COALITION OF

Wound Care Manufacturers

September 30, 2022

Mr. Harvey Dikter
President and Chief Executive Officer
Guidewell Source
532 Riverside Avenue
Jacksonville, FL 32202

Mr. Tom Anderson
Vice President and Chief Legal Counsel
Guidewell Source
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Ms. Lisa Dees
Vice President and Deputy General Counsel
Guidewell Source
532 Riverside Avenue
Jacksonville, FL 322002

Ms. Kim Martin
Vice President of Operations for Novitas
Guidewell Source
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Dear Mr. Dikter, Mr. Anderson Ms. Dees and Ms. Martin,

On behalf of the Coalition of Wound Care Manufacturers, I am respectfully writing to request that Guidewell intervene and request that two of your companies – Novitas and First Coat Service Options (FCSO) – withdraw their proposed Local Coverage Determinations (LCDs) Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL35041 and DL36377) and Local Coverage Articles (LCAs): Billing and Coding: Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DA54117 and DA57680) as they are fraught with language that is not only contrary to clinical practice guidelines and research, but also are in conflict with the very evidence cited in the draft policies. The draft LCDs and LCAs also violate several statutory provisions – which is problematic given the negative impact to patient care and access.

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 these policies are clinically sound and based on clinical evidence – which they are not currently.

The Coalition is extremely concerned with these draft policies for a number of reasons including but not limited to:

1. They did not take any stakeholder feedback into consideration.
2. They seem to be strongly suggesting manufacturers comply but fall short of requiring certain actions – yet coverage will be based on the suggested language.
3. Maintain an unworkable deadline for compliance.
4. Have a stricter requirement than even CMS currently maintains.
5. They are placing significant administrative burdens on manufacturers which will also cause a disruption in care/access to products.

Not only are the requirements being placed on manufacturers troublesome, but the LCDs do not adhere to current clinical practice and the language contained in the policies do not resemble the

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evidence that is cited to support the limitations or other clinical language. The MACs have ignored clinician feedback who practice in their jurisdictions, they have ignored clinical associations and societies comments - whose members are experts in wound care, they have ignored clinical practice guidelines and they have ignored the evidence.

The Coalition requests that your company intervene by requesting that both Novitas and FCSO withdraw their policies in the best interest of patient care and work with their respective Contractor Advisory Committees (CACs) and appropriate clinical stakeholders to ensure that these LCDs and LCAs are clinically sound and based on scientific evidence.

The Coalition is specifically concerned with the following areas which justify the withdrawal of these policies.

First, the number of applications of CTPs permitted in these policies are not based on evidence. In fact, the evidence cited either shows the number of applications to be higher than the two permitted under these policies or that the number of applications should be based on the labeling instructions for the specific product being used. Yet, both Novitas and FCSO placed an arbitrary application limitation in their policies that is not based on the evidence in general nor is it based on any evidence cited in the policies themselves. In fact, the number of applications cited in the evidence ranges from 1-8.9 applications and is based on individual product labeling. In addition, 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's labeling instructions is to reapply the product 5 times every 3 weeks – the clinician will be over the number of applications under these policies while following the labeling instructions for the product being used to treat their patient 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.

Second, both Novitas and First Coast also define these products as surgical supplies. Specifically, the language used in these draft LCDs state, "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". We submit that skin substitutes are not and should not be referred to as surgical supplies. This reference is clinically incorrect. A skin substitute 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 skin substitutes is not to cover and protect wounds like a surgical dressing but rather to stimulate endogenous healing, although whether or not an individual skin substitute is capable of exerting effects on wound healing must be determined by adequate evidence. A skin substitute is simply not a supply. A wound or surgical dressing is a supply. It is a material that is utilized for covering and protecting a wound, helping to maintain an optimal wound environment, and shield the wound against the environment without exerting any direct effect in the wound bed. Even CMS has indicated in rulemaking that these products are not supplies and are considered biologicals.[i] Often a surgical dressing is used to cover the skin substitute. As such, it is completely inappropriate to refer to skin substitutes as surgical supplies and as such this language should be stricken from the policies.

Third, both Novitas and FCSO appear to institute TRG letters as requirements for coverage. Yet, the LCDs do not explicitly mandate the certification of 361 compliance, but strongly imply that proposed covered products (Group 2 codes) could be removed from coverage if 361 compliance is not demonstrated, perhaps as early as the September 24th comment deadline.[ii] This deadline is not only unworkable it is more aggressive than even CMS proposed language.[iii] These LCDs are

effectively requiring a TRG letter on a far more expedited basis than CMS would be requiring in regulation if it finalizes the above policies[iv]. This apparent requirement (although the policies only states it is recommended) is extremely problematic as **patients are at risk of losing long-standing access to medically necessary care with biologic products proven efficacious in wound healing. It is imperative that Novitas and FCSO do not implement any final LCD language until CMS finalizes its position on this topic.**

Fourth, the moving of over 40 products from the Group 2 covered list from Novitas and FCSO's original draft policies to the non-covered Group 3 in their most recent draft lists without any explanation as to why these products were moved is extremely disconcerting and lacks in transparency. This movement also violates the 21st Century Cures Act as Novitas and FCSO have placed absolutely no evidence to support the movement of these products in the bibliography. The Coalition does not support any product being included in the non-covered list until the policies are finalized and a reasonable amount of time has been afforded to manufacturers to obtain and submit the necessary information. Until these policies are finalized with specific requirements identified, the Coalition believes that all products should be covered.

Moreover, Novitas and FCSO should also clearly identify the type of evidence which is being required of manufacturers for coverage. Just simply stating evidence based literature is recommended is not specific enough, we request that Novitas and FCSO state what type of evidence based literature they are willing to accept in order for products to be placed and maintained in the Group 2 covered list. There needs to be a more transparent process and evidentiary requirements need to be identified clearly in these policies.

Furthermore, the provision of evidence is not only a manufacturer requirement. If products will be moved from one category to another, Novitas and FCSO are required to provide evidence in the bibliography supporting their decision. This information needs to be clearly identified in the policies. However, no new evidence was placed in the bibliography and the evidence that is in it currently does not support the movement of these products to the non-covered list. In fact, the evidence that is currently sited in the policies supports these products being utilized and covered. Novitas and FCSO need to clearly identify why products have been moved from the covered group to the non-covered group. There is no consistency in products that have been moved and therefore there is no clarity as to why some products were moved to the non-covered list. The movement of these products seems arbitrary. Novitas needs to be more transparent in their decision making process and provide the evidence it is using to make any changes in coverage.

Finally, we are concerned that **these policies in general are not based on clinical and scientific evidence as is required under the 21st century cures law.** We recognize that there are studies and literature cited in these policies that are supposed to substantiate the Novitas and FCSO positions. However, under review of this literature, it is clear that the evidence cited does not substantiate the significant changes being proposed.

The Coalition also has concerns about the following specific issues:

- The lack of a consistent and accurate definition of what is a chronic non healing wound. We believe it should be 30 days or 4 weeks as it is already standardized and used by CMS and other A/B MACs.
- Incorrectly describing the application of skin substitutes as an adjunct therapy rather than an advanced therapy.
- Omitted coverage of products in the LCA.
- Inappropriate use of the term "wound" given the title of this LCD/LCA.

- The use of the terms pressure ulcer, decubitus ulcer, burns, and trauma throughout these policies which specifically state they only address DFUs and VLUs.
- Omission of a significant number of ICD-10 codes from the LCA that should have been included in these policies. It is concerning that Novitas and FCSO only identified codes with the .621 suffix – which is for the foot only and have excluded patients with a diabetic ulcer even above the ankle.
- Increase in the smoking cessation timeframe prior to the use of a skin substitute not based on clinical evidence.
- The requirement for a venous diagnosis to implement treatment.
- The number used for the measurement of hemoglobin A1C – which is contrary to clinical evidence.
- No reference for the ABI of 0.9 so there is uncertainty as to where this number came from.
- The inability to switch products or use additional applications when medically necessary.
- Inconsistently stating something is recommended and then later being required – for example VCSS and SEEP scores.
- Reference to the Tissue Reference Group or TRG. TRG is used for coding not coverage.
- Intended use of the product for DFU and VLU.
- Reference to synthetic occlusive skin substitutes and singling them out multiple times in the policies.

Based on all of the issues above, the Coalition requests that Guidewell intervene and require both Novitas and FCSO to withdraw their proposed Local Coverage Determinations (LCDs) Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL35041 and DL36377) and Local Coverage Articles (LCAs): Billing and Coding: Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DA54117 and DA57680) and work with their respective CACs and stakeholders to ensure that the policies' language are based on evidence and will not negatively impact patient care.

Should you have any questions or require additional information please do not hesitate to contact me.

Sincerely,

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[i] *86 FR 63563 "The CY 2014 OPPS/ASC final rule with comment also described skin substitutes as "...a class of products that we treat as biologicals..."*

[ii] *See corresponding article DA57680 and DA52117 "It is recommended that the manufacturer of the particular skin substitute graft or CTP product obtain the appropriate information for FDA regulatory compliance and send to the MAC along with evidence-based literature, if available. Once this information has been received by the MAC, the product will be considered for coverage and placed into the appropriate Code Group"*

[iii] *87 FR 45860 - requires the manufacturer of any HCT/P product that has not already been provided with a recommendation from the Food and Drug Administration's (FDA) Tissue Reference Group (TRG) to submit a HCPCS Level II re-application within 12 months of the effective date of the final rule (that is, January 1, 2023).*

[iv] *Ibid.*