ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

May 23, 2015

Dr. James Corcoran
Medical Director
First Coast Service Option
Medical Policy
532 Riverside Ave
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Submitted electronically to: Medical.Policy@fcso.com

RE: DRAFT Local Coverage Determination (LCD) for Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (DL36013)

Dear Dr. Corcoran:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the First Coast Service Option (FCSO) draft local coverage determination for Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (DL36013). The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient 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. Many of our members utilize skin substitutes or more accurately Cellular and/or Tissue Based Products for Wounds (CTPs) in their practices as an adjunctive therapy when treating a patient with a chronic non-healing wound. As such, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org.

General Comments

The Alliance applauds FCSO in taking the approach to allow clinicians to determine what treatment options are best for their patients. There are many products in the marketplace and we appreciate FCSO allowing for our clinicians to choose the most appropriate product for their patients in the market, thus expanding their options for treating their patients.

The Alliance recognizes the challenges and difficulties that the A/B MAC contractors such as FCSO are facing in managing the LCD development process with new Cellular and/or Tissue Based Products for Wounds (CTPs) entering the marketplace. We know that FCSO has attempted to establish a fair, balanced and accurate coverage policy. For the most part, the Alliance supports the draft policy as written, however, we do have areas of concern with respect to some of the language

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contained in this draft policy, as well as areas in which we are seeking clarification.

The title of this draft LCD, "Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities" specifically states that the policy is for the application of CTPs when clinicians are treating diabetic foot ulcers and venous leg ulcers of the lower extremity. Yet, FCSO states in its policy, 'Though arterial insufficiency ulcers, pressure sores, traumatic wounds, mixed ulcers and post-surgical wounds are not directly addressed by this LCD, the comprehensive patient assessment and treatment plan requirement would apply to any patient with lower extremity ulcers/chronic wounds." This language appears to insinuate that these types of wounds may be eligible for coverage under this Policy although in fact they are not covered. If FCSO is planning on utilizing this policy to determine coverage for other wound types when treating lower extremity wounds, then FCSO needs to make this point clear throughout the policy. If FCSO has no intention to cover other wound types, then it should not have any part of this policy apply. To have documentation requirements contained in this policy apply to other types of wounds – including arterial insufficiency ulcers, pressure ulcers, traumatic ulcers and post surgical wounds - is misleading and not very transparent – especially given the possibility of pre and/or post payment audits.

The Alliance believes that this policy addresses chronic non-healing wounds and while a majority of the chronic wounds may be DFU and VLU, there are other wound types that would be applicable under this policy. As such, we recommend that this policy should address chronic non healing wounds – defined as those wounds that have not healed within 4 weeks which have not responded to conservative treatment. These wounds may result from trauma, pressure, arterial and/or venous insufficiency, surgery and/or diabetes.

In addition, the Alliance recommends that FCSO change the title of this policy to be more inclusive. We would recommend that the title be, "Application of Cellular and/or Tissue Based Products for Wounds (CTPs) for Treatment of Chronic Wounds'

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

Specific Comments

Coverage Guidance - Chronic Non Healing Wound Definition

The Alliance is concerned regarding the definition of a chronic non-healing wound provided in the FCSO draft LCD. The policy language states, "A wound that has not healed within one to three months may be considered chronic and the application of a skin substitute graft may be considered for certain patients." Defining a chronic non healing wound as a wound that does not respond to standard wound treatment for 4 weeks is more consistent with the literature, and with all other LCDs and NDCs related to wound products, therapies and devices. The AHRQ stated in its 2012 technology report, "*….chronic wounds, those wounds with a duration greater than 30 days that have not adequately responded to standard wound care.*"

Furthermore, when providing a graft to patients, our clinicians will not know whether FCSO will

cover the application and product if provided to their patients after one month versus waiting for three months based on this definition. Providing a range such as this does not afford our clinicians with the specificity they need to ensure they are meeting your coverage requirements correctly. Therefore, the Alliance recommends that FCSO utilize the standard by which all policies have been written and use the 30 day or 4 week timeframe and not a range of one to three months as the measure of a chronic non -healing wound.

Coverage Guidance - 12 Weeks of Treatment and Number of Applications

The Alliance has concerns about the timeframe of "only 12 weeks treatment", which may be in conflict with the FDA labeling and clinical practice for many of the CTPs which are only applied every 2-3 weeks to allow incorporation and to see results. In its draft policy, FCSO states, "It is the expectation that only one specific skin substitute graft product will be used for the episode of skin replacement surgery wound care (defined as 12 weeks from the first application of a skin substitute graft) assuming its use is not in conflict with Food and Drug Administration (FDA) assessments and assuming there is one related wound (definitions in CPT)". The FCSO draft policy also states, "Utilization of more than 1 application of a skin substitute product in the 12 week episode of skin replacement surgery may be subject to prepayment medical review".

FCSO is stating that all physicians will be subject to prepayment medical review after the first application of a skin substitute, yet the clinicians can use product for 12 weeks of treatment. This not only seems extreme, it is contrary to FDA labeling. The FDA labeling for some products requires reapplication every 7 days, while the FDA labeling for other products requires reapplication every 2-3 weeks. So it is very likely if a product requirement is to reapply the product 5 times every 3 weeks – the clinician will be over the time frame for the number of weeks permissible under this policy. It is also clear from the labeling requirements that more than 1 application will take place for all of the products in the marketplace. So why would FCSO potentially place all clinicians under medical review for following the labeling instructions for the products that they believe are the best treatment options for their patients?

Moreover, if the LCD 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 always have to justify utilizing the product chosen to treat their patients – even though they are following the FDA labeling. Therefore, the physicians will always have to overcome the documentation hurdles and will need to further justify why they need to continue to use the product for more than one application.

Furthermore, 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, it is unclear under this draft policy whether the clinician can switch to another product. Is the draft policy stating that only one specific CTP can be utilized per episode of care? As a physician, surely FCSO can recognize that sometimes a treatment option chosen is not successful. This policy seems to be 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. Also, 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. 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 FDA label and placing the burden on the physicians to document the need for multiple products.

Finally, FCSO is proposing to potentially place a physician under pre or post payment review after one application of a CTP product. This seems a bit extreme and will highly likely discourage clinicians from choosing appropriate applications of CPTs for non-healing wounds

As such, the Alliance recommends the removal of the following statements, "It is the expectation that only one specific skin substitute graft product will be used for the episode of skin replacement surgery wound care (defined as 12 weeks from the first application of a skin substitute graft) assuming its use is not in conflict with Food and Drug Administration (FDA) assessments and assuming there is one related wound (definitions in CPT)", and "Utilization of more than 1 application of a skin substitute product in the 12 week episode of skin replacement surgery may be subject to prepayment medical review". A simple statement that the products should be applied in accordance with their FDA labeling places the responsibility on the physician to apply the product correctly and documentation in their files should be sufficient to show that the physician was following labeling instructions for the product being utilized. If the products are not utilized according to their FDA labeling – then a clinician can and should be placed under prepayment medical review.

Clinical Evidence

FCSO states that "specific products may be listed as non covered in the future based on clinical literature that establishes inferiority". This is suggesting fluidity of decision-making but does not specify what evidence is considered to show 'inferiority'. Does FCSO intend to require a specific amount or types of evidence to compare one product against another in the future? As an ethical concern, comparing one advanced tissue to another may not always be appropriate as each has specific indications, application intervals that may be different and may be more applicable for a particular patients' wound, thereby complicating this 'inferiority' comparison that is fair and clinically relevant.

The Alliance would like to know what type of evidence will FCSO be reviewing when making a non coverage determination? Furthermore, how will the non-coverage decision be made? It is unclear how FCSO will use this literature to make non-coverage decisions. It seems as though one minute a product can be covered and then based on the clinical literature of a competitor- which may or may not include bias – a product may be placed in a non-coverage policy.

The Alliance recommends that FCSO provide the criteria by which it will be making any non coverage determinations. This will allow for a more transparent process for manufacturers when submitting a CTP for coverage. We further urge FCSO to issue a document for comment prior to any changes in coverage status and not simply place a product in the non-coverage policy and publish in the newsletter or email updates.

The Alliance believes that evidence can be established for coverage not only through RCTs but also through registry data, retrospective clinical studies (includes populations of patients with

multiple co-morbid conditions that are commonly eliminated in most RCTs), scientific evidence and expert knowledge. This approach is consistent with the widely accepted definition of evidence-based medicine but also adopted by the newly created important organization Patient Centered Outcomes Research Institute (PCORI). We believe that payers should cover these CTPs if the manufacturers provide clinical evidence in peer reviewed journals showing positive outcomes of their products without regard of how they are regulated by the FDA—Class II, III or HCT/Ps nor how they compare to other products in the marketplace.

The draft language in the policy gives the appearance that FCSO will allow expanded treatment options for clinicians based upon providers clinical decision-making by including more CTPs as covered. The Alliance supports this medical decision making approach. However, the language is conflicting and makes statements such as "specific products may be considered non-covered based on clinical literature that establishes inferiority in head to head studies with other products" and "overall body of published evidence regarding the safety and efficacy of bioengineered skin substitutes is limited and does not clearly demonstrate established or reproducible benefits of these products compared with optimal wound care". These statements lead us to believe that if a product does not have adequate studies then FCSO will not cover the product despite the clinicians' decision making process to use a specific product. Furthermore, FCSO needs to clarify its position in such situations as how new products will be treated and if a competitor issues a comparator study showing its product is more effective than another, then FCSO may stop coverage of a product as a result. This leaves some level of uncertainty for our clinical community as to what will/will not actually be covered under this policy.

CTP products – as an advanced therapy – have helped our provider members treat patients with chronic wounds that have not progressed to healing [non-healing] despite best standard of care approaches. Therefore, clinicians use CPTs for these non-healing wounds to achieve closure and avoid complications. We question whether most of the products currently in the marketplace will be covered, even with the patient's medical necessity has documented as part of the clinical decision making. We recommend that FCSO utilize more straightforward language in the LCD. It is currently unclear whether FCSO will cover all products currently in the marketplace and how FCSO will judge the supportive clinical evidence for each product used. If this is the case – then we would also recommend that FCSO clearly identify what evidence they are seeking and if a product meets those criteria – then it would be covered.

Indications for Use – Differentiation between DFU and VLU

FCSO makes a clear distinction when providing coverage for DFU and VLU. The policy stated that the application of a CTP on a DFU will be covered when the DFU fails to respond to documented conservative measures of greater than 4 weeks. Yet, the policy also states that the application of a CTP on a VLU will be covered when the wound fails to respond to conservative treatment after 6 weeks. It is unclear what evidence FCSO is using to support their decision to separate out the timing for recognizing "failed treatment" for DFU (4 weeks) versus VLU (6 weeks). The Alliance does not agree with this distinction and requests that FCSO provide the evidence supporting this separation. The Alliance believes that the percentage of change after 4 weeks of healing is a robust indicator of healing at 12 weeks. Delays in alternative or additional therapies contradict prevailing thoughts on ulcer treatment. As such, the Alliance recommends that application of CTPs for both DFU and VLU

should be covered when the wound fails to respond to conservative measures after 4 weeks**.**

Indications for Use – Requirement of a Duplex Scan

Within this draft policy, in order to cover the application of a CTP for patients with venous leg ulcers an assessment of history, a physical exam and an ABI are required. The Alliance agrees with these requirements. No other AB MAC or private payer requires a duplex scan to confirm clinical etiology-anatomy-pathophysiology (CEAP) classification. While the Alliance supports this requirement, we would also like to request that FCSO provide the basis for this new requirement as well as the clinical evidence to support it. The treatment of venous insufficiency is based in understanding and confirming the CEAP classification. This is demonstrated with ultrasound. Procedures designed to treat venous insufficiency cannot be performed without ultrasound confirmation. Demonstrating reflux in axial veins, tributaries, perforators and deep veins will further justify the diagnosis of venous insufficient with ulceration. Ultrasound confirmation of venous pathology will justify the diagnosis. There can be less confusion in treating a wound "labeled" as a venous ulcer that may not be. As such, the Alliance supports this new requirement.

Limitations – Application procedure and supply must be coded correctly

We applaud the requirement that FCSO has placed on the provider community: that the application procedure and supply must be coded correctly. Furthermore, we agree that the number of units must be reported correctly. It is our understanding that too often, 1 unit instead of the number of square centimeters being used is being billed for CTP products – which clearly is not correct. We would request that FCSO, in conjunction with CMS, place a MED LEARN matters article in its bulletins to inform its readers about correct billing to ensure that the correct number of units is being billed. The Alliance believes that it is the responsibility of the contractor to ensure that correct coding and billing information has been provided to the clinical community. To our knowledge the contractor has not provided this information. If FCSO is requiring that the number of units be reported correctly, we urge FCSO to provide education to its clinical community to ensure the requirement on the correct coding for the procedure and the number of units for the product is being met.

Documentation – Legible signatures and notes?

FCSO expects that in order for a physician to meet the documentation requirements in this policy, the medical record documentation must be legible and the physician's signature needs to be legible. This seems to be a rather subjective standard which physicians will be held accountable. How will the determination be made as to whether a signature or medical record note is legible? One reviewer may be able to read and comprehend the information while another may not. This seems to be a requirement which could arguably never be met – yet again, clinicians will be held accountable and their payment can depend on it.

The Alliance does not believe, that a policy which requires much documentation already should contain language that is subjective at best. We urge you to delete this requirement.

Anticipated needs?

While the documentation section lays out the FCSO expectations regarding what should be kept in the medical record– the Alliance questions the language that states, "documentation should include an assessment outlining the plan for skin replacement surgery and the choice of skin substitute product for the 12 week period as well as any anticipated repeat applications in the 12 week period". The documentation section is stringent enough without adding the requirement of having physicians anticipate their needs. As such, we recommend that the language referring to anticipated needs be eliminated.

Conclusion

In previous comments, the Alliance had stated our rationale for requesting a change in terminology from "skin substitutes" to "cellular and/or tissue based products for wounds (CTPs)". While we understand that FCSO would currently rather follow the CPT®[1] description, we would respectfully point out that other organizations and contractors are beginning to adopt this verbiage. For instance, ASTM is currently revising its nomenclature on its guidance documents on this product sector and using the CTP term. In addition, two other A/B MACs are using this terminology-- Cigna Government Services is utilizing the term "Cellular and/or Tissue Based Products for Wounds" as the title for its LCD and Novitas refers to these products as CTPs throughout their recently released LCD. Historically, the CPT Editorial Panel would have changed the code descriptor in 2012, but they were concerned that it would affect Medicare payment and coverage for this work. If the MACs begin referring to these products with correct terminology, we can then request a correction to the CPT® code descriptors. We recognize that you may not be inclined to change the terminology at this time. Therefore we would respectfully request that you consider referring to these products as CTPs in a similar fashion as Novitas as well as at some other point in time to allow the Alliance to further discuss this issue with you.

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

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director

[1] CPT is a registered trademark of the American Medical Association