approved with specific indications for use and have FDA approved package labels. These products will receive an approval letter from the FDA. However, Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) have another FDA pathway, have package instructions for use, but do not receive FDA "approval."

The authority for the HCT/P framework 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 manufacturing 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.

The overarching policy for this two-tiered framework is that, in developing the regulatory framework for HCT/P products, FDA considered the long history of clinical use of tissue products and the existing body of clinical evidence for human tissue. Based on this body of evidence, the FDA determined that when they are minimally manipulated, intended for a homologous use, not combined with other articles, and do not have a systemic effect, tissue products are ***safe*** and may be marketed and used without any FDA pre-market review, clearance, or approval – thus they do not have any FDA approved package instructions nor do they receive FDA "approval."

Recommendation: The Alliance recommends that Texas Medicaid edit the draft policy language and utilize the following language, "each marketed product is eligible for Medicare reimbursement if it is provided in accordance with their proposed use or provided in accordance with its package label or Instructions for Use."

Exclusions 125

Electrical stimulation and electromagnetic therapy 125.6 – Medicare has a national policy on the use of electrical stimulation for wounds. It is curious that while most state Medicaid offices emulate the CMS policy, Texas is excluding a treatment modality that has been used for years in helping to treat patients with wounds. There are countless studies regarding the use of electrical stimulation to treat wounds.
Recommendation: It is the Alliance recommendation that Texas Medicaid remove this limitation and provide coverage for electrical stimulation for patients with wounds.

CTPs not billed concurrently with procedure codes 15271-15278 are not separately reimbursed 125.10. However, these codes are specific to the hospital outpatient department. Not all CTPs are provided in a hospital outpatient setting – in fact, many are provided to patients in an office setting. Is it the intention of Texas Medicaid to disregard those patients who receive care in settings other than a hospital outpatient department?
Recommendation: The Alliance requests clarification whether the policy impacts all settings of care: HOPD and Physician's Office.

Conclusion

The Alliance of Wound Care Stakeholders appreciates the opportunity to provide our comments. We have significant concerns with the current draft of this policy and urge Texas Medicaid to adopt our recommendations. As mentioned previously, our members are experts in this field and many provide wound care services to Texas beneficiaries. The Alliance has served as a resource to CMS and its contractors to educate the staff on wound care. As noted above, we would be pleased to provide an educational inservice to you and your staff on these very important issues. Should you need any additional information, please feel free to contact me or our Alliance Co-chair, Dr. Caroline Fife (cfife@intellicure.com).

Sincerely,

Marcia Nusgart R.Ph.
Executive Director