COALITION OF

Wound Care Manufacturers

September 24, 2022

Dr. Leslie Stevens
Medical Director Novitas
Medical Affairs
Suite 100
2020 Technology Parkway
Mechanicsburg, PA 17050

Dr. Juan Schaening
Medical Director
First Coast Service Options
Medical Affairs
Suite 100
2020 Technology Parkway
Mechanicsburg, PA 17050

RE: Novitas and FCSO Draft Local Coverage Determinations (LCD) – Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL35041and DL36377) and Local Coverage Article: Billing and Coding: Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DA54117 and DA57680)

Submitted electronically to ProposedLCDComments@novitas-solutions.com and to ProposedLCDComments@FCSO.com

Dear Drs. Stevens and Schaening:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition") I am pleased to submit comments on the draft LCD for Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL35041/DL36377) and the accompanying Local Coverage Article-Billing and Coding: Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DA54117/DA57680). Founded in 2000, the Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. Our members manufacture cellular and or tissue-based products for skin wounds (CTPs) – also referred to as "skin substitutes" – and therefore have a vested interested in ensuring that this policy is clinically sound and based on evidence.

The Coalition continues to have major concerns with the proposed LCD and LCA. In addition to the significant comments that were submitted to both Novitas and FCSO on the first draft policy in May 2022, Novitas and FCSO issued another draft policy in which there is no basis for the changes made and nothing to substantiate them. There are laws that govern policy decisions made by Medicare contractors which have been ignored by Novitas and FCSO. This is not only disappointing, it is of great concern to our members.

5225 Pooks Hill Rd | Suite 627S
Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410
www.woundcaremanufacturers.org

As multiple stakeholders already stated during the August 2022 open meetings, these policies need to be withdrawn for the following reasons

- They are not in the best interest of patients.
- They are not well written and they are not supported by clinical evidence or guidelines.
- There is no detailed discussion of the pertinent evidence that was cited.
- Evidence has been omitted from this policy review and what has been utilized is either not the most currently available, or is used in such a way that is contradictory to the points Novitas/FCSO is trying to make.
- Furthermore, there is NO new evidence to support the movement of over 40 products from the covered to the non-covered list – which is required by the 21st Century Cures Act. This is extraordinarily concerning as these policies have important implications to patient care and access.

Moreover, we have concerns that the reason behind Novitas/FCSO deciding to create this draft LCD/LCA in the first place was to make uniform LCDs with other MAC jurisdictions. It has always been our understanding that the rationale for creating the LCDs was to be different and reflect local clinical practice which we support. However, the initiative to make CTP LCDs more uniform would seem to lend itself in moving toward an NCD which we do not support.

With such problematic concerns outlined in this comment letter which we believe severely impact patient care, the Coalition recommends that neither Novitas or FCSO move forward to finalize this draft LCD/LCA and instead pull them and work with stakeholders and your Carrier Advisory Committees (CAC) to craft a more accurate and well-balanced policy.

NEW CONCERNS WITH THE DRAFT LCD/LCA

Lack of Stakeholder Engagement

We are disappointed that Novitas/FCSO did not engage any stakeholders – including convening a meeting of its CAC to answer questions and discuss the evidence for this draft LCD. Many of the clinical errors in this policy as well as the incorrect use of the evidence could have been caught prior to this draft being released. As stated in our written comments above as well as in our oral testimony, both Novitas and FCSO include evidence that is contrary to the positions taken in the LCD and LCA and which supports the comments submitted by stakeholders. Yet no substantive changes were made between the release of the first draft policy and the one issued August 11, 2022. Both Novitas and FCSO seem to have a complete disregard for evidence supporting the use of CTPs and the number of applications to be a successful treatment option for patients - which is extremely concerning.

We recommend that the LCDs and LCAs be withdrawn so as to not adversely impact patient care and that Novitas/FCSO utilize the Carrier Advisory Committee (CAC) and outside expert stakeholders such as the Alliance of Wound Care Stakeholders ("Alliance") to serve as resources for the Novitas/FCSO medical directors. The Alliance consists of physicians, surgeons (general, vascular and foot/ankle), podiatrists, physical therapists, nurses, dieticians and includes the Coalition as a non-voting member. The Alliance can:

- Serve as an unbiased multidisciplinary knowledgeable clinical resource for information and as a collaborator
- Address any wound/ulcer care related subject matters

- Help Novitas/FCSO with:

  o Technical questions
  o Creating educational seminars for staff
  o Convene an educational seminar on CTPs as they have done with CMS staff in the past

Concerns with Moving Products from the Covered to the Non Covered list

TRG Requirement

The Coalition has serious concerns that in addition to the complete and total disregard to what the evidence cited in these draft policies actually states, both Novitas and FCSO have failed to accurately understand the regulatory requirements put forward by CMS. Dr. Schaening stated multiple times during the open meeting that manufacturers had to provide evidence of regulatory compliance and cited the CMS regulations related to TRGs. However, the language in the current regulations only require that NEW HCT/Ps coming into the marketplace obtain a TRG to include in their HCPCS application to receive a code.[1] This requirement is not being applied to ALL HCT/Ps at this point in time. Therefore, Novitas/FCSO cannot base their non-coverage of products on this requirement. Should the MACs determine that this is going to be a new requirement for coverage (which CMS currently does not even require), then this policy would have to be finalized and afford manufacturers a reasonable amount of time to obtain these letters BEFORE non-coverage is considered. At this point in time the TRG is taking close to a year to issue letters. **So, both Novitas and FCSO are making policy decisions based on language they are incorrectly interpreting to mean that currently all HCT/Ps require a TRG OR on language contained in a CMS proposed rule that is not yet finalized.[2] This is a violation of the Administrative Procedures Act and is a due process violation. Manufacturers cannot be responsible for providing information based on a proposal and at the same time Novitas and FCSO cannot be making coverage determinations based on receiving this information until it becomes finalized.**

Finally, should Novitas and FCSO require TRG letters, as it appears in the current draft, there will be a disruption in care as many manufacturers do not currently have TRG letters (as they are not required as stated multiple times) and will not be able to obtain one for at least a year. As a result, products that are currently being utilized on patients will become non-covered as soon as this policy is finalized.

Evidence Requirements

FCSO and Novitas also cannot make general statements about regulatory compliance without providing the specific requirements that need to be met. There needs to be information contained in this policy to identify what regulatory compliance manufacturers are being required to adhere to. HCT/P manufacturers of minimally manipulated products used for homologous use are currently required to follow requirements and adhere tissue bank compliance.[3] So it is unclear what regulatory compliance FCSO and Novitas are referring. As mentioned, nothing is identified in the proposed rule.

---

[1] *87 FR 46251*
[2] *87 FR 46251-2*
[3] *21 CFR part 1271 and 361 Public Health Services Act*

Moreover, many products that were moved to the non-covered list DO have TRG letters and therefore, it is baffling as to why these products were moved. Neither **FCSO and Novitas met their 21 Century Cures requirement of providing evidence as to why these products were moved from the covered list to the non-covered list.** No new evidence is contained in the bibliography and as such, the movement of these products is not based on evidence as is required. No explanation was provided either as to this significant movement in product coverage as to why these products were even moved. This change in coverage therefore can only be viewed as **arbitrary and capricious and a violation of the laws that have been issued to protect this very action from occurring.**

Coverage Decisions Cannot Be Made In An Article

Local coverage determinations (LCDS) are defined in Section 1869(f)(2)(B) of the Social Security Act (the Act). This section states: "For purposes of this section, the term 'local coverage determination' means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered in accordance with section 1862(a)(1)(A)

Local Coverage Articles (LCAs) however are typically published by a local Medicare Administrative Contractor to provide coding and billing guidance or provider education that is complementary to an existing LCD.

However, both Novitas and FCSO have made coverage decisions in the policy article by non-covering over 40 products from covered to non-covered in the Article without new evidence, without any rationale as to why these products are now going to be non-covered, and without providing the evidentiary threshold for coverage. By moving these products from the covered to the non-covered list in the Article Novitas and FCSO violate the very nature of what can be done in an Article versus an LCD.

As stated, both FCSO and Novitas must withdraw this policy and work with stakeholders to ensure a balanced policy – that is not arbitrary and capricious – and is not only based on evidence but created following the rules of law.

COALITION CONCERNS WITH THE DRAFT LOCAL COVERAGE DETERMINATION (LCD)

General Comments

The Term "Skin Substitute" is not Clinically Accurate and Should Be Changed to Cellular and/or Tissue Based Products for Skin Wounds (CTPs)

We are concerned with Novitas/FCSO using the term "skin substitutes". This term is not clinically accurate and does not describe the technology that is intended for use in the management, treatment, or healing of chronic ulcers. Historically, these products have been referred to as **"skin substitutes" in reference to their initial use as substitutes for skin grafts in clinical procedures**. However, over time, the **usage of these products shifted toward chronic ulcers where skin grafts are infrequently used and not the standard of care.** Moreover, newer products in this category may look nothing like skin and, indeed, have not been designed to function as skin replacements. Thus, there is a need to define terminology in the context of chronic non healing ulcers as opposed to skin grafting procedures.

The Coalition recommends that Novitas/FCSO adopt the term "Cellular and/or tissue- based products for skin wounds (CTPs)" which does accurately describe these products and is broad and inclusive of both current and future technology. We would respectfully point out that other organizations, Medicare contractors and the wound care clinical community have adopted this verbiage. The ASTM has updated its standard guide to define CTP nomenclature and they have also included synthetic products within the definition of a CTP (which is also consistent with CMS adopting synthetics into the definition as well).[4] [5]

Other Wound and Ulcer Types Inappropriately Included In This Policy

Moreover, since this policy applies to only DFUs and VLUs, we respectfully request that Novitas/FCSO not refer to other types of ulcers or wounds throughout this policy. Specifically, the policy states; "This LCD addresses the medically reasonable and necessary threshold for coverage of skin replacement surgery for application of skin substitute grafts for diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs). Application of skin substitute grafts for wound care indications other than for DFU or VLU are not addressed by this LCD." Novitas/FCSO refers to pressure ulcers, decubitus ulcers, burns and trauma wounds throughout this policy. None of these are the subject of this policy as clearly identified by Novitas/FCSO and therefore any reference to them is inappropriate and should be removed.

Specific Comments

Lack Of A Consistent And Accurate Definition Of A Chronic Non-Healing Ulcer

The Coalition has concerns regarding the definition of a chronic non-healing wound provided in the Novitas/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, an advanced treatment modality, may be considered medically reasonable and necessary for certain patients." We submit that the range of 1-3 months is too long and creates ambiguity. When providing a CTP to patients, clinicians will not know whether Novitas/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 clinicians with the specificity they need to ensure they are meeting these coverage requirements correctly.

Furthermore, the lack of a consistent and accurate definition of what is a chronic non healing ulcer is not only concerning, it is confusing and contradicts already established policy. In some places, the LCD defines a chronic non-healing wound as one that has not healed in 1-3 months as stated above; in other places, it says greater than 4 weeks, or at least 4 weeks. These different non-specific measures of time are problematic. The definition of a chronic ulcer is already standardized. Defining a chronic non healing ulcer as a wound that does not respond to standard wound treatment

[2] Standard Guide for Categories and Terminology of Cellular and/or Tissue-Based Products (CTPs) for Skin Wounds, ASTM F3163-22, Current edition approved Feb. 15, 2022. Published March 2022. DOI:10.1520/F3163-22

[5] 42 CFR Parts 410, 411, 412, 414, 416, 419, 482, 485, 512 [CMS–1736–FC, 1736–IFC] RIN 0938–AU12 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; December 29, 2020

for 4 weeks or 30 days is more consistent with the literature, and used by CMS, other A/B MACs and AHRQ in technology assessments related to wound products, therapies and devices.[6]

Therefore, the Coalition recommends that Novitas/FCSO utilize the definition of 30 days or a 4 week timeframe and not a range of one to three months as the measure of a chronic non -healing ulcer.

Limitation of Number of Applications of CTPs in an Episode is not Supported by the Clinical Literature

The limitation of 2 applications in an episode (defined as 12 weeks) being not medically reasonable and necessary is an **arbitrary application limitation that is contradictory to other statements in the draft policy (that products should be used based on their labeling instructions)**. It is also not supported in the literature cited or in any evidence that we have reviewed. In fact, the evidence cited in this policy and/or clinical literature we reviewed either shows a higher number of applications or is very clear that the number of applications should be based on the labeling instructions for the specific product being used. [7]

More specifically, the number of applications cited in the evidence that both FCSO and Novitas has cited actually ranges from **1–8.9 applications and is based on individual product studies because a specific number of applications is not included on most product labels.** Instead, the FDA labeling for some products requires reapplication every 7 days, while the FDA labeling for other products requires reapplication every 2-3 weeks.

If the clinician follows the instructions as per the product labels, the clinician would reapply the CTP multiple times in a 12 week period. Based on the language in this policy, the clinicians following the label will either exceed the number of applications allowed under this policy OR they will be required to stop treatment midstream, prior to the wound being healed, in order to comply with the requirements of this LCD. This seems counter intuitive and is clinically detrimental to patient care. Furthermore, this 2 application limitation is also contrary to several provisions of the LCD in which Novitas/FCSO specifically states that the labeling instructions need to be followed. Moreover, since the draft LCD limits treatment to 12 weeks, some of these products will not be able to be used since some of them, according to their FDA labeling, require multiple treatments in a span of time that would exceed 12 weeks. This, in itself, is problematic.

Finally, the Coalition also questions the evidence to support an episode of care – which is more of a payment methodology. There is no evidence cited in this draft in which payment is defined by an episode of care for CTPs. As such, given the 21st Century Cures requirement for evidence to support language requirements in LCDs, any reference to an episode of care should be removed.

---

[6] *Peter Sheehan, Peter Jones, Antonella Caselli, John M Giurini, Aristidis Veves; Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial; Diabetes Care 2003 Jun;26(6):1879-82. doi: 10.2337/diacare.26.6.1879*

[7] *Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg. 2016 Feb;63(2 Suppl):3S-21S. doi:10.1016/j.jvs.2015.10.003.)*

The Coalition is in complete disagreement with the 2-application limitation and urges Novitas/FCSO to simply include a statement that CTP products should be applied in accordance with the FDA labeling of the product. This places the responsibility on the physician/clinician to apply the product correctly and the documentation in their files should be sufficient to show that the physician/clinician was following guidelines for the product being utilized.

CTPs Are NOT Surgical Supplies

Novitas/FCSO describes CTPs as surgical supplies. Specifically, the draft states, "Although skin substitutes have attributes of both biologicals and devices, the current position is that these products are best characterized as surgical supplies or devices because of their required surgical application and their similarity to other surgical supplies." CTPs are not considered surgical supplies and should not be referred to as such since this statement is clinically incorrect. A CTP promotes wound healing by interacting directly or indirectly with the body tissues. There is direct biological effect in the wound bed as a result. The role of CTPs is not to cover and protect wounds but rather to stimulate endogenous healing.

Additionally, this characterization of these products is inconsistent with CMS's discussion on the distinction between CTPs and surgical dressings. As discussed in the CY 2014 OPPS/ASC final rule, CMS has previously acknowledged the distinction between skin substitutes and surgical dressings/supplies.[8] Skin substitutes are applied to wounds to aid healing through various mechanisms of action that stimulate the host to regenerate lost tissue, and should be defined as such.

It is completely inappropriate to refer to CTPs as surgical supplies and as such, this language should be removed from the policy.

Increase in Smoking Cessation Timeframe is Arbitrary and Not Substantiated in Clinical Literature

The increase in the smoking cessation timeframe prior to the use of a CTP to 6 weeks is arbitrary and not substantiated in the evidence. Citing the evidence that is the basis for a coverage policy is required by the 21st Century Cures Act. Although it is well documented that smoking impairs wound healing, the actual time required for smoking cessation to reverse the effects on wound healing is not known.[9][10][11] In fact, there is no evidence to support smoking cessation at any particular time frame. While the Coalition supports the provision which requires counseling patients on the effects of smoking on wound healing, until Novitas/FCSO can provide literature to support the smoking cessation time frame, the Coalition recommends that the timeframe be eliminated from this policy.

---

[8] *See* 78 FR 74932

[9] Jensen JA, Goodson WH, Hopf HW, Hunt TK. Cigarette smoking decreases tissue oxygen. Arch Surg. 1991;126(9):1131–1134.

[10] Sherwin MA, Gastwirth CM. Detrimental effects of cigarette smoking on lower extremity wound healing. J Foot Surg. 1990;29(1):84–87.

[11] *Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg. 2016 Feb;63(2 Suppl):3S-21S. doi:10.1016/j.jvs.2015.10.003.)*

Concerns with Requiring Clinicians to Utilize the Smallest Package Size Available For Purchase From the Manufacturer

The draft LCD would require that clinicians use "the smallest package size available for purchase from the manufacturer that could provide the appropriate amount for the patient." The Coalition recognizes that Novitas/FCSO wants to ensure that clinicians use the most appropriate size product available to them at the time of treatment is utilized. However, the requirement that clinicians utilize the smallest package size available for purchase from the manufacturer is not appropriate. Clinicians often do not control what products are purchased or on formulary, thus on hand at their facilities. They simply use the best product to treat the patient that is either on the hospital formulary or on the shelf at their clinic.

There are different types of CTPs in the marketplace which come in different sizes and not all come in multiple sizes. In the hospital-based outpatient setting, these products are packaged into payment for the procedure and not paid separately based on the amount of product furnished. Hospitals contract for a small number of products through purchasing intermediaries and clinicians may have no choice in the size of product available, nor will the size impact the payment rate. Products come in a limited number of sizes and even a private practitioner may not be able to match the size of the product to the size of the wound.

The Coalition believes that Novitas/FCSO should delete this requirement in the LCD of clinicians using the smallest package size available for purchase since it may be out of the clinician's control to do so as stated above. Instead, the Coalition recommends that Novitas/FCSO modify the current language to read, " CTPs must be used in an efficient manner utilizing the most accurate size product available to the provider at the time of treatment. The provider must document in the patient file the size of the wound, the product used and how the product was used (i.e., if a large CTP was used on multiple wounds for the same patient) and the amount of product wasted. Should the wound begin to heal and a smaller size CTP is necessary, the provider may switch products in order to have the least amount of product wastage."

Concerns with Not Allowing Clinicians to Switch CTP Products During Course of Treatment

Novitas/FCSO has a restriction in the draft policy which would not allow switching CTP products and while exceptions can be made – as stated in the policy "they are rare and may be consider upon appeal when the medical necessity of the change is clearly documented in the medical record."

The restriction on switching CTP products would limit treatment options for the clinician and inhibit a patient from receiving the best optimal treatment. Clinicians often use one CTP to achieve a certain goal of wound healing, such as to initiate granulation. Then, depending on the presentation of the wound and the patient's current health status, clinicians may use a different product to close the wound. The clinician should be able to use the best product available to continue the healing process of the wound. A clinician should not have to appeal to the contractor to switch products when in their clinical judgement the patient would benefit from the change, especially when in mid treatment. This disrupts patient care and is not in the best interest of the patient. This policy would limit a physician's ability to change course in treating their patients upon the realization that the product chosen is not successfully working for a specific patient.

In order to afford all clinicians the autonomy needed to customize their treatment plan to individual patients, we recommend that the language be modified to read, "If a clinician determines that the original CTP being utilized needs to be switched, documentation must be provided in the medical record to justify the use of multiple products."

Incorrectly Describing the Application of CTPs as an Adjunct Therapy Rather than an Advanced Therapy.

There are several places within this policy in which Novitas/FCSO describes the application of CTPs as an adjunct therapy. This is not a correct description. It is widely known and supported in the literature that after a wound fails to heal after 30 days or 4 weeks of standard of care the application of advanced therapies such as CTPs is warranted. [12] As such, the Coalition recommends that Novitas/FCSO remove references to CTPs being an adjunct therapy and instead refer to them as an advanced therapy.

Inconsistencies and Clarification of Terminology

We are providing below examples of inconsistencies or terminology which need to be clarified.

- There is language in the draft policy that seems to indicate that HCT/Ps are not reasonable and necessary. Specifically, the language on page 6 states*, "considered not medically reasonable and necessary: Refer to the CFR, Title 21, Volume 8, Chapter 1, Subchapter L, Part 1271.10 for Human-derived products regulated as human cells, tissues, or cellular or tissue-based product."*

  The language as written suggests that any product regulated under the Public Health Service (PHS) as an HCT/P is not considered reasonable and medically necessary and despite the fact that Novitas/FCSO indicated that a letter from the Tissue Reference Group for these products would be sufficient to provide coverage. Furthermore, this language contradicts other sentences in the policy which states, "*Coverage will be provided for products in the associated billing and coding guideline meeting the necessary FDA regulatory requirements as of publication.*"

  As a result of the contradictory language, confusion will ensue. As such, the Coalition recommends that the sentence in the draft policy which states," *considered not medically reasonable and necessary: Refer to the CFR, Title 21, Volume 8, Chapter 1, Subchapter L, Part 1271.10 for Human-derived products regulated as human cells, tissues, or cellular or tissue-based product"* be deleted.

- The reference to "synthetic occlusive dressings" throughout the policy is confusing since a synthetic CTP is not a dressing. Synthetic products should be treated like all other CTPs. CMS has included them in the definition of a skin substitute in recent rulemaking and as such, reference to synthetics as dressings is inappropriate. The Coalition believes that if Novitas/FCSO meant to describe "surgical dressings" then the terms "synthetic occlusive" should be deleted and instead use "surgical dressings" instead.
- Throughout the draft policy, Novitas/FCSO refers to "conservative" treatment when in fact, the appropriate terminology is "standard of care." As such, the Coalition would like to better understand why the standards of care are being referred to as conservative treatment?

LCDs Should be Based in Evidence as Required by 21st Century Cures

[12] Sheehan et al.

As noted above, we are concerned that this draft LCD/LCA are not based on evidence as is required under the 21st Century Cures Act. We recognize that there are studies and literature cited in this policy that are supposed to substantiate Novitas/FCSO's positions. However, after review of this literature, it is clear that the evidence cited does not substantiate the significant changes that Novitas/FCSO is attempting to make. As such, the Coalition asks that Novitas/FCSO withdraw this policy and requests that Novitas/FCSO work with the CAC and stakeholders to ensure that any future policy is based on evidence and will not negatively impact patient care.

Furthermore, neither Novitas or FCSO provided any new literature after moving over 40 products from the covered to the non-covered listing. In order to justify non coverage, the MACs are required to provide evidence to substantiate the change. However, NO additional literature was added to the bibliography. This again violates the 21st Century Cures Act

COALITION CONCERNS WITH THE LOCAL COVERAGE ARTICLE (LCA)

In addition to the concerns that the Coalition has with the LCD, we have significant concerns with the LCA as well. These concerns include the following:

Sheet Products Omitted from Group 2 List

The LCA omits coverage of many sheet products, despite them meeting the requirements provided in the LCD. Additionally, there is no transparency or reasons provided as to why products that are currently covered have been moved to the non-covered grouping. The Coalition does not agree with the removal of products from the Group 2 covered product list and recommends that these products be added back prior to this policy being finalized. Furthermore, in the future, Novitas/FCSO should provide metrics as to when and what criteria will ensure a covered product versus those that will be placed in the non-covered grouping.

Neither Novitas nor FCSO has followed the requirements of the 21st Century Cures Act which states that in order to not cover an item that has been covered, evidence needs to be provided to support the non-coverage. However, NO NEW LITERATURE has been provided to substantiate the move of over 40 products from the covered to the non-covered list. Nor has ANY information been provided as to why these products were moved OR what the metrics are for coverage. Therefore, the Coalition recommends and urges Novitas/FCSO to reinstate all products into the Group 2 covered product category and until Novitas and FCSO can provide the literature supporting the movement to the non-covered grouping, these products should remain as covered.

Omission of a Significant Number of ICD-10 Codes

There are a significant number of ICD-10 codes that have been omitted from this policy – which we believe must have been an oversight. We have provided in **Attachment A** to this comment letter a list of codes that should be reinstated into the policy. We note several issues/examples within the article related to ICD-10 (Group 1) coding including but not limited to:

- **The diabetes codes (EXX.621) contain only those codes with the .621 suffix.** We submit that the proposed LCD focuses on DFUs. However, although industry uses the term "DFU," most policies actually mean to include diabetic lower extremity ulcers.
- **The code list as written allows diabetic foot only, and precludes any diabetic ulcer even as low as the ankle.** (Per coding instructions, EXX.621 uses additional code L97.4XX and

L97.5XX to identify site of ulcer. These are heel and midfoot, and other part of foot respectively. Anything ankle or above is not included).

- **The article does not allow for the necessary EXX codes that are captured with the .622 suffix.**
- **The included L97 codes capture only "fat layer exposed."** No other depth of ulcer is included in this list (such as *breakdown of skin, muscle involvement without evidence of necrosis, bone involvement without evidence of necrosis*). While some product Instructions for Use (IFUs) or FDA labelling may prohibit application over muscle, joint capsule, tendon or bone, this is not true for all of them.
- Moreover, these patients with deeper ulcers are the ones at highest risk for infection, hospitalization, amputation and death. As written, this administrative list creates a reality where the patients who need advanced care most, these codes are "not covered" by their local MAC.

The list omits L97 codes that capture *other part of the foot* (L97.5XX). L97.5XX are not unspecified codes, but rather very specific codes that capture anything on the foot that is not on the heel or midfoot. Toes are included in L97.5XX. The current list implies that diabetic ulcers on the toes or other parts of the foot cannot meet medical necessity for skin substitutes.

- **The below instruction is contradictory and confusing:**

For example: As noted above, the EXX codes listed within the article do not allow for the .622 suffix. This means that the ankle codes L97.3X2 that *are* listed do have the correct mapping available.

- **As well, the instruction states, "the L97 codes are standalone codes if they are listed in the table above."** This does not fit with the expressed purpose of the draft LCD, which is to address DFU/VLU only. To capture (accurately) DFUs or VLUs, two codes are needed: one to identify the underlying etiology and basic location, and one to identify the exact site and depth. L97 codes by themselves do not capture diabetes or venous insufficiency. There are no possible standalone L97 codes if the LCD and article are devoted to these two etiologies.
- **The list of covered venous insufficiency codes does not capture patients' needs.** Omitted codes include those that represent varicose veins with ulcer, or post thrombotic syndrome with ulcer. As an example, we request that Novitas/FCSO include the following (but many more are included in Attachment A).

o I83.0XX Varicose veins ...with ulcer (left, right, bilateral)
o I83.2XX Varicose veins ...with both ulcer and inflammation (left, right, bilateral)

o I87.0XX Postthrombotic syndrome with ulcer (left, right, bilateral)

o I87.03X Postthrombotic syndrome with ulcer and inflammation (left, right, bilateral)

As stated above, we have provided all the codes that should be placed in this LCA in Attachment A to this comment letter.

CONCLUSION

For all the reasons and issues identified above, the Coalition strongly recommends that Novitas/FCSO withdraw this policy and work with stakeholders to craft a clinically accurate policy based on evidence and the rules of law.

The Coalition appreciates the opportunity to provide our written comments. Should you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,

Karen Ravitz, JD
Health Policy Advisor
Coalition of Wound Care Manufacturers
301 807 5296
Karen.ravitz@comcast.net